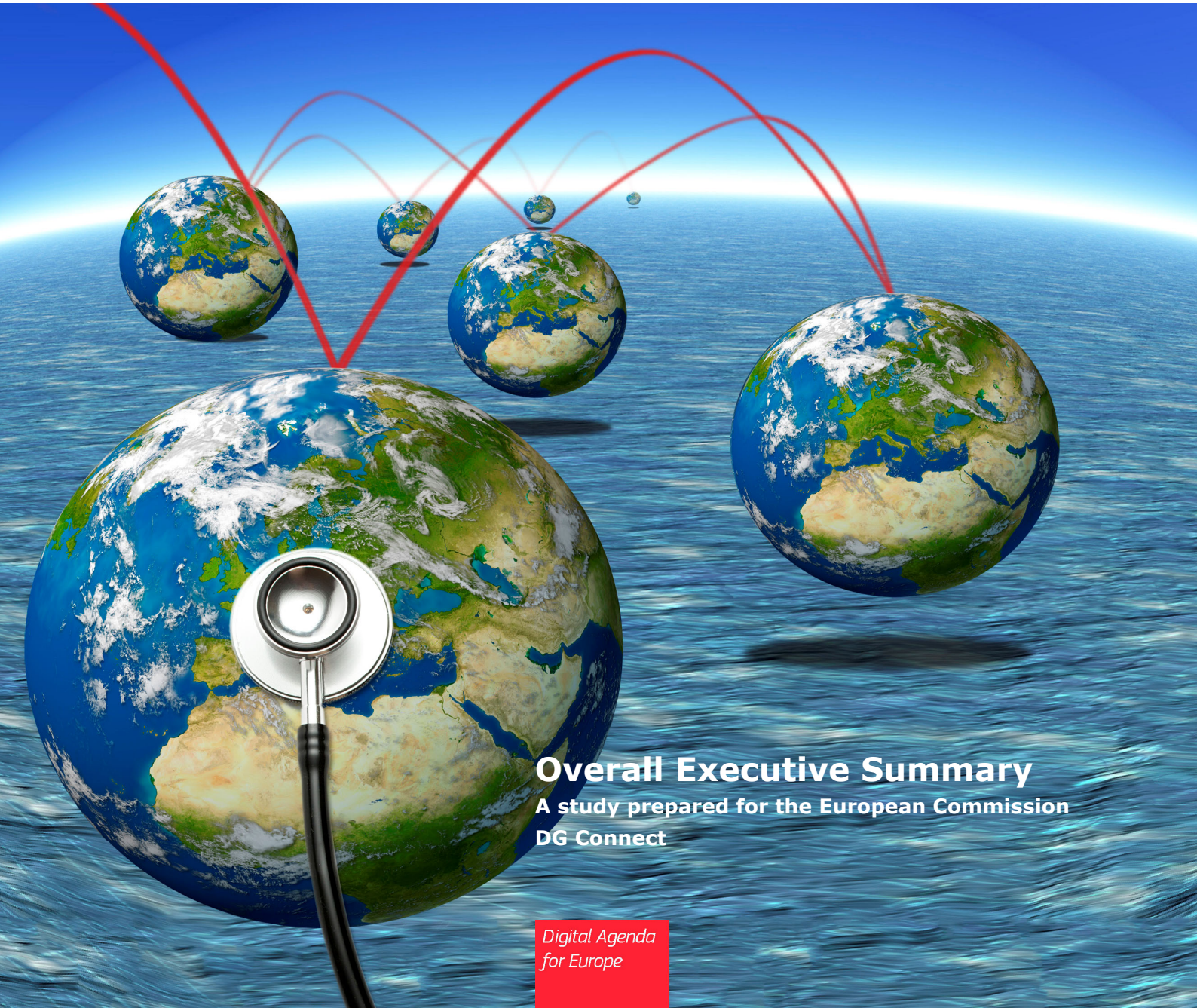
European Commission

eHealth EIF

eHealth European Interoperability Framework

European Commission – ISA Work Programme



Overall Executive Summary

A study prepared for the European Commission
DG Connect

Digital Agenda for Europe

This study was carried out for the European Commission by

DISCLAIMER

By the European Commission, Directorate-General of Communications Networks, Content & Technology.

The information and views set out in this publication are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein.

ISBN 978-92-79-30389-0
DOI: 10.2759/10138

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

This report was prepared by the Deloitte study team[1]:
Philip van Langenhove, Ken Decreus, Anna Rogala, Thomas Olyslaegers, Diane Whitehouse

[1] The Deloitte study team acknowledges the substantial input of Dipak Kalra (University College London) and Jos Devlies (EuroRec) to this report.

Overall Executive Summary

In 2012, the European Commission set the objective to develop, with the advice of the eHealth Network, an eHealth European Interoperability Framework in the context of the generic European Interoperability Framework (EIF). As a result, it is the goal of this study to describe the background and rationale of the study (Deliverable 1), to propose a high-level structure of the eHealth EIF (Deliverable 2) and to help to define the technical part of the framework (Deliverables 3 and 4). In total, four reports are submitted in the context of the study, each of which is stand alone:

Deliverable 1 aims to provide a reading guide to the study by illustrating the background and rationale of the study, and by describing the policy context behind the European Union eHealth interoperability and links to recent European eHealth interoperability studies. This deliverable outlines the study context using a descriptive format. Its content is non-exhaustive, as only the main representative activities undertaken during the study are presented.

Deliverable 2 aims to build a consensus on the vision of the eHealth EIF. It lays out a non-exhaustive overview of the direction in which the eHealth EIF should evolve. In other words, this deliverable is a first high-level proposal for the eHealth EIF, and can be seen as a prototype of that framework.

Deliverable 3 aims to provide a working tool to assess profile development organisations and their profiles. The assessment framework is of exhaustive nature as it is scoped by the Regulation on European Standardisation.

Deliverable 4 aims to create a preliminary, non-exhaustive version of the technical part of the eHealth EIF. Its scope is determined by a list of ten prioritised use cases and their corresponding profiles, and shares the assessment 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 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.

Interoperability of ICT-enabled solutions and of data exchange is the precondition for better coordination and integration across the entire chain of healthcare delivery and health data exchange, while unlocking the EU eHealth single market.

The eHealth EIF is positioned as an **operational tool kit for implementers and purchasers to deploy eHealth systems**. It is intended to be used as a reference guide in calls for proposals and tenders for the Connecting Europe Facility (CEF) deployment, but possibly also for deployment at the national and regional levels. The vision is that the eHealth EIF will be leveraged by the eHealth Network for eHealth deployment that takes place in Member States. By offering such a toolkit, the eHealth Interoperability Framework will promote convergence on the use of interoperability standards and technical specifications and contribute to increasing the interoperability of deployed eHealth Systems.

The eHealth EIF is based on the generic European Interoperability Framework (EIF)[2], which

[2] In 2010, the European Commission published a Communication entitled "Towards Interoperability for European Public Services" (European Commission, 2010e), of which the second annex introduced the generic EIF.

offers a sector-independent approach to interoperability for joint delivery of public services[3]. The EIF promotes and supports the delivery of European public services by fostering cross-border and cross-sectoral interoperability. The EIF is maintained under the Interoperability Solutions for European Public Administrations (ISA) programme, in close cooperation with the Member States and the European Commission. As the intention of this study is to **apply the generic EIF to the domain of eHealth**, the structure of the generic EIF acted as a basis for the structure of the eHealth EIF.

In addition, the CALLIOPE working model was used to perform a completeness check for all the different concepts used in the eHealth domain: it became clear, as a result, that the notion of eHealth services, or more generally, high-level use cases, should be included in the eventual eHealth EIF. The importance of this additional concept was confirmed by the mandate M/403 study and the eHGI discussion paper on semantic and technical interoperability[4]. Finally, an analysis of Member State specifications confirmed the importance of principles, organisational interoperability, semantic interoperability and technical interoperability.

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

- **Governance**: This section shows the difference between the governance in the eHealth domain and governance of the eHealth EIF. It describes the different actors within the eHealth domain (eHealth Network, eHealth Governance Initiative, CEF Governance, ICT standards multi-stakeholders platform).

- **Principles**: Six principles were extracted by the study team from the generic EIF: security and privacy, transparency, preservation of information, reusability, technological neutrality and adaptability, and openness. Two additional principles have been added to this list: they are patient centricity and an approach based on use cases. More principles could be considered.

- **Interoperability agreements**: For each interoperability level, the organisations involved should formalise cooperation arrangements in interoperability agreements. This plays a crucial role in the context of the eHealth EIF, as an interoperability agreement is an essential tool to accelerate the transformation process to achieve higher degree of eHealth interoperability.

- **Legal interoperability**: In terms of legal interoperability, eight binding instruments and six non-binding legal instruments are pertinent to the work of the eHealth EIF. On the binding side, in sequential order, four instruments have been in existence for some years are the Directive 1995/46/EC, the Directive 1999/93/EC, Directive 2007/47/EC and the Directive 2011/24/EU. Four recently EC adopted instruments are the Regulation on European Standardisation, the Draft Regulation on Data Protection, the Draft Regulation on eID and eSignature; and the Draft Regulation on medical devices. Six non-binding legal instruments are perceived to have had influence over the issue of

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

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

eHealth interoperability. The first four are a Recommendation on interoperability, a Communication on telemedicine, Guidelines relating to the medical devices directive, and a Green paper on card, internet and mobile payments. In December 2012, two additional non-binding instruments were published, i.e. the eHealth Action Plan 2012-2020 and the Commission Staff Working Paper on the applicability of the existing EU legal framework to telemedicine services.

- **Organisational interoperability**: From an organisational perspective, to support the development of the eHealth EIF, three recommendations have been extracted by the study team from the eHealth Governance Initiative (eHGI) discussion paper[5] on semantic and technical interoperability (i.e., encourage greater cooperation between Member States; between national authorities and standardisation bodies; and consider incentivisation of healthcare providers). Others have been adapted from discussions held during the course of the study on quality labelling and testing at a European Union level.

- **Semantic interoperability**: Three categories of semantic artefacts are proposed: (a) systems for concept representation, (b) clinical models which assemble data items and map to specific terminology subsets for each item, (c) EHR information models that provide a higher level containment framework and provenance context. From a semantic perspective, to support the development of the eHealth EIF, four recommendations have been extracted by the study team from the eHGI discussion paper on semantic and technical interoperability (i.e., foster data portability; link and harmonise coding systems; facilitate access to existing standards and medical vocabularies; and stimulate usability engineering for structured and encoded data). Further recommendations on semantic interoperability are made based on the SemanticHEALTH[6] and ARGOS[7] studies.

- **High-level use cases**: The eHealth EIF follows a use case-based approach. In this way, an eHealth interoperability project can "reach out" to other EU prioritised use cases addressing the same high-level use. Therefore, a list of ten high-level use cases is to be proposed to the eHealth Network. This list of the proposed use cases falls into four categories (cross-border; national/regional; intra-hospital; and at the level of citizens, whether they are on the move or at home). It deals with the following aspects: e-Prescription / e-Dispensation, patient summary, radiology, laboratory, medical summaries, ever-present care outside conventional care facilities using personal computer or web-based applications, mobile phones, and sensor devices. More information about these ten high-level use cases is given in the table below:

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.

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

Nr	Level	Use case
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	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, COPD, 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, COPD, 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

- **Technical interoperability**: As the eHealth EIF follows a use case-based approach, it recommends a specific set of profiles for these high-level use cases. To this end, a set of candidate profiles was analysed against an assessment framework. The conclusions of the assessment are the following:

    - For IHE, no major non-compliance was found, though minor improvement needs were highlighted.

    - For Continua, major non-compliance on transparency, openness and consensus was found and communicated to the consortium. In December 2012, the Board of Continua approved changes to their rules and procedures in order to move toward more transparency, openness and consensus.

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

European Commission

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

2013 – 8 pages

ISBN 978-92-79-30389-0
DOI: 10.2759/10138

KK-01-13-171-EN-N

DOI: 10.2759/10138
ISBN 978-92-79-30389-0