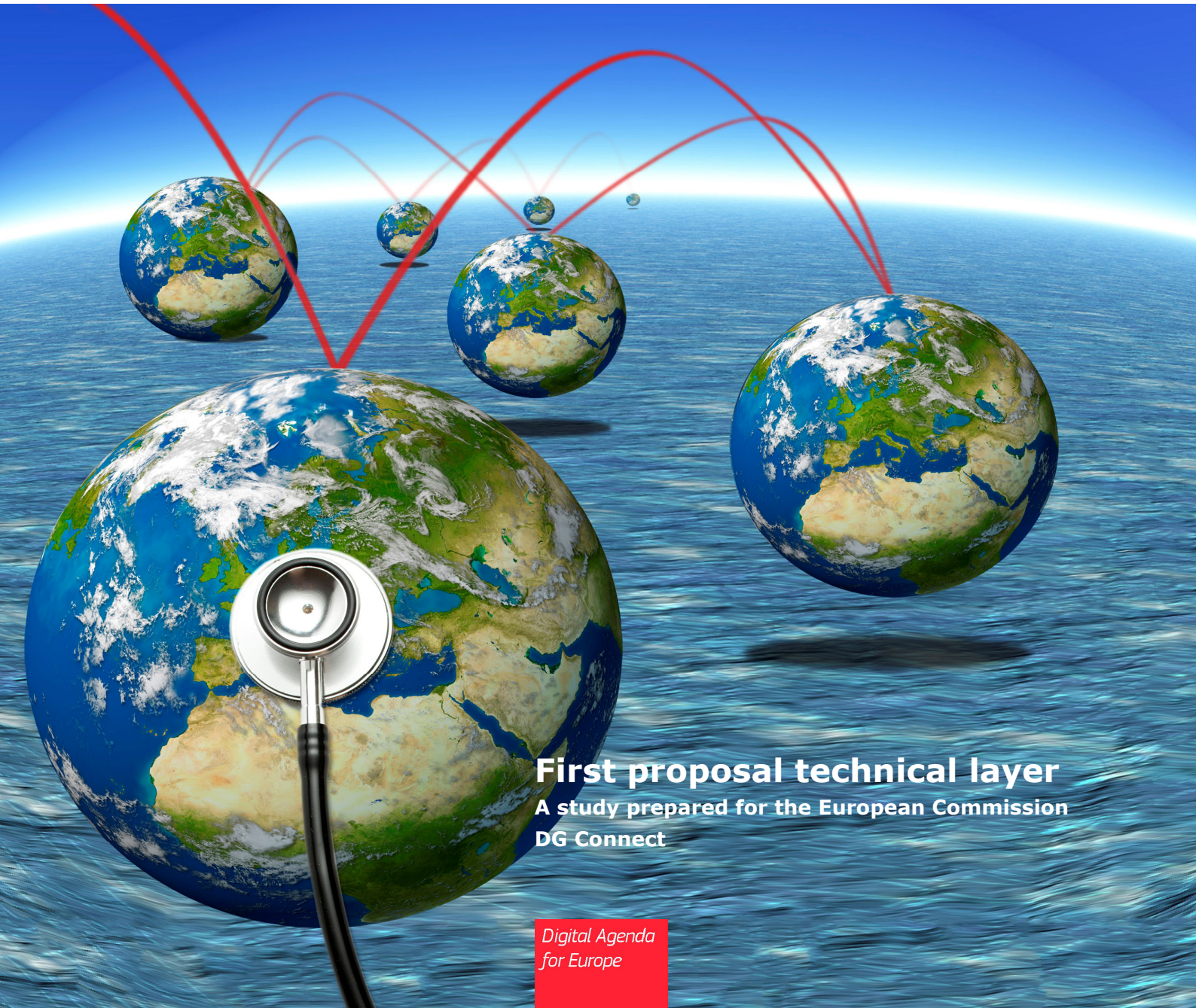
European Commission

# eHealth EIF

## eHealth European Interoperability Framework

## European Commission – ISA Work Programme



**First proposal technical layer**

**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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ISBN 978-92-79-30358-6
DOI: 10.2759/15204

**Specific contract N° 60**
**Framework contract N° DI/06691-00**

***Version 1.2***
**14/02/2013**

**The study was launched and guided by Benoît Abeloos from DG Connect**

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# Contents

# 1 – Executive Summary

This report has three main objectives. All focus on the technical level of the eHealth European Interoperability Framework (EIF). They relate to the creation of relevant use cases, their sharing and their testing.

This report describes the ten use cases that will populate the technical level of the eHealth EIF; describes the profiles related to each of the use cases; and shares the results relating to Continua Health Alliance ('Continua') and Integrating the Healthcare Enterprise (IHE), which were selected as representative examples of profile development organisations. For the purpose of this study, the epSOS (European Patients Smart open Services) large-scale pilot was also considered to be a temporary organisation that developed (non-IHE) technical specifications, and that supported the extension / development of IHE profiles. Note that this study concentrates on the technical level of the eHealth EIF (and does not focus on the legal, organisational or semantic levels of the framework, although it acknowledges synergies between the technical and the semantic levels).

In the case of each of the three objectives, the key messages involved in their approaches and results are described as follows.

- Describing ten use cases that populate the technical level of the eHealth EIF (without focusing on the legal, organisational or semantic levels)

  The ten use cases fall into four categories: cross-border; national/regional; intra-hospital; and at the level of citizens, whether they are on the move or at home. Their relevance and association with the epSOS large-scale pilot are described. The approach used to collate, refine and select these ten cases was a Delphi exercise. The exercise consisted of three rounds of Delphi iterations. Input was collected through a workshop, an online poll, and more detailed feedback from experts (cf. Annex 1). As a result, ten high-level use cases are described both at a generic level (cf. Table 1 and Figure 1) and, then, at a more detailed level. This list of ten use cases deals with the following aspects: e-Prescription / e-Dispensation, patient summary, radiology, laboratory, medical summaries, ever-present care outside conventional care facilities using PC or web based applications, mobile phones, and sensor devices. Each detailed example of a use case contains a short description, an illustration of the use case's potential use in the health care field, and the precise motivation for considering it as a useful use case in relation to the EIF.

- Describing the profiles related to each of the use cases

  Profiles[2] are provided for each of the ten use cases. Both of the two profile development organisations, Continua and IHE, were asked to provide the study team with a list of profiles that corresponded to the list of use cases prioritised in the beginning of this report. The results show that relevant profiles[3] fall into the fields of IT infrastructure, laboratory, patient care coordination, patient care device, pharmacy and radiology (listed here in alphabetic order).

- Sharing assessment results for Continua, IHE and epSOS, the large-scale pilot

[2] The concept of profile is defined in the glossary of this report.
[3] The IHE profiles are indicated with a * and the Continua profiles with a +.

The report lays out the assessment results for the two profile development organisations, Continua and IHE, and the "temporary" organisation, epSOS, the large-scale pilot. The assessment framework used to assess the work of the profile development organisations was extracted from the Regulation on European Standardisation approved by the European Council on 4 October, 2012, and its Annex II, which is aimed at modernising and improving the European standardisation system. Two types of assessment took place: organisational assessment and technical specification assessment. The conclusions of the IHE and Continua 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.

For the epSOS large-scale pilot, the analysis has revealed full alignment with the requirements defined by Annex II of the Regulation on European Standardisation (although epSOS is not, and is not seeking to set itself up as a profile development organisation). Therefore, no recommendations have been formulated for epSOS.

# 2 – Introduction

As discussed in deliverable 1 of this study, the Council adopted the new Regulation on European standardisation on 4 October 2012, which aims at modernising and improving the European standardisation system (European Commission, 2012c).[4] This regulation offers a legal basis for the identification of technical specifications that could be referred to in public calls for tender. Note that it is the role of the Information and Communication Technology (ICT) standards multi-stakeholders platform[5] to advise the Commission on the identification of ICT standards.

Our study aims to assess the technical specifications issued by two consortia, the Continua Health Alliance ('Continua') and the IHE-International ('IHE') (supported by the epSOS (European Patients  Smart open Services) project in the case of the two cross-border use cases) against the criteria described in Annex II of the Standardisation Regulation. As such, the recommendations described in this report allow these organisations and profiles to be better prepared for formal identification by the multi-stakeholders platform.

## 2.1 – Objectives of this report

This report has three main objectives: to describe the use cases; to describe the profiles related to each of the use cases; and to describe the assessment results for the two profile development organisations and for the epSOS large-scale pilot. Thus, this report focuses on the technical and to a certain extent the semantic level of the eHealth EIF.

Firstly, it was the **responsibility of the study team to provide a recommendation for ten use cases** that should form part of the initial version of the eHealth EIF. This report therefore describes each of the use cases, and their appropriateness for the healthcare sector.[6] Section 3.1. provides an overview of the 10 use cases proposed by the study team. More details about the description, illustration and motivation of the use cases are all laid out in sections 3.2 to 3.5. The specific research approach followed by the study team is documented in Annex 1 of the report.

Secondly, this report has the **purpose of describing the relevant profiles for each of the use cases**. The two profile development organisations, Continua and IHE, were asked to provide the study team with a list of profiles that corresponded to the prioritised used cases. As a result, these are listed in table format in Chapter 4 of this report.

Thirdly, the report aims at describing the assessment results for the two profile development organisations, and for the epSOS large-scale pilot. This analysis was based on the organisational criteria extracted from Annex II of the Regulation on European Standardisation, and the study team's interpretation of the meanings of the various criteria. The profile development organisations selected were Continua and IHE. Furthermore, the study considered the epSOS project as a temporary organisation that developed (non-IHE) technical specifications, and that supported the extension / development of IHE profiles. Proposals for enhancement (or "recommendations") of these aspects of their work are offered to the relevant profile development organisations as a result of the analysis undertaken.

[4] http://register.consilium.europa.eu/pdf/en/12/pe00/pe00032.en12.pdf
[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:349:0004:0006:EN:PDF
[6] While the number of ten use cases is often cited, two of the use cases (use case 2 and 5) in fact contain two sub-use cases, use cases 2a and 2b, and 5a and 5b.

## 2.2 – Structure of this report

This report consists of seven 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 not only lists the high-level use cases brought together by the study team but also describes them in some detail. This chapter describes the origins of the selection procedure, and makes recommendations with regard to these use cases. In tabular format, Chapter 4 presents the profiles associated with each of the high-level use cases provided in the list. Chapter 5 provides an introduction to the profile development organisations IHE and Continua. Chapter 6 lays out the results of the organisational assessment undertaken on IHE and Continua, and a third "temporary profile development organisation" (the epSOS large-scale pilot). Proposals for changes referred to as "recommendations" are also made. Chapter 7 describes the results of the technical specification assessments applied to the two profile development organisations, Continua and IHE. Chapter 8 provides a summary of all assessment results for IHE, Continua and epSOS.

The document finishes with a glossary, and a description of the research approach used to collect and refine the ten potential use cases (Annex 1).

# 3 – List of high level use cases

This chapter describes each of the ten use cases, and their appropriateness for the healthcare sector[7]. Section 3.1 of the report outlines the full list of ten use cases proposed by the study team. More details about the description, illustration and motivation of the use cases are all laid out in sections 3.2 to 3.5. The specific research approach followed by the study team is documented in Annex 1 of the report. Please note, that the result of this prioritisation work could be further refined by using additional steps of the Delphi method incorporating additional stakeholders.

## 3.1 – Overview of 10 high level use cases for the eHealth EIF

Table 1 shows the list of the ten use cases resulting from the research approach followed (cf. Annex 1) – including the first two epSOS use cases – and highlights the main rationale for their inclusion. The ten use cases fall into four categories: cross-border; national/regional[8]; intra-hospital; and at the level of citizens, irrespective of whether they are on the move or at home.

Please note that the set of use cases that is presented below is only a first step in this whole process, and should be expanded in the future in additional areas such as medication safety, and connectivity between primary and secondary care.

**Table 1 - List of ten eHealth EIF use cases**

| Nr | Level | Use case |
|---|---|---|
| **1** | Cross-border | epSOS project : e-Prescription and e-Dispensation for cross-border information sharing for citizens travelling in Europe |
| **2a** | Cross-border | epSOS project : patient summaries for cross-border information sharing for citizens travelling in Europe |
| **2b** | Cross-border | epSOS project - patient having access to his or her patient summary. |
| **3** | National/Regional | Request and results (imaging results, diagnostic examinations) sharing workflow for radiology in inter-hospital setting on national/regional scale |
| **4** | National/Regional | Request and results (laboratory reports, test results) sharing workflow for laboratory in inter-hospital setting on national/regional scale |
| **5a** | National/Regional | Cross-Enterprise Sharing of Medical Summaries IHE Integration Profile: Ambulatory Specialist Referral |
| **5b** | National/Regional | Cross-Enterprise Sharing of Medical Summaries IHE Integration Profile: Acute Care Discharge to Ambulatory Care Environment |
| **6** | Intra-Hospital | Request and results (imaging diagnostics tests) distribution workflow for radiology in intra-hospital setting |

[7] While the number of ten use cases is often cited, two of the use cases (use case 2 and 5) in fact contain two sub-use cases, use cases 2a and 2b, and 5a and 5b.
[8] National and regional use cases need to be compliant with national legislation

| Nr | Level | Use case |
|---|---|---|
| **7** | Intra-Hospital | Request and results (clinical laboratory tests) sharing workflow for laboratory in intra-hospital setting |
| **8** | Citizens at home and on the move. | 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, chronic obstructive pulmonary disease, hypertension) |
| **9** | Citizens at home and on the move. | 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, chronic obstructive pulmonary disease, hypertension) |
| **10** | Citizens at home and on the move. | For ever-present care outside conventional care facilities, involving the interoperability necessary from sensor devices to monitor activity, e.g. of elderly people |

The figure below illustrates the spectrum of medical care provision covered by the selected ten use cases. It demonstrates that in the scope of this study, based on this selection, a broad set of medical services in different geographical settings (both national and regional) is supported.

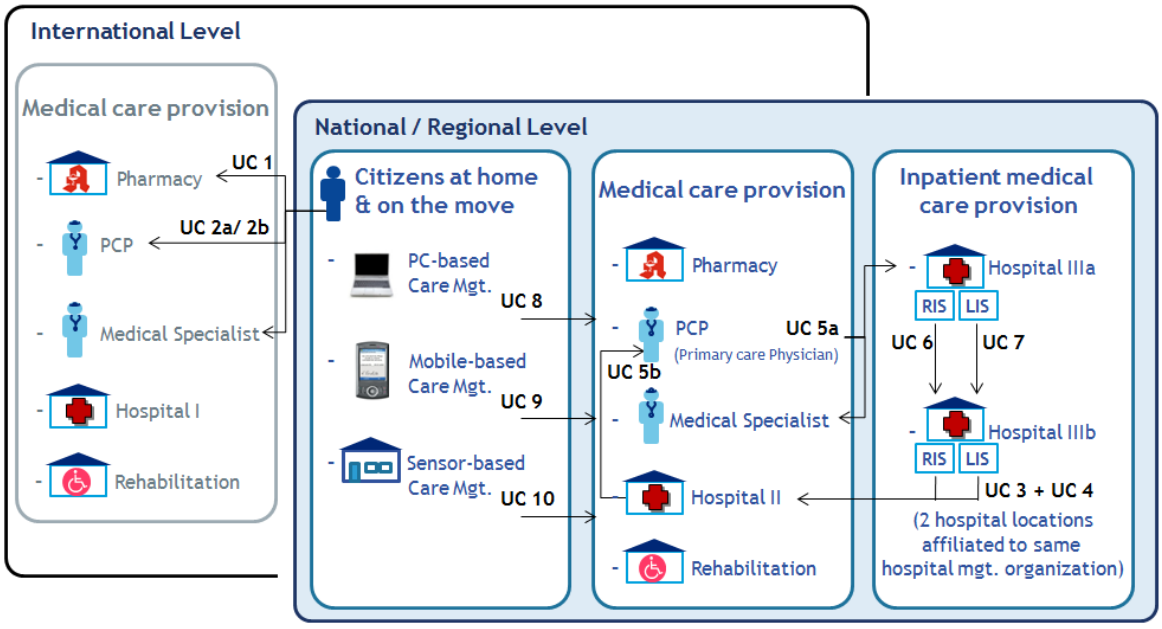


**Figure 1. Medical care provision and selected use cases**

In the next sections of this chapter, more use case details are given. The following structure is used to present each use case:

- A short description of the use case;
- An illustration of its application in health care;

- A description of why a specific use case should be considered on the first list of use cases that are proposed to be included in the eHealth EIF.

## 3.2 – Cross-border level

### 3.2.1 – Use Case 1: e-Prescription and e-Dispensation for cross-border information sharing for citizens travelling in Europe[9]

*Short description:* ePrescription has been used by the epSOS project as the overall term for supporting the processes of prescription and dispensation through the electronic exchange of supporting data for citizens who are travelling inside Europe:

- Firstly, ePrescribing is defined as prescribing medicines through the support of software by a health care professional who is legally authorised to do so, so that the medicine can be dispensed at a pharmacy;
- Secondly, eDispensing is defined as the act of electronically retrieving a prescription and reporting on giving out the medicine to the patient as indicated in the corresponding ePrescription.

Once the medicine is dispensed, the dispenser will report, via software, information about the dispensed medicine(s). To appropriately define the context of the use case relevant aspects require consideration. These aspects include:

- Is an existing prescription filled out in a different European country from where it originated or is a new medicine prescribed in a country visited by the patient?
- The different legislative contexts in the various European countries have led to the decision of the epSOS project that information about a newly prescribed medicine, in a country visited by a patient, will not be transferred back to the country in which the patient resides.

*Illustration:* From an overall perspective, the use case contains the following steps[10]:

- The patient visits an epSOS Health Professional and gives his/ her consent to share his/her medical information;
- The patient receives his/ her epSOS ePrescription;
- The patient then travels abroad where s/he requires medication in another epSOS pilot country;
- S/he visits a pharmacy that is participating in the epSOS network;
- S/he identifies himself/herself to the pharmacist/ staff at the pharmacy;
- The patient asks for his/ her ePrescription. By doing so, the patient gives the dispenser/ pharmacist his/ her consent to access his/her personal information[11];

[9] It could be of interest to consider the same use in a national setting, given that national level is a starting point before a move to the cross-border context.

[10] epSOS indicated that, for the unambiguous identification of the medicinal product of cross - border ePrescription, there is a need for three items: a European reference terminology, standardised data model and an open access for health professionals to national/ European database of medicinal products. This should allow health professionals to unambiguously identify the product involved. The European Medicines Agency (EMA) has initiated a streamlining work on databases' interoperability for medicinal products under new Pharmacovigillance legislation. It requires submissions to EMA of summary of products characteristics (SPC), including drug-to- drug interactions and safety reports. The new legislation also foresees the use of five new ISO/ CEN standards on medicinal products structured information.

[11] Prior consent is allowed in some countries, e.g., in Austria.

- The pharmacist retrieves the patient's ePrescription via the pharmacy's computer in a secure way;
- The requested medication is then dispensed to the patient.

More information about this use case, including the full description of the requirements and different versions of the use case, can be found in the epSOS deliverable, "D3.1.2 Final definition of functional service requirements – ePrescription".

*Motivation:* This use case represents a high level of consensus on what constitute European eHealth services, as this use case was described by the Directive 2011/24 of 9 March 2011 on the application of patients' rights in cross-border healthcare.

### 3.2.2 – Use Case 2a: Patient summaries for cross-border information sharing for citizens travelling in Europe

*Short description:* A patient summary is a concise clinical document that provides an electronic patient health data set that is applicable both for unexpected as well as expected healthcare contact[12]. The content of the patient summary is defined, at a high level, as the non-exhaustive data set of information needed for health care coordination and continuity of care. Such patient summary could contain information that includes:

- Demographic information about the patient (e.g., name, birth date, gender);
- A medical summary consisting of the most important clinical patient data (e.g. allergies, current medical problems, medical implants, or major surgical procedures during the last six months);
- A list of the current medication including all prescribed medication that the patient is currently taking;
- Information about the patient summary itself (e.g., when and by whom the patient summary was generated).

*Illustration:* From an overall perspective, the use case contains the following steps:

- The patient consults a health professional in his/ her home country;
- The patient gives consent to the health professional. The health professional will then register this confirmation to participate in the epSOS network;
- The patient travels abroad and consults an epSOS health professional;
- The patient identifies himself/ herself to the attending health professional with his/ her ID card or health insurance number;
- S/he confirms his/ her willingness to participate;
- The health professional retrieves the patient summary and uses it for the consultation. The patient summary is electronically transferred from the patient's country of origin to the health professional in the country that s/he is visiting (the "visiting country") in a secure way.

More information about this use case, including the full description of the requirements and different versions of the use case, can be found in the epSOS deliverable "D3.2.2 Final definition of functional service requirements - Patient Summary"[13].

As a possible example, imagine that a French employee is travelling to Italy on business. In a rush while on the way to the airport, the person cuts his or her arm on the staircase of a

[12] http://www.epsos.eu
[13] http://www.epsos.eu/uploads/tx_epsosfileshare/D3.2.2_Final_Definition_Functional_Service_Req_Patient_Summary.pdf

multi-storey car park. Since the cut was apparently not serious, s/he did not pay particular attention to the gash. As a consequence, over time, however, the wound becomes infected. The business executive decides to consult an Italian physician who examines the cut. The general practitioner would normally have prescribed penicillin. Yet, based on the patient summary, the physician can see that this patient is allergic to penicillin. It is therefore important to prescribe another type of antibiotic, to which the patient is not allergic, so that any negative side effects can be prevented.

*Motivation:* This use case represents a high level of consensus on what constitute European eHealth services, as this use case was described by the Directive 2011/24 of 9 March 2011 on the application of patients' rights in cross-border healthcare.

Furthermore, the definition of a patient summary was laid down by the epSOS project as a starting point for the development and pilot testing of a patient summary for citizens who are travelling abroad. The project started its pilot testing in April 2012. Through the piloting, practical experiences can be gathered systematically. For example, they might be related to the level of data required and the quality of information relevant to support patient treatment effectively across different participating European countries. The countries already participating in the pilot operate different health care systems. Each country follows its own respective national jurisdiction, supports a different culture for healthcare provision, and uses a different (or several different) language(s) (which may also involve different connotations of similar medical terminology in literal translation).

As a consequence of such complexities in national health care delivery, no common specification of the exact content of a patient summary currently exists. Thus, other than epSOS, today there is no clinical consensus or mutual understanding of the term 'patient summary'. The subsequent definition of a patient summary, in particular from a semantic point of view as described in Mandate 403, will therefore remain subject to future development efforts[14] that lie beyond the scope of both the epSOS large-scale pilot and this eHealth EIF study.

### 3.2.3 – Use Case 2b: patient having access to his or her patient summary

*Short description:* During the epSOS project, participants agreed that the patients involved in the large-scale pilot should be informed that they are involved in the collection of personal patient data that is collected in the patient summary. They should also receive access to their personal data. In addition a patient should be supported by other value added services, in particular with an adequately translated version of his/her patient summary which s/he may in turn want to make available to medical services providers of his/her personal choice.

In brief these requirements summarise the contents of the epSOS Patient Access Service (epSPA service). It represents an obvious requirement for interoperability in a European market for healthcare provision.

It was an important design decision that the epSOS project decided to support a patient's access to his/her personal patient summary[15]. This is a service that adds value to the existing national patient access services. Therefore, the implementations of relevant requirements for patient identification, authentication and authorisation have been delegated to either regional or national access services.

[14] eHealth-INTEROP- Report in response to eHealth Interoperability Standards Mandate (SA/CEN/ENTR/000/2007-20 eHealth Mandate M/403 – Phase 1), chapter 2.2.5.

[15] A patient's access to his/her personal patient summary is limited to the information created for the cross-border care. It is not about the access to the full patient summary in his/her home country.

*Illustration:* The defined epSOS use case considers the following steps[16][17]:

- The health professional in the country of the patient's origin updates/produces the medical information used in the patient summary on the basis of an encounter;
- The patient requests his or her patient summary from the national patient access service;
- The national patient access service (including patient identification, authentication and role authorisation) verifies that the patient access rights to the information, including his or her age, is sufficient to allow access to the data;
- The national patient access service provides the requested document;
- The epSPA service is invoked to produce a translation of the coded content of the document into the language of the country that is being visited. The epSPA service uses the MTC (Master Translation/Transcoding Catalogue) for the language of the country visited, produced by that country[18];
- The patient receives the translated document;
- The patient reads, copies, uses and distributes the document as he or she considers appropriate.

  Remark: One possible way in which the patient may want to distribute the information is to give it to a new health professional on the occasion of a new medical encounter, whether this intervention is scheduled or unscheduled. This step is relevant only if the health professional does not, for some reason, have access to the patient summary[19].

*Motivation:* This use case provides the patient with flexibility to make use of his/her personal patient summary. On the one hand, the service provides a translation of data into the suitable medical terms of the home country of the patient. On the other hand, it offers the patient the freedom to make the translation available to a healthcare practitioner who is not participating actively in the epSOS project.

## 3.3 – National / regional level

### 3.3.1 – Use case 3: Request and results (imaging results, diagnostic examinations) sharing workflow for radiology on national/regional scale

*Short description:* Imaging information-sharing supports the secured sharing of reports (including their publishing, finding and retrieval) and imaging studies across a group of hospitals and practices within a region or nation. This use case provides ambulatory providers with secure yet easy online access to patients' imaging results, as well as to any prior diagnostic examinations from imaging departments (which can be used either for comparison or to avoid duplicating imaging procedures).

*Illustration:* As an example, we can consider a patient who is suffering from lung cancer and who has received surgical treatment in a hospital. After discharge from the hospital, imaging information – such as results from computer tomography – should be made

[16] Smart Open Services for European Patients: Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription - D1.4.1 EED SERVICES including use cases for all services - Use-cases description, p. 17 ff
[17] This use case is still not yet implemented
[18] This workflow is only valid for ePrescription and the patient summary. In Use Case Patient Access, the document will be translated into the language of the home country of a patient. For example, an Austrian patient will receive ePrescription and the patient summary always only in German.
[19] Suitable mechanisms that meet organisational information security policies would need to be agreed.

available to the patient's primary care physician as well as to an office-based medical oncological specialist or a centre for rehabilitation for follow-on treatment.

*Motivation:* This use case has the objective of sharing imaging information beyond the boundaries of a typical, single hospital organisation. It can be used to make the information available to practitioners in outpatient treatment settings in another regional, national or international context. It builds on the 'request and results sharing workflow for laboratory' use case which is described immediately below (see Use Case 4).

### 3.3.2 – Use case 4: Request and results (laboratory reports, test results) sharing workflow for laboratory on national/regional scale

*Short description*: This use case supports the secure sharing of laboratory reports (such as their publishing, finding and retrieval) and test results across a group of hospitals and practices within a region or nation. This use case provides ambulatory providers with secure yet easy online access to new laboratory test results for their patients, as well as earlier test results for comparison.

*Illustration*: Today, in modern healthcare, about 60-70% of all diagnoses are based on clinical laboratory testing. The spectrum of testing ranges from highly standardised cost efficient commodity testing, such as blood counts, to innovative, personalised testing procedures for analysis of human genetics.

*Motivation*: Due to the relevance of laboratory information for diagnosis and decision-making about appropriate treatment, regimen-specific information should ideally be made available to all the physicians involved in the treatment of a particular patient episode on a need-to-know basis. The sharing of this sensitive information ought to be enabled across both organisational and regional boundaries.

### 3.3.3 – Use case 5a: Sharing of Patient Summaries: Ambulatory Specialist Referral

*Short description:* For the two use cases, 5a and 5b, the IHE integration profile has defined three categories for the clinical purpose of medical patient summaries. These cover three different levels of complexity – collaborative, episodic, and permanent – patient summaries[20]*:*

- Collaborative: A collaborative patient summary is defined as serving the interests of a specific provider by "providing the most relevant information about the patient". A referral letter may serve as an example of this type of patient summary.

- Episode: "Episodic summaries have the primary purpose of highlighting the most relevant details of focused periods of time in a patient history. Examples include discharge summaries[21]".

- Permanent: Permanent patient summaries "summariz[e] the entirety of a patient's medical history and therefore cover a broader range of patient problems". A

[20] http://wiki.ihe.net/index.php?title=PCC_TF-1/XDS-MS - Cross-Enterprise_Sharing_of_Medical_Summaries_.28XDS-MS.29_Integration_Profile

[21] There is an important difference between a Patient Summary and a Discharge Summary. Patient Summary is the history of a patient, including the actual discharge summary. Discharge summary is the actual situation of one treatment or one stay in a hospital / hospital organisation. One could also argue that patient summary is generally used for a set of patient data essential for continuity of care intended to be used by a healthcare professional other than the usual general practitioner who is requested to provide unexpected / urgent care.

permanent patient summary is often referred to in the context of a longitudinal medical record.

At this point in time, both collaborative and episodic patient summaries have been specified in IHE profiles. Interoperability of transferred data between the sending and receiving system, and users, may be supported at different levels of complexity. The range of types of transferred data may start from relatively unstructured content data suitable only to human reading and interpretation and extend to content data that is explicitly structured in granular data fields (and can thus enable the automated interpretation of medication information). Therefore the IHE profiles Cross-Enterprise Sharing of Medical Summaries (XDS-MS) support different data formats by defining required sections for mandatory structured header metadata and optional medical content information.

Permanent patient summaries are intended to be the subject of future work by the IHE.

*Illustration:* If a patient is to be referred for more specialised medical treatment, i.e., typically secondary care, the IHE profile defines the respective use case as an "Ambulatory Specialist Referral". In this instance, a primary care physician makes use of the collaborative patient summary, consolidates the respective medical information from an assumed electronic medical record, and transfers the relevant data securely to a medical specialist.

*Motivation:* The concept of the staging of different levels of content and transmission of medical care between primary, secondary and tertiary care is fundamental to virtually all national health systems. Secondary medical care provision is typically structured hierarchically: the institutions involved range from university clinics, to hospitals of different sizes and structures, and to individual medical specialists who run their own practices. This range of types of services facilitates the effective allocation of scarce medical resources according to the severity of the patient's disease or condition and where and at what level research into it is being conducted. A patient's transfer between the different healthcare sectors (whether primary, secondary or tertiary) should be supported by appropriate use cases that are subject to the proposed eHealth EIF.

### 3.3.4 – Use case 5b: Sharing of Patient Summaries: Acute Care Discharge to Ambulatory Care Environment

*Short description:* Use case 5b describes patient referral from specialised care (specifically, acute care discharge) to primary care (ambulatory care). It thus makes use of the same definition of terms that can be found in the IHE profile XDS-MS described above in use case 5a.

*Illustration:* After having received specialised treatment in a hospital setting, the patient is released. Episode-based patient summary information (with a focus on the treatment of the specific disease) is prepared by the attending physician in the hospital. If appropriate, the information is transferred to the primary care physician and medical specialists.

*Motivation:* To complement the flow of data or patient summary information in such a bi-directional context, this use case supports the notion that the treatment data is made available by the hospital sector to the primary care sector.

## 3.4 – Intra-hospital level

### 3.4.1 – Use case 6: Request and results (imaging diagnostics tests) distribution workflow for radiology in intra-hospital setting

*Short description:* This use case supports the workflow related to imaging diagnostic tests performed inside a healthcare institution, for both identified orders and unknown orders, with regard to both identified patients and unidentified or misidentified patients.[22]

*Illustration:* In a hospital setting, a physician from a medical department in charge of patient treatment may typically request some form of imaging diagnostics for the specific patient. Ideally, the radiological department receives all the relevant information about the patient's identity, his/her personal condition, and the exact subject of the examination. This is used so as to conduct adequate and appropriate treatment. Therefore this use case is expected to be sufficiently robust so as to cope with real-life situations in which information about the patient does not provide all the required contextual information.

As an example, consider a breast cancer patient who has been diagnosed with a local tumour that is at an advanced stage. According to medical guidelines, in order to exclude possible metastases, unless the cancer has been confirmed to be node-negative, x-raying of the chest is recommended.

*Motivation:* Results from a radiological examination that has been requested should be made available to medical staff members who are working in multiple medical departments within the hospital organisation on a need-to-know basis. This use case should ensure the availability of timely, complete and consistent patient information as well as avoidance of potential duplicate testing within the hospital organisation.

The Digital Imaging and Communications in Medicine (DICOM) standard has gained broad acceptance in the field: it is a data standard for transmitting medical imaging information as well as complementary clinical information. The degree of complexity implicit in medical imaging has contributed over time to vendor-specific implementations of image archiving technologies in picture archiving and communications (PACS) systems based on the DICOM standard. Therefore, the term of "vendor neutral (image) archives" (VNA) has emerged. These vendor-neutral solutions provide a single, enterprise-wide repository for patient-centric medical images.

Although this specific market trend focuses on the technical aspects of data storage and data management, it still demonstrates the need to support the interoperability of the distribution of imaging information within hospital organisations, polyclinics or other larger healthcare provider organisations that provide radiology services.

### 3.4.2 – Use case 7: Request and results (clinical laboratory tests) sharing workflow for laboratory in intra-hospital setting

*Short description:* This use case supports the workflow related to tests performed by a clinical laboratory whether it is inside a healthcare institution or whether it is being done on behalf of a healthcare institution, for both identified orders and unknown orders, with regard to both identified patients and unidentified or misidentified patients.[23]

[22] Annex 1 of COCIR Position Paper on eHealth Interoperability
[23] Annex 1 of COCIR Position Paper on eHealth Interoperability

*Illustration:* In a typical hospital setting, a physician from a medical department in charge of patient treatment would request clinical laboratory services to examine the samples or tissue of his/her patient. The patient may already have been diagnosed with a specific indication. More subtle testing or additional complementary testing may be requested in order to confirm the initial diagnostic process, support planning for subsequent medical intervention, or exclude alternative diagnoses. All the information relevant to select and configure adequate and appropriate clinical laboratory testing for the specific patient should be made available to the laboratory department.

This use case is expected to be robust enough to cope with real-life situations in which information about the patient may not provide all the required contextual information.

*Motivation:* Test results from clinical laboratory services may be requested and should be made available to medical staff who works in multiple medical departments within the hospital organisation on a need-to-know basis. This use case should ensure the availability of timely, complete and consistent patient information as well as avoidance of potential duplicate testing within the hospital organisation.

## 3.5 – Level of citizens at home and on the move

### 3.5.1 – Use case 8: Involvement of patient in documentation of his/her specific chronic disease and making it available via personal computer (PC) or web based applications to healthcare provider

*Short description:* There is a group of use cases that support the concept of 'for ever-present care'. They aim at involving a patient actively in the documentation of his/her specific chronic condition (or conditions), and making this physiological information available to medical staff either at a hospital or another medical service provider so as to assist in the diagnosis and/or monitoring of the patient's treatment.

One option that can encourage patient interaction and compliance with an appropriate treatment regimen involves the provision of PC-based or web-based applications. These applications can request a patient to provide regular personal information about his/her well-being and health status.

The data may include quantitative information such as weight or blood pressure as well as qualitative information about personal health. The process for interpreting the patient data depends on the specific medical indication and the chosen clinical pathway. It may either involve a physician directly in an inpatient or outpatient setting or, alternatively, the data may be monitored by a trained nurse, and involve an intervention on the part of a physician when necessary.

*Illustration:* As an example, consider a middle-aged patient who has Diabetes Mellitus Type II. The patient lives an independent life. This patient regularly measures his/her level of glucose. S/he enters this data, and any additional disease-related data, in a personal computer (PC)-based disease management application (i.e., a personal patient diary) or a web based application linked to chronic care management centre or directly transferring the data to a responsible healthcare professional on a daily basis. The information is monitored both by rules-based logic implemented as part of the application and by qualified nurses on an on-going basis. If needed, a physician is informed about any relevant degradation in the patient's health status, so that preventive measures can be taken at an early stage. As a result, the patient enjoys a healthier lifestyle, and any unplanned hospitalisation can often be avoided.

*Motivation:* The relative importance of chronic diseases such as diabetes, cardiac disease, chronic obstructive pulmonary disease (COPD) and hypertension is constantly growing in Western Europe, and more widely. It is broadly accepted that about 20 per cent of all patients in healthcare systems incur 80 per cent of the overall costs of healthcare delivery in Europe or the US. For the well-being of this extremely relevant patient segment, an appropriate treatment concept should consider both medical therapies and close monitoring of disease-specific clinical parameters so as to provide a continuous stimulus for healthy living.

The concept of 'for ever-present care' which takes place outside conventional care facilities provides numerous benefits for patients, providers, payer organisations and health care systems. These benefits include:

- Patients benefit from a closer monitoring of their health status that is based on a large number of data points gathered more often. As a consequence, medication typically fits the patient's individual context better and any unplanned hospitalisation can often be avoided. On average, the patient leads a healthier lifestyle and benefits psychologically from the awareness of participating in a well-organised treatment concept.
- Providers underline the positive aspects that result from of a better knowledge of recent patient health status as well as a longer patient history. This enables more solid decision-making about further therapeutic action.
- Studies on disease management initiatives in multiple countries have proven that, on average, patients benefit from a better health status at a lower treatment cost. This is a major driver for payer organisations and/or for the public health care system which may have a high interest in efficient and effective health care provision.

### 3.5.2 – Use case 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

*Short description:* There is a group of use cases that support the concept of 'for ever-present care'. They aim at involving a patient actively in the documentation of his/her specific chronic condition (or conditions), and making this physiological information available to medical staff either at a hospital or another medical service provider so as to assist in the diagnosis and/or monitoring of the patient's treatment

One option that can encourage patient interaction and compliance with an appropriate treatment regimen involves the provision of mobile monitoring devices and mobile telephones, e.g. smart-phones that request patients to provide regular personal information about their health status.

The mobile devices measure and monitor temperature, blood pressure, weight and other vital signs for clinical review at a remote medical service delivery location, and use either phone lines or wireless technology. Depending on the supporting application, more qualitative information about the patient's personal health may be included into the data transmission process. The approach chosen for the interpretation of the patient data depends on the respective medical indication and the chosen clinical pathway. It may either involve a physician directly in an inpatient or outpatient setting or, alternatively, the data may be monitored by a trained nurse, and it may involve an intervention on the part of a physician when necessary.

*Illustration:* As an example, consider the same patient from use case 8. This is a middle-aged patient who has Diabetes Mellitus Type II. The patient uses the monitoring device to measure his/her blood sugar level. The data is transferred to a smart phone wirelessly and automatically. The mobile phone forwards the data to an application server where it may be retrieved by the patient or authorised medical staff, e.g. via a web-based interface. Monitoring of the data, its classification and potential medical intervention may be organised in a similar fashion as that outlined in use case 8.

*Motivation:* The motivation for this use case is basically the same as that described in use case 8. The benefits for the stakeholders of healthcare provision are fundamentally the same. This use case differs only from use case 8 because it takes advantage of the more contemporary technologies of mobile monitoring devices and mobile telephony.

### 3.5.3 – Use case 10: For ever-present care outside conventional care facilities, involving the interoperability necessary from sensor devices to monitor activity, e.g., of elderly people

*Short description:* There is a group of use cases that support the concept of 'ambient assisted living'. They aim at providing information about a person's health status independent from face-to-face personal interaction and making such information available to medical staff in the case of need.

One of the many different options for collecting information about the person's personal activity involves the use of sensor technology set up in appropriately equipped rooms and buildings. In the context of this use case, as no decisions need to be taken by the person who is supported by these sensor devices, such solutions are well suited to supporting elderly or disabled people in leading an independent individual life as much as possible.

Sensor devices can suit requirements for easy manageability. They can provide different types of services in a building, such as lightning, navigation aids, locking and security. They can also enable communication services with peers, different medical services, and emergency information, etc. They may be conveniently managed via television (TV) sets through a complementary set-top box. Thus, elderly or disabled people may manage easily their personal environment at home just by sending simple commands through their TV.

*Illustration:* As a single example out of a wide range of possible applications, consider the implementation of sensors in the floor of a flat rented by an elderly person. The sensors can identify specific situations related to an emergency situation where, e.g., the resident may have collapsed or fallen in a part of the flat where s/he is not capable to call for help or to call an ambulance. Sensors embedded in the floor can identify such a specific situation and trigger an emergency call autonomously.

*Motivation:* The rapid demographic changes taking place in European countries demands innovative solutions that can support a rapidly growing percentage of elderly people. The major motivation for ambient assisted living solutions is to support elderly citizens to live longer independently in their private homes, and thus avoid both the public and private costs of increasing the number of nursing homes.

From the perspective of interoperability, the technology life cycle of ambient assisted living solutions is at an early stage of development today. Introducing interoperability standards early on addresses the objective of cost efficiency.

The European Innovation Partnership on Active and Healthy Ageing is dedicated to foster active and healthy ageing as a major societal challenge for Europe. The selection of a use

case from this particular category would foster closer cooperation of the two interrelated fields of eHealth and healthy ageing.

# 4 – Profiles associated with the list of high-level use cases

Profiles are provided for each of the ten use cases. In terms of approach, both of the profile development organisations Continua and IHE were asked to provide the study team with a list of profiles that corresponded to the prioritised used cases. The results show that relevant profiles fall into the field of IT infrastructure, laboratory, patient care coordination, patient care device, pharmacy, and radiology (see Table 2 below, indicating the IHE profiles with a * and the Continua profiles with a +).

**Table 2. Profiles associated with list of high-level use cases**

| Nr | Level | Use case | Profiles |
|---|---|---|---|
| **1** | Cross-border | epSOS project : e-Prescription and e-Dispensation for cross-border information sharing for citizens travelling in Europe | • IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA*<br>• Pharmacy: PRE*, DIS* |
| **2a** | Cross-border | epSOS project : patient summaries for cross-border information sharing for citizens travelling in Europe | • IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA*<br>• Patient Care Coordination: XPHR* |
| **2b** | Cross-border | epSOS project - patient having access to his or her patient summary. | • IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA*<br>• Patient Care Coordination: XPHR* |
| **3** | National/Regional | Request and results (imaging results, diagnostic examinations) sharing workflow for radiology in inter-hospital setting on national/regional scale | • IT Infrastructure: PIX*, PDQ*, XDS*, CT*, ATNA*, BPPC*, XUA*<br>• Radiology: XDS-I* |
| **4** | National/Regional | Request and results (laboratory reports, test results) sharing workflow for laboratory in inter-hospital setting on national/regional scale | • IT Infrastructure: PIX*, PDQ*, XDS*, CT*, ATNA*, BPPC*, XUA*<br>• Laboratory: XD-LAB* |
| **5a** | National/Regional | Cross-Enterprise Sharing of Medical Summaries: Ambulatory Specialist Referral | • IT Infrastructure: PIX*, PDQ*, XDS*, CT*, ATNA*, BPPC*, XUA*<br>• Patient Care Coordination: XDS-MS, XPHR* |
| **5b** | National/Regional | Cross-Enterprise Sharing of Medical Summaries: Acute Care Discharge to Ambulatory Care Environment | • IT Infrastructure: PIX*, PDQ*, XDS*, CT*, ATNA*, BPPC*, XUA*<br>• Patient Care Coordination: XDS-MS, XPHR* |
| **6** | Intra-Hospital | Request and results (imaging diagnostics tests) distribution workflow for radiology in intra-hospital setting | • IT infrastructure: CT*, ATNA*, PDQ*, PAM*, SVS*<br>• Radiology: SWF* |

| Nr | Level | Use case | Profiles |
|---|---|---|---|
| **7** | Intra-Hospital | Request and results (clinical laboratory tests) sharing workflow for laboratory in intra-hospital setting | • IT infrastructure: PAM*, PDQ*, CT*, ATNA*, SVS*<br>• Laboratory: LTW*, LCSD* |
| **8** | Citizens at home and on the move. | 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) | • IT Infrastructure: PIX*, PDQ*, XDS*, XDR*, XDM*, CT*, ATNA*, BPPC*, XUA*<br>• Patient Care Device: HRN+, WAN+, DEC*/RTM*, LAN+ or PAN+ |
| **9** | Citizens at home and on the move. | 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) | • IT Infrastructure: PIX*, PDQ*, XDS*, XDR*, XDM*, CT*, ATNA*, BPPC*, XUA*<br>• Patient Care Device: HRN+, WAN+, DEC*/RTM*, LAN+ or PAN+ |
| **10** | Citizens at home and on the move. | For ever-present care outside conventional care facilities, involving the interoperability necessary from sensor devices to monitor activity, e.g. of elderly people | • IT Infrastructure: PIX*, PDQ*, XDS*, XDR*, XDM*, CT*, ATNA*, BPPC*, XUA*<br>• Patient Care Device: HRN+, WAN+, DEC*/RTM*, LAN+ or PAN+ |

# 5 – Introducing IHE and Continua

This chapter provides an introduction to the two profile development organisations IHE and Continua. General information is given about the profile development organisation, and more specifically about the key processes, organisational overview, membership and voting procedures. IHE is introduced in section 5.1, and Continua is discussed in section 5.2.

## 5.1 – Introducing IHE

### 5.1.1 – General information[24]

Integrating the Healthcare Enterprise (IHE) International, Incorporated is a non-profit organization incorporated under the laws of the State of Illinois, U.S.A. IHE International enables users and developers of healthcare information technology to achieve interoperability of systems through the precise definition of healthcare tasks, the specification of standards-based communication between systems required to support those tasks and the testing of systems to determine that they conform to the specifications. For example, the IHE profiles discussed in chapter 4, are defined by IHE International.

The work within IHE International is managed by IHE committees and sponsored by various national and international bodies. One of the active members of IHE International is IHE Europe, which coordinates deployment of IHE activities in Europe, and federating national IHEs (Austria, France, Germany, Italy, Netherlands, Spain, UK, etc). By testing every year integration profiles including clinical contents and medical vocabularies in the European Connectathons, IHE-Europe participates to the development of the quality of interoperability between products of various companies working in Europe but also qualifies the use of the standards in such profiles.

### 5.1.2 – Key processes[25]

IHE brings together users and developers of healthcare information technology (HIT) in an annually recurring four-step process:

1. Clinical and technical experts define critical use cases for information sharing.
2. Technical experts create detailed specifications for communication among systems to address these use cases, selecting and optimizing established standards.
3. Industry implements these specifications called IHE Profiles in HIT systems.
4. IHE tests vendors' systems at carefully planned and supervised events called Connectathons.

[24] http://www.ihe.net/governance/index.cfm
[25] http://www.ihe.net/About/

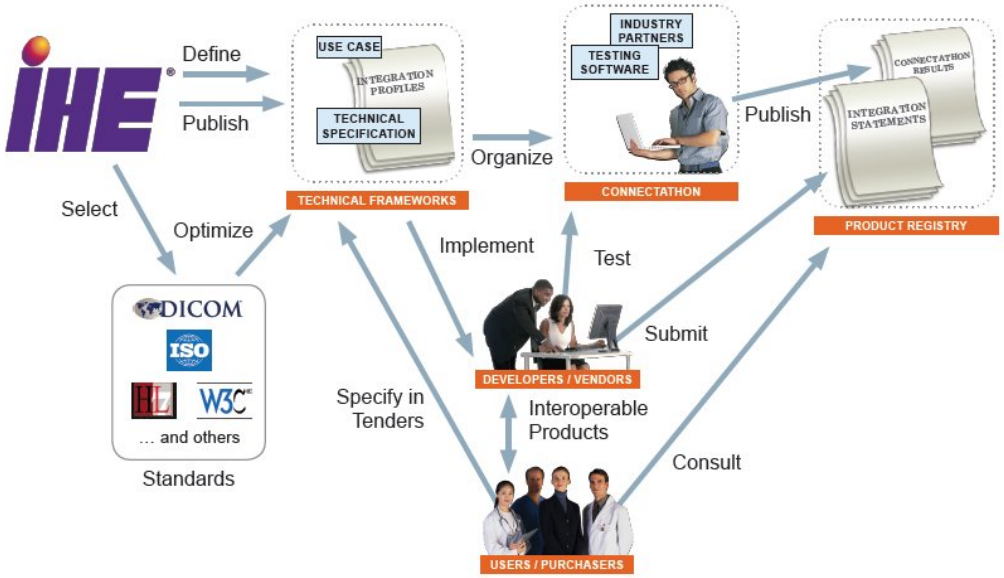


**Figure 2 – Overview of main IHE processes**

IHE also organizes demonstrations of IHE-compliant systems working in real-world clinical scenarios at medical meetings and other venues.

### 5.1.3 – Organisational overview[26]

The scope of responsibilities and composition of the committees are briefly described here:

- The *Board* and its *Board Operations Committee* govern the other committees of IHE International. They empower and coordinate National and Regional Deployment Committees.
- The *Testing and Tools Committee* coordinates IHE testing activities conducted by National and Regional Deployment Committees, including the development of testing software and other tools.
- The *Marketing and Communication Committee* coordinates IHE marketing and communication activities and resources.
- The *Advisory Panel* is a group of invited leaders in healthcare information technology and related fields, who agree to provide guidance to the IHE Board.
- *Domain Committees* (Planning and Technical) develop the IHE Technical Frameworks, the interoperability specifications which are the foundational work product of IHE.
- The *Domain Coordination Committee ensures consistent processes across IHE Domains and promotes effective communication and coordination among them.*
- *National and Regional Deployment Committees* are empowered by the IHE Board to conduct testing, demonstrations, educational events and other deployment activities within their geographic area. They also develop National Extensions to the IHE Technical Frameworks to address local variations in care delivery.
- *Liaison Organizations*, including relevant Standards Development Organizations, enter into mutual agreements with IHE International to communicate on and coordinate complementary activities.

[26] http://www.ihe.net/governance/upload/IHE_Intl_Governance_amended_2011-08-11.pdf

### 5.1.4 – Membership[27]

#### *5.1.4.1 – Board membership*

The Board shall be composed of representatives of Member Organizations. There are six categories of Board Members with the following qualifications:

1. Each IHE International Sponsor shall designate a principal representative and an alternate, both drawn from the community represented by the sponsor.

2. The Member Organizations shall elect, for 2-year terms, four voting members-at-large. Half of their terms shall expire in alternate years. They shall belong to member organizations other than those already represented on the Board.

3. Each Domain Planning Committee shall designate for two-year terms a principal representative and an alternate, who may be drawn from either the Domain Planning or Technical Committee active membership (Co-chairs are recommended). They shall belong to other member organizations than those already represented on the Board.

4. The Board shall elect, for 2-year terms, two voting representatives drawn from the pool of past Domain co-chairs. Their terms shall expire in alternate years. They shall belong to member organizations other than those already represented on the Board.

5. Each Regional Committee shall designate a principal representative and an alternate.

6. Each National Committee shall designate a principal representative and an alternate.

If a current Board Member no longer a representative of a member organization, affected Board rep is removed and alternate replaces him/her (subject to normal procedures). If a Board rep designated by a body within IHE (such as sponsors, domains, deployment committee) moves to another organization, he/she will continue in current position until the designating body selects a replacement. For at-large Board representatives, the Board will, at its next meeting consider and vote on a motion whether to hold a new election or allow the representative to fulfill his or her term.

#### *5.1.4.2 – IHE organisational membership and committee participation*

IHE International is composed of Member Organizations interested in improving the interoperability of healthcare information systems. An organization that becomes a member of IHE International may designate representatives to participate in Domain Committees relevant to its interest. A member organisation may also apply to relevant National/Regional Deployment Committees.

A Member Organisation shall designate a principal voting representative to each Committee on which it wishes to be represented, by notifying the Secretary of that Committee. One or more alternate representatives may also be designated.

Where two or more Member Organisations have Parent/Subsidiary relationships with one another, they will be allowed only one voting representative collectively for each Committee on which one or more of the Member Organisations is represented.

[27] http://www.ihe.net/governance/upload/IHE_Intl_Governance_amended_2011-08-11.pdf

Committees are generally open to all interested parties. Specific committees may choose to establish additional participation procedures, subject to review by the Board, so long as they do not contradict the principles expressed in the bylaws.

#### *5.1.4.3 – Membership categories*

Any stakeholder with interests that might be directly and materially affected by the activity of an IHE development or deployment committee shall have the opportunity for fair and equitable participation without dominance by any single interest.

Each IHE International member shall propose its own membership interest category: User, Developer and General Interest. Organizations that could fall into more than one category must choose a single affiliation for membership and voting purposes. Committees may choose to establish membership rules or voting procedures based on interest categories.

### 5.1.5 – Voting procedures[28]

Overall, the voting procedures are based on the following:

- Decisions taken by a committee, whether at a face-to-face meeting, by teleconference or by letter ballot, and whether reached by consensus or vote, shall require a quorum of 50% of the Members that have voting privileges.
- Decisions shall be recorded by the Secretary in the minutes. In the event that more than one position receives substantial votes, the Chair may request the details of the majority and minority positions also be recorded in the minutes.
- Whenever possible, committee decisions shall be achieved by consensus. When a matter is put to a recorded vote, approval is determined by no less than a 66% affirmative vote of those voting.
- Each Member Organization shall have one vote to be cast by the principal representative (or by an alternate if the principal is not available to vote).
- All committee votes shall be open, and the results of the voting shall be recorded in the minutes.
- Whenever possible, in order to enable fair participation by committee Representatives regardless of location, matters to be voted on will be announced in advance and voting via email or teleconference will be permitted.

## 5.2 – Introducing Continua

### 5.2.1 – General information[29]

Continua Health Alliance is a non-profit, open industry organization of healthcare and technology companies joining together in collaboration to improve the quality of personal healthcare. With more than 220 member companies around the world, Continua is dedicated to establishing an eco-system of interoperable personal connected health solutions with the knowledge that extending those solutions into the home fosters independence, empowers individuals and provides the opportunity for truly personalized health and wellness management.

[28] http://www.ihe.net/governance/upload/IHE_Intl_Governance_amended_2011-08-11.pdf
[29] http://www.continuaalliance.org/about-the-alliance

### 5.2.2 – Key processes[30]

The key processes of Continua include:

- Developing design guidelines that will enable vendors to build interoperable sensors, home networks, telehealth platforms, and health and wellness services.
- Establishing a product certification program with a consumer-recognizable logo signifying the promise of interoperability across certified products.
- Collaborating with government regulatory agencies to provide methods for safe and effective management of diverse vendor solutions.
- Working with leaders in the health care industries to develop new ways to address the costs of providing personal telehealth systems.

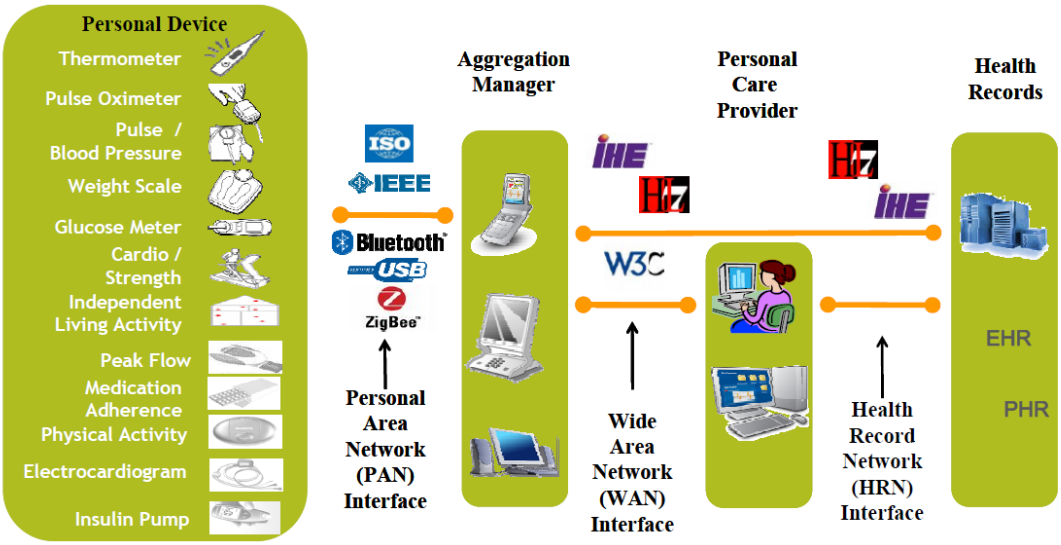


**Figure 3 – Different categories of Continua's design guidelines**

### 5.2.3 – Organisational overview[31]

The organisation is primarily staffed by volunteers from the member organisations that are organised in to working groups that address the goals of the Alliance. Below the board of directors sit the following main working groups:

- *Marketing Council* – Focus on creating marketing materials, website social media and promotion of the Alliance.
- *Market Adoption Work Group* - Establish a value proposition for innovative connected health solutions that effectively manage the health, wellness and fitness of the health consumer by using Continua-certified solutions and systems. Grow membership in targeted industries (providers & payers) and geographic markets (APAC, EU).
- *Emerging Markets Work Group* – Includes developing regional working groups – China Brazil, India and Southeast Asia along with Australia Policy Working Group, and Latin America Policy Working Group
- *Japan Working Group* – works with the governmental and commercial bodies on deployments in Japan region.

[30] http://www.continuaalliance.org/about-the-alliance/mission-and-objectives
[31] http://www.continuaalliance.org/about-the-alliance/working-groups

- *European Union* - works with the European Union institutions and European governments on policies to promote the adoption of health information technologies
- *US Policy* - Committed to supporting, pursuing and expanding federal and state policies that are committed to the advancement of interoperable personal health and wellness solutions.
- *Technical* - Evaluate existing standards against requirements in order to identify gaps and take steps to reconcile.
- *Use Case* - Responsible for identifying and prioritizing user experiences to be addressed by the Continua Interoperability Guidelines.
- *Regulatory* - Clarification and description of interoperable devices functions in a regulatory environment.
- *Test & Certification* - Create and maintain the Test and Certification Program for Continua Health Alliance.

### 5.2.4 – Membership[32]

#### *5.2.4.1 – Board membership*

The Board of Directors consists of between 5 and 15 directors appointed for 1 year (Elected Seat representing Promoters) or 2 years (Permanent Seat representing Originating Promoters). The quorum of the Board of Directors is 2/3 of the total current number of directors and the affirmative action takes place with more than 1/2 of votes.

The role of the Board of Directors within the Guidelines creation process is threefold:

- it establishes policies and procedures for the consideration of changes or refinements to Design Guidelines of the Corporation;

- it considers Draft Design Guidelines and Design Guidelines for adoption and submission to Promoters for final approval or rejection;

- it considers for approval or rejection any public statement, press release or similar public materials concerning the Design Guidelines or the business of the Corporation prior to making such materials public.

#### *5.2.4.2 – Work group participation*

Subject to the approval of the Work Group chairperson and the board of directors, an Originating Promoter or Promoter may propose candidates for membership in a Work Group; provided, however, that only Originating Promoters or Promoters shall be entitled to vote on any output or action of a Work Group.

All Originating Promoters shall be permanently entitled to appoint representatives to any Work Group. With the exception of Special Participants who may not join any Technical Work Groups, any Participant in good standing may join any Work Group; provided, however, that the board of directors may, from time to time, develop objective minimum standards for membership in Work Groups as part of the general Work Group Procedures or a Work Group may through its chairperson, propose specific minimum standards for membership which are subject to ratification by the board of directors as Specific Work Group Procedures.

[32] http://www.continuaalliance.org/sites/default/files/Continua_Bylaws_July_28_2011.pdf

#### *5.2.4.3 – Membership categories*

Any for-profit corporation, nonprofit corporation, or other enterprise supportive of this Corporation's purposes and not otherwise prohibited by treaty, law or regulation from abiding by the terms of these Bylaws and who pays the then current annual dues applicable to its Participation Classification may become a Participant of the Corporation.

These annual membership fees are:

- Promoter: $25,000
- Contributor: $6,500
- Supporting Participant: $6,500
- Developing Region: $1,000 (first year); $2,500 (second year); $6,500 (as of third year)

The main benefits for contributor members are:

- Right to use Continua technical Guidelines and use cases. This includes access to pre-publication drafts of the Design Guidelines and internal documents through the Working Groups as well as the opportunity to review and comment on new Design Guidelines prior to their adoption.
- Right to participate (non-voting) in Continua Working Groups to help create and influence the use cases, technical guidelines, marketing materials, lobbying efforts, and all other Continua work products. May hold lead positions in Task forces and Tiger teams.

The main benefits for promoter members are:

- All Contributor Member benefits.
- Voting rights in all Continua Working Groups. Including the selection of use cases, standards, industry technologies, and other key Working Group decisions.
- Ability to hold leadership positions within the Working Groups.
- Right to be elected to the Board of Directors.

### 5.2.5 – Voting procedures[33]

A selection of the voting procedures is given below:

- If a quorum is present when a vote is taken, the affirmative vote of two-thirds (2/3rds) of directors present when the act is taken is the act of the board of directors, provided, however, that no action may be taken without an affirmative vote of more than one half (1/2) of the total current number of directors.
- With the exception of voting for Elected Board members, each Participant shall have one vote on each matter submitted to a vote by the Participants. The Participant's designated employee shall do all voting in person (including via telephonic means) and not by proxy.
- Voting at meetings shall be by a show of hands if held in person, or by voice ballot if held by audio, videoconferencing or teleconferencing, unless otherwise required.

[33] http://www.continuaalliance.org/sites/default/files/Continua_Bylaws_July_28_2011.pdf

# 6 – Organisational assessment results

This chapter describes the organisational assessment results for the two analysed profile development organisations, and for the epSOS large-scale pilot. Section 6.1 discusses the impact of Continua's remedy plan on the organisational assessment recommendations. Section 6.2 provides a high-level recapitulation of the approach followed to obtain the organisational assessment results (for more details, see Deliverable 3). Section 6.3 discusses the organisational assessment results for Continua, section 6.4 explains the organisational assessment results for IHE, and section 6.5 describes the organisational assessment results for the epSOS large-scale pilot.

## 6.1 – Impact of Continua's remedy plan on the organisational assessment recommendations

After sharing our assessment results with Continua, Continua decided to introduce modifications, which were agreed as a result of the Continua's Board of Directors meeting that took place on December 12th 2012. A brief summary of these modifications can be found at the end of every subsection of section 6.3 (cfr "Continua's proposed improvements").

At the time of writing, these decisions taken by Continua's board are being executed with some aspects still to be implemented. Hence, the study team was not able to take these changes into account during the assessment, as it is not possible to gauge if all decisions will be implemented and also how they will be implemented. Therefore, the material that has been analysed so far has been developed according to the old Continua processes and it is only when that material will be revised with the new Continua processes that their compliancy could change. Nevertheless, in this regard, Continua undertook a constructive shift towards compliance. These changes are expected to have a positive impact on the future assessment of Continua specifications by the ICT Standards Multi-Stakeholder Platform.

## 6.2 – High-level approach

This analysis was based on the organisational criteria extracted from Annex II of the Regulation on European Standardisation, and the study team's interpretation of the meanings of the various criteria (for more details, see Deliverable 3). The profile development organisations selected were Continua and IHE. The epSOS large-scale pilot was also considered, for the purpose of this study, as a temporary organisation that developed (non-IHE) technical specifications, and that supported the extension / development of IHE profiles. Proposals for enhancement (or "recommendations") of these aspects of their work were offered to the relevant profile development organisations as a result of the analysis undertaken[34].

[34] In the study, an assessment framework based on the Regulation on European Standardisation was used to assess profile development organisations i.e., IHE and Continua, with epSOS, the large-scale pilot seen as a temporary profile development organisation. In some instances, such as "Is standardisation process collaborative and consensus based and did it not favour any particular stakeholder?" the concept of a standardisation process is used.

More specifically, the following categories are included in the organisational assessment:

**Table 3. Organisational assessment criteria**

| Category | Question |
|---|---|
| **Type of organisation** | Are the technical specifications developed by a non-profit making organisation which is a professional society, industry or trade association or any other membership organisation that within its area of expertise develops standards in the field of information and communication technologies and which is not a European, national or international standardisation body? |
| **Openness** | Are the technical specifications developed on the basis of open decision-making accessible to all interested actors in the market or actors in the markets affected by those technical specifications? |
| **Consensus** | Is the standardisation process collaborative and consensus based and did it not favour any particular stakeholder? |
| **Transparency** | Is all information concerning technical discussions and decision making archived and identified? |
| | Is information on new standardisation activities widely announced through suitable and accessible means? |
| | Is participation of all categories of stakeholders sought with a view to achieving balance? |
| | Is consideration and response given to comments by interested parties? |
| **Maintenance** | Is on-going support and maintenance of published specifications guaranteed over a given time period (i.e. 3 - 5 years)? |
| **Intellectual Property Rights** | Are intellectual property rights essential to the implementation of specifications licensed to applicants on a (fair) reasonable and non-discriminatory basis ((F)RAND), which includes, at the discretion of the intellectual property right-holder, licensing essential intellectual property without compensation? |

## 6.3 – Organisational assessment results for Continua

Based on the analysis of the Continua Health Alliance organisation (hereinafter Continua), a set of recommendations was provided for the following categories: openness (section 6.3.1), consensus (section 6.3.2), and transparency (section 6.3.3). At the end of every section, a brief summary is given of the modifications Continua proposes to address the recommendations (cfr "Continua's proposed improvements"). In this analysis, the term "we" refers to the Deloitte study team that undertook the analysis.

### 6.3.1 – Recommendation for openness

According to the study team's interpretation, the category of openness refers to the decision-making process accessible to all possible interested parties (including Small and

Medium Enterprises[35]) directly or indirectly affected by the technical specifications in the market.

#### *6.3.1.1 – Main Findings*

After the analysis of the decision making process concerning the design and approval of profiles (guidelines), we found that no public comment process was identified apart from comments that can be made via industry groups. Only paying members can provide input in the profile development process.

#### *6.3.1.2 – Overall Conclusion*

We conclude a non-compliance with the category openness of the Regulation since Continua does not have a public comment process allowing all stakeholders to provide feedback on profiles.

#### *6.3.1.3 – Recommendation*

Based on the above findings and the resulting conclusion, we recommend that **the profile development process should be based on a decision making process** in which all interested actors can take part on equal terms.

#### *6.3.1.4 – Continua's proposed improvements*

Continua's proposition concerns the introduction of a public commenting period before closing a new version of the public guidelines. The duration of the period was agreed to last 2 months, which is part of the 8 month long interoperability testing period and was proposed to be performed within the Errata process. According to Continua's further discussions of January 15th 2012, the public commenting phase is proposed to take place at or after month 6th of the interoperability testing period. It is proposed that the public commenting period should be limited to one round.

### 6.3.2 – Recommendation for consensus

According to Deloitte's interpretation, the category of consensus refers to the standardisation process providing a level playing field for all stakeholders which should be based on collaboration and consensus defined by the Regulation in the following way: "*consensus means a general agreement, characterised by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments. Consensus does not imply unanimity*."

#### *6.3.2.1 – Main Findings*

The analysis of the category consensus is based on the following findings:

- A Technical Working Group drafts and develops the Design Guidelines, which are reviewed by the Participants (members) and submitted for the final review and approval to the Board of Directors.

[35] Continua's working definition of Small and Medium Enterprises (SME) is any organisation employing 20 persons. This definition is not aligned with the definition put forward by the European Commission (SME has 50 to 250 employees or a turnover between €10m and €50m or a balance sheet total between €10m and €43m), which is for example used by ETSI to differentiate between different categories of members (see: http://portal.etsi.org/directives/29_directives_jan_2012.pdf).

- There exist three types of members within Continua organisation. These are Promoters, Contributors and Supporting Participants;

- Promoters are the only category of members having voting rights concerning selection of use cases, standards, industry technologies and other key Working Group decisions. They are also the only category of members that can be elected to the Board of Directors;

- The Board of Directors is composed of directors that "must be employees of an Originating Promoter, or, commencing at the second (2nd) annual meeting of the board of directors, a Promoter"[36]. At present (29.11.2012), out of 15 members of the Board of Directors, there are 13 Promoters;

- It costs $25,000 per year to be a Promoter.

#### *6.3.2.2 – Overall Conclusion*

The above findings lead to the conclusion that Continua is partly compliant with the category consensus of the Regulation as the decision making process is collaborative among the Continua members. However, it does not avoid possible favourism as the final review and approval of Design Guidelines lies with the Board of Directors, mainly composed of Promoters – the only member category with decisive voting rights.

#### *6.3.2.3 – Recommendation*

The findings and the resulting conclusions lead to the recommendation **to grant voting rights to all members**. A solution could be to grant voting rights to any member and define number of votes in terms of other measures.

#### *6.3.2.4 – Continua's proposed improvements*

Continua's proposition concerns giving all members of the Technical Working Group (TWG) equal voting rights pending appropriate participation in the work group (i.e. attendance in 2 or 3 meetings). However, at the time of writing, the Board of Directors still has to give full approval to the vote from the TWG. In addition, all members will be able to propose use cases, and Contributors will be allowed to provide input throughout the use case process. Further clarification in February for voting rights is foreseen.

### 6.3.3 – Recommendation for transparency

As indicated by Table 3, the category of transparency consists of four questions. Firstly, the study team interprets the requirement of information archiving and identification as a necessary condition for a profile development organisation to be credible. Secondly, we understand the requirement of publishing information about new standardisation activities via public channels as a necessary condition contributing to transparency of a profile development organisation. Thirdly, the requirement of a balanced composition of all stakeholders is seen by us as a necessary condition to create a level playing field for all stakeholders. Finally, the Regulation requirement of addressing comments by interested parties is interpreted by Deloitte as a necessary condition to ensure opinions and inputs of technical specifications expressed by different parties are given consideration.

[36] Bylaws of Continua Health Alliance, an Oregon non-profit corporation, July 28th 2011, section 4.3

#### *6.3.3.1 – Main Findings*

The analysis of the category transparency is based on the following findings:

- Only paying members can access information;
- Only information about the standardisation process is made available. Information on new standardisation activities is not public;
- Voting rights are granted only for members paying $25,000 yearly (Promoters category);
- Only comments from paying members are addressed. No public comment process was found.

#### *6.3.3.2 – Overall Conclusion*

The conclusion stemming from the above findings is that Continua is only partially compliant with the requirement of information archiving, and that no balanced pool of stakeholders of all relevant categories is sought. Voting rights are granted only to the members paying the highest membership fees.

#### *6.3.3.3 – Recommendation*

Given the findings and conclusion presented in the previous sections, the following recommendations are proposed:

- In order to ensure full transparency of the profile creation process for all stakeholders, **all information concerning organisation's activities should be disclosed publicly;**
- In order to ensure a balanced pool of stakeholders, **all interested parties should be given the same opportunity** to contribute to the profile development process.

#### *6.3.3.4 – Continua's proposed improvements*

Continua's proposition is to make all key working documents related to the development of the guidelines (archives, working groups content anonymized minutes and votes of working group activities) public. In this context, only documents related to the standard, and without any intellectual property, will be included. To this end, a new member collaboration tool provided by the new Continua website would allow for a more streamlined way to do this. Further Continua's discussion, that took place on January 15th 2013, yielded a proposition to allow access to all Use Cases (within formally related Public Guidelines).

Continua Action (Jan 15, 2012)

> Motion: To approve changes to the Guidelines approval process by making public all documents and working group content for the formally released Public Guidelines
>
> To allow access to all Use Cases and decisions
>
> To allow access to anonymized minutes and votes of working group activities.

## 6.4 – Organisational assessment results for IHE

Based on the analysis of IHE as an organisation, a set of recommendations was provided for the category of transparency.

### 6.4.1 – Recommendation for transparency

As indicated by Table 3, the category of transparency consists of four questions. Firstly, the study team interprets the requirement of information archiving and identification as a necessary condition for a profile development organisation to be credible. Secondly, we understand the requirement of publishing information about new standardisation activities via public channels as a necessary condition contributing to transparency of a profile development organisation. Thirdly, the requirement of a balanced composition of all stakeholders is seen by us as a necessary condition to create a level playing field for all stakeholders. Finally, the Regulation requirement of addressing comments by interested parties is interpreted by Deloitte as a necessary condition to ensure opinions and inputs of technical specifications expressed by different parties are given consideration.

#### *6.4.1.1 – Main Findings*

The following findings were identified:

- There exists a process to archive and identify technical discussions and decision making;
- Not all information is stored on the IHE wiki: there are 55 examples[37] of lacking agenda and lacking meeting minutes identified for the Domain Committees (Technical Committees) and IHE International Committees. (listed among 13 domains and for each domains, 2 committees with an average of 3 meetings including monthly teleconferences and face to face meetings).

#### *6.4.1.2 – Overall Conclusion*

We conclude a partial non-compliance with the Regulation as the process to archive and identify technical discussions and decision making is not always rigorously applied.

#### *6.4.1.3 – Recommendation*

In order to ensure a full transparency of the profile creation process for all stakeholders, **all information concerning organisation's activities should be disclosed publicly in a more rigorous way**.

## 6.5 – Organisational assessment results for epSOS

The epSOS large-scale pilot was also considered, for the purpose of this study, as a temporary organisation that developed (non-IHE) technical specifications, and that supported the extension / development of IHE profiles.

### 6.5.1 – Main findings

The following findings were identified within the categories of the organizational assessment: openness, consensus, transparency, maintenance and intellectual property rights.

[37] Excluding cancelled meetings

Within the category **openness,** we found that technical specifications were defined as a result of joint activities between epSOS beneficiaries and industry team members. The study team also learnt that the decision making is open to any actor at all times.

Within the category of **consensus,** the study team found that work packages are led by a selection of key experts (representing 5 to 7 MS), and that this selection of experts conducts further discussions with other stakeholders. In this sense, the standardization process does not favour any stakeholder: the work package information is eventually presented to all MS. If the MS agree by consensus, the decision is tested and implemented. The voting process applies when the technical team does not reach consensus. The voting is based on a majority rule (so far no decision has been taken following the majority rule). Note that the Project Steering Committee (PSC) is the only entity having voting rights, composed of MS delegates from Ministries of Health.

Within the category of **transparency,** the study team found that the decision making process is traced in epSOS minutes and reports. As it comes to the epSOS project specifications, they are publicly available and can be downloaded from the epSOS portal free of charge. In addition, all interested actors can provide input for the specifications at all times.

Within the category of **maintenance,** the study team found that a range of epSOS specifications are based on IHE profiles, HL7 documents and coding systems from international standardisation bodies, for which ongoing support and maintenance is guaranteed over a long period. The maintenance of the open source products is still being discussed.

Within the category of **intellectual property rights,** the study team found that the employed IHE profiles are licensed to applicants on a FRAND (fair, reasonable and non-discriminatory) basis, without any compensation. Moreover, the documentation of IPR for IHE profiles is publicly available.

### 6.5.2 – Overall conclusion

Based on the presented findings, the study team found that epSOS meets the requirements of each of the categories of the organizational assessment.

### 6.5.3 – Recommendation

The analysis of the epSOS project revealed **full alignment with the requirements defined by Annex II of the Regulation on European Standardisation**. Therefore, no recommendations were formulated[38].

[38] epSOS, the large-scale pilot, is different from both IHE and Continua as it is a project that is funded and supported by the Member States. It should therefore not be directly compared with IHE or Continua.

# 7 – Technical specification assessment results

This chapter describes the results of the technical specification assessments applied to the two profile development organisations, Continua and IHE. Section 7.1 discusses the impact of Continua's remedy plan on the technical specification assessment recommendations. Section 7.2 provides a high-level recapitulation of the approach followed to obtain the technical specification assessment results (for more details, see Deliverable 3). Section 7.3 discusses the technical specification assessment results for Continua, and section 7.4 explains the technical specification assessment results for IHE.

## 7.1 – Impact of Continua's remedy plan on the technical specification assessment recommendations

After sharing the assessment results with Continua, Continua decided to introduce modifications, which were agreed as a result of the Continua's Board of Directors meeting that took place on December 12th 2012. A brief summary of these modifications can be found at the end of every subsection of section 7.3 (cfr "Continua's proposed improvements").

At the time of writing, these decisions taken by Continua's board are being executed with some still aspects to be implemented. Hence, the study team was not able to take these changes into account during the assessment, as it is not possible to gauge if all decisions will be implemented and also how they will be implemented. Therefore, the material that has been analysed so far has been developed according to the old Continua processes and it is only when that material will be revised with the new Continua processes that their compliancy could change. Nevertheless, in this regard, Continua undertook a constructive shift towards compliance. These changes are expected to have a positive impact on the future assessment of Continua specifications by the ICT Standards Multi-Stakeholder Platform.

## 7.2 – High-level approach

This analysis was based on the technical specification criteria extracted from Annex II of the Regulation on European Standardisation, and the study team's interpretation of the meanings of the various criteria (for more details, see Deliverable 3). In terms of approach, both of the profile development organisations, Continua and IHE, were asked to provide the study team with a list of profiles that corresponded to the prioritised use cases. As discussed in chapter 4, the relevant profiles fall into the field of (in alphabetic order) IT infrastructure, laboratory, patient care coordination, patient care device, pharmacy, and radiology. Proposals for enhancement (or "recommendations") of these aspects were offered to the relevant profile development organisations as a result of the analysis undertaken[39].

[39] In the study, an assessment framework based on the Regulation on European Standardisation was used to assess profile development organisations i.e., IHE and Continua, with epSOS, the large-scale pilot seen as a temporary profile development organisation. In some instances, such as "Is standardisation process collaborative and consensus based and did it not favour any particular stakeholder?" the concept of a standardisation process is used.

More specifically, the following categories are included in the technical specification assessment:

**Table 4. Technical specification assessment criteria**

| Category | Question |
|---|---|
| **Market acceptance** | Do technical specifications or their implementations not hamper interoperability with the implementations of existing European or international standards? |
| | Are there demonstrations by operational examples of compliant implementations from different vendors? |
| **Coherence** | Are the technical specifications coherent? That is to say, do they cover domains where the adoption of new European standards is not foreseen within a reasonable period, where existing standards have not gained market uptake or where these standards have become obsolete, and where the transposition of the technical specifications into European standardisation deliverables is not foreseen within a reasonable period? |
| **Availability** | Are technical specifications publicly available for implementation and use on reasonable terms (including a reasonable fee or free of charge)? |
| **Relevance and effectiveness** | Does the usage of the technical specifications ensure achievement of implementation of required functionalities? |
| | Do the technical specifications respond to market needs? |
| | Do the technical specifications respond to regulatory requirements? |
| **Neutrality and stability** | Are the technical specifications whenever possible performance-oriented rather than based on design or descriptive characteristics? |
| | Do the technical specifications not distort the market or limit the possibilities for implementers to develop competition and innovation based upon them? |
| | Are the technical specifications based on advanced scientific and technological developments? |
| **Quality** | Are the quality and level of detail sufficient to permit the development of a variety of competing implementations of interoperable products and services? |
| | Are standardised interfaces not hidden or controlled by anyone other than the organisations that adopted the technical specifications? |

## 7.3 – Technical specification assessment results for Continua

Based on the analysis of the Continua Health Alliance organisation, a set of recommendations was provided for the following categories: relevance and effectiveness (section 7.3.1), neutrality and stability (section 7.3.2), quality (section 7.3.3). At the end of every section, a brief summary is given of the modifications Continua proposes to address the recommendation (cfr "Continua's proposed improvements").

### 7.3.1 – Recommendation for relevance and effectiveness

Within the category of relevance and effectiveness, the study team understood that the technical specifications should be formulated in a way to support high-level uses cases, as described by the eHealth EIF, which are patient/health care provider centric. As it comes to compliance with regulatory requirements, we recommend a mechanism that checks regulatory compliance. Installing such a procedure would contribute to relevance and effectiveness.

#### *7.3.1.1 – Findings*

The following findings were identified for the category of relevance and effectiveness:

- The structure of Continua's Guidelines was checked in order to test how they could support the eHealth EIF high-level use cases. The finding is that the Guidelines are product centric, while the eHealth EIF high-level use cases can only be supported by patient/health care provider centric technical specifications (Guidelines). In that sense, the Continua Guidelines do not match the eHealth EIF. However, the study team considers that Continua meets the requirements of the Regulation in the category relevance and effectiveness within the following elements:
    - *the usage of the technical specifications (Guidelines) ensure achievement of implementation of required functionalities*
    - *the technical specifications (Guidelines) respond to market needs*
- No explicit process was found to check the EU regulatory requirements during the profile development process. Continua only mentions the existence of a working group in the US and the EU that deals with regulatory bodies in order to implement and adjudicate issues in the Regulatory process.

#### *7.3.1.2 – Overall Conclusion*

Given the above findings, we give a partial non-compliance with the Regulation for the category of relevance and effectiveness.

#### *7.3.1.3 – Recommendation*

Given the findings and conclusion presented in the previous section, a set of recommendations is proposed:

- It is recommended to create patient/health care provider centric Guidelines in order to support the eHealth EIF use cases.
- As the eHealth EIF is use case driven, it is recommended to **translate, in addition, device based information into use case based information**.
- It is recommended to implement a mechanism to **ensure compliance with all relevant EU regulatory requirements** in order to assure quality of profiles and to avoid a series of risks.

#### *7.3.1.4 – Continua's proposed improvements*

Continua's proposition is to make use cases available to the public and to add them as a formal document and addendum to the guidelines. As it comes to a mechanism to check for

EU regulatory compliance, Continua's Board of Directors decided to reach out to regulatory experts for their feedback on the matter, but stated that it would still be the organisation's responsibility using the guidelines to ensure that their products meet regulatory requirements.

### 7.3.2 – Recommendation for neutrality and stability

According to our interpretation, this criterion aims to identify whether the standards that support technical specifications are the most appropriate ones, which are conditions for the advanced scientific (i.e., academia based) and technological (i.e., the state-of-the-art) developments in the context of technical specifications development.

#### *7.3.2.1 – Findings*

The finding identified for category neutrality and stability is that there is no process to review versions of used standards and decide if an upgrade makes sense.

#### *7.3.2.2 – Overall Conclusion*

We conclude a partial non-compliance with the Regulation as no justification of the selection of the base standards is provided.

#### *7.3.2.3 – Recommendation*

Given the above finding and conclusion, the recommendation is proposed to **periodically review whether a new version of base standards is available and is more appropriate.** There can be good reasons not to make use of the latest version of a base standard, e.g., in case of problems with stability, but these reasons should be **clearly documented and shared** with the members.

#### *7.3.2.4 – Continua's proposed improvements*

Continua's proposition is to have a public log that maps up-to-date versions of base standards to the latest version of the guidelines, and to document those instances where the latest version of a base standard is not being used. In addition, Continua's Board of Directors decided on a process for reviewing and, if needed, replacing expired standards.

### 7.3.3 – Recommendation for quality

Within the category of quality, the requirement concerning the level of detail of profile descriptions was given attention. In particular, the level of detail is considered to be sufficient if competitive interoperable products and solutions can be created based on a given profile.

#### *7.3.3.1 – Findings*

For the category of quality, we found that little or none diagrams, interface descriptions, process models or data models are provided for profiles.

#### *7.3.3.2 – Overall Conclusion*

Given the above finding, we conclude partial non-compliance with the Regulation as the quality and level of detail is not sufficient to permit the development of a variety of competing implementations of interoperable products and services as there are little or

none diagrams, process models or data models. A more detailed and complete profile description helps to avoid any misinterpretations between different stakeholders.

#### *7.3.3.3 – Recommendation*

Given the above finding and conclusion, it is recommended that all profiles provide necessary details, including **explicit interface descriptions**, **data models, process models, business rules**, etc. for the stakeholders to create competitive products and services. The more a profile description is complemented by visual representations, the less room for interpretation is left for profile implementers, which, as a consequence, helps to foster competition and contributes to completeness of profile documentation.

#### *7.3.3.4 – Continua's proposed improvements*

Continua's proposition is to improve the documentation by including the appropriate pictures and diagrams into the guidelines, a task to be completed by the Guidelines Control Board. It was recognised that taking this action would be helpful to the members and the public.

## 7.4 – Technical specification assessment results for IHE

Based on the analysis of the IHE organisation, a set of recommendations was provided for the following categories: relevance and effectiveness (section 7.4.1), neutrality and stability (section 7.4.2), and quality (section 7.4.3).

### 7.4.1 – Recommendation for relevance and effectiveness

Within the category of relevance and effectiveness the study team understood that the technical specifications should guarantee meeting functional requirements by providing solutions for the identified use cases. As it comes to compliance with regulatory requirements we understood that a mechanism to check regulatory compliance is one of the conditions of the quality and risk avoidance contributing to relevance and effectiveness.

#### *7.4.1.1 – Findings*

For the category of relevance and effectiveness, no explicit process was found to check the EU regulatory requirements during the profile development process.

#### *7.4.1.2 – Overall Conclusion*

The above finding leads to the conclusion that in some cases the legal compliance is uncertain.

#### *7.4.1.3 – Recommendation*

It is therefore recommended to implement a mechanism to **ensure compliance with all relevant EU regulatory requirements** in order to assure quality of profiles and to avoid a series of risks.

### 7.4.2 – Recommendation for neutrality and stability

According to our interpretation, this criterion aims to identify whether the standards that support technical specifications are the most appropriate ones, which are conditions for the advanced scientific (i.e., academia based) and technological (i.e., the state-of-the-art) developments in the context of technical specifications development.

#### *7.4.2.1 – Findings*

The finding identified for category neutrality and stability is that there is no publicly documented process to review versions of used standards and to decide if an upgrade makes sense.

#### *7.4.2.2 – Overall Conclusion*

We conclude a partial non-compliance with the Regulation as no justification of the selection of the base standards is provided.

#### *7.4.2.3 – Recommendation*

Given the above presented finding and conclusion, the recommendation is proposed to **periodically review whether a new version of base standards is available and is more appropriate.** There can be good reasons not to make use of the latest version of a base standard, e.g., in case of problems with stability or in case a new standard is not mature or not enough used, but these reasons should be **clearly documented and shared** with the members.

### 7.4.3 – Recommendation for quality

Within the category of quality, the requirement concerning the level of detail of a profile description was given attention. In particular, a level of detail is considered to be sufficient if competitive interoperable products and solutions can be created based on a given profile.

#### *7.4.3.1 – Findings*

For the category of quality, we found that some of the profiles. Provide little or none diagrams, interface descriptions, process models or data models. For instance, the PIX profile does not provide data models or diagrams. Underlying base standards provide technical information for guidelines implementation. However, the study team suggests that the guidelines should be complemented by graphical models and diagrams. Graphical models and diagrams in profile documentation play an important role as they can avoid possible misunderstandings between different stakeholders.

#### *7.4.3.2 – Overall Conclusion*

Given the above finding, we conclude partial non-compliance with the Regulation as the quality and level of detail is not sufficient to permit the development of a variety of competing implementations of interoperable products and services as there is a need for more **explicit interface descriptions**, data models, process models, business rules, etc. A more detailed and complete profile description helps to avoid potential misinterpretations by the different stakeholders.

#### *7.4.3.3 – Recommendation*

Given the above finding and conclusion, it is recommended that all profiles provide necessary details, including **explicit interface descriptions**, **data models, process models, business rules**, etc. for the stakeholders to create competitive products and services. The more profile description is complemented by visual representations, the less room for interpretation is left for profile implementers, which, as a consequence, helps to foster competition and contributes to completeness of documentation.

# 8 – Summary of assessment results

This chapter provides a summary of all organisational and technical specification assessment results. Section 8.1 provides an overview of the assessment results for IHE, section 8.2 of the assessment results for Continua, and section 8.3 of the assessment results for epSOS.

## 8.1 – Overall assessment result for IHE

For IHE, no major non-compliance was found, though minor improvement needs were highlighted. These improvement needs related to the implementation of the archiving process, checking of EU regulatory requirements, reviewing versions of base standards, and having explicit interface descriptions. The Deloitte study team stresses that most IHE processes are compliant, but their implementation should be more rigorously applied.

As these assessment findings need to be validated by the ICT standards multi-stakeholders platform, the Deloitte study team proposes to submit the IHE profiles to the ICT standards multi-stakeholders platform for identification.

## 8.2 – Overall assessment result for Continua

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. Those changes will only affect new specifications or specifications that will be updated with the new processes. That is why the Deloitte study team does not advise to submit Continua's specifications for identification today. Though improvements were made, at least two aspects are worth a particular analysis:

(1) Continua’s working definition of Small and Medium Enterprises (SME) is not aligned with the definition put forward by the European Commission;

(2) Continua’s Board of Directors consists of 13 out of 15 Promoters members, who have to pay $25,000 per year and who are the only category of members having voting rights concerning selection of use cases, standards, industry technologies and other key Working Group decisions.

## 8.3 – Overall assessment result for epSOS

For the epSOS large-scale pilot, the analysis has revealed full alignment with the requirements defined by Annex II of the Regulation on European Standardisation (although epSOS is not, and is not seeking to set itself up as a profile development organisation). Therefore, no improvement recommendations have been formulated for epSOS.

# Glossary

| Concept | Description | Source |
|---|---|---|
| (Base) Standard | "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:<br><br>- international standard: a standard adopted by an international standardisation organisation and made available to the public,<br><br>- European standard: a standard adopted by a European standardisation body and made available to the public,<br><br>- national standard: a standard adopted by a national standardisation body and made available to the public." | Generic EIF |
| Certification | "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." | HITCH D6.4 Final Report |
| eHealth Interoperability project | "An eHealth interoperability project, taking place in a EU cross border, national, regional, or local context." | Mandate 403 study |
| Interoperability | "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." | Generic EIF |
| Interoperability Agreements | "Written interoperability agreements are concrete and binding documents which set out the precise obligations of two parties | 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) | "A chartered organisation tasked with producing standards and specifications, according to specific, strictly defined requirements, procedures and rules.<br><br>Standards developing organisations include:<br><br>- recognised standardisation bodies such as international standardisation committees such as the International Organisation for Standardisation (ISO), *International Telecommunication Union (ITU)*, 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);<br><br>- 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), *International Health Terminology Standards Development Organisation (IHTSDO).*" | Generic EIF<br><br>*(italic: addition of study team)* |

| Concept | Description | Source |
|---|---|---|
| Technical Interoperability | "Discuss technical issues involved in linking computer systems and services" | Generic EIF |
| Technical specifications: profile and guideline | "A technical specification means a document that prescribes technical requirements to be fulfilled by a product, process, service or system" (Regulation of European Standardisation).<br><br>*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).<br><br>*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.* | Regulation of European Standardisation<br><br>ETSI standard ETS 300 406<br><br>*(italic: addition of study team)* |
| Use case | "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)<br><br>*In the context of our study, a use case can be trigged 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.* | ISO TR 28380-1 IHE Global Standards Adoption<br><br>*(italic: addition of study team)* |

# Annex 1. Research approach for the identification and selection of the use cases

## Research Approach

For the initial version of the EIF, in conjunction with the two epSOS use cases selected, a structured approach was applied to support the identification and selection of eight additional use cases. (As noted elsewhere in this report, two of the eight use cases are in fact illustrated by two sub- use cases: these are use cases 2a and 2b, and 5a and 5b.)

In order to come to a selection of a total number of use cases, the study team applied the Delphi method. The Delphi method is a structured communication technique, developed in its origins as a systematic, interactive forecasting method, which relies on a panel of experts. This effort was initially not planned to be part of the study. However, during the initial phase of study it became obvious that, as defined in M403, it would be a requirement that different stakeholders should validate relevance and timeliness of the use cases.

The Delphi method involves the following steps. Selected stakeholders answer questions in two or more rounds. After each round, the study team provides an anonymous summary of the experts' forecasts from the previous round as well as the reasons they provided for their judgements. Thus, the stakeholders involved are encouraged to revise their earlier answers in light of the replies of other experts. It is generally agreed that during this structured process of selection and revision, the range of the answers will decrease and the overall opinion of the members of the group will converge towards a consensus.

During the first phase of the study, three Delphi iterations were executed, as displayed in Figure 4. The iterations involve telephone interviews, polling and a workshop:

- The first iteration started by taking the initial list of use cases proposed by M403, and requesting feedback about these use cases via a set of telephone interviews;
- The second iteration took the resulting list of use cases, and requested feedback about these use cases via an online poll;
- The third iteration started with the processed results of the online poll. They were discussed and prioritised during the eHealth EIF workshop. This resulted in a list of eight use cases. The outcome of this Delphi iteration aligns with the seven prioritised use cases proposed by COCIR in mid-2012. [40]

[40] COCIR Position Paper on eHealth Interoperability, COCIR, May 2012.

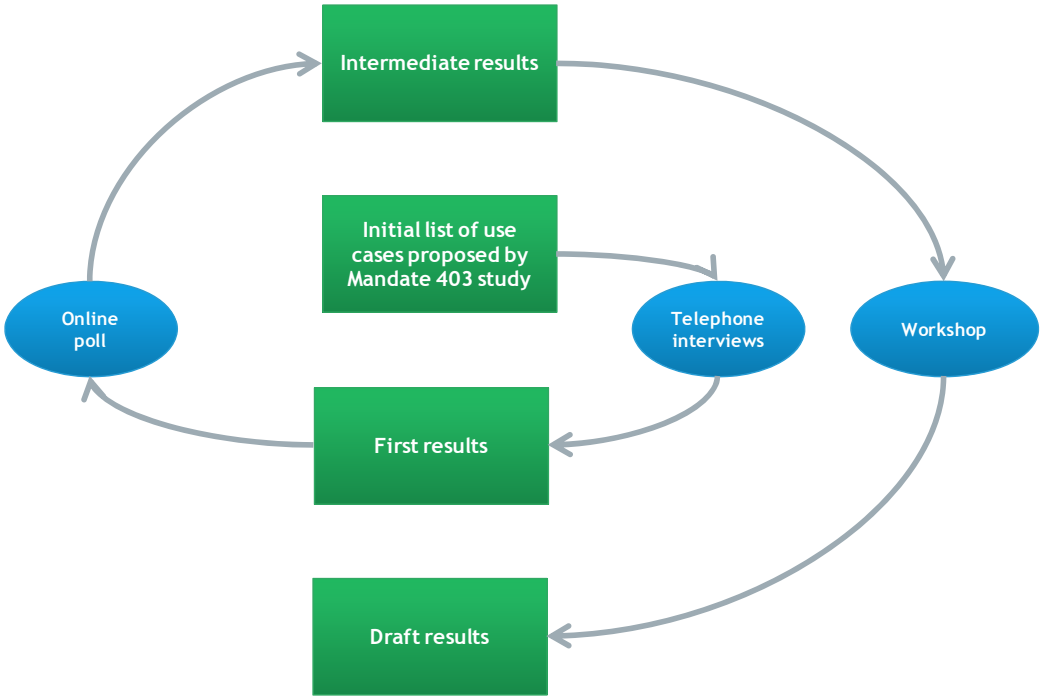


**Figure 4 – Overview of three Delphi iterations (Phase 1 of the study)**

The process used in each iteration step was as follows.

**First Delphi iteration: Mandate 403**

Using the findings of Mandate 403 as a basis, feedback on these findings was requested during an initial set of interviews. After these interviews, all feedback received was documented in meeting minutes, which were validated by the interviewees.

This first Delphi iteration ended with a consolidated list of use cases that was accompanied by a text stating the rationale for each inclusion of a use case.

**Second Delphi iteration: Online poll**

Taking the results of the first Delphi iteration into account, an online poll was organised to gather further input from stakeholders. The online poll asked for additional input concerning the relevance of the identified use cases.

The questions listed below were posed to each of the stakeholders participating in the online poll:

- Use cases
    - Can you assess the relevancy of including the suggested use case into the eHealth EIF? (Select a value from: Very relevant, Relevant, Neutral, Not relevant)

- In case you indicated a use case to be relevant, could you please explain the rationale of your choice? (open question)
- Are there any other use cases you propose to be included in the eHealth EIF? If yes, please add the rationale for inclusion in the eHealth EIF.

The results defined as values were prioritised according to the following points-based scheme:

- Very relevant: 2 points
- Relevant: 1 point
- Neutral: 0 points
- Not relevant: -1 points

A screenshot of the online poll is provided in Figure 5 below:

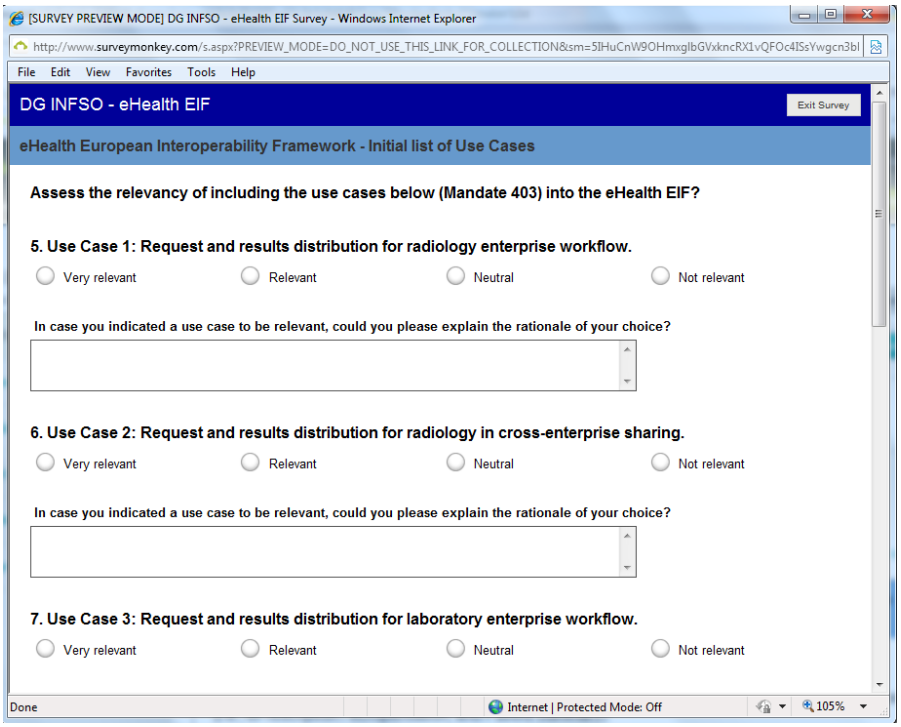


**Figure 5 - Screenshot of online poll**

### Third Delphi iteration: Workshop

Taking the results of the second Delphi iteration into account, the selected list of use cases was presented and discussed during a workshop in Brussels on 16 April 2012.

After presenting and discussing the results from the online poll, the workshop participants were requested to provide further input about the use cases by means of Post-Its. As illustrated in Figure 6, the participants received three Post-Its. They were requested to take 5 minutes to select their top three use cases, and to add their motivations and reasoning

for their selection. As a next step, the Post-Its were consolidated into a long list of use cases. The results were assessed.

At this stage of the study, the intention was to develop a "long list" of use cases that included all cases of interest and concern to the stakeholders.

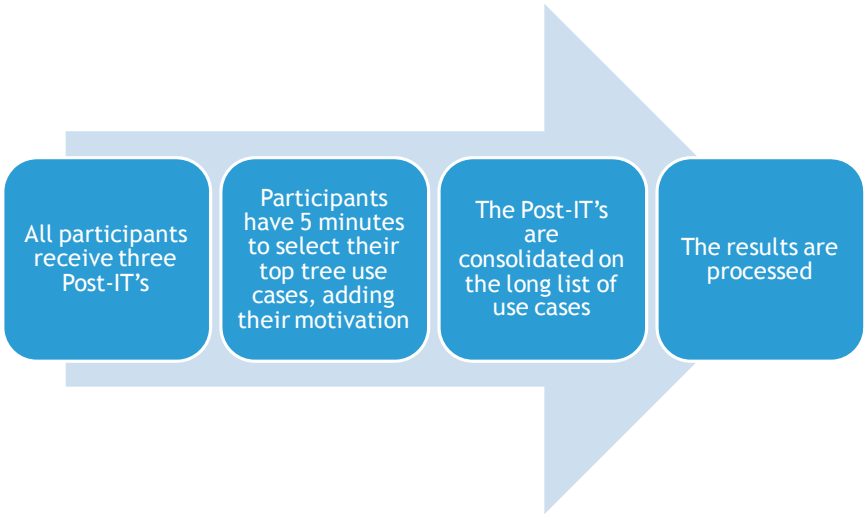


**Figure 6 - Steps taken at the workshop Post-It exercise**

## Findings from three Delphi iterations

### Findings from first Delphi iteration

As in the first Delphi iteration exercise, an initial round of interviews was conducted with stakeholders. Using the findings of Mandate 403 as the basis for the candidate alternative use cases for the long list, a discussion was initiated. Figure 7 provides the list which was included in the slide deck during these interviews.

| | Use case | |
|---|---|---|
| Use cases from mandate 403 | Prescriptions for regional / national information sharing | epSOS Use Cases |
| | Patient summaries for regional / national information sharing | |
| | Request and results distribution for radiology enterprise workflow | |
| | Request and results distribution for radiology in cross-enterprise sharing | |
| | Request and results distribution for laboratory enterprise workflow | |
| | Request and results distribution for laboratory information cross-enterprise sharing | |
| | For ubiquitous care outside conventional care facilities, involving the interoperability necessary from mobile and/or home-based monitoring devices | |
| Other | ICT for risk management, reporting and learning systems on adverse events in health care | |

**Figure 7 – Example list of use cases as discussed during interview**

**Use case findings**

The following use cases were extracted from the Mandate 403 report as use case candidates for the long list:

- Request and results distribution for radiology enterprise workflow;
- Request and results distribution for radiology in cross-enterprise sharing;
- Request and results distribution for laboratory enterprise workflow;
- Request and results distribution for laboratory information cross-enterprise sharing;
- For ever-present care outside conventional care facilities, involving the interoperability necessary from a mobile monitoring devices for a specific chronic disease;
- For ever-present care outside conventional care facilities, involving the interoperability necessary from a data-entry application for a specific chronic disease.

During the initial interviews, the following use cases were suggested as additional candidates for the long list:

- ICT for risk management, reporting and learning systems on adverse events in health care (treatment, medication etc.), alongside and complementary to other adverse incident reporting systems, such as the pharmacovigilance and medical device vigilance systems;
- The patient having access to his or her patient summary in different languages;
- New medication prescriptions requiring comprehensive information on concurrent medication and details of known allergies and conditions (not simple Electronic Transfer of Prescription (ETP));
- 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;
- Care transfers, referrals and within-team workflow prompts such as the degree of urgency and the expectations of the referring clinician from another team member;
- Care coordination ensuring that a high-level view can be taken of distributed (multi-team) care to protect against duplication, delay and incompatible interventions.

**Findings from second Delphi iteration**

A request to fill in an online poll was sent to 160 people. Thirty-six responses from 30 different organisations were registered.

Taking the input of these participants into account, an overview of the relevance of these use cases was prepared (Figure 8). One of the main findings was that the prescriptions use

case was high on the agenda of desirable use cases. Also, all six use cases originally proposed by Mandate 403 were still considered to be relevant.

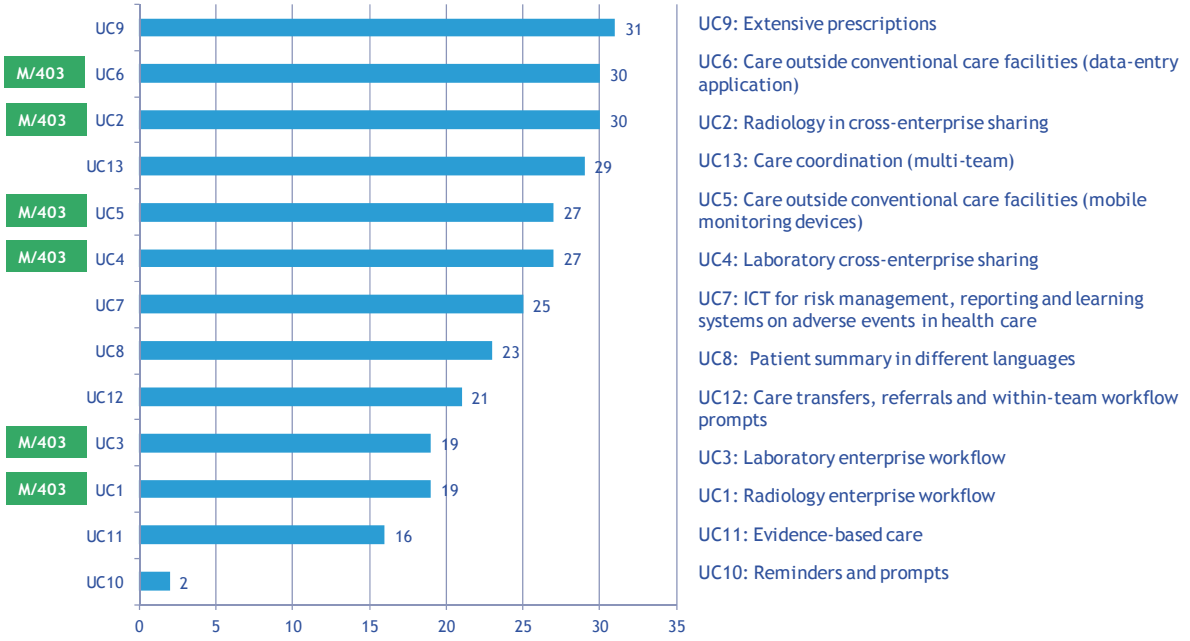


**Figure 8 - Poll results on relevance of use cases**

### Findings from third Delphi iteration

The results of the second iteration were presented during the eHealth EIF workshop on 16 April 2012, by means of both summary slides and more detailed slides that documented the results of the online poll for each single use case.

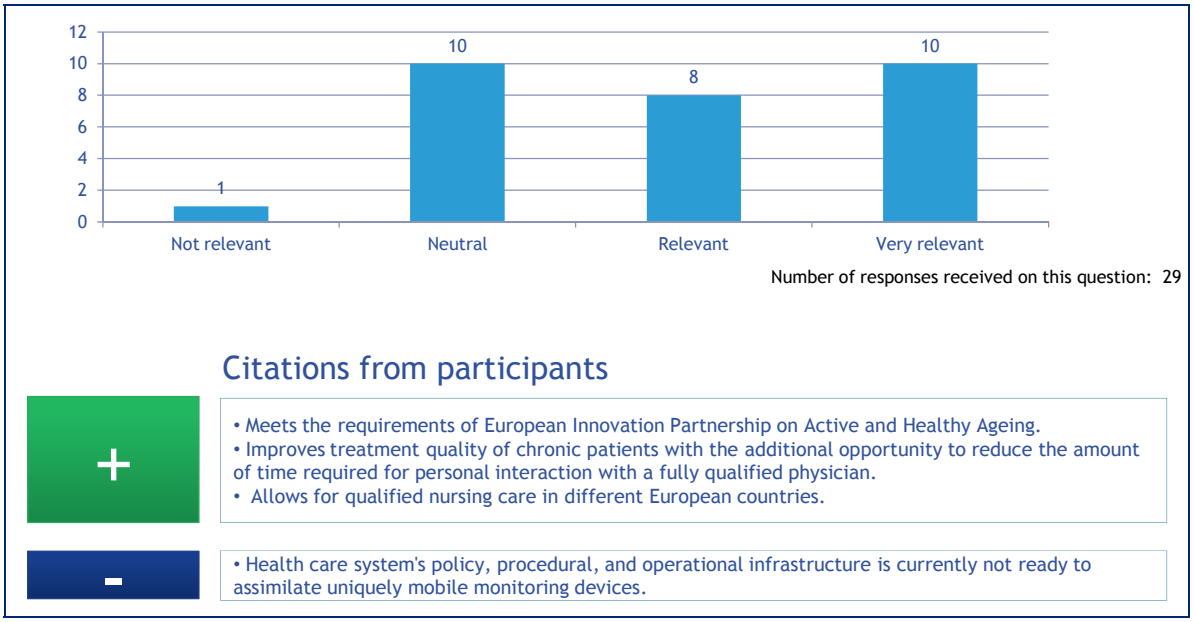

**Figure 9 - Example of poll results – Use case on care outside conventional care facilities (mobile monitoring devices)**

During the workshop, the following input was collected from the stakeholders:

- "Try to make a distinction between the different strategic objectives for use cases, and the different levels, such as EU cross-border, national/ regional eHealth, hospital and home care. This distinction was also recommended by the Mandate 403 approach";

- "There is a need for further description of these use cases, as many interpretations can exist for the same use case title";

- "The use cases presented in the list do not have the same level of granularity (e.g., evidence based medicine is a broad area, but not a specific use case)".

As described in the third Delphi iteration, as a result the participants were requested to provide additional input on their own individual use case selection and their reasoning via the use of Post-Its.

During the processing of collecting Post-IT input, it became clear that a large consensus existed on the following 12 use cases:

- epSOS project: e-Prescription and e-Dispensation for cross-border information sharing for citizens travelling in Europe;

- epSOS project: patient summaries for cross-border information sharing for citizens travelling in Europe;

- epSOS project: patient having access to his or her patient summary;

- Request and results (imaging results, diagnostic examinations) sharing workflow for radiology in inter-hospital setting on national/regional scale;

- Request and results (laboratory reports, test results) sharing workflow for laboratory in inter-hospital setting on national/regional scale;

- Cross-Enterprise Sharing of Medical Summaries (XDS-MS) IHE Integration Profile: Ambulatory Specialist Referral;

- Cross-Enterprise Sharing of Medical Summaries (XDS-MS) IHE Integration Profile: Acute Care Discharge to Ambulatory Care Environment;

- Request and results (imaging diagnostics tests) distribution workflow for radiology in intra-hospital setting;

- Request and results (clinical laboratory tests) sharing workflow for laboratory in intra-hospital setting;

- 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);

- 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);

- For ever-present care outside conventional care facilities, involving the interoperability necessary from sensor devices to monitor activity, e.g. of elderly people.

These 12 use cases were used to create the ultimate list of ten uses that are proposed as a result of this study. (The dozen use cases have, in two cases (use cases 2 and 5), been aggregated into ten use cases.)

European Commission

**eHealth – European Interoperability Framework**
Luxembourg, Publications Office of the European Union

**2013** – 31 pages

ISBN 978-92-79-30358-6
DOI: 10.2759/15204

KK-03-13-199-EN-N



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