eHealth Network

RECOMMENDATION PAPER
for
The Rolling Plan on ICT Standardisation

The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth. The Joint Action supporting the eHealth Network (JAseHN) provides scientific and technical support to the Network.

Adopted by consensus by the eHealth Network, Brussels, 15 May 2018

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LIST OF ABBREVIATIONS

ACRONYM	DEFINITION
BSI	UK NATIONAL STANDARDIZATION BODY
CAS	CONFORMITY ASSESSMENT SCHEME
CAS4EU	CONFORMITY ASSESSMENT SCHEME FOR THE EUROPEAN UNION
CBEHIS	CROSS BORDER EHEALTH INFORMATION SERVICES
CEF	CONNECTED EUROPE FACILITY
CEN TC215	EUROPEAN COMMITTEE FOR STANDARDISATION, TECHNICAL COMMITTEE 215
CEN TC251	EUROPEAN COMMITTEE FOR STANDARDISATION, TECHNICAL COMMITTEE 251
CGM	CONTINUOUS GLUCOSE MONITOR
CIP	COMPETITIVENESS AND INNOVATION FRAMEWORK PROGRAMME
CISE	COMMON INFORMATION SHARING ENVIRONMENT
CLAML	CLASSIFICATION MARKUP LANGUAGE
COCIR	EUROPEAN COORDINATION COMMITTEE OF THE RADIOLOGICAL, ELECTROMEDICAL AND HEALTHCARE IT INDUSTRY
CSA	COORDINATION AND SUPPORT ACTIONS
DICOM	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE
DOW	DESCRIPTION OF WORK
DSI	DIGITAL SERVICE INFRASTRUCTURE
DSM	DIGITAL SINGLE MARKET
EHEALTHDSI	EHEALTH DIGITAL SERVICE INFRASTRUCTURE (ALSO NOTED AS EHDSI)
eHMSEG	EHEALTH MEMBER STATE EXPERT GROUP
EHN	EHEALTH NETWORK
eHOMB	EHEALTH OPERATIONAL MANAGEMENT BOARD
EHRHER	ELECTRONIC HEALTH RECORD
EIF	EUROPEAN INTEROPERABILITY FRAMEWORK
ERN	EUROPEAN RESERACH NETWORKS
ESENS	ELECTRONIC SIMPLE EUROPEAN NETWORKED SERVICES
ETSI	EUROPEAN TELECOMMUNICATION STANDARDISATION INSTITUTE
EU	EUROPEAN UNION
GDPR	GENERAL DATA PROTECTION REGULATION
GS1	GLOBAL STANDARD ONE
GSVML	GENOMIC SEQUENCE VARIATION MARKUP LANGUAGE
HDO	HEALTHCARE DELIVERY ORGANISATION
HL7	HEALTH LEVEL 7
ICSR	INDIVIDUAL CASE SAFETY REPORT
ICT	INFORMATION AND COMMUNICATION TECHNOLOGY
IDMP	IDENTIFICATION OF MEDICINAL PRODUCTS

IEEE11073	INSTITUTE OF ELECTRICAL AND ELECTRONICS ENGINEERS
IHE	INTEGRATING THE HEALTHCARE ENTERPRISE
IHTSDO	INTERNATIONAL HEALTH TERMINOLOGY STANDARDS DEVELOPMENT ORGANISATION
IMIA	INTERNATIONAL MEDICAL INFORMATICS ASSOCIATION
IMM	INTEROPERABILITY MATURITY MODEL
INR	INTERNATIONAL NORMALIZED RATIO
IOT	INTERNET OF THINGS
IPS	INTERNATIONAL PATIENT SUMMARY
IS	INTERNATIONAL STANDARDS
ISA²	INTEROPERABILITY SOLUTIONS ARCHITECTURE
ISO	INTERNATIONAL STANDARDISATION ORGANISATION
JAseSEHN	JOINT ACTION FOR THE SUPPORT OF THE EHEALTH NETWORK
mHealth	MOBILE HEALTH
MS	MEMBER STATES
MSP	MULTISTAKEHOLDER PLATFORM
NCC	NATIONAL COMPENTENCE CENTRE
NCPEH	NATIONAL CONTACT POINT FOR EHEALTH
NIS	NETWORK INFORMATION SECURITY DIRECTIVE
PACS	PICTURE ARCHIVE AND COMMUNICATION SYSTEM
PAS	PUBLICLY AVAILABLE SPECIFICATION
PCHA	PERSONALCONNECTED HEALTH ALLIANCE
PHRSFM	PERSONAL HEALTH RECORD SYSTEM FUNCTIONAL MODEL
PSP	POLICY SUPPORT PROGRAMME
ReEIF	REFINED EHEALTH INTEROPERABILITY FRAMEWORK
SDO/NCC	STANDARDISATION DEVELOPMENT ORGANISATION
SNOMED-CT	SYSTEMATIZED NOMENCLATURE OF MEDICINE--CLINICAL TERMS
TR	TECHNICAL REPORT
TS	TECHNICAL SPECIFICATIONS
WHO	WORLD HEALTH ORGANISATION
WP	WORK PACKAGE

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1. Introduction

1.1 Executive Summary

In the context of the JAseHN description of work (DOW), D5.4.3.1 is a report of current and recent developments in the domain of Standards in eHealth while D5.4.3.2 is a short recommendations document for the DSM rolling plan.

D5.4.3.1 provided a library of references to the developments of Standards in the eHealth domain. This deliverable has a dependency with T5.4 D5.4.2 Policy paper proposing actions to promote the use of common standards or technical specifications in eHealth within the EU, where a set of recommendations that are the result of the analysis of D5.4.3.1 material. D5.4.3.1 is a report for information to the eHN as a supportive document. D5.4.3.2 is a set of high level recommendation for the DSM Rolling plan secretariat, that would facilitate the uptake of common interoperability standards and technical specifications by member states (MS) and the consequent enablement of cross border healthcare.

This deliverable (D5.4.3.2) is complimentary to the D5.4.3.1 and it includes recommendations for the Rolling Plan. The recommendations take into consideration the work done in the D5.4.2 and D5.5 as well.

The Digital Single Market (DSM) strategy aims to open up digital opportunities for people and business and enhance Europe's position as a world leader in the digital economy.

The DSM[1], Rolling Plan is further explained in chapter two of this document. The European Multi Stakeholder Platform (MSP) on ICT standardisation was set up at the end of 2011 as a group of experts set-up by Commission Decision 2011/C349/04 with the aim to advise the Commission on all matters related to ICT standardisation.

The EU Rolling Plan provides an overview of the needs for preliminary or complementary ICT standardisation activities to be undertaken in support of EU policy activities. The Rolling Plan on ICT Standardisation is drafted by the European Commission in collaboration with the European Multi-Stakeholder Platform (MSP) on ICT Standardisation and is updated annually. It lists all the topics identified as EU policy priorities where standardisation, standards, or ICT technical specifications ought to play a key role in the implementation of the policy. It covers technologies of 'horizontal importance', ones whose application have a wide impact across different technical fields, in the context of ICT infrastructures and ICT standardisation. JAseHN via D5.4.3.2 will propose some recommendations for inclusion in the next versions of the Rolling Plan for eHealth.

[1] http://ec.europa.eu/transparency/regdoc/rep/1/2016/EN/1-2016-176-EN-F1-1.PDF

As a conclusion in the DSM Rolling plan for the eHealth domain, Interoperability of ICT-enabled solutions and of data exchange is the precondition for an improved coordination and integration of healthcare unlocking the EU eHealth single digital market. The use of European and international standards is a way to ensure the interoperability of ICT solutions in general. The eHealth network identified more detailed specifications, which could be used for public procurement, in the framework of the new EU standardization regulation, contributing to the technical and semantic levels of the eHealth Interoperability Framework. One example is the IHE set of specifications identified for use in procurement by Commission Decision (EU) 2015/1302 of 28 July 201533 under Article 14 of the EU Regulation 1025/2012. A refined eHealth European interoperability framework (ReEIF) was adopted by the eHealth Network in November 2015. It represents a common refined framework for managing interoperability and standardisation challenges in the eHealth domain in Europe, offering a framework of terms and methodologies for reaching a common language, and a common starting point for the analysis of problems and the description of eHealth solutions throughout Europe.

1.2 Purpose of this document

The JAseHN DOW in 2015 for the objectives of the whole Task 5.4 is the following:

One of the barriers for the large-scale implementation and adoption of eHealth comes from the lack of clarity around the adequate standards and profiles for interoperability of eHealth solutions. There is a need to align the relevant organizations that have a role in eHealth standards and profiles, and promote the use of the standards and profiles. Task 5.4 will provide a proposal for a platform consisting of the relevant Standards developing organizations in order to:

- *provide input to the eHN on actions to promote the coordination and acceptability of standards and technical specifications in eHealth;*
- *Create a single entry point into the standards world for any questions, wishes and requirements the eHN might have. Furthermore, report(s) will be produced focusing on standardization developments in eHealth and on the effective use of common standards or technical specifications in eHealth within the EU. The first focus will be on the standards and profiles that are in use at the application- and semantic levels of the Antilope refined EIF. The WP will closely work together with WP 4 Stakeholder coordination and other relevant projects such as eStandards.*

In the context of the JAseHN DOW, D5.4.3.1 was delivered as a report of current and recent developments in the domain of Standards in eHealth. The scope of this deliverable was to provide a library of references to those developments. Some of those references have also been the source of documentation for the recommendation proposed in D5.4.2. The present D5.4.3.2 concludes with some refined recommendations for the DSM Rolling Plan

1.3 Interdependencies

As in D5.4.2, the main dependency is to all sub tasks of T5.4 (5.4.1, 5.4.3, 5.4.4) and T5.5.- D5.5 Report on European semantic interoperability in eHealth and T6.2 Challenges of legal interoperability in a cross-border context - D6.2 Proposal for a sustainable legal basis for cross-border exchange of personal health data.

D5.4.3.2 shall be submitted to DG SANTE for potential integration in their recommendations for the rolling plan. Several activities have been either completed or are in the process of completion in relation to standards and technical specifications. This document is closely related to the work- in terms of policy recommendations- of other EU projects namely: eStandards, openMedicine and AssessCT as presented in the D5.4.2.

2. DSM Rolling Plan Overview

2.1 DSM overview

The internet and digital technologies are transforming our world. But existing online barriers mean citizens miss out on goods and services, internet companies and start-ups have their horizons limited, and businesses and governments cannot fully benefit from digital tools. It's time to make the EU's single market fit for the digital age – tearing down regulatory barriers and moving from 28 national markets to a single one. This could contribute €415 billion per year to our economy and create hundreds of thousands of new jobs[2]. The DSM[3] strategy aims to open up digital opportunities for people and business and enhance Europe's position as a world leader in the digital economy.

Having reached the middle of its mandate, the European Commission has published the mid-term review[4] of its DSM strategy. It takes stock of the progress made, calls on co-legislators to swiftly act on all proposals already presented, and outlines further actions on online platforms, data economy and cybersecurity[5].

The mid-term review is accompanied by the European Digital Progress Report which gives an in-depth assessment of how the EU and MS are progressing in their digital development and identifies potential steps to help improve national performance in digital.

[2] https://ec.europa.eu/commission/priorities/digital-single-market_en
[3] COM(2015) 192 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - A Digital Single Market Strategy for Europe, Brussels, 06.05.2015.
[4] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1496330315823&uri=CELEX:52017DC0228
[5] https://ec.europa.eu/digital-single-market/en/news/digital-single-market-commission-calls-swift-adoption-key-proposals-and-maps-out-challenges

A concept paper on "Digitisation, employability and inclusiveness – the role of Europe"[6], looks at the impact of digitisation on the labour market. Digitisation is not a choice but a necessity for European businesses and economies as a whole. It brings plenty of opportunities, but also repercussions, and above all change: some jobs will be replaced, new jobs will be created, and many jobs will be transformed. Thus it is important to accompany citizens in this transition.

A selection of case studies accompanies the concept paper. Several fact sheets and videos illustrate how businesses in the various areas of the DSM manage the transition and thrive thanks to EU digital policies and targeted support - from eHealth to eCommerce, from digital skills to the digitisation of industries, from smart cities to the shared economy.

In the COM(2016) 176 final document on ICT Standardisation Priorities for the Digital Single Market[7], it is stated that “Common standards ensure the interoperability of digital technologies and are the foundation of an effective Digital Single Market”. They guarantee that technologies work smoothly and reliably together, provide economies of scale, foster research and innovation and keep markets open. Effective interoperability guarantees that connected devices such as cars, phones, appliances and industrial equipment can communicate seamlessly with each other, regardless of manufacturer, operating system, or other technical components. Open standards ensure such interoperability, and foster innovation and low market entry barriers in the DSM, including access to media, cultural and educational content. Differing national standards[8] may significantly slow down innovation and put European businesses at a disadvantage vis-à-vis the rest of the world.

The recent revision of the EU's standardisation policy resulted in the adoption of **Regulation 1025/2012 on European Standardisation**[9] and the creation of a framework for a more transparent, efficient and effective European standardisation system for all industry sectors. This Regulation emphasised the fast evolution of ICT and the way in which new products and services, such as ‘smart’ or connected devices (referred to as the ‘Internet of Things’ or IoT) or the Cloud, transform markets.

The DSM builds on Regulation 1025/2012 and is linked to the planned Joint Initiative on Standardisation that is part of the wider Single Market Strategy. The European Multi Stakeholder Platform (MSP) on ICT standardisation was set up at the end of 2011 as a group of experts set-up by Commission Decision 2011/C349/04 with the aim to advise the Commission on all matters related to ICT standardisation. Based on a European

[6] http://ec.europa.eu/newsroom/document.cfm?doc_id=44515, http://ec.europa.eu/newsroom/document.cfm?doc_id=44549

[7] http://ec.europa.eu/transparency/regdoc/rep/1/2016/EN/1-2016-176-EN-F1-1.PDF

[8] Regulation (EU) 1025/2012 on European standardisation defines the meaning of the terms “standard” and “technical specification”. In this document the term “standard” is used with both meanings for the sake of brevity

[9] Regulation (EU) 1025/2012 OJ L 316, 14.11.2012, p. 12. 3 http://www.consilium.europa.eu/en/press/press-releases/2015/06/26-euco-conclusions/

Commission Decision[10] to advise on matters related to the implementation of ICT standardisation policies, it deals with:

- potential future ICT standardisation needs in support of European legislation, policies and public procurement;
- technical specifications[11] for public procurements, developed by global ICT standards-developing organisations;
- cooperation between ICT standards-setting organisations;
- the Rolling Plan[12], which provides a multi-annual overview of the needs for preliminary or complementary ICT standardisation activities in support of the EU policy activities

The MSP is composed of representatives of national authorities from EU MS & EFTA countries, by the European and international ICT standardisation bodies, and by stakeholder organisations that represent industry, small and medium-sized enterprises and consumers. It is co-chaired by the European Commission Directorate General for Internal Market, Industry, Entrepreneurship and SME (DG GROW)[13] and Directorate General for Communications Networks, Content and Technology (DG CONNECT)[14]. It meets four times per year. Its tasks include, inter alia, providing advice on the content of the Rolling Plan and on the ICT technical specifications susceptible to be identified by the Commission for referencing in public procurement (Regulation EU 1025/2012, Art. 13 and 14).

For the Healthcare interoperability domain the Multi-stakeholder Platform (MSP) already adopted as technical specification for procurement 27 IHE profiles[15] that are mapped to the European eHealth Interoperability Framework, paving the way for common approach in MS on Healthcare information exchange.

2.2 Rolling plan methodology

The EU Rolling Plan provides an overview of the needs for preliminary or complementary ICT standardisation activities to be undertaken in support of EU policy activities. The Rolling Plan on ICT Standardisation is drafted by the European Commission in collaboration with the European Multi-Stakeholder Platform (MSP) on ICT Standardisation and is updated annually. It lists all the topics identified as EU policy

[10] Commission Decision of 28 November 2011 - setting up the European multi-stakeholder platform on ICT standardisation (2011/C 349/04), https://ec.europa.eu/digital-single-market/en/news/commission-decision-28-november-2011-setting-european-multi-stakeholder-platform-ict

[11] Identification of ICT specifications, https://ec.europa.eu/digital-single-market/en/identification-ict-specifications

[12] Rolling plan for ICT standardization, https://ec.europa.eu/digital-single-market/en/rolling-plan-ict-standardisation

[13] http://ec.europa.eu/growth/about-us/

[14] https://ec.europa.eu/info/departments/communications-networks-content-and-technology_en

[15] Commission Decision (EU) 2015/1302 of 28 July 2015 on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement (Text with EEA relevance), http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D1302&from=EN

priorities where standardisation, standards, or ICT technical specifications ought to play a key role in the implementation of the policy. It covers technologies of 'horizontal importance', ones whose application have a wide impact across different technical fields, in the context of ICT infrastructures and ICT standardisation.

The Rolling Plan is a Commission document, collaboratively and regularly reviewed, on the basis of input from the EU Services and the advice of the MSP, on an annual or by-need basis. In between two versions of the Rolling Plan, factual updates are provided on a need basis in the form of Addenda to the Rolling Plan. The Rolling Plan does not claim to be comprehensive or complete. It provides a perspective at a given point in time and subject to the contributions received and integrated.

The Rolling Plan for ICT Standardisation provides a unique bridge between EU policies and standardisation activities in the field of information and communication technologies (ICT) and thus, it allows for increased convergence of the efforts of standardisation makers towards European policy goals. This document is the result of a yearly dialogue involving a wide range of representatives of the major standardisation stakeholders as represented in the multi-stakeholder platform on ICT standardisation. The Rolling Plan focuses on those actions that can support EU policies and does not provide a comprehensive overview as regards the work programmes of the various standardization bodies

The Rolling Plan details the requirements for ICT standardisation in the form of actions and provides a follow-up mechanism for these actions. The Rolling Plan 2016 identified 162 actions in total, of which 127 have started and 19 are completed by now. A summary of the sections of the Rolling Plan 2017 can be found below organised around four thematic areas: key enablers, societal challenges, innovation for the single market and sustainable growth.

The Commission has identified five priority domains in its Communication on ICT Standardisation Priorities for the Digital Single Market[16] —5G, cloud, cybersecurity, big data and internet of things (IoT) —where ICT standardisation is considered most urgent for the completion of the DSM, as well as a number of application domains that will benefit from standard setting in those horizontal technologies, in particular eHealth, intelligent transport systems, smart energy and advanced manufacturing.

The Rolling Plan 2017 includes actions in support of the priorities indicated in the Communication. The Rolling Plan is a living instrument. Compared to the 2016 edition, in the Rolling Plan 2017 some domains have disappeared because of completion of activities (RFID) and new domains have been added (5G, FinTech, Building information modelling (BIM) and Common information sharing environment (CISE) for the EU maritime domain).

[16] COM (2016) 176 final, Standardisation Priorities for the Digital Single Market

The Rolling plan methodology is based on the fact that this document is revised annually to reflect the new demands of the MS and the new priorities. Those priorities are mapped to so the basic Key enablers of the Rolling plan so that the path towards the DSM is made possible by having tangible advancements on a yearly basis. Those key enablers are depicted in the following picture.

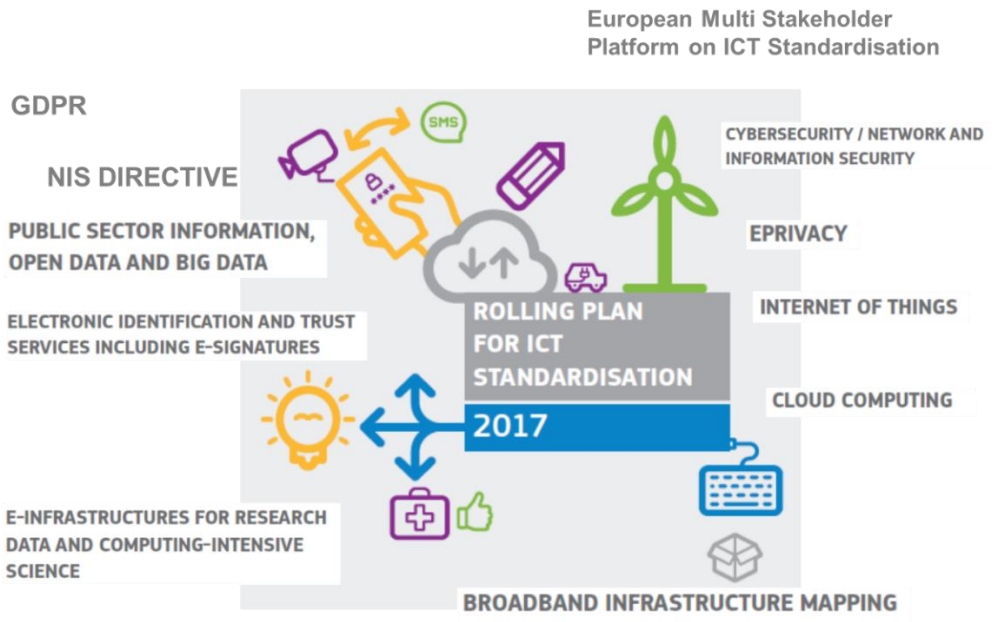


Figure 1 Key Enablers of the DSM

An important objective of this Rolling Plan is to create awareness of the importance of ICT standards in the context of policy making and to promote the use and uptake of standards in general in order to increase ICT interoperability in those policy areas that were identified as needing ICT standardisation activities. To this end, the Rolling Plan may look at the full spectrum of available instruments for promoting awareness about standardisation and standards; for identifying and mapping standards, finding standardization gaps and kicking off new activities in ICT standardisation; and for making use of standardisation, standards and technical specifications in policies. International cooperation regarding ICT standardisation is also addressed. As such, governments can promote the uptake and implementation of standards and specifications via public procurement. The Regulation on European Standardisation 1025/2012, which came into force in January 2013, **offers the possibility to identify relevant ICT specifications** under conditions defined in Articles 13 and 14. Identified ICT technical specifications get the status of common technical specifications and may be referenced by public procurers.

If standards are to be successful in terms of widespread deployment, it is necessary to ensure that there are products and services implementing them and that they are truly interoperable. Therefore, one of the main aims of European and global standardisation is to enable interoperability in a multi-vendor, multi-network, multi-service environment. Interoperability gives users a much greater choice of products and services, and enables manufacturers and service providers to benefit from economies of scale in a wider market. There is a broad stakeholder demand in the marketplace to

ensure interoperability. The validation of standards and products through open interoperability events is an example of how to achieve this in a pragmatic and efficient manner. Organizing such events in the earlier phases of the development of standards can give quality assurance and facilitates the development of commonly agreed standardised solutions. Interoperability testing leads not only to better products but to better standards, suited to the user needs. It gives stakeholders confidence to implement standards and to release products in a timely manner.

Standards bodies, governments and other organisations regularly organise interoperability events, e.g. in the form of plug tests, plug fests, etc. Some examples are, for instance, the ETSI "PlugtestsTM events", the PCHA plugfests, the IHE Connectathons. Typically, these interoperability events gather different vendors (often competitors) in order to check whether their products properly implement standards and are interoperable between them. This approach has proven to be a practical way to boost interoperability further to the development of standards, and has been applied with some success to standards and specifications issued by other organisations, including formal standards bodies and industry consortia. Some fora and consortia also have internal interoperability and conformance testing requirements applied to specifications as a quality control matter prior to their finalisation as standards. One example is the proposed IHE conformity assessment scheme (CAS)[17].

2.3 Rolling plan recommendations

Under the domain of Societal Challenges, the DSM Rolling map has identified the current challenges for eHealth and Active and Healthy Ageing. In 2016, CEN's Technical Committee 251 on Health Informatics started to work on standardising an international patient summary, drawing from elements of the guidelines developed under the eHealth network. Completion of the standards is expected in 2018. This activity is funded by the Commission and ensures European participation in an international initiative which is expected to enable people to access and share their health data information for emergency or unplanned care anywhere and as needed. In a similar way, CEN's Technical Committee 215 has identified a list of existing standards for eHealth. Those are shortly described in another section of this document.

In 2015 a subgroup on mHealth was established as part of the eHealth Network[18]. The purpose of the subgroup is to "collect experiences on approaches in dealing with mobile health apps, to identify common challenges and recommend possibilities for future collaboration among Member States". In 2017, the development of a European guidance document based on the Publicly Available Specification (PAS) 277 was developed by the UK national standardization body (BSI) for the use of the eHealth and wellness app developers to set out quality criteria and principles to be followed throughout the app

[17] http://www.ihe.net/Conformity-Assessment/
[18] eHealth Network „The establishment of a sub-group on mHealth", 2015. Retrieved from http://ec.europa.eu/health/ehealth/docs/ev_20151123_co04_en.pdf

development life cycle. This standardisation activity addresses some of the concerns related to the apps' quality and reliability.

MS have responded quickly, demonstrating a high-level commitment to the eHealth policy agenda, notably through their participation in the eHN, in JAseHN, and in the eHealth Digital Service Infrastructure (DSI) to exchange electronic prescriptions and patient summaries. In 2016, 16 MS committed to deploy eHealth services (exchange of patient summaries & eprescriptions) with the support of the connecting Europe facility (CEF) work programme. As a basic recommendation from the DSM Rolling plan, it is important to put measures in place in the areas of eGovernment and eHealth to ensure the accessibility of the relevant services to the general public and to patients in the health service using assistive technologies.

The DSM Rolling plan is based on the following policy and legislation material:

- **Directive 2011/24** on the application of patients' rights in cross-border healthcare http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF
- **(COM(2016) 179 final):** " EU eGovernment Action Plan 2016-2020: Accelerating the digital transformation of government"http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0179&from=EN
- **COM(2015) 192** : "A Digital single market strategy for Europe
- http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1447773803386&uri=CELEX-:52015DC0192
- **COM(2010) 245:** "A Digital Agenda for Europe", actions 76, 77 and 78
- http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52010DC0245R(01)&-from=EN
- **COM(2008) 689:** Communication of the Commission on telemedicine for the benefit of patients, healthcare systems and society, https://ec.europa.eu/transparency/regdoc/rep/1/2008/EN/1-2008-689-EN-F1-1.Pdf
- **SWD(2012) 413 final** — eHealth Action Plan 2012-2020 — Innovative healthcare for the 21st century http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0413:FIN:EN:PDF
- **European Commission Green Paper** on mobile health ("mHealth") issued to stakeholders for comments April 2014' (now completed) http://ec.europa.eu/digital-agenda/en/news/green-paper-mobile-health-mhealth
- **Refined eHealth European Interoperability Framework (ReEIF) adopted by the eHN on 23.11.2015**
- http://ec.europa.eu/health/ehealth/docs/ev_20151123_co03_en.pdf
- **EU-US memorandum of understanding** http://ec.europa.eu/digital-agenda/en/news/memorandum-understanding-eu-us-ehealth

- Directory for eHealth policies, World Health Organisation, http://www.who.int/goe/policies/en
- French national strategy

http://proxy-pubminefi.diffusion.finances.gouv.fr/pub/document/18/17721.pdf#page=23

- Strategy of the Federal Council for an Information Society in Switzerland[19]:

http://www.e-health-suisse.ch/index.html?lang=en

- Legally eHealth — Putting eHealth in its European Legal Context

http://www.epsos.eu/uploads/tx_epsosfileshare/Legally-eHealth-Report_01.pdf

Under the eHealth domain, the DSM Rolling plan focuses on promoting activities such as:

- Listing key aspects requiring identification (patients, hospitals clinics, doctors, diseases, etc.) should be considered at European level as a priority for work on eHealth, since many other areas depend on identifiers. In particular, agreement should be reached on the categories of healthcare professionals who can access patient summaries, including a solution for secure authentication of these professionals and their authorisations. The eIDAS Regulation (EU) No 910/2014 may solve parts of the issues on identification and authentication processes, and the eHN is working in that specific area. Work is ongoing in the MS to finalise the transposition of the eIDAS Regulation.
- Standardised drug identifiers to achieve national and international interoperability of health services (online or other), while complying with the legislation protecting patients, and including specific rules of enforcement of delivery on medical prescriptions
- Agreements on a terminological profile for a revised minimum set of fields included in the patient summary, and on a technical profile for the cross-border exchange of patient summaries, in particular with regard to security aspects, based on the guidelines on a minimum/non exhaustive patient summary dataset for electronic ex-change (eHN, November 2016).
- The ICT services to be provided to European reference networks (ERNs) and healthcare providers, to satisfy the needs of communication and data sharing within and between the reference networks, addressing areas such as fast and easy sharing of digital medical images through picture archive and communication systems (PACS); telemedicine solutions, allowing healthcare providers to share real-time knowledge and decisions; sharing of best practices and clinical decision- making tools (i.e. guidelines); solutions to support collaborative research between healthcare providers, through the development of clinical trials and/or epidemiological studies; and establishment of shared databases and registries.

[19] https://www.bag.admin.ch/bag/fr/home/service/gesetzgebung/gesetzgebung-mensch-gesundheit/gesetzgebung-elektronisches-patientendossier.html?_organization=317

- The move towards personalised medicine requires standardization of data related to the field of biology and biomarkers.
- Quality criteria for the development of health and wellness apps. Taking into account the fast growing market of health and wellness applications and the concerns about their quality and reliability, there is a need for technical specifications at the European level that would provide guidance to app developers by setting out quality criteria and principles to be followed throughout the app development life cycle. These technical specifications should envision to remove the silos effect while developping mHealth apps and allowing the exchange of patient / citizen related data amongst systems and services.
- Evaluate the need to produce an initial report listing all the necessary types of identifiers and identification processes

Another domain affecting eHealth is the domain of **e-Privacy**. The enforcement of the EU data protection and privacy legal framework would be made easier if data processing products and processes are designed and built from the beginning with legal requirements in mind. This is referred as 'data protection by design'. Standards may lay out the basic requirements for data protection by design for products and processes, minimising the risk of (i) divergent national approaches, with their related risks to freedom of movement of products and services, and (ii) the development of several, potentially conflicting, private de-facto standards. This could be combined with the emergence of certification services: businesses who want their products and processes audited as being "privacy by design"-compliant, would have to fulfil a set of requirements defined through appropriate EU standards and robust, independent third-party certification mechanisms. The principles of data protection by design and by default, as well as the need to undergo a data protection impact assessment for data protection and privacy are included in the recently adopted General Data Protection Regulation 2016/679/EU (GDPR). This regulation replaces the Data Protection Directive 95/46/EC and will apply from 25 May 2018. In the meantime, national laws implementing the Directive 95/46/EC remain valid. The following legal instrument should be considered at European level: The Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (ePrivacy Directive). This Directive is under revision with the Commission that adopted on 10 January 2017 a proposal for a Regulation on privacy and electronic communications that will replace the old directive and address its flaws to ensure an increased level of protection of citizens' confidentiality of communications[20].

[20] Proposal for a Regulation of the European Parliament and of the Council concerning the respect for private life and the protection of personal data in electronic communications and repealing Directive 2002/58/EC (Regulation on Privacy and Electronic Communications), 10.01.2017, COM (2017)10 final https://ec.europa.eu/digital-single-market/en/news/proposal-regulation-privacy-and-electronic-communications

In the context of e-Privacy also related to the healthcare sector, the rolling plan suggest that:

- Continuing work on standardising browser functionalities and defaults to enable users to easily control whether they want to be tracked.
- Develop a certification scheme, based as much as possible on existing best practices and standards, in order to create a EU reference point on the topic.
- Promote EU-wide attention to standardization of privacy statements and terms & conditions, given that there is mandatory acceptance of diverse, ambiguous and far-reaching online privacy conditions, and taking into account the new data protection Directive.
- SDOs to continue investigating technical measures apt to make personal data anonymous or pseudonymised (and therefore unintelligible by those who arenot authorised to access them)[21].
- SDOs to continue investigating how to warrant a user-centric approach in privacy & access management.

As a conclusion, Interoperability of ICT-enabled solutions and of data exchange is the precondition for an improved coordination and integration of healthcare unlocking the EU eHealth single digital market. The use of European and international standards is a way to ensure the interoperability of ICT solutions in general. The eHealth network identified more detailed specifications, which could be used for public procurement, in the framework of the new EU standardization regulation, contributing to the technical and semantic levels of the eHealth Interoperability Framework. One example is the IHE set of specifications identified for use in procurement by Commission Decision (EU) 2015/1302 of 28 July 201533 under Article 14 of the EU Regulation 1025/2012.

A refined eHealth European interoperability framework (ReEIF) was adopted by the eHealth Network in November 2015. It represents a common refined framework for managing interoperability and standardisation challenges in the eHealth domain in Europe, offering a framework of terms and methodologies for reaching a common language, and a common starting point for the analysis of problems and the description of eHealth solutions throughout Europe. In addition to European and international standards and specifications, interoperability testing, labelling and certification processes are also essential[22]. Several projects are successfully testing and implementing standards, open and secure architecture, clinical workflows and subsets of terminologies and making policy recommendations, to prepare the deployment of eHealth services on a large scale.

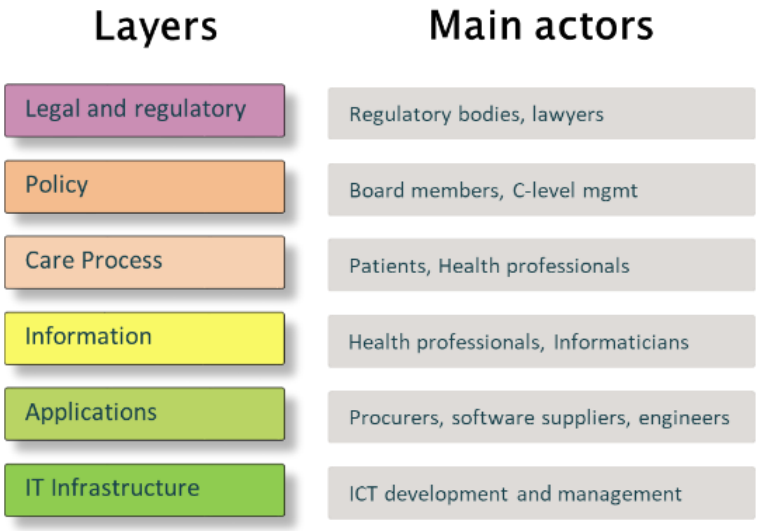
[21] http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Handbook_De-Identification_Rev1.1_2014-06-06.pdf

[22] Antilope Project, https://www.antilope-project.eu/front/index.html and EURO-CAS project, https://www.euro-cas.eu/

The eHealth Interoperability Framework Study[23] is identifying a representative set of the most relevant use-cases within the eHealth environment and initiating the specification of requests to

foster ICT products and services. Further user-centred work may be needed to cover different forms of user integration in the systems. The framework covers: (a) patient summaries, ePrescription, common cross-border semantics approaches and subsets of ontologies in clinical contexts; (b) standardised processes in a specific clinical context; (c) technical specifications (including immunity) for eHealth systems, especially cross-border. Several projects and initiative are mentioned as valuable input for the DSM Rolling plan[24].

As a conclusion, the DSM rolling plan is already well aligned with the current activities and eHealth policies at the EU Commission Level. The most important recommendations



that needs to be kept in the future versions of the rolling plan should focus on:

- Promoting the use and methodology of the ReEIF
- Propose a use-case driven approach for interoperability to build a library of use-cases that are linked to specific integration profiles and their underlying standards set.
- Promote the adoption of Clinical Information Models.

2.4 Standardisation in view of the ReEIF

In its meeting of November 2015, the eHN adopted and endorsed the so-called Refined eHealth European Interoperability Framework (ReEIF), on the basis of a document describing this framework. The document can be found here: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf

Figure 2 ReEIF LAYER

[23] http://ec.europa.eu/digital-agenda/en/news/ehealth-interoperability-framework-study
[24] See Rolling plan for ICT Standardisation 2017 pp 50-52, http://ec.europa.eu/information_society/newsroom/image/document/2017-13/grow_rolling_plan_ict_2017_web_170302_C7EC62EB-0196-6C12-45229D71D00B0D6B_43894.pdf

In the ReEIF it is proposed to structure the discussions on eHealth, from policy to technology, along the lines of a six-layer model, showing that every solution needs partial solutions on six significantly different aspects, but in a coordinated manner. Figure 2, taken from the ReEIF document, shows in brief these layers. It is stipulated in the document that the complexity of information solutions in healthcare lies mainly in two facts:

- The objects of thinking are totally different in the six layers: in "Care Process" we find health professionals and patients at work, in "Applications" we find pieces of software and related artefacts, "Information" is an abstraction of again different nature, etc.
- The main actors, responsible for these parts of the total solution, are very different professionals that do not automatically understand each other (lawyers, board members, health professionals and patients, information analysts, software engineers, IT engineers, etc.

The value of the splitting in these six aspects thus lies in the fact that the partial solutions and their actors are made clear, in order to put the right responsibility on the right level. It also serves as a reminder, not to forget certain partial solutions.

If we broaden this thinking to interoperability the landscape of course consists of two (or more) individual solutions, that should be brought to collaboration, again by applying interoperability thinking on all six layers, as shown in figure 3:

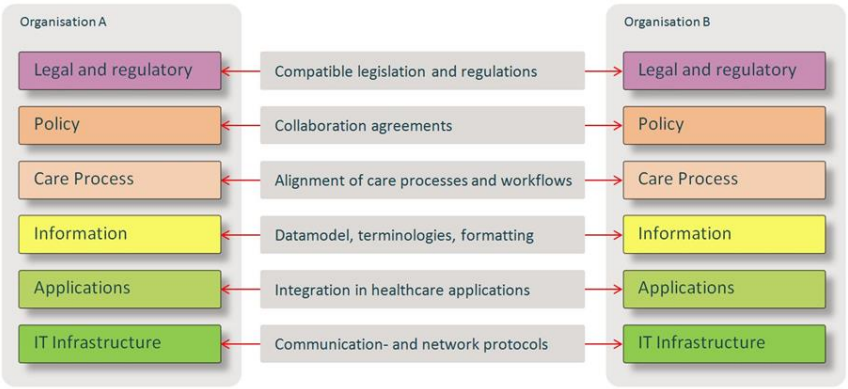


Figure 3 applying interoperability for each ReEIF layer

It is clear in this figure that agreements on all different layers have to be reached on how to act for the interoperability purpose. Then, of course, when scaling this up from two parties to a large number of parties (27-member states in Europe, hundreds of hospitals within a country, etc) broader agreements become necessary, and it is here where the term standard comes in.

Since it is deemed necessary to create partial solutions per layer, it is also very much preferred to proclaim standards per layer as well, in order to ensure scalability and reusability, and in order to be able to have the right actors involved on every layer.

Very central in this whole picture is of course the Care Process layer, where standards are seen in the form of clinical protocols. Health professionals in different institutions have to have a certain agreement on how to do diagnosis and treatment, in case they have to collaborate for the benefit of the same patient, but each from their own institution. Right below that is the Information layer, because this collaboration can only function when agreement exists on the structure and the content of the information about the patient, relevant to the care process. This can be expanded on both sides of course, saying that this can only work if the applications in both institutions "understand" each other, and, finally, if the information can flow from one institution to the other via secure networks, which again can only function by the virtue of (technical) standards.

Special attention is necessary for the Information layer with regards to the standardisation. Whereas on the application layer in theory always software can be design to connect Organisation A with Organisation B (rather standardised than not-standardised of course), this is not always, or often not, possible for the information. Information elements that are not documented in care processes in A, cannot be transferred to B, but for the consistency in B these elements might be crucial. Moreover, information elements that are documented in A in a semantic form other than the semantic form of B, cannot be transferred without loss of (often essential) details. In other words, in the information field, often referred to as the semantic field, not only standardisation for interoperability transfer is needed, but also standardisation of the very content of the information. The most important concepts in this standardisation of content are terminologies (fine-grained computable "languages" for health and care, e.g. SNOMED CT) and Clinical Models, i.e. small meaningful elements of the health and care field, each comprised of a number of data elements represented in the terminologies. Examples are Blood Pressure, Tobacco Usage, Hearth Rate, etc. While the terminologies standardise the detailed content, Clinical Models give the structure to the information landscape. While terminologies always have been recognised as essential parts in the standards landscape, Clinical Models have been described ever since, but not used widely in national or regional solutions. This situation is changing: several countries have implemented / are implementing or considering Clinical Models as an essential part of the standards landscape. This is why the authors of this are convinced that Clinical Models should be more seriously adopted in standards discussions.

In healthcare many different organisations exist for these standardisation efforts, from worldwide organisations that define basic standards in a very broad sense (commonly referred to as Standards Developing Organisations SDO), to nationally operating organisations (often referred to as National Competence Centres, NCCs), that take these international standards, and further define the necessary standards on a national (or regional) level, either by constraining the worldwide standards for the country, or by adding national extensions or even national standards. SDOs operate on national level in addition to global or regional SDOs. Thus, in many cases, competence centres are not the only relevant organizations in constraining or extending standards, unless

competence centres include national SDOs and/or "national chapters of international SDOs" as well. In many cases, these actors are significant in addition to or instead of "national competence centres" as mentioned above.

This brings forward the necessity of the vertical integration: six partial solutions only form an over-all working solution when the integration between the layers is done correctly and consistently. That is the task of every solution provider, and on a national scale often of the NCC. Also, here some help is available from internationally operating organisations. These organisations are commonly referred to as profiling organisations after the products they produce: profiles. The profile is a standardised multilayer solution for a specific use case. In other words: a use case is a specific generalised (piece of a) care process, and the profile contains a receipt for the creation of a model solution, suggesting which standards to take on which layer and how.

As such the ReEIF is a basic component of many recommendations of this document. In fact all recommendations have been assessed in relation to their impact on the ReEIF adoption for healthcare interoperability in Europe.

3. Recommendation for the DSM Rolling Plan

3.1 Recommendation 1 - Use-case driven approach for healthcare interoperability

A well-known problem in eHealth is the fact there are competing and overlapping standards and sometimes it is difficult to choose which standards or standard sets to use. By focusing on use-cases the SDOs can help purchasers and vendors to make that choice and at the same time it will ensure benefits for the end-users. This is supported by the methods described in ReEIF and the 7-step method in the eStandards deliverable D4.2.r2 as follows:

1. *Identify use cases* from an end-user perspective, including glossary, scenario, actors, privacy requirements and variations.
2. *Select profiles and standards* that support the use case. IHE[25] and Personal Connected Health Alliance (PCHA) have developed such profiles.
3. *Refine data content*, including document templates, metadata, master files, and terminology. HL7 and other SDOs have developed document template repositories to support clinical content profiles, frequently associated with terminology value sets.
4. *Write interoperability specifications (implementation guides)* that describe the standards / profiles selected, the refined data content, and other project specific

[25] Commission Decision (EU) 2015/1302 of 28 July 2015 on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement (Text with EEA relevance), http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D1302&from=EN

local needs. This specification enables implementation of the use case across the various IT systems and devices.

5. *Organise testing* by preparing test cases and adopting a test environment for implementers to demonstrate component interoperability and by organising cross-implementer connectivity testing.
6. *Educate end-users on interoperability:* Develop communications materials to familiarise end-users on the benefits and impact of Interoperability. This step may already begin earlier on, once the use case has been identified.
7. *Support or participate in communities of practice* to promote sustainable standards-based implementation and offer feedback to standards and profiling organisations.

As a consequence, eStandards deliverable D4.2.r2 provided a practical approach to interoperability successfully applied by various eHealth projects in Europe and internationally. The purpose of that document was to provide practical guidance to eHealth deployment projects, in particular large-scale and cross-border projects, on the challenges, costs in terms of implementation requirements and possible approaches to achieving interoperability. A special focus of this document is the question how coexistence between competing or overlapping standards and standard options can be achieved in practical terms, which is a challenge that affects most eHealth projects. It is recommended that the next DSM Rolling plan builds up in more details on this approach that is also in compliance with the Multi-stakeholder Platform (MSP). For the Healthcare interoperability domain the Multi-stakeholder Platform (MSP) already adopted as technical specification for procurement 27 IHE profiles[26] that are mapped to the European eHealth Interoperability Framework, paving the way for common approach in MS on Healthcare information exchange.

3.2 Recommendation 2 – Put more emphasis on Common Information models

It is recommended that the SDOs create common information models to be used by the healthcare stakeholders.

Health and care information models[27] are building blocks for creating data sets for any use case in healthcare. By using those, the data sets of the use cases become mutually consistent and thus interoperability is enhanced. Some of the key issues of semantic interoperability are being addressed by adopting this recommendation. However, these should not be developed from scratch but they should be based on already existing

[26] Commission Decision (EU) 2015/1302 of 28 July 2015 on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement (Text with EEA relevance), http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D1302&from=EN

[27] An **information model** in software engineering is a representation of concepts and the relationships, constraints, rules, and operations to specify data semantics for a chosen domain of discourse. Typically it specifies relations between kinds of things, but may also include relations with individual things. It can provide sharable, stable, and organized structure of information requirements or knowledge for a specific domain context, i.e. a clinical building block of information necessary to be orchestrated for clinical use.

specifications. The search for such models from multiple sources should always be carefully performed before suggesting any new specification work. These common information models can be packaged into reusable buildings blocks within a use case for example ePrescription, Patient Summary or laboratory result.

The common information models should be the smallest unit of information that is clinically meaningful, yet able to be used in a variety of use cases, so as much as possible use case independent. They should also be technology neutral. By making the building blocks technology neutral they can be reused and converted among many technologies. When creating building blocks clinician should be put in the leading role or considered to work with in close cooperation. Since the purpose is to define clinical concepts the clinicians are the experts and to make sure they are fit for purpose they have to be created and validated by clinicians.

Examples of common information models could be heart rate measurement or tobacco habits.

It is recommended that the next DSM Rolling plan puts more emphasis on the adoption of common information models that will act as semantic building block of information that are consistent enough to clinicians to adopt them in their daily practice. Creating and adopting such clinical information models will enable cross border healthcare to move forward into supporting more intensively the European Reference Networks concerning Rare diseases.