XpanDH

Expanding Digital Health through a pan-European EHRxF-based Ecosystem

D2.1-Digital health compass for the application of EEHRxF

WP2 – Standards and Technical Artefacts

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What did this document aim to achieve?	Provided an overview to previous eHealth interoperability efforts in the EU, recovering relevant frameworks and setting up the adequate framework for work under WP6 and more broadly the sustainability of future EHRxFormat efforts
Present the main methodological approaches in bullet point format	Starting from the eStandards roadmap and the ValueHealth methodology, revisits recent policy developments, to evolve the framework set up by these projects and help make the activities of XpanDH future proof supporting the openEHRxF community.
What were the main findings or take-away messages? What implications does it have for the XpanDH project?	A European EHRxF Standards and Policy hub needs to be established to sustain the aligned development and maintenance of standards and specifications supporting the European EHRxF in the context of the European eHealth Data Space.
Which project stakeholder group would benefit the most from the document and why?	
List any relevant organizations or social media accounts for wider visibility	

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List of abbreviations and Glossary

Table 1. List of abbreviations

Abbreviation	Term
CoP	Community of practice
EC	European Commission
eD	eDispensation
EEHRxF	European electronic health record exchange format
EHDS	European health data space
eHDSI	eHealth digital service infrastructure
eHN	eHealth Network
EHR	electronic health record
eP	ePrescription
IDMP	identification of medicinal products
ISO	International Organisation for Standardization
NCPeH	national contact point for eHealth
PS	patient summary

For the XpanDH glossary of terms please consult: https://glossary.ramit.be/public/home.cfm?pid=10.

Executive summary

eHealth interoperability has a long history in the European Research and Innovation Agenda for the health data sector. The COVID19 era that accelerated the digital health transformation combined with the renewed hype of Artificial Intelligence, have further highlighted the importance of semantic, technical, legal and organizational interoperability for health and healthcare in the data economy. As a result, interoperability standards are a central element in the provisionally accepted EHDS[1] regulation, where the key role of the European EHRxF or "Format" is recognized.

This report starts with a non-exhaustive account of key interoperability projects of the last three decades, revisiting seminal papers and roadmaps where participants of XpanDH have been involved directly or indirectly. since the early days of Electronic Health Record Systems. Special attention is given to the digital health compass of eStandards and the associated roadmap that has inspired this deliverable, aiming to set the stage for sustainability considerations in XpanDH T6.1.

The application of the eStandards methodology to business needs in the health sector that drive the development of the EEHRxF in the EHDS across primary and secondary use of data, is the segway for the EEHRxF Standards and Policy Hub or simply the "Hub". Building on these insights we present initial idea of the Hub which aims to serve as a steward of interoperability assets for the EEHRxF, and an accelerator for its adoption, with sustainability and change management at the centre of its operation. The Hub responds to the need for co-creation, governance and alignment among stakeholders of different priority health data categories. Coordinating among SDOs, national agencies and competence centres in Europe, it will be able to exert influence upon developments in health information technology interoperability standards globally.

The EEHRxF Standards and Policy Hub, "Hub" also contributes to the development, sustainability, and maintenance of X-Bundles for business use cases across priority data categories, elaborating on a digital health compass as a live roadmap guidance for industry, patients, the workforce, and health systems. While the Hub brings together all stakeholders of business use cases, it has a strong focus on the industry that will be called to implement the Format and reap the benefits of innovation and entrepreneurship in the digital health ecosystems to which the EHDS will be instrumental.

[1] Original text: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197, Compromised text: https://us06web.zoom.us/j/84445741015?pwd=XZ7GIOhmc3JpgpHkbBvQ2vcwHeGo6R.1

1. Introduction

XpanDH WP2 is developing standardization artifacts to advance the European Electronic Health Record Exchange Format (EEHRxF). Task 2.1 follows the methodology developed in eStandards to elaborate standards and technical artefacts for business use cases and application domains selected in T6.1, using the specifications and technical assets developed in previous or ongoing projects such as X-eHealth as building blocks. In this way, and in collaboration with other tasks, we will support and strengthen the EEHRxF communities of practice with an inventory of available standard format specifications and their implementations. Besides developing and experimenting with FHIR-based rest API specs and value sets in alignment with the European Semantic Strategy, the deliverable D2.1 aims to support the open EEHRxF community of practice[2] building a digital health compass that consolidates findings and lessons learned in 20 years of eHealth interoperability projects to facilitate coordination with other initiatives contributing to a culture of collaboration and alignment across business use cases and stakeholders.

Section 1 of the deliverable contains the present introduction.

Section 2 presents our methodology of building the digital health compass for the EEHRxF which comprises (1) building a historical perspective on interoperability and standards using the snowball method going back to the early days of electronic health record systems.

Section 3, Historical Background provides a review of key findings and recommendations from selected support and coordination actions funded by the European Union to support interoperability in the health IT sector, starting from AIM projects and moving to more recent ones such as Semantic Health (2006), Calllope (2010), Semantic Healthnet, Trillium Bridge (I and II), AssessCT, openMedicine & UNICOM, ValueHealth, X-eHealth, Digital Health & Digital Health Update and Label2Enable. Section 3 also presents the EHDS regulation and its pillars. myHealth@EU and HealthData@EU.

Then, section 4, revisits the eStandards methodology taking into account recent developments as described in section3, and presents recommendations that will be considered in the EHRxF standards and policy Hub.

Building on these recommendations, Section 5 presents key elements of the European Standards and Policy Hub for developing, sustaining and maintaining standards and specifications in support of the EHDS health information domains.

[2] Greenhalgh T, Jackson C, Shaw S, Janamian T. Achieving research impact through Co-creation in Community-Based Health Services: Literature Review and Case Study. The Milbank Quarterly. 2016;94(2):392-429.

As part of next steps (section 6), we explore how the concept of the European Standards and Policy Hub can support WP6.1 activities with a methodology to package and promote, per adoption scenario, the relevant standards, resources, profiles value sets as xBundles i.e., “interoperability asset bundles" including the corresponding interoperability testing and certification processes, procurement organisational change guidance etc. In this way, the path from EHR data exchange standards to interoperable services is laid out.

2. Methodology

XpanDH as a coordination and support action, aims to establish the digital health ecosystem for the EEHRxF. In this context the "Digital Health Compass for the EEHRxF" revisits the eStandards roadmap methodology and applies it to the business need that the EEHRxF, the format for the EHDS is called to meet.

eStandards was a Horizon 2020 project aimed at building consensus on eHealth standards, promoting knowledge-sharing, and encouraging their adoption across Europe and globally (more details in section 3.3.3). Since the eStandards roadmap methodology was developed in 2016-17 and adopted by the eHealth stakeholders' group of the European Commission in 2018, we decided to provide some historical perspective using the experience of members of the XpanDH consortium from European funded research projects, coordination and support actions, as well as studies. Thus, we present a mini survey of key projects using opportunistic convenience selection of projects and initiatives. In other words, the projects and initiatives selected are not in any way exhaustive. They are indicative and reflect the team's prior knowledge and engagement. In that sense, the review presented here is to a certain degree biased.

Thus, we take into account seminal developments before and after eStandards (2015-2017), as we address the topic of the digital compass for the EEHRxF and the ways that the EEHRxF Standards and Policy Hub will operate to serve as steward of business use cases and associated X-Bundles, and as accelerator for the adoption of EHDS in a rapidly changing sociotechnical and policy environment driven by the digital transformation of the health sector, in the digital decade for Europe 2030[3].

3

3. Historical Background

3.1. The first generation 1980-2005

As early as the 1980's or even earlier we have the first pan-European projects addressing in semantic interoperability and standards. These are projects linked to the development of medical informatics as a discipline.

In 2020, in an interview, Dr Francis Rogier France, an imminent health professional that established DRGs in Belgium and was instrumental in the creation of the European Federation for Medical Informatics, shared his hopes for the advancement of the international patient summary, an idea going back to the 1980s. In the interview captured in the first issue of EFMI Inside[4], Francis shared his recollection of early efforts to establish the foundations of the European patient summary in the early 1980s, in a form of a minimal data set harmonized across Europe. Dr. Rogier shared that in health policy cycles of that time, almost half a century ago, the patient summary objective was deemed easier than a European medicines database. A decade later, we had some truly ground-breaking interoperability projects with SESAME, GALLEN [5], and SYNAPSES [6]. These projects are connected to the establishment of CEN TC251 the technical committee for European Standards, which set the stage for OpenEHR and the family EN13606 EHR standards. In yet, another decade, OpenECG[7] (2002-2004) investigated the problem of maintaining the ECGs in the EHR in a standard waveform format.

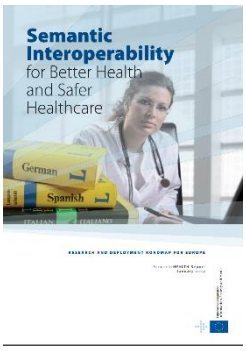
The European Medicines database took a bit longer and has been the topic of projects such as OpenMedicine (2017-2018) and UNICOM project (2019-2024) supporting implementation of the ISO/IDMP standard across Europe.

3.2. The second Generation 2006-2014

There are several projects that contributed to significantly advanced interoperability in Europe. Each of these projects has produced significant assets that can and should be taken into account in current efforts to accelerate interoperability in Europe. Some of them are listed below:

[4] EFMI Inside, Interview with Francis Roger France, EFMI Founding member, President 1984-1986 https://www.bibliomed.org/mnsfulltext/6/6-1631094195.pdf?1698619951, page 21.
[5]GALLEN- Generalised Architecture for Language Encyclopaedias and Nomenclature in Medicine, 1992-1994, AIM Program, https://cordis.europa.eu/project/id/A2012
[6] SYNAPSES Federated Electronic Health Record Server https://cordis.europa.eu/project/id/HC1046 1996-1998
[7] OpenECG Computerized ECG Standards Interoperability Portal https://cordis.europa.eu/project/id/IST-2001-37711 2002-2004

3.2.1. SemanticHealth



The Semantic Health project (2006-2008) was an EU funded support action aimed at developing a short (2-5 years) and medium term (5-10 years) R&D roadmap for semantic interoperability in eHealth systems and infrastructures [8] coordinated by Empirica. The project engaged experts in different use cases e.g. direct patient care, clinical research and translational medicine, public health and different granularities of health data e.g. gene, organ, population. Taking a scenario driven approach, different levels of interoperability were identified i.e. none (Level 0), syntactical/technical via an exchange infrastructure (Level 1), partial semantic specified by percentage (Level 2), and full semantic interoperability allowing translation and coding of health data along with pseudo anonymized data availability for research and public health (Level 3). Semantic Health engaged experts around the globe and WHO[9]. The topics addressed included nomenclatures, classifications, terminologies, and ontologies in use and their relationships and mapping needs (as seen in Figure 1, EHRs and messaging models, public health and secondary uses, as well as decision support as seen in Figure 1[10].

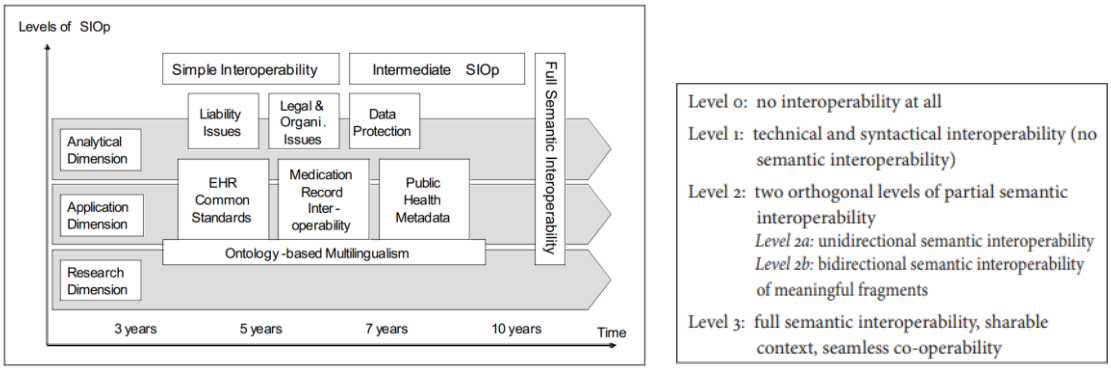


Figure 1: Preliminary Semantic Health Roadmap, from Lewalle P, et all in MIE2008.

Reflecting on the Roadmap actions in Figure 2, we can only be impressed how relevant the actions are, and how technology has developed, while some of these actions are relevant 15 years later in 2024. The Semantic Health project was instrumental in the development of the eHealth action plan and was followed by the CallIopE support action, the epSOS large scale pilot for ePrescription and Patient

[8] European Commission, Directorate-General for the Information Society and Media, Virtanen, M., Ustun, B., Rodrigues, J. et al., Semantic interoperability for better health and safer healthcare: deployment and research roadmap for Europe, Stroetmann, V.(editor), Publications Office, 2009, https://data.europa.eu/doi/10.2759/38514
[9] https://cordis.europa.eu/project/id/027328
[10] Pierre Lewalle, Jean M Rodrigues, Pieter Zanstra, Bedirhan Ustun, Dipak Kalra, Gyorgy Surjan, Alan Rector, Veli Stroetmann, Martti Virtanen. A Deployment and Research Roadmap for Semantic Interoperability: The EU SemanticHEALTH project. In: eHealth Beyond the Horizon – Get IT There. Proceedings of MIE2008, edited by Andersen, S. K.; Klein, G. O.; Schulz, S.; Aarts, J.; Mazzoleni, M. C., https://pubmed.ncbi.nlm.nih.gov/18487802/

Summaries, joint Action and eHGI (eHealth Governance Initiative), as well as Semantic Healthnet, the first effort to directly engage standards developing organizations and HL7 with EU funded research projects.

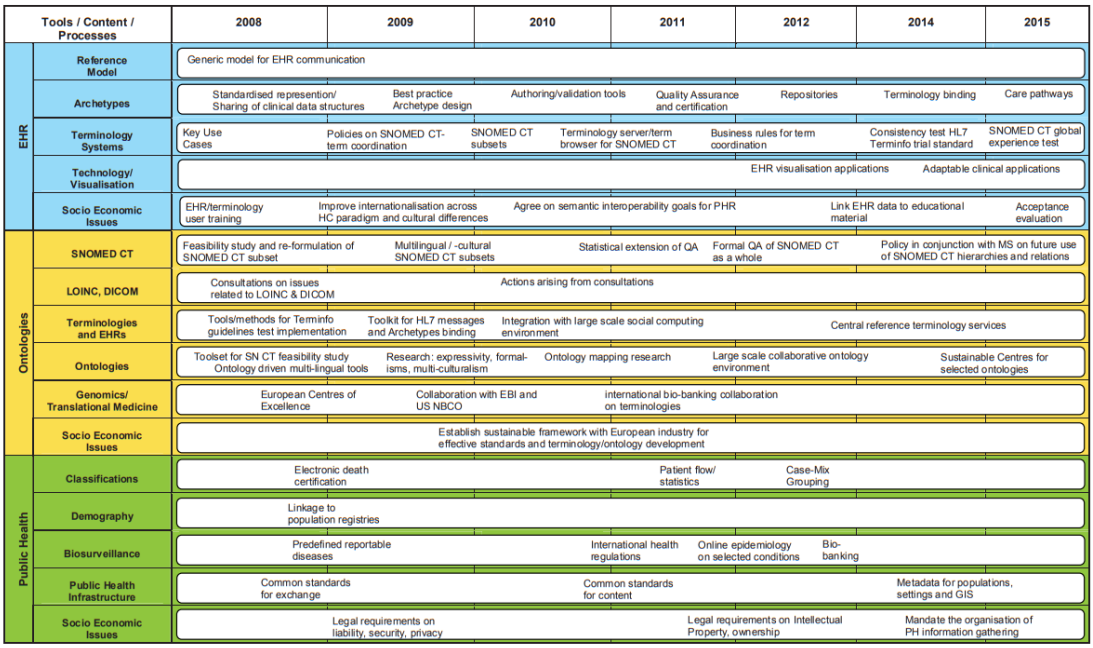


Figure 2: Semantic Health Roadmap, action plan summary (2009) from https://data.europa.eu/doi/10.2759/38514

3.2.2. epSOS smart open services 2008-2014

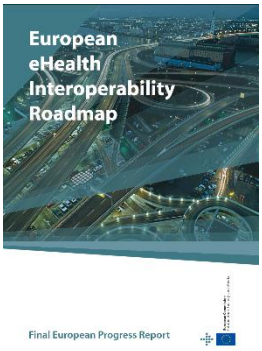
EPSOS – Smart Open Services - Open eHealth Initiative for a European Large-Scale Pilot of Patient Summary and Electronic Prescription (2008-2014)[11] was a large-scale pilot, which along with STORK[12] large-scale pilot of secure identification, established the foundations of what is now known as myHealth@EU, coordinated by regional authorities of Sweden. While it started with a few partners, it grew to include 25 member states, and about 50 organizations, with a total budget exceeding 50M€. epSOS grounded itself on national eHealth strategies of European member states many of which addressed patient summary/emergency data sets and medication record/ePrescribing solutions. Besides myHealth@EU the project established the notion of "building blocks" that is now advanced by common services of the European Commission, and the cycle of trust comprising national centres for eHealth, setting the foundations for a pan-European approach to interoperability. The Open National Contact Point (Open NCP) community established under epSOS is still alive building upon a sense sharing and

[11] ePSOS - Smart Open Services - Open eHealth Initiative for a European Large Scale Pilot of Patient Summary and Electronic Prescriptionhttps://cordis.europa.eu/project/id/224991

[12] Secure idenTity acrOss boRders linked https://cordis.europa.eu/project/id/297263

mutual learning[13]. Its influence stays also in the XpanDH with the community of doers in WP5. Trillium Bridge mentioned in a later section collaborated with epSOS to extend its work across the Atlantic and EXPAND took over the maintenance of key interoperability assets developed in epSOS, in anticipation of the Connecting Europe Facility (CEF) funding scheme.

3.2.3. CALLIOPE – Call for Interoperability



CALLIOPE (2008-2010), "CALL for InterOPErability: Creating a European coordination network for eHealth interoperability implementation"[14] was a thematic network part of the Open eHealth initiative that was coordinated ICCS Greece and was linked to the epSOS large Scale pilot for ePrescription and Patient Summaries. Comprising 17 health authorities and 10 organisations representing networks of physicians, community pharmacists, patients, industry and health insurers, its aim was to support Member States to implement interoperable eHealth solutions, with a structured open forum were key actors participated.

[13] https://digital-strategy.ec.europa.eu/en/news/cross-border-health-project-epsos-what-has-it-achieved

[14] CALLIOPE: "CALL for InterOPErability: Creating a European coordination network for eHealth interoperability implementation" on Cordis, https://cordis.europa.eu/project/id/224986

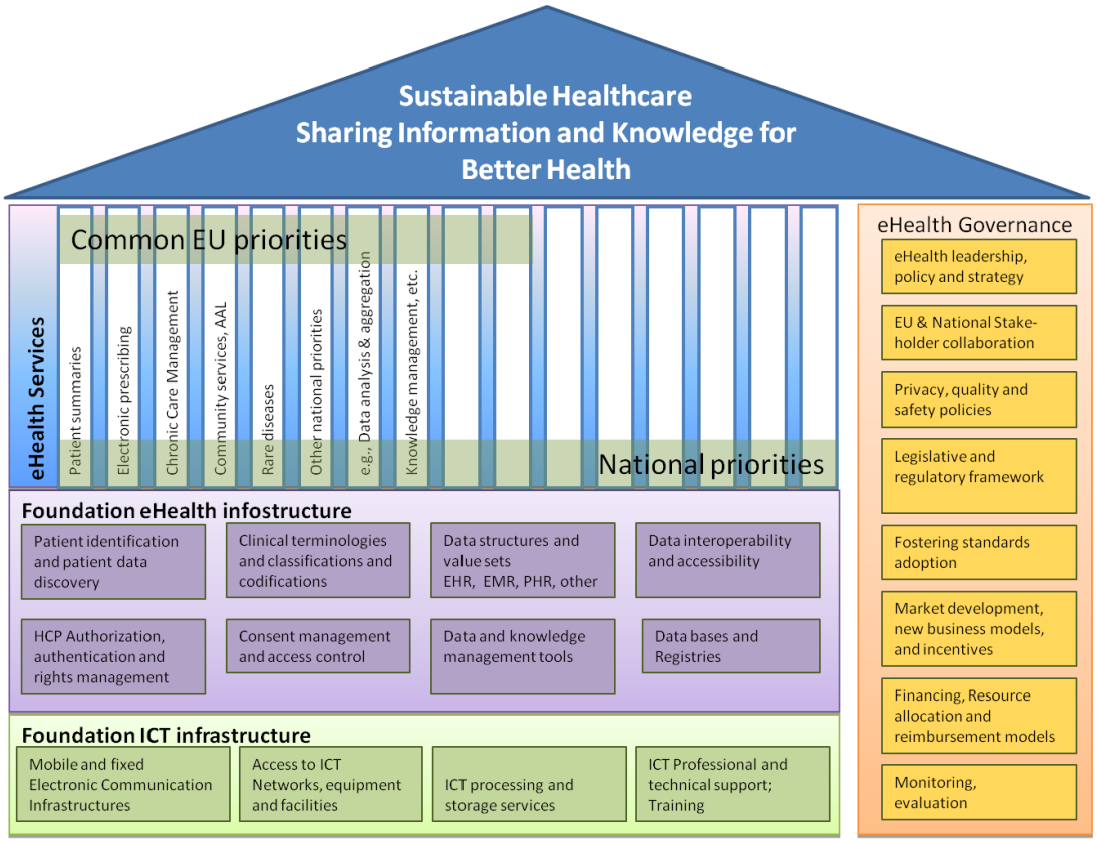
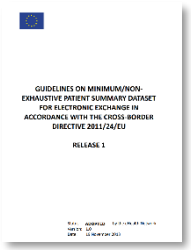


Figure 3: The CALLIOPE roadmap leveraging national and common European priorities. (https://data.europa.eu/doi/10.2759/51197)

The project's first set of operational objectives were elaboration of a common Interoperability Road map, review and advancement of the EU Interoperability Recommendations, contribution to future programme funded activities in cross border eHealth, and facilitation of pre-standardisation processes through liaison with Standards development Organizations[15]. CALLIOPE achieved its objectives with the CALLIOPE interoperability roadmap[16] and was instrumental in the development of article 14 in the EU Directive 2011/24[17], on the application of patients' rights to cross-border healthcare. The CALLIOPE roadmap leverages the knowledge gained in epSOS and was instrumental in identifying common services with a clear focus on governance, that were taken up by the follow-up Joint Action and eHealth Governance Initiative, projects that worked closely with the eHealth Network (eHN), the voluntary network of ministry of health representatives established under article 14 of the EU Directive 2011/24.

[15] https://ec.europa.eu/information_society/activities/ict_psp/projects/portfolio/h1_documents/calliope.pdf
[16] European Commission, Directorate-General for the Information Society and Media, European eHealth interoperability roadmap, Publications Office, 2011, https://data.europa.eu/doi/10.2759/51197
[17] DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients' rights in cross-border healthcare https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF

3.2.4.Joint Action / eHealth Governance Initiative (2010-2014)



The Joint Action and eHealth Governance initiative followed the steps of the CALLIOPE thematic network, both coordinated by the Austrian Ministry of Health, and were instrumental for the creation and update of the guidelines for Patient Summaries [18] and ePrescriptions (see Figure 4), achieving consensus among the members of the eHealth network and eHealth stakeholders. The first Joint action was the only one that included umbrella stakeholder organizations among its beneficiaries. Later the eHealth stakeholders' group was established and is still functioning complementing the member state driven initiatives.

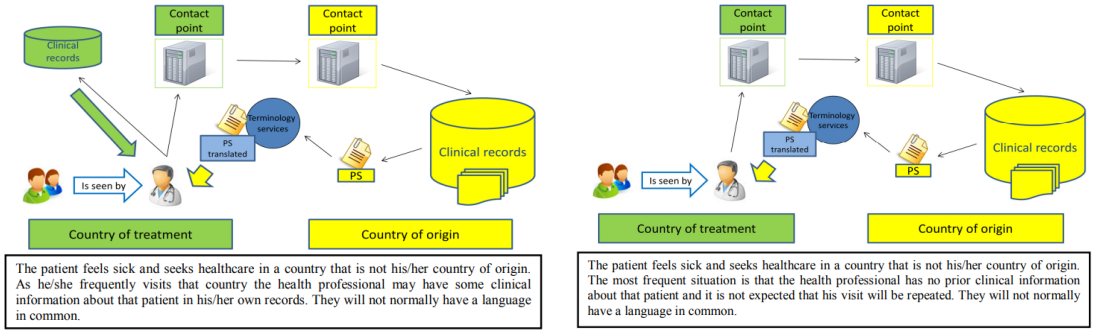


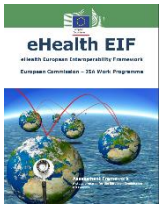
Figure 4: Example use cases from the patient summary guidelines.

3.2.5.Semantic Healthnet (2011-2015)

Semantic Healthnet was a thematic network coordinated by RAMIT in Belgium that engaged a truly multistakeholder community and for the first time brought together standards organizations [19] . SemanticHealthNet aims were to enhance the interoperability of clinical and biomedical knowledge across Europe's healthcare systems. It focused on optimizing Electronic Health Record (EHR) systems for patient care, public health, and research, with a special focus on cardiovascular medicine. The project involved experts tailoring resources based on clinicians' needs, engaging with stakeholders, and developing best practices for semantic interoperability. It also establishes a business model and explored establishing a Virtual Organization for sustainability. Clearly the concepts of the EHRxF Standards and policy hub can be first be connected to this groundbreaking program. Moreover, some of the content work on patient summaries for cardiovascular medicine are worth revisiting.

[18] https://health.ec.europa.eu/system/files/2019-02/guidelines_patient_summary_en_0.pdf
[19] Semantic Healthnet Thematic Network https://cordis.europa.eu/project/id/288408

3.2.6.Hitch and Antilope (2013-2015)



The Antilope project- "Adoption, taking up and testing of standards and specifications for eHealth interoperability"[20] was led by MedCom in Denmark and IHE-Europe, brought together several standards development organizations (CEN, IHE-Europe, HL7 Europe, and ETSI) and core European National organisations supporting the adoption and testing of existing eHealth standards and specifications closely aligned with eHealth interoperability framework. Based on the results and recommendations in the Hitch – "Healthcare Interoperability Testing and Conformance Harmonization" project (2010-11)[21] coordinated by INRIA, Antilope geared up to promote and drive adoption of testing guidelines as well as testing tools on a European and National level. The intended outcome aimed was a common approach for testing and certification of eHealth solutions and services in Europe. Both projects and the follow-up EuroCAS project[22] were instrumental in the IHE-Europe approach to testing in IHE-Europe Connectathons, its focus to the eHealth Interoperability Framework[23] and its revision of the ReEIF.

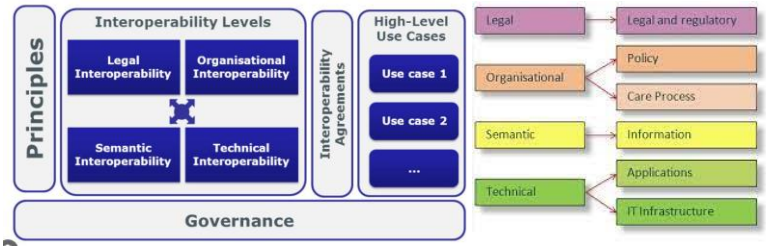


Figure 5: Overall vision and layers in the eHealth Interoperability Framework.

[20] Antilope https://cordis.europa.eu/project/id/325077
[21] HITCH project https://cordis.europa.eu/project/id/248288
[22] EUROCAS https://cordis.europa.eu/project/id/727028
[23] European Commission, Directorate-General for the Information Society and Media, EHealth European Interoperability Framework – Overall Executive Summary 2013, https://data.europa.eu/doi/10.2759/10138

3.2.7. Trillium Bridge (2013-2015)

The Trillium Bridge project, "Bridging Patient Summaries across the Atlantic"[24] was a feasibility study of exchanging patient summaries across the Atlantic, linking the epSOS project in Europe with Meaningful Use in the United States. Trillium Bridge, coordinated by HL7 Europe, carried out a gap analysis comparing patient summary specifications in EU/US and identified shared clinical elements: problems, medications, allergies. Then it established a set of interoperability assets: terminology prototype CTS-2 service: http://extension.phast.fr/STS_UI, and a transformer of Patient summaries: http://informatics.mayo.edu/trillium-bridge. Through validation activities engaging four European member states with one of the Kaiser Permanente health systems in the United States, it identified and mediated differences in EU/US IHE XCPD/XCA profiles for Patient Identity and Document Query/Retrieve. It carried numerous demonstrations including EU/US Marketplace; HIMSS 2015; IHE-Europe Connectathon 2015, eHealthWeek 2014 and 2015.

The validation activities and demonstrators it carried out, prepared the ground for a feasibility study where experts reflected upon standards, cross-vendor integration, incentives, clinical research, security and privacy, innovative business models, education. It delivered 20 recommendations, but the key one was to "*Advance an International Patient Summary (IPS) standard to enable people to access and share their health information for emergency or unplanned care anywhere and as needed. At minimum the IPS should include immunizations, allergies, medications, clinical problems, past operations and implants.*" This recommendation underpinned not only the EU/US MoU on eHealth collaboration, but also led to the Trillium II project (2017-2019)[25] and other seminal initiatives in G7[26], GDHP[27], and the world Economic Forum.

3.2.8. EXPAND - Expanding Health Data Interoperability Services (2014-2015)

The EXPAND - Expanding Health Data Interoperability Services[28] Project was created to steward, maintain, and further develop the technical specifications for cross-border health services, until the next financial cycle would begin to continue the

[24] Trillium Bridge project https://cordis.europa.eu/project/id/610756
[25] Trillium II project https://cordis.europa.eu/project/id/727745
[26] G7 International Patient Summary Roadmap https://assets.publishing.service.gov.uk/media/61d82fbd8fa8f505893f1c93/G7-international-patient-summary-roadmap.pdf
[27] Global Digital Health Partnership https://gdhp.health/
[28] EXPAND https://cordis.europa.eu/project/id/620980

funding of the scaling up of cross border eHealth services. EXPAND, coordinated by the Serviços Partihados do Ministério da Saúde (SPMS), Portugal, elaborated on the concept of interoperability assets and their maturity, creating a framework that provides essential input to current developments.

3.3. The third Generation 2015-2018

The next generation of interoperability projects involved four interacting projects: AssessCT, VALUeHEALTH - Establishing the value and business model for sustainable eHealth services in Europe[29] (2017-2018) coordinated by the European Institute of Medical Records (EuroRec), eStandards, and OpenMedicine (2015-2016)[30]. All of them were seminal project that took a life of their own. In the following paragraphs we cover, more extensively, AssessCT and eStandards projects. However, Value Health contributed immensely to assessing business models for eHealth and OpenMedicine and its follow-up currently ongoing projects UNICOM-"Up-scaling the global univocal identification of medicines"[31] and Gravitate-Health[32] have shaped collaboration between regulatory agencies for medicine and eHealth services.

During this period, the eHealth Network established a subgroup for the Implementation of the eHealth Digital Health Services (eHDSI). This created the concept of Waves, established the processes for the setup of a governance framework for the first set of cross-boarder voluntary services (ePrescription/eDispensation and Patient Summary) materializing many of the previous efforts. This resulted in Finland and Estonia going live in late 2018 with cross-border sharing of ePrescriptions, followed by 4 more countries going live in 2019 and a second service, Patient Summary, spearheaded by Portugal as Country A and Country B. So, while new projects continued to develop concepts, use cases, and frameworks, the real services served as inspiration as well as the first test bed for governance and industry engagement ideas.

3.3.1. OpenMedicine 2015-2016

The aim of the OpenMedicine coordination and support action, led by Empirica was to enhance the safety of cross-border healthcare through interoperable ePrescriptions. epSOS solved the message transfer problem but encountered 2 serious "delivery" problems: the univocal identification of medicinal products (MPs) dispensed abroad, and substitution challenges. Bringing together global SDOs (WHO, HL7, IHTSDO, ISO/CEN, GS1), EU regulatory agencies (EMA), MS Competent

[29] VALUEeHELTH https://cordis.europa.eu/project/id/643847
[30] Openmedicine https://cordis.europa.eu/project/id/643796
[31] UNICOM https://cordis.europa.eu/project/id/875299
[32] Gravitate-Health https://www.gravitatehealth.eu/

Authorities, major stakeholders (industry, health professionals, patients), OpenMedicine worked to harmonize their related efforts to deliver:

- common data models - expanding upon epSOS and existing standards (ISO/IDMP) - for prescribed MPs
- a common meta-vocabulary for unambiguous definition, description, and identification of MPs
- rules to harmonize practices of therapeutic and economic substitution
- a roadmap for post-project actions and implementations
- policy recommendations for the EU-USA road mapping process (MoU)

Work will link to related research & innovation activities of SDOs, epSOS, policy and regulatory processes (eHealth Network), the three other PHC34 projects VALUeHEALTH, eStandards, and AssessCT[33]. OpenMedicine was the first project to look closely at the implications of implementing IDMP in Europe, clarifying the role of different identifiers. (see Figure 6)

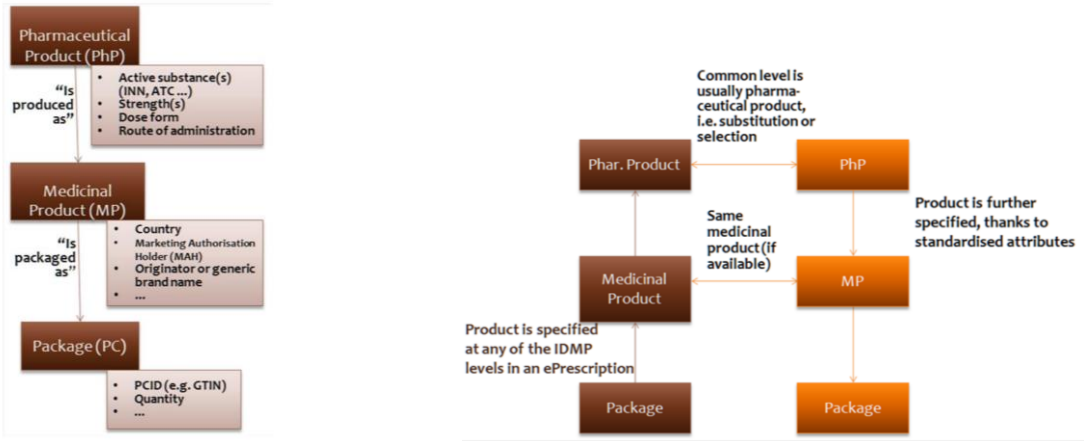


Figure 6: IDMP identifiers and their attributes (left). Exploring the cross-border context (right) from

The key recommendations of OpenMedicine are here.[34] The UNICOM project set out to implement the OpenMedicine recommendations and was recently concluded. The outcome of the UNICOM project has helped move closer to implementation across member states as the new elements are already featured in the myHealth@EU guideline specifications.

3.3.2. VALUeHEALTH 2015-2017

The aim of VALUeHEALTH (Establishing the value and business model for sustainable eHealth services in Europe), coordinated by the European Institute for Health Records was to establish an evidence-based business plan to show how eHealth interoperability can create and deliver value for all stakeholders, for a sustainable market in scaling up cross-border services. The business plan included EU (CEF Connecting Europe Facility in 2020) and other sustainable revenue streams for

[33] AssessCT https://cordis.europa.eu/project/id/643818
[34] UNICOM https://unicom-project.eu/wp-content/uploads/2020/09/d6.3_openmed_recommendations_and_roadmap_after_atr.pdf

developing and operating self-funding priority pan-European eHealth Services beyond 2020. Starting with use cases already proposed by the eHealth Network, we will adopt a robust methodology to prioritize additional use cases relevant to Member States for cross-border and also within border health needs. Through the design of a business model and multiple stakeholder Value Propositions for European-scale interoperability, it was possible to identify market needs and perform Cost Benefit Assessment and risk assessments.

VALUeHEALTH identified costs for delivering the prioritized use cases, developing and maintaining the required assets and derive a costed deployment roadmap for generic and healthcare-specific services. A gap analysis of standards, specifications and translations plus their priority and estimated cost. Strategies for promoting EHRs, and of organizational changes needed to capitalize on richly interoperable EHRs, as a roadmap of scale-up adoption strategies, incentives and funders were also developed.

The outcomes of VALUeHEALTH, although focused on cross border services can inform the development of the Hub with supports specifications in cases that go beyond the cross-border setting.

3.3.3. eStandards 2015-2017

The eStandards project[35], coordinated by RAMIT vzw, had the aim of develop a roadmap for large scale eHealth deployment in Europe. The eStandards roadmap comes shortly after the midterm review of the digital single market[36],[37] to elaborate on the proposed actions for employing standards to facilitate large-scale eHealth deployment and adoption at lower cost. Digital transformation of health services promises the triple win, better quality healthcare at affordable cost with timely access, whilst boosting innovation and business growth[38]. This roadmap is revisited in section 4 in the context of the digital compass for the EEHRxF.

3.3.4. AssessCT 2015-2016

The project "Assessing SNOMED CT for Large Scale eHealth Deployments in the EU" or ASSESSCT[39], coordinated by Hochschule Niederrhein, run for 18 months in 2015 to elicit recommendations about the use of SNOMEDCT in the European Union. Defining

[35] eStandards https://cordis.europa.eu/project/id/643889 2015-2017
[36] A Connected Digital Single Market for All – Communication from the commission COM(2017) 228, May 2017, http://eur-lex.europa.eu/resource.html?uri=cellar:a4215207-362b-11e7-a08e-01aa75ed71a1.0001.02/DOC_1&format=PDF
[37] https://ec.europa.eu/newsroom/sante/newsletter-archives/3546
[38] Blueprint for transforming the future of health and care ec.europa.eu/newsroom/document.cfm?doc_id=40787
[39] Assessing SNOMED CT for Large Scale eHealth Deployments in the EU https://cordis.europa.eu/project/id/643818

semantic interoperability in healthcare as the ability to exchange health related data with precise meeting shared among stakeholders, ASSESS CT recognises the crucial decision that the European Commission needs to make to advance primary and secondary use of health data. ASSESS CT investigated whether SNOMEDCT as a clinical terminology is fit for EU-wide eHealth deployments.

ASSESS CT addressed this question by looking into a number of issues related to the current use of SNOMED CT, lessons learned, success factors, type and purpose of use, multilingualism, cultural differences, strengths & weaknesses. By means of literature review, survey, interviews; focus groups and workshops, the project reviewed the current state of use of SNOMED CT, the fulfilment of semantic interoperability use cases, known technical and organizational drawbacks, and the way SNOMED CT is improved and maintained.

Two alternative scenarios were under evaluation: to abstain from actions at the EU level, or to devise an EU-wide semantic interoperability framework alternative without SNOMED CT. The impact of SNOMED CT adoption from a socio-economic viewpoint, encompassing management, business, organizational, and governance aspects was also considered.

In analysing the role of SNOMEDCT the terms of reference terminology, core-reference terminology, aggregation terminology, and user interface terminology were considered:

- Reference terminologies (RTs) describe the meaning of terms of a domain (i.e., concepts) together with the properties of the objects that these terms denote, in a neutral sense, i.e., uncommitted to any specific purpose. Among the reference terminologies, a core reference terminology is a large reference terminology that plays a pivotal role within a terminology ecosystem, in terms of conceptual coverage and linkage with other terminologies.
- Aggregation terminologies (ATs) are systems of non-overlapping classes in single hierarchies, enhanced by classification rules, as commonly used for data aggregation and ordering. Aggregation terminologies are also known as classifications, e.g., the WHO classifications.
- User interface terminologies (UITs) are collections of terms that are used in written and oral communication within a group of users, for example in a data entry form in a healthcare IT system or in clinical documents. UITs provide value sets for data entry as well act as dictionaries for human language processing systems.

AssessCT after more than 12 months of deliberation based on surveys, interviews and workshop proposed the following recommendations[40]:

1. Any decision about the adoption and role of terminological resources, including SNOMED CT, must be part of a wider, coherent, and priority-driven strategy for optimising the benefits of semantic interoperability in health data, and of the overarching eHealth strategy of the European Union and its Member States.
2. SNOMED CT is the best available core reference terminology for cross-border, national and regional eHealth deployments in Europe.
3. SNOMED CT should be part of an ecosystem of terminologies, including international aggregation terminologies (e.g., the WHO Family of Classifications) and user interface terminologies, which address multilingualism in Europe and clinical communication through multidisciplinary professional language and lay language.
4. The adoption of SNOMED CT should be realised incrementally rather than all at once, by developing terminology subsets that address the interoperability requirements for priority use cases and expanding these sets over a number of years.
5. Mechanisms should be established to facilitate and co-ordinate European Member State co-operation on terminology and semantic interoperability, including common areas of governance across national terminology centres, eHealth competence centres (or equivalent national bodies).

Rationale: A European terminology strategy should be part of an overarching European eHealth strategy. The strategy should support the principles of collecting clinical data once and using them multiple times, wherever allowed and required. Thus, administrative, public health and research information should almost always be derived from routinely collected clinical information. This strategy should have Member State commitment and should consider human and financial resource implications, incentives, as well as technical and semantic requirements.

The advantage of SNOMEDCT is in its content coverage, which is superior to any other single terminology, making it the most complete point of reference for health-related concepts. Another advantage of SNOMEDCT over a set of other clinical terminologies is its principled ontology-based architecture, with a logic-based coordination syntax.

No country sees SNOMED CT as a stand-alone solution, but rather as an important part of the national terminology infrastructure that is incrementally employed. Such

[40] https://hl7.de/wp-content/uploads/ASSESS_CT_Final_Brochure.pdf

incremental use, across all Member States, might be subject to specially negotiated licences on behalf of the whole of European Union. Solutions must be in place for legacy conversion, guaranteeing the continued exploitation of historical data, for user interface terminologies, and for assuring the continuation of global mortality and morbidity statistics. This should maximise the value of Member State and SDO alignment on the approach to advancing semantic interoperability, including the implementation and deployment of SNOMED CT.

3.4. The fourth generation 2019-2023

3.4.1. X-eHealth – EHRxF Communities of Practice

3.4.1.1. Registries of products, tools, initiatives

The X-eHealth project, a Horizon 2020 Coordination and Support Action, coordinated by SPMS, was set up to support the European eHealth Interoperability roadmap for deployment aiming to accelerate the implementation of the European eHealth Record exchange Format (EEHRxF) through standardisation and harmonisation of health data, thus providing patients, healthcare professionals and health institutions with improved quality, safety and efficiency.

Aimed at promoting a faster and sustainable EU digital transformation, this project was made up of 8 Work Packages in which 4 exclusively focused on technical-functional activities (WP4 to WP7). From Generic Aspects to System Architecture and Integration, passing by Functional and Technical Specifications, X-eHealth objective was to move towards a uniform interoperable data-sharing format framework. In addition, to enhance EU's public health state of play, WP1 and WP8 were responsible for implementation studies, practicality, and continuity of eHealth interoperability development.

WP8 focused mainly on development of Communities of practice (CoP) in order to engage engaging stakeholders including patients, implementers, developers, clinicians, researchers, business analysts, and policy makers in adoption of the EEHRxF and to build Infrastructure for innovation.

3.4.1.2. Definition of Community of Practice (CoP)

According to Etienne Wenger communities of practice "are groups of people who share a concern or a passion for something they do and learn how to do it better as they interact regularly"[41]. Compared to formal workgroups, informal networks and

[41] https://www.wenger-trayner.com/introduction-to-communities-of-practice/#:~:text=Communities%20of%20practice%20are%20groups

project teams, CoPs are driven by people that share a common interest for what they do and the need to do it better, therefore they interact regularly, collaborate, and develop a sense of commitment.

Unlike other forms of collaboration, like working groups, project teams or informal networks, community of practice are focused on developing members capacities, building and sharing knowledge, and lasts as long as there is an interest in maintaining it. Communities of Practice were initially described as essentially informal and mostly self-organising; however, experience has shown that most CoPs need some nurturing to make certain that its members get what they hoped. Therefore:

- CoPs are voluntary and it is essential that they generate enough value to engage members and keep them interested.
- CoPs are both formal and informal: The more they are used for developing strategic competence, the more likely they are to go through some formal process.
- There is leadership and facilitation most of the times. Wenger et al. introduced the roles of leaders (sometimes called champions, coordinators or stewards) and facilitators. Normally, the leader is a well-respected member of the Community of Practice who often holds a leadership position in their own organization. He/she is responsible for strategic conversations and practical decisions, recruits, and finding resources for group activities.
- The facilitator is mostly responsible for the group's daily activities. This role is most often performed by a skilful and experienced senior manager who understands the overall mission of the CoP, is resourceful, and is well connected with its members. The involvement of the facilitator is perhaps one of the most important features of the CoP, and quite often the success or failure of the community is linked to the presence and efficiency of the facilitator. However, the actual responsibilities and the organisational support provided for this role may vary. For example, in some communities the leader and the facilitator are two distinct roles, while in other groups they merge into one. The choice of management mostly depends on the size of the community and the availability of human resources. Good facilitation can help members recognise the value and the results of their participation, and - although it is merely an enabler and not the main reason for involvement - it has been reported that facilitator fatigue can even lead to the failure of a community[42].
- Providing the necessary supportive infrastructure is a major step towards getting communities going and sustaining them. For CoPs to operate smoothly and accomplish their goals, appropriately appointed people should be able to intervene when they run into obstacles. It has been broadly

[42] Evolution of Wenger's concept of community of practice. Linda C Li, Jeremy M Grimshaw, Camilla Nielsen, Maria Judd, Peter C Coyte & Ian D Graham Implementation Science volume 4, Article number: 11 (2009)

recognised that CoPs can be vulnerable because they lack legitimacy and budgets. Therefore, it has been suggested that communities should have sponsors and support teams to ensure adequate resources and coordination, to organise meetings and agendas, and so on.

- It should be noted that communities of practice don't substitute teams or networks or other joint enterprises. Also, communities of practice are more focused on capacity building rather than specific tasks.

3.4.1.3. EEHRxF Community of Practice

With all the above in mind, and with the notion that the community would not only share experience and knowledge but also innovate, introduce new practices, solve problems, create tools, develop an implicit understanding on focal points and eventually a collective voice, a Community of Practice that supports the accelerated implementation of the European EHRxF aims to:

- Advance European EHRxF
- Promote European EHRxF awareness
- Enrich the knowledge base, improve tools and create data sets
- Enable and empower connected multidisciplinary communities

3.4.1.4. EEHRxF Functional specifications and data sets

X-eHealth project developed functional specifications in four domains and five new use cases:

- Laboratory:
  1) Laboratory result report and
  2) laboratory test order
- Imaging:
  3) Imaging result report
- Hospital care:
  4) Hospital discharge letter
- Patient summary:
  5) Extension of the patient summary for patients with rare disease[43]

[43] https://rd-connect.eu/

Use case driven methodology of X-eHealth [44], five data sets [45] and a logical information model[46] has been built for each of the four domains and use cases.

3.4.1.5. EEHRxF Implementation guidelines

Implementable guidelines had been developed in X-eHealth project for all four domains mentioned above for both HL7 CDA and HL7 FHIR communication standard. Project also prepared associated testing tools to help European member states, national, regional, and local projects in the adoption and deployment of these services.

Specifically, the tool called ART-DECOR has been used for specifying, managing, and publishing the CDA R2 Templates; and the combination of GitHub, FSH [47], FHIR Publisher and the build.fhir.org site for specifying, managing, and publishing FHIR based specifications.

Figure 7 summarises the overall process from the use cases defined by X-eHealth WP5 to the specifications developed by WP6: from the use cases agreed, information needs to have been collected and use-case agnostic building blocks (i.e., the information models) agreed, including the common terminologies to be used. These implementation independent models have therefore been used to refine the selected standard HL7 CDA templates and HL7 FHIR profiles, iterating among these artefacts.

[44] X-eHealth X-eHealth https://cordis.europa.eu/project/id/951938
[45] X-eHealth, P. (2022). *D5.1 X-eHealth use cases driven methodology.*
X-eHealth, Project. (2022). *D5.3 Laboratory Requests and Reports guideline and functional specifications.*
X-eHealth, Project. (2022). *D5.4 Medical Imaging and Reports guideline and functional specifications.*
X-eHealth, Project. (2022). *D5.5 Hospital Discharge Reports guideline and functional specifications.*
X-eHealth, Project. (2022). *D5.6 Refine PS functional specifications to account for eHN Guidelines and rare diseases.* All these can be accessible through: https://www.x-ehealth.eu/documentation/
[46]X-eHealth Data model https://x-ehealth.min-saude.pt
[47] FHIR Shorthand http://build.fhir.org/ig/HL7/fhir-shorthand/index.html

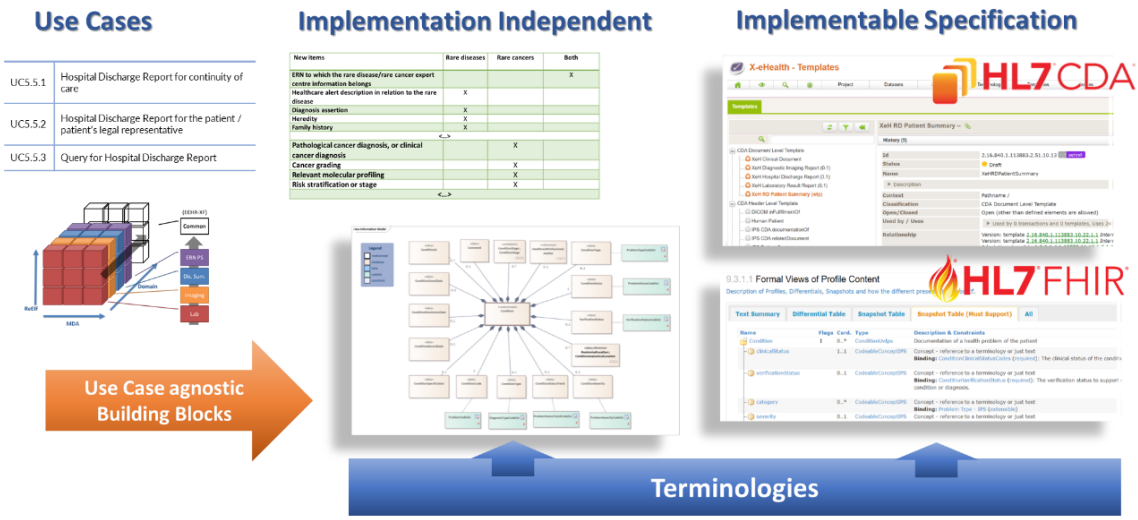


Figure 7: From analysis to specifications

X-eHealth CDA specifications are published in the ART-DECOR X-eHealth project environment[48].

The X-eHealth FHIR IG provides a human readable representation as browsable web site and a list of artifacts including:

- Resource Profiles
- Extension Definitions
- Terminologies
- Examples

FHIR Implementation guide can be found online [49]. Source code for the implementation guide is stored in the GitHub repository[50].

3.4.1.6. Proposal of a sustainable governance model

X-eHealth developed functional and technical requirements for four new domains that aimed to be implemented in the MyHealth@EU project. For this reason, the current governance structure of the MyHealth@EU project may not be sustainable long term, thus new governance model has been proposed. This model uses the current structure as a basis to tweak and improve, so that it better fits current and future situation; with the four new domains added to the EEHRxF and the EHDS in mind. Key recommendations on governance are:

[48] X-eHealth ART-DECOR https://art-decor.org/art-decor/decor-project--eehrxf-
[49] X-eHealth FHIR Implementation guide https://build.fhir.org/ig/hl7-eu/x-ehealth
[50] GitHub repository at https://github.com/hl7-eu/x-ehealth

1) To create a governance structure with one Executive Board on the tactical level and create four horizontal taskforces to translate policy into actions and deliverables: an architecture, semantic, technical and legal taskforce
2) To use regulatory sandboxes to innovate, allow for swift adaption, for example on alignment between primary and secondary use
3) To have a clear mission of purpose and set of responsibilities for each entity in the governance structure
4) To preserve and strengthen a multi-stakeholder approach
5) To adopt a mindset of working in cycles and have a strategic/tactical thinking cycle operate simultaneously together with an operational cycle, rather than that strategy, tactics and operations are consecutive
6) To decrease the risk of having limited resources available, where possible, at least with the Solution Provider and
7) to provide for engaging leadership and create procedure that distributes leadership to MS over time. These aspects relate to a more agile form of governance, able to prompt responses in the face of change and giving the ecosystem better resilience and efficiency.

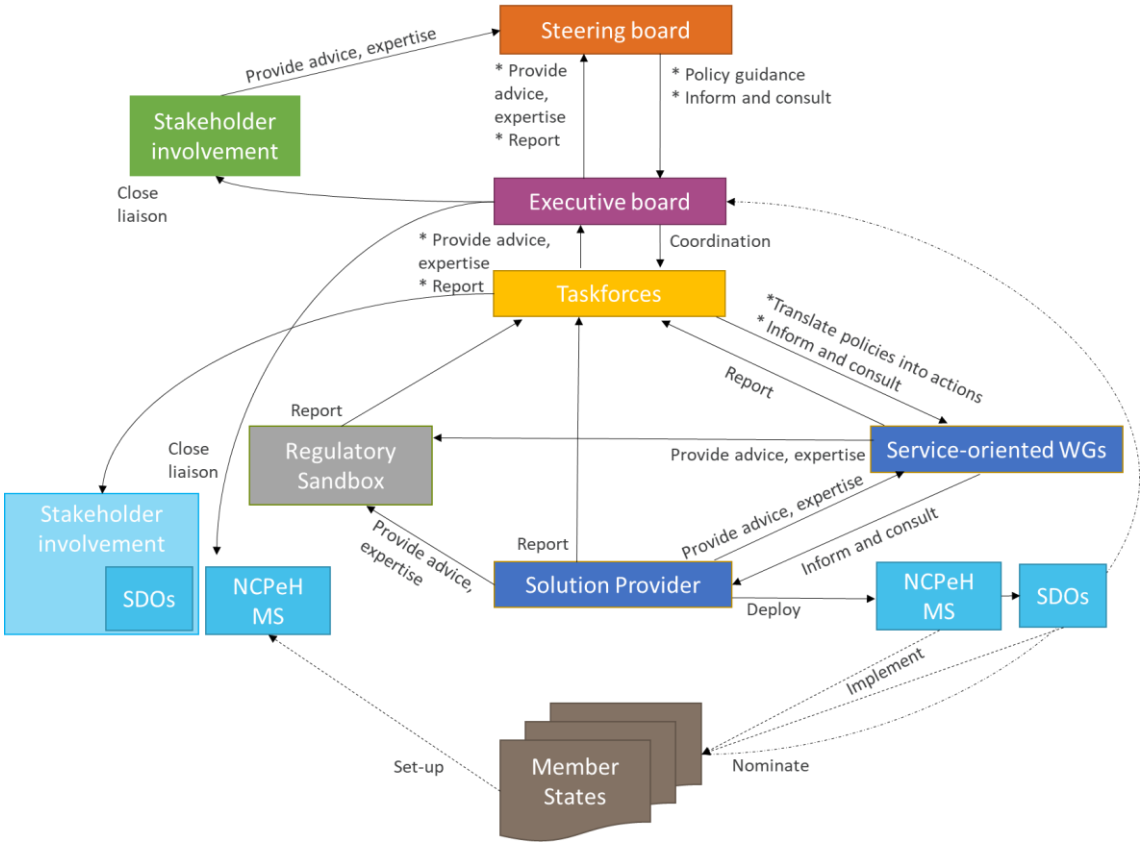


Figure 8: Governance structure – activities and responsibilities within Agile Governance Cycle

3.4.2.Label2Enable

The EU funded Label2Enable project, coordinated by Leiden University Medical Center (https://label2enable.eu/; (101057522, May 2022-May 2024)), currently in progress, is meant to promote the adoption of CEN-ISO/TS 82304-2 and its quality label for health and wellness apps[51]. By doing so Label2Enable aims to increase the quality level of care and create an environment for innovative, sustainable, and competitive care in the Digital Single Market. Label2Enable provides guidelines for the implementation of CEN-ISO/TS 82304-2 and the tools for assessments organisations to validate the implementation of the standards. Furthermore, the project provided use cases to stimulate adoption and provide handholds for research to lower the threshold as much as possible.

The project consists of three major pillars: Trust, Use and Adoption.

- **Trust**: the L2E Consortium will co-create and test the CEN-ISO/TS 82304-2 handbook for accredited health app assessment organizations, in ISO terminology resulting in a certification scheme according to ISO/IEC 17065. The Consortium will ensure that the handbook contains appropriate

[51] Label2Enable uses the term "Health apps" to refer to both health and wellness apps. In this section "health apps" shall thus be used with same intention.

accepted assessment methodologies, aligns with EU legislation and values, produces the same consistent results regardless of the assessment organization involved, and works as well for app manufacturers who wish to carry out self-assessment. The Consortium will secure maintenance of the handbook after the project and enable accreditation of assessment organizations, while also investigating if legislation for the label is sensible and who is to pay for the assessment.

- **Use**: L2E Consortium partners will, in this pillar, investigate who consumers trust most to give them recommendations on health apps and what will also help people with low health literacy to use the quality label. They will find out what healthcare professionals need in the detailed health app quality report to be able to recommend health apps and how to display the label effectively in app stores, app libraries and trusted sources.
- **Adoption**: the L2E Consortium promotes CEN-ISO/TS 82304-2 involving stakeholders through various channels. With "use stories" of pilots with CEN-ISO/TS 82304-2 in Italy, Catalonia, and the Netherlands and potentially more countries or regions, the Consortium will provide insights on how to implement the assessment framework effectively. Finally, they will explore with health insurers and health technology assessment bodies how the ISO assessment framework can help in decision-making on reimbursement of health apps.

The Label2Enable Project is extremely relevant for XpanDH also and especially regarding Task 2.3 – Technical requirements for quality labelling of consumer health products. The Label2Enable project is based on the CEN/ISO TS 82304-2 "Quality and reliability of health and wellness apps", providing a conformance assessment framework and quality label that can be expanded/extended to cover Digital Health Consumer Products (DCHPs), including EHRs. More details of the project and the task can be found in 2.3).

3.4.3.Smart4Health 2019-2023[52]

Smart4Health, coordinated by UNINOVA Citizen-centred EU-EHR exchange for personalised health, aim was to enable the citizen-centred EU EHR exchange for personalised health. This would pave the way for the full deployment of citizen-centred solutions and services in a digital single market for wellbeing and healthcare, while providing for interoperability, complementarity and cooperativity with profiles in use by Member States and regions. In this way it would help bridging between the diverse EU EHR data and citizen-generated health data, connecting citizens to science and personalised health services, helping mee the priorities of the Digital Single Market, i.e. secure access to EHRs and possibility for cross border sharing mediated by patients. Additionally, SMART4Health supported data infrastructure,

[52] https://cordis.europa.eu/project/id/826117

would advance research, disease prevention and personalised health and care, while facilitating feedback and interaction between patients and healthcare providers, to support prevention and citizen empowerment as well as quality and patient-centred care. Smart4Health addresses these priorities with an outstanding consortium that develops, tests and validates a platform prototype for the Smart4Health citizen-centred health record EU-EHR exchange. Smart4Health provides an easy-to-use, secure, constantly accessible and portable health data and services prototype, thus advancing citizen health and wellbeing, and digital health innovation. Smart4Health aligned with large European infrastructures like CEF, ELIXIR, EIT Health, BBMRI=ERIC, I-LAB, Medical informatics initiative, and a network of foreign countries. Smart4Health empowers citizens to manage and bridge their own health data throughout the EU and beyond, advancing own and societal health and wellbeing.

The findings of Smart4Health can benefit the digital health ecosystem for the EEHRxF Standards and Policy Hub.

3.4.4. InteropEHRate 2019-2022

InteropEHRate [53] Interoperable EHRs at user edge, coordinated by Engineering Ingegneria Informatica S.p.A., explored interoperability standards and implementation guides with particular focus on HL7 FHIR. The electronic health record (EHR) collects, systematises and stores patient data in a digital format in order to improve healthcare systems. However, there is a low level of systems interoperability in Europe since data are collected in different silos and managed under converging security and safety conditions. This creates legal hurdles in the availability of data. InteropEHRate project aspires to provide patients with full control in usage and routes of their medical information through device-to-device and peer-to-peer protocol standards. It will also outline a set of new protocols for secure and cross-border exchange of medical evidence.

The specifications and methodology provided makes it easy to navigate amongst different systems. In any event, the methodology developed to explore work moving forward.

3.5. EHDS regulation, myHealth@EU, HealthData@EU

3.5.1. New social Contract: The European Health Data Space regulation

The European Health Data Space regulation[54], approved by the European parliament on the 24th April 2024 foresees a major advancement to interoperability as reflected

[53] https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

in a number of its articles. The form in which these articles will be finally adopted is not clear.

For the purpose of completion, we list here some relevant definitions:

1) **personal electronic health data** means data concerning health and genetic data as defined in Regulation (EU) 2016/679, as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services, processed in an electronic form;
2) **primary use of electronic health data** means the processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services;
3) **secondary use of electronic health data** means the processing of electronic health data for purposes set out in Chapter IV of the Regulation. The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of the secondary use;
4) **interoperability** means the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact towards mutually beneficial goals, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support;
5) **European electronic health record exchange format** means a structured, commonly used and machine-readable format that allows transmission of personal electronic health data between different software applications, devices and healthcare providers;
6) **electronic health data access service** means an online service, such as a portal or a mobile application, that enables natural persons not acting in their professional role to access their own electronic health data or electronic health data of those natural persons whose electronic health data they are legally authorised to access;
7) **telemedicine** means the provision of healthcare services, including remote care and online pharmacies, through the use of information and communication technologies, in situations where the health professional and the patient (or several health professionals) are not in the same location;
8) **EHR (electronic health record)** means a collection of electronic health data related to a natural person and collected in the health system, processed for healthcare purposes;
9) **EHR system (electronic health record system**) means any appliance or software intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records;

10) **wellness application** means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy lifestyles.

These definitions are important as they set the stage for the articles that follow. The definition of Electronic Health Record is noteworthy as it reflects what has customarily been known as Electronic Medical Record.

3.5.2. MyHealth@EU

MyHealth@EU is a major European initiative to enable sharing health data across European member states. MyHealth@EU is using eHealthDigital Infrastructure as its technology backbone and significantly contributes to development of European interoperability standards and functional specifications. In addition to developing technical configuration and integration skillsets, a key objective was networking of EU countries, and confirming progress of health integration within EU member states.

MyHealth@EU currently allows exchanging of electronic prescriptions and dispensations, exchange of patient summaries and original clinical documents. Currently eleven member states can exchange data using at least one of these services.

European Commission in collaboration with eHealth Network (EHN) and MyHealth@EU initiatives established several working bodies that are responsible for specification and implementation of common European standards for EEHRxF.

Operational experience from MyHealth@EU project clearly shown complexity of preparation of interoperability specifications and mainly of their implementation as member states are on different levels of preparedness for semantic interoperability. Nevertheless, despite all difficulties, this initiative shown that:

- Use-case-driven approach has proven successful.
- Interoperability in healthcare is difficult to achieve and requires time, effort, and investment, but it is feasible and worth the effort.
- Agreement on functional specifications and technical implementation standards could be achieved relatively easily by European countries working together, if there is a common interest.
- Implementing and deploying agreed standards and specifications at national level is an order of magnitude more difficult task.
- As the number of use cases increases, so does the complexity of maintaining the overall system, specifications, infrastructure, testing and troubleshooting.
- There is still insufficient support for implementers and users. Healthcare professionals would need more information about the system and its capabilities as well as training on its use.

- The European Union must continue to build a robust, secure, and reliable infrastructure for health data exchange, which must include, between others, centralised terminology and translation services.

3.5.3.Xt-EHR joint action

While X-eHealth project, coordinated by NeHA, touched some of the priority areas and significantly contributed to its European wide standardization, it also identified many other aspects of European interoperability that needs to be further elaborated. Xt-EHR is one of the initiatives aimed to resolve them further in collaboration between member states represented by ministries, regions, SDOs, and public companies.

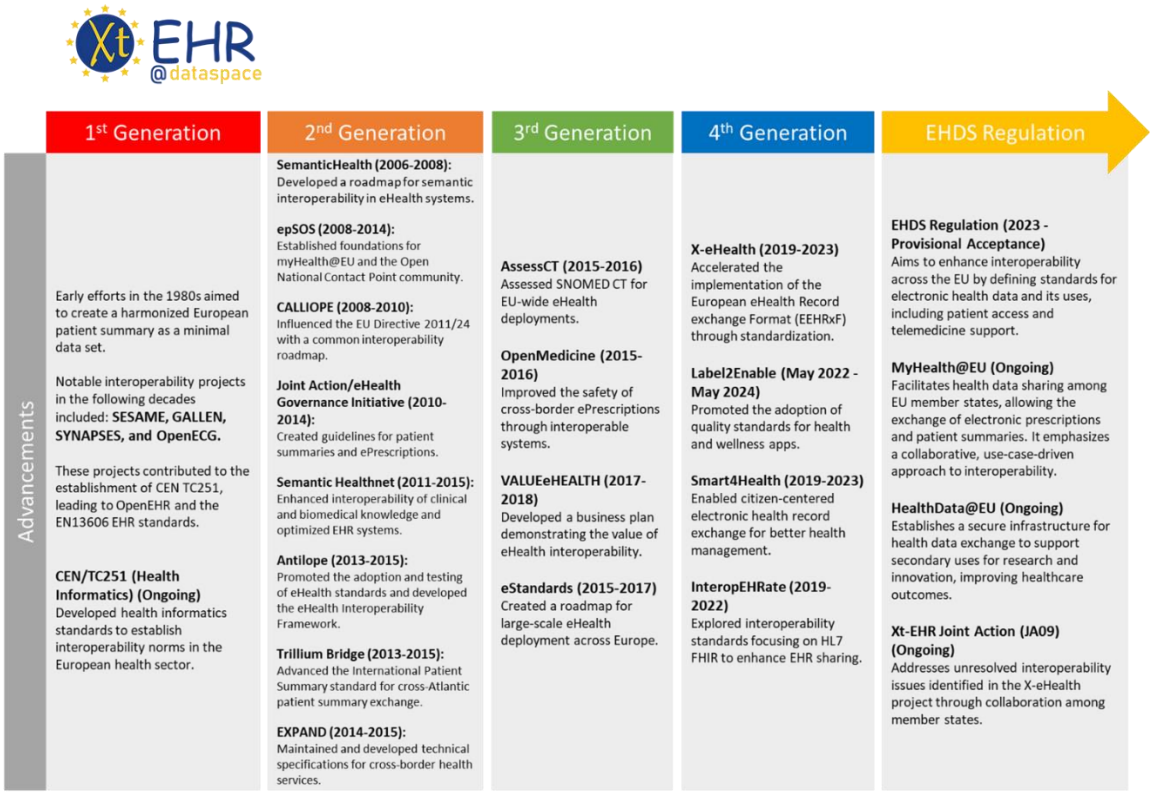


Figure 9: European Union funded projects contributing to Interoperability and standards that were discussed in this section.

4. Revisiting the eStandards Digital Health Compass for the application of EEHRxF

4.1. eStandards Digital Health Compass and Roadmap

The first wave of digitization in healthcare started in the 60s and 70s, resulting in the accumulation of large amounts of health data primarily for documentation purposes. However, these data sources are still underutilized[55]. In the 80s and 90s, efforts were made to electronically share information, leading to the implementation of simple workflows and transactions. After 2000, systems of innovation emerged, with digital platforms using data to enhance user experiences. The healthcare sector has been slower to adopt digital health technologies but now there are greater opportunities for innovation through data-driven knowledge creation and improved user experiences. Thus, we move from "systems of record" to "systems of differentiation", and "systems of innovation", ecosystems driven by the use of data and the gradual acceptance of automation (see Figure 10). These digital health ecosystems encourage use of standards and specifications to create a level playing field for complementors of the core platform providers. Still, as the pace of change increases, gaps in governance emerge, and governance in standards becomes more complex and dynamic. Standards development organizations had to become more agile and collaborate, leading to creation of the Joint Initiative Council and HL7 FHIR accelerators. In HL7 FHIR accelerators, SDOs are urged to collaborate more closely with practitioners of interoperability to timely deliver quality and timely standards at an affordable cost. This collaborative effort should be inclusive, taking into account user experience and reevaluating standards and tools that support the full life cycle of eStandards.

[55] Attitudes towards the impact of digitisation and automation on daily life, Eurobarometer 460, May 2017 ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2160

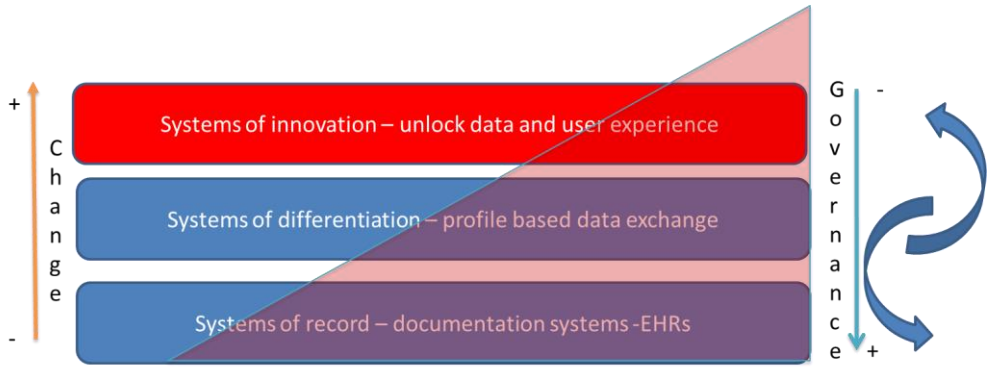


Figure 10: In the move to systems of innovation, standards create a level playing field for ehealth platforms[56].

4.1.1. eStandards Lifecycle

The eStandards' vision is a global eHealth ecosystem, where people experience safe and informed health and care, while interoperability assets fuel creativity, entrepreneurship, and innovation driven by a new generation of 'live' eStandards (see Figure 11). HL7 Europe, CEN/TC 251, IHE Europe and eHealth competence centres across Europe, with support from the eHealth Network, ISO/TC 215, GS1, SNOMED International, IEEE11073 and IMIA worked together to build consensus on eHealth standards, accelerate knowledge sharing, and promote wide and rapid adoption of eStandards. Notably, **eStandards are much more than specifications: they encompass the full specification life cycle comprising tools, sample data, and a testing infrastructure.** The eStandards life cycle combines different base standards, supports testing and deployment, and encourages feedback from implementation. This expanded approach to SDOs includes all stakeholders involved in delivering and deploying eStandards, such as patient and professional associations, national eHealth competency centres, provider and vendor associations, and government agencies.

In the XpanDH initiative, as we will examine, the eStandards life cycle model is being further developed to support global standards and incorporate elements of adoption and engagement with stakeholders in the digital health compass.

[56] This understanding has been inspired by the pace-layered application architecture and bi-modal organisation of IT as developed by Gartner.

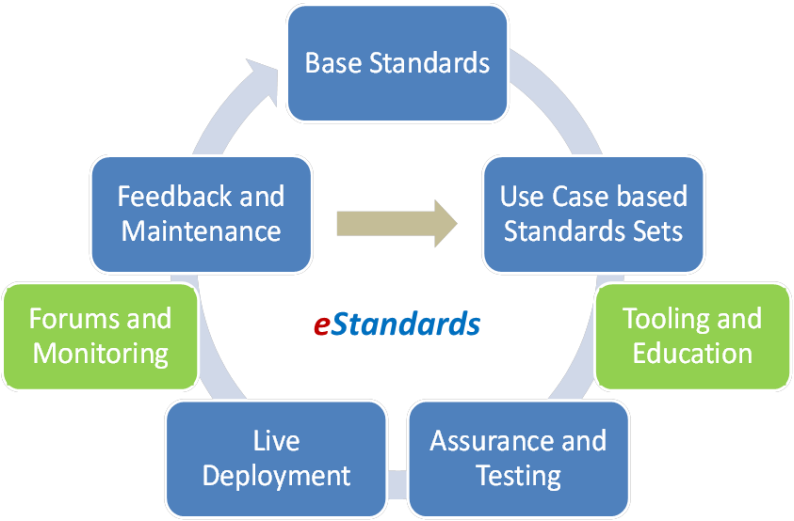


Figure 11: The Health Informatics Standards Life Cycle drives creation of digital standards - eStandards

4.1.2. eStandards Digital Health Compass: principles

The eStandards Digital Health Compass is at the core of the roadmap for large scale adoption of eStandards. Building on the overlapping perspectives of the workforce, the health system, the citizen, and the industry, the Compass sets principles that have the potential to create a virtuous cycle that welcomes adoption of common to drive the trust and flow of data. The digital health compass aims to support **collaboration across the healthcare spectrum**, ensuring trust and flow of health data, aligning views and perspectives, reusing innovative health information assets, promise to meet the linked targets of efficacy, quality and access in a sustainable way. The four key principles of the digital health compass underpinning the use-case-driven eStandards lifecycle are trust and flow of health data; respect of stakeholder perspectives; maintenance of interoperability artefacts; and iterative cycles of cocreation, governance and alignment.

1st principle: Trust in the Flow of health data for well-functioning health systems

The **recognition** that **trusts** in the dynamic **flow** of health data forms the basis of well-functioning health systems, since it allows personal health information to be used safely and efficiently, bring information and knowledge at the point of need. **Trust in dynamic flow of health data** are grounded in that well-functioning modern European healthcare systems meet: (a) the increasing need, expectation, and cost of healthcare tech for aging societies; (b) the changing nature of the doctor patient relationship as patients being closely involved with their care; (c) the increasing demand for online "just-in-time" care; (d) the need to extend the capacity of the

dwindling healthcare workforce to face chronic disease[57]. The business case for Cost-Containment Policies in Hospital Expenditure in the European Union[58] noting that health service planners and procurers seek support to reduce the costs and sustain the quality of health services. This requires healthcare market solutions that meet proactively the needs of patients, informal care givers, and the healthcare workforce, complying with regulations and good practice guidelines. To that end, data trust and flow is critical in the future of health systems.

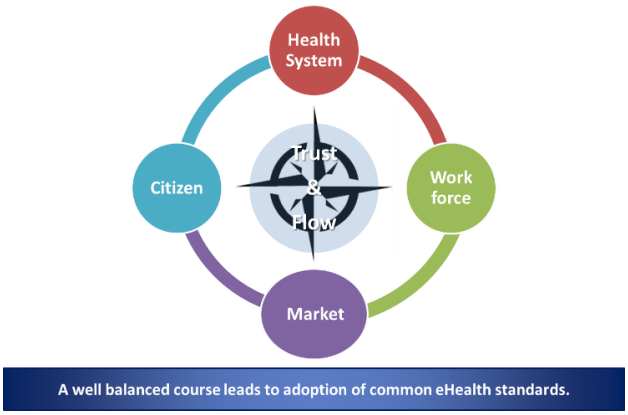


Figure 12: The eStandards Digital Health Compass builds on the perspectives and incentives of the market, citizen, workforce, and health system, with trust and flow of data driving common eHealth standards.

2nd Principle: Respect for differing stakeholder perspectives

Respect for stakeholder perspectives helps build, nurture and maintain trusted flow of health data, with key perspectives being those of citizens, workforce, health system, and industry. Respecting the perspective of stakeholders in an eStandards roadmap towards establishing large-scale interoperable eHealth solutions in Europe, involves their production, regulation, and use of common specifications and implementation guides for key use cases. This roadmap serves as a tool for communication with key players to embed eStandards lifecycle thinking in their requirement setting, procurement frameworks and ultimately deployment of eHealth solutions in support of their personal, professional or health system objectives:

- **Citizen**. The needs and desires of citizens are part of the roadmap landscape, so that the citizens' perception of 'true north' is understood by standards developers and implemented by integrators of eHealth systems. Teaming up with citizens in standardisation can nurture citizen empowerment to navigate the health system for prevention, care, and wellness, supporting their active

[57] https://chrodis.eu/

[58]EUROPEAN ECONOMY Cost-Containment Policies in Hospital Expenditure in the European Union - a European Commission Staff Working Paper by Christoph Schwierz ISSN 2443-8022 https://op.europa.eu/en/publication-detail/-/publication/d0416734-b535-11e6-9e3c-01aa75ed71a1/language-en

involvement in health maintenance and care decisions[59]. To accommodate the need of citizens to engage in their own care, we must understand the impact of this need on the way the standard is developed, deployed, and maintained.

- **Healthcare workforce**: The use of digital health tools impacts healthcare professionals, who face challenges due to sub-specialization, rapid innovation, and access to vast amounts of information. While precision medicine can improve patient outcomes, excessive documentation, fragmented processes, and questionable quality can consume more time, erode trust with patients, and strain patient-doctor relationships. It is thus crucial to understand the perspectives of the healthcare workforce and develop standards that facilitate adoption and productive use of interoperable technologies, enhancing organizational interoperability and fostering a culture of information sharing.
- **Health System**. The health system perspective focuses on the role of governments and regulators in healthcare, as well as the overall quality and accessibility of health services for the population. Implementing eHealth systems and services that comply with standards can contribute to improving health outcomes, while also ensuring cost-effectiveness and transparency in healthcare delivery in a paradigm akin to value-based care. Balancing face-to-face and remote visits can lead to lower costs and higher availability of healthcare services. Standardization of services including data availability are needed to ensure quality.
- **The Market**. The complexity of digital health services makes it hard for a single vendor to meet the needs of multiple provider organisations. Standards are necessary to enable the deployment of integrated digital Health services on top of a variety of core systems. Core systems vendors need to collaboratively engage in designing standard interfaces for advanced eHealth services. Development of eStandards, i.e. a coherent set of standards and use-case driven interoperability artefacts needs to be aligned with the vendor perspective to build standards-based solutions that meet the demands of patients, doctors and health systems in well-functioning digital health ecosystems.

In XpanDH we are looking into these key perspectives, but also elaborate X-Bubbles and X-Nets as ways to organize stakeholders in the digital health ecosystem.

[59] While primary prevention is about treating risk factors to prevent a chronic disease, primordial prevention refers to avoiding the development of risk factors in the first place.

3rd principle: reusing eHealth artefacts and interoperability assets

Dynamic flow of data is enabled by a reusable set of standardised **eHealth artefacts** that allow data to flow through eHealth with approval of involved people and organisations.

eHealth artifacts, established through projects supported by the European Union over two decades, contribute to interoperability and standards. The EXPAND project introduced the notion of interoperability assets in 2015. The eStandards project, building on this foundation, emphasizes the importance of fostering sustainability of these assets to promote continuous improvement in interoperability. It aligns these artifacts with the layers of the Refined eHealth European Interoperability Framework (ReEIF) and identifies fifteen categories of standards crucial for eHealth delivery (see Figure 13). The principle of maintaining and refining these artifacts ensures they remain relevant amid evolving user needs, technological trends, regulatory frameworks, and governance systems.

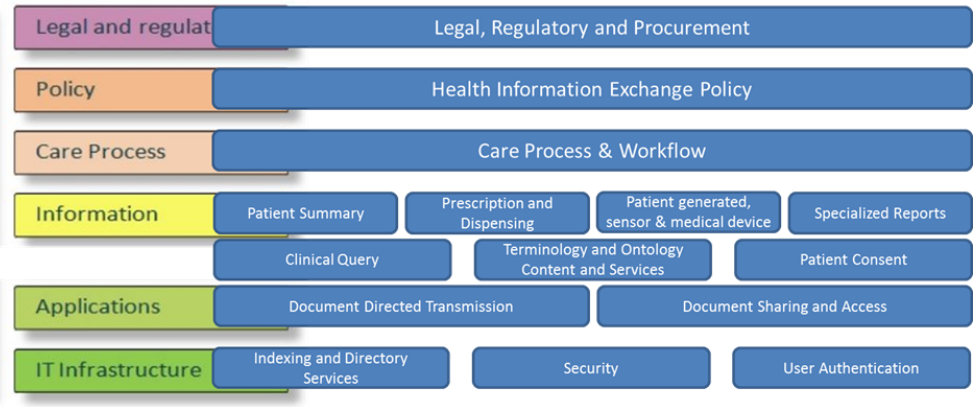


Figure 13: Fifteen roadmap components, reusable eHealth assets linked to the ReEIF.

In XpanDH we expect to further elaborate and improve these assets introducing new ones. Inspired by HL7 FHIR accelerators we introduce additional components that aim at accelerating adoption, while also collecting tools and data sets that help developers and implementors.

Co-creation – standards are not developed in a vacuum: stakeholders are engaged throughout the cyclic process of analysis, development, deployment, testing, certification, and monitoring of specifications.

Governance – recognition and referencing of legal and organisational rules in development of standards, while flexible organisational rules present the standards and their lifecycle.

Alignment - the ability to remain flexible, to use evidence constructively in order to refine and maintain the co-creation loop as a continuous virtuous circle of alignment between all players in the system, and across standard sets.

Figure 14: The CGA Model

4.1.2.1. 4th principle: the CGA model of Co-creation, Governance and Alignment

Standards organizations engage with stakeholders in the eStandards life cycle, a process to **co-create, govern** and **align** the interoperability specifications to well-defined needs. The methodology for standards development - and for the creation of a specific roadmap for adopting a specific set of standards – is based on upon the idea of a continuous flow between three acts of design, development, and interaction: Co-creation, Governance and Alignment (Figure 14). The 4th priority advocates that eStandards development, deployment, and maintenance throughout its life cycle is based upon the idea of continuous flow between three acts of development and interaction: co-creation, governance, and alignment. This approach contrasts on-time harmonization specifications with collaborative efforts where experts discuss, share experiences, and align specifications.

Co-creation: The Hippocratic Oath, believed to have been written between the 5th and 3rd century BC states: "The physician must not only be prepared to do what is right, but also make the patient cooperate". Co-creation involves collaboration among various stakeholder perspectives including patients, healthcare workers, health systems, and vendors. It encompasses co-design, co-delivery, and co-assessment of services, aiming to understand each other's perspectives and engage in a learning process focused on standards[60]. Co-creation goes beyond simple cooperation, emphasizing active involvement in product development or service provision. In healthcare, it aims to select and deliver interventions efficiently while ensuring safety and sustainability. Considerations include governance systems, workflow continuity, ease of use, adherence to legal requirements, and integration of existing standards. Developing a co-creation strategy in the eStandards context requires utilizing the Compass framework to involve relevant stakeholders and understand their perspectives. Adequate tools for gathering and sharing views are essential for successful co-creation.

Governance in this context of eHealth standards follows the perspective of the World Health Organization (WHO) and encompasses a broad range of regulatory and political processes aimed at supporting national health policy objectives. To the extend relevant it involves steering policy development and implementation, correcting undesirable trends, advocating for health in national development, regulating various actors within the healthcare system, and establishing transparent accountability mechanisms. Beyond the formal health system, governance involves collaboration with sectors such as the private sector and civil society to promote population health inclusively. Effective governance manages resources to support national leadership, policy goals, and health system strengthening. Key players in

[60] The Learning Healthcare System: Workshop Summary, Institute of Medicine, Roundtable on Evidence-Based Medicine, 2007, https://books.google.gr/books?id=VWmjvCZOFjoC

governance include hospital boards and local medical committees. In the context of the CGA model, governance necessitates regulatory involvement in the standards life cycle and standards developers' awareness of relevant regulations. Monitoring and evaluation are crucial for aligning with standards, regulatory frameworks, and governance requirements.

Alignment within the CGA model ensures its cyclical and flowing nature, ensuring changes in the perception of stakeholders or changes in governance to accommodate collaboration across initiatives. In standards development, alignment involves vigilance from standards organizations to adapt to potential shifts in governance or stakeholder needs. Monitoring and feedback systems are essential to capture and address relevant changes effectively. While alignment may appear less active, it is crucial for success. Co-creation efforts often falter when stakeholders feel their participation is merely a checkbox activity rather than genuine engagement. In eHealth standardization, flexibility and alignment are vital, potentially requiring the adjustment of national norms to benefit from internationally agreed standards. Finding the right balance between global standards and locally adapted implementation is key.

4.1.3. The eStandards Roadmap Methodology at Work

The core concept of the eStandards Roadmap Methodology emphasizes inclusive development, implementation, evaluation, and refinement of standards. It stresses the importance of incorporating stakeholders' perspectives at every step of the process. Applying the *e*Standards Roadmap Methodology as set out above has clear steps (see Figure 15):

1. Use the four principles of the eStandards Compass across the healthcare spectrum to identify and engage with stakeholders that should benefit standards-based solutions that respond to well understood needs. It's crucial to educate these actors about the value of standards and reflect on their perspective providing feedback and acknowledgment because it is vital to maintaining continued cooperation.

2. Assess **the Use Cases, Roadmap Components, and standardised artefacts** that already exist and critically assess the extent to which they are able to drive trust and flow of data or need to be further enhanced.
3. Develop a co-creation-governance-alignment process:
    a. create tools for co-creation that involve diverse stakeholders, fostering collaborative learning and development.
    b. evaluate the relevance of existing governance frameworks and adapt them dynamically to meet evolving needs and capacities.

c. continuously align co-creation efforts, challenge governance structures, and embrace new alignment models to ensure flexibility and responsiveness.

The activities outlined above help create specific roadmaps for a given topic or focus area or need. In this methodology, we combine the following three key tools or concepts: (a) Compass of perspectives to inform the needs for trusted flow of data; (b) Roadmap components, helping to identify supporting standardised artefacts; and (c) CGA model to define the necessary actions to be taken or supported by Standards Developing Organisations working collaboratively with all relevant stakeholders.

The methodology entails collaborative efforts across healthcare levels, resulting in an eStandards Roadmap within a broader health innovation program. This roadmap targets specific eHealth deployment areas and ensures alignment and support for standards-based deployment. Utilizing concepts like the eStandards Compass and CGA model, it identifies key waypoints and considerations for various healthcare sectors, addressing needs, standardized artifacts, and actions in co-creation, governance, and alignment. Stakeholder involvement is essential for articulating needs, and standardized artifacts evolve through testing and implementation. Proposed actions were exemplified for unplanned emergency care, chronic disease management, ERNs, and common identification for medication in pharmacovigilance. Each of these cases was recognized as an outstanding case for eStandards due to the way it relates to existing specifications in which significant investment has been vested.

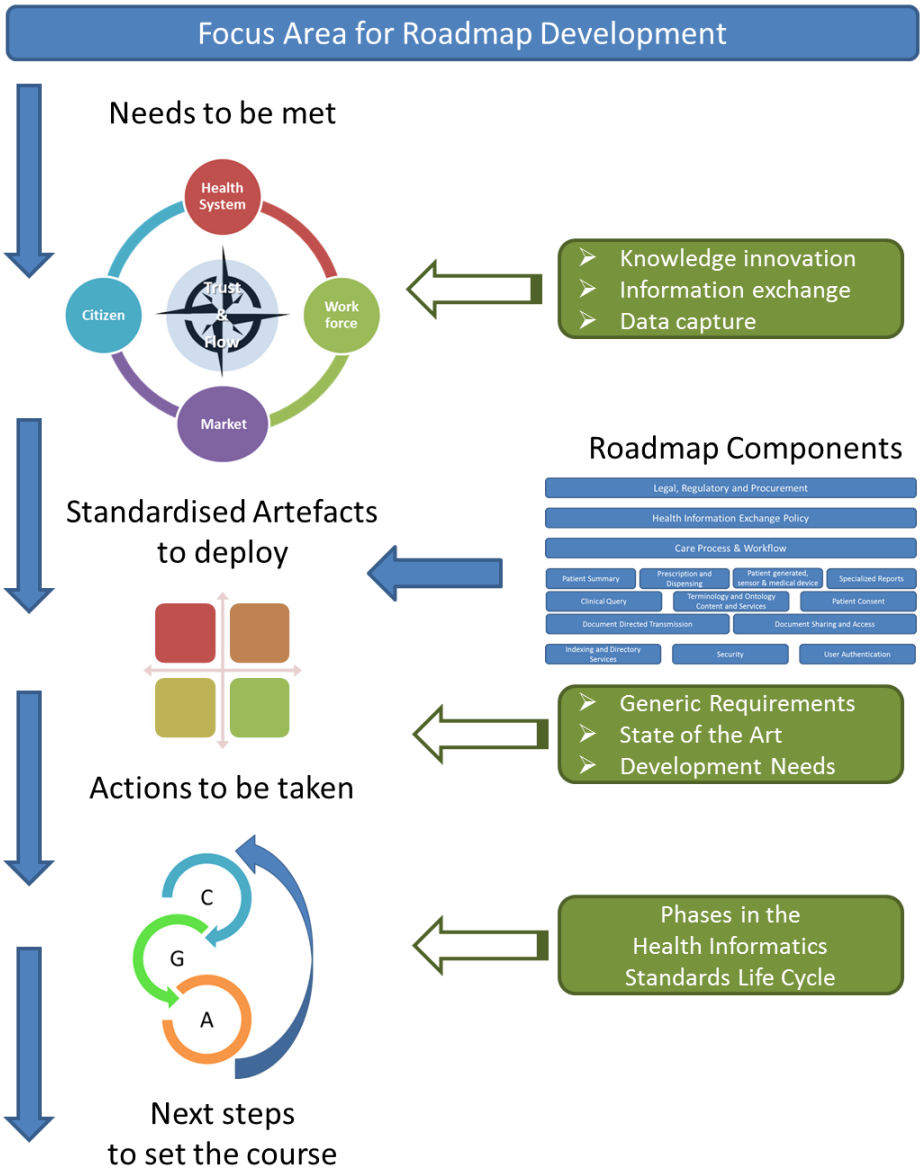


Figure 15: Methodology for roadmap development

4.1.4. Revisiting the eStandards roadmap and recommendations in XpanDH for the EEHRxF

The efforts of the Joint Initiative Council on the Patient Summary Standards Set,[61] reveals the complexity and importance of connecting the pieces in a live ecosystem. Providing for IPS validation and conformance testing through supporting actions such as the HL7 FHIR Connectathon and the more mature IHE Connectathon is important, but not enough. We need to support the full *e*Standards lifecycle transparently, connecting the different complementing steps and initiatives, applying co-creation, governance, and alignment every step of the way.

[61] Patient Summary Standards Set http://www.jointinitiativecouncil.org/registry/standards.set.patient.summary.asp

The eStandards approach, integrating standards into early user need discussions and engaging Standards Developing Organisations throughout, promises added value for EU citizens, patients, researchers, and entrepreneurs. However, limited adoption of eHealth standards poses a significant challenge. Coordinated action is needed to promote the eStandards approach within national and local entrepreneurial initiatives, facilitated by eHealth stakeholders and Standards Developing Organisations. Outreach and education on the eStandards Roadmap Methodology at a national level are crucial for success. Within XpanDH, collaboration at the European level is essential to continue and to leverage the European Health Data Space for eHealth solutions and strengthen Europe's position in the global Health IT marketplace. Establishing Europe as a competitive health data hub requires radical thinking about digital health standards. eStandards, serving as innovation infrastructure, foster patient interaction, preventive care, and citizen empowerment. These initiatives must align with a common vision and infrastructure to ensure a trusted flow of health data within and across borders.

Revisiting the recommendations and concrete follow-up actions to the *e*Standards final report, the following elements are still to some degree relevant:

1) Identify grass-roots keystone projects within Member States involving stakeholders across the eStandards Compass, including citizens as patients and caregivers. These projects should embrace the eStandards life cycle with an entrepreneurial spirit to build momentum within healthcare provider organizations and engage vendors, citizens, and the workforce.

2) Support these projects in using eStandards through expertise networks, leveraging collaboration among national member bodies of Standards Developing Organizations and eHealth competency centres. This collaboration will contribute to local eStandards roadmaps, benefiting local, regional, and European investments.

3) Invest in national outreach and education on the eStandards Roadmap Methodology to strengthen expertise networks and connect them with European and global eStandards communities.

4) Consider establishing a European platform representing eHealth Standards Developing Organizations and national eHealth competency centres, as recommended by the eHealth Network. This platform could coordinate and safeguard roadmap components and standardized artifacts across eStandards Roadmaps, focusing on specific health management and healthcare delivery areas across Europe.

Engaging innovative vendors and users of eHealth solutions, will help them build upon an existing basis of eStandards in action. Concrete topics suggested for further investigation are:

1. Join forces between the different Patient Summary initiatives to consider the development of a joint eStandards roadmap for unplanned and emergency care.
2. Request all projects aimed at further development of integrated care and chronic disease management to establish an eStandards roadmap for their project to break down the traditional silos in healthcare delivery.
3. Establish an eStandards roadmap in close collaboration with the stakeholders of the Clinical Patient Management System for ERNs for rare diseases[62].
4. Take a European approach to medication safety follow-up of XpanDH and UNICOM based on EMA regulatory requirements, eHealth DSI ePrescription support, national pharmaceutical agencies and vendors of decision support systems for prescription and dispensing of medication.

[62] http://www.eucerd.eu/wp-content/uploads/2015/03/WP8_Registries_MDS.pdf

5. EHRxF Standards and Policy Hub

Since the CALLIOPE thematic network, the need for a governed multistakeholder body was necessary to advance pan European interoperability, supporting national initiatives. The digital health compass methodology in the eStandards project roadmap also addressed the question of a sustainable entity that would advance European specifications. The xShare project proposed the EEHRxF Standards and Policy Hub as the sustainability mechanism of the Format, and the xShare label, an industry label for the EHRxF. Thus, "the Hub" aims to capitalize on the efforts of XpanDH and Xt-EHR to strengthen the digital health ecosystem in Europe, while contributing to global standardization. The "Hub" aims to create a one-stop-shop for X-Bundles, serving as an accelerator for the adoption of the format in the data economy.

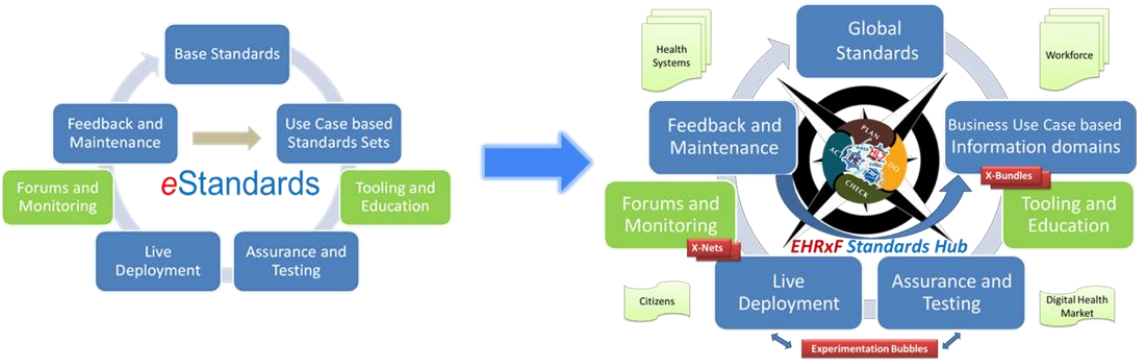


Figure 16: Elaboration of the eStandards lifecycle in XpanDH introducing x-Bundles, experimental Bubbles and X-Nets.

Taking a business use case driven approach to the adoption of the Format, requires that the Hub supports adoption of X-Bundles associated with specific business use cases. It also requires measuring and advancing maturity of individual interoperability assets, while supporting different licencing schemes and business models. Individual business use cases may be developed by different projects or initiatives national, regional or European. The challenge for the Hub is to develop a scheme that allows the maintenance and harmonization of specifications, while addressing new ones. In this way the Hub will be able to:

1. Enable all stakeholders to adopt, implement and evolve the EHRxF to improve interoperability within the European Health Data Space (EHDS).
2. Provide guidance, advice, tools, and experience on implementing the EHRxF in digital health systems for different use cases. For example, it could provide sandboxes and sample data sets to experiment and learn how to implement specific business use cases.
3. Offer links to testing and assurance services to assess and demonstrate compliance with the Format, as required by the proposed EHDS regulation and/or the related implementing acts.

4. Support the continuous maintenance of existing common content specifications and the development of new ones, while ensuring alignment of all services to be provided with these evolving specifications.
5. Providing alignment between the regulatory domain (Digital Single Market, MyHealth@EU, and HealthData@EU) on the one hand and the digital health industry, the digital health system operators, and the standards communities on the other hand.

The European and International patient summary can influence the global uptake of the Format and the EHDS, in line with current developments in the G7 and G20 countries, as well as the GDHP. For that to happen, firstly, clear links of the European specification to global standards need to be maintained, under a clear harmonization and alignment strategy. Secondly the Hub needs to provide a level-playing field and engage European and global stakeholders (regulators, industry, operators, and standards communities) with clear terms of reference, providing opportunities to localise the specifications for European and other regional implementation domains based on common global ones. As seen in Figure 17, community collaboration is central to the success of the "Hub". The enlarging digital health ecosystem of XpanDH nurturing the community of doers, the early adopters of the Format, and the work of the Xt-EHR joint action responsible for implementing acts, will connect to the strong standards and industry perspective of xShare. Methods will be developed to integrate X-Nets and experimental bubbles and through them share lessons learned and further accelerated adoption of X-Bundles. The business use case repository will be the entry point of X-Bundles, when interoperability assets the individual components of X-Bundles, have their own lifecycle, in pursuit of maturity, harmonization, and business value.

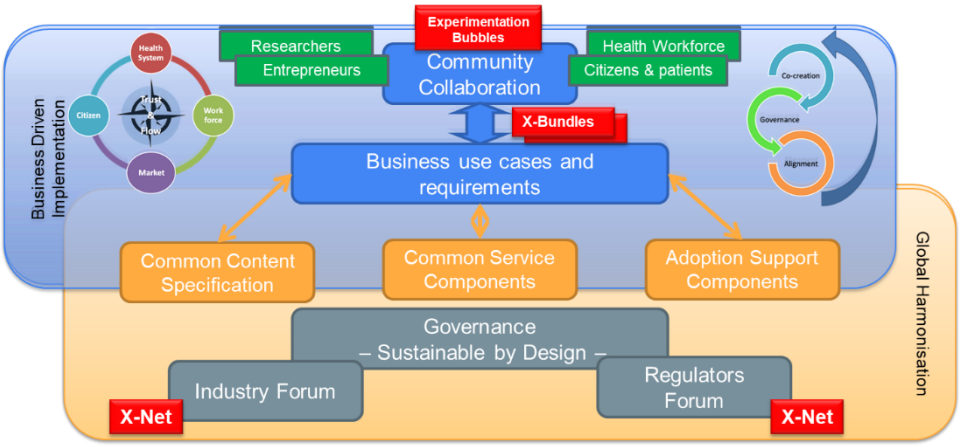


Figure 17: Operational strategy concept for the EEHRxF standards and policy hub to be established in the first part of the xShare project.

Operational Strategy: In a nutshell the hub, as an envisioned sustainable partnership of key standards organizations, industry associations and policy makers with the European Commission, aims to accelerate adoption of the Format, while lowering the cost in time and effort of implementing and maintaining the format. Key standards development organizations provide and maintain the common content specifications and service components, including CEN TC251, HL7 Europe, IHE-

Europe, CDISC, SNOMED International, and IEEE, in close collaboration with competence centers, health authorities, and professional societies that provide the requirements to be included in the EHDS regulation through implementing acts. An important aspect of the Hub is the prominent role of trade associations, with DIGITALEUROPE playing a key role as a trade association in the Industry Forum, and the Ministry of Health in the Netherlands co-leading the Regulators Forum, building on their connection with the Global Digital Health Consortium (GDHP).

A critical element is to allow implementers and policy makers to share best practices but also examples and tools that can accelerate adoption. By involving the communities that are implementing and extending the EEHRxF offering business use cases and associated specifications and services, we expect that EHRxF specifications will be a driver for innovation and a competitive advantage for Europe. The collaboration of standards development organizations, policy makers, and the implementation community of doers will contribute to nurturing digital health ecosystems with mutual support and continuous learning, where best practices will emerge, and innovation will be stimulated. The Standards Hub will serve the needs of the wider industry and operator communities, as well as innovation initiatives, providing services to promote, facilitate and assess the implementation of the European EHRxF. Besides early adopters, it is essential to develop mechanisms to receive new business use cases, while engaging the wider ecosystem through open calls that reach every corner of the European union, entities engaged in patient care, in public/population health and clinical research.

Community collaboration and helpdesk. The success of the Hub depends in part on its ability to effectively outreach to and gain the trust of communities of implementors and industry members across Europe. Thus, the Hub making sure that the processes are implemented, and the services are delivered, empowers the community in achieving their goals through the adoption, implementation, and evolution of the Format. Three key areas are identified:

a. The business-driven approach through requirements and business registry
b. The harnessing of external initiatives, to be engaged through an open call for partnership underpinning a clear value proposition.
c. The operation of the helpdesk to answer questions and efficiently respond to incidental enquiries, as a trusted intermediary matchmaking when needed requests and offers.

As the full scope of the Hub may be too broad and demanding taking into consideration all specifications and service components, there is a risk to overwhelm any implementer community. Therefore, reducing the complexity is key to supporting community collaboration and helpdesk services. A key element in that respect is the connection to the xShare industry label and a potential list of capabilities to manage the Format in its specific priority data categories.

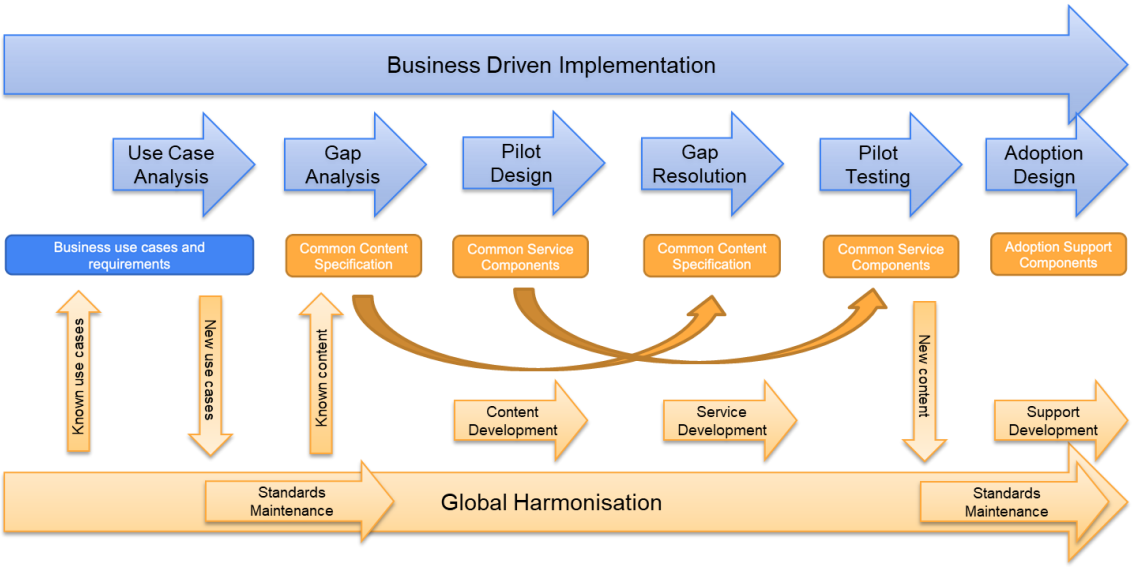


Figure 18: Development of new uses cases goes hand in hand with gap analysis, pilot design, resolution, and testing, as well as standards and maintenance.

Business use case and requirements repository. The core assumption of the Hub, as an industry supporting entity is a relentless focus to business-driven implementation and value creation. As noted in Figure 18, a new business use case and its requirements for EHDS priority health data categories are considered in the frame of existing, "known", business use cases and their requirements, which are part of the business use case repository.

The maintenance of a structured and searchable repository of the business use cases that are addressed and their requirements, as incorporated in the European EHRxF specifications, can start with simple elements such as download and upload in the different priority data categories. The repository will identify the priority categories of personal health data referenced, and include user stories, use case descriptions, security and privacy requirements as indicated by the infrastructure in which the data is moving. These requirements may be generic functional requirements referencing for example the eHN guidelines or non-functional requirements pertaining to the specific use case. As shown in Figure 19, developing or incorporating new business use cases, engages a process of co-creation, governance, alignment, which takes into account existing business use cases and their requirements, for the purpose of maintenance and reuse. Should new specifications be developed or provided to the Hub, by an initiative promoting that business use case, a process of harmonization may be initiated to examine how this new specification impacts other specifications in terms of data elements, terminologies and structures. This way, with each use case the maturity of existing use cases is potentially maximized.

Common content specifications: Common content specifications relevant to the priority categories of health data implicated in the user story of the business use case. In line with the EHDS Article 23, the common specifications will focus on several elements, that need to be addressed and aligned in close collaboration: Terminology

services and assets, Data sets and common data elements, Content technical specifications and HL7 FHIR implementation guides.

In addition, the way in which these specifications are made available to the users, as well as the way in which they need to be maintained for the effective operations of the Hub, need to be studied and, when necessary, evolve: Develop and validate interoperability formats to be used in collaboration with MyHealth@EU, HealthData@EU and Xt-EHR which is responsible for implementing acts. In its mandate the Hub should work with managing change, concerning at present research of future interoperability formats as technology changes, shared ontologies and their knowledge representation, fostering patient contributed and patient-corrected data, as well as federated access to data for machine learning and AI, etc…

It is well understood that current interoperability specifications do not (yet) meet the full expectations of semantic and pragmatic interoperability as outlined by the ReEIF. Promising results are being reported from the ontology field and the application of the generic reference architecture (through the work on the ISO 23903 standard). However, these developments are not deemed mature enough to be included in the EEHRxF at this time. A development that may lead to improved semantic interoperability in a shorter time frame is the inclusion of OpenEHR archetypes in HL7 FHIR specifications, which is being studied in close collaboration with HL7 International[63]. Of course, together with the stakeholders, the Hub will continue to monitor these developments and incorporate them into future versions of the common content specifications.

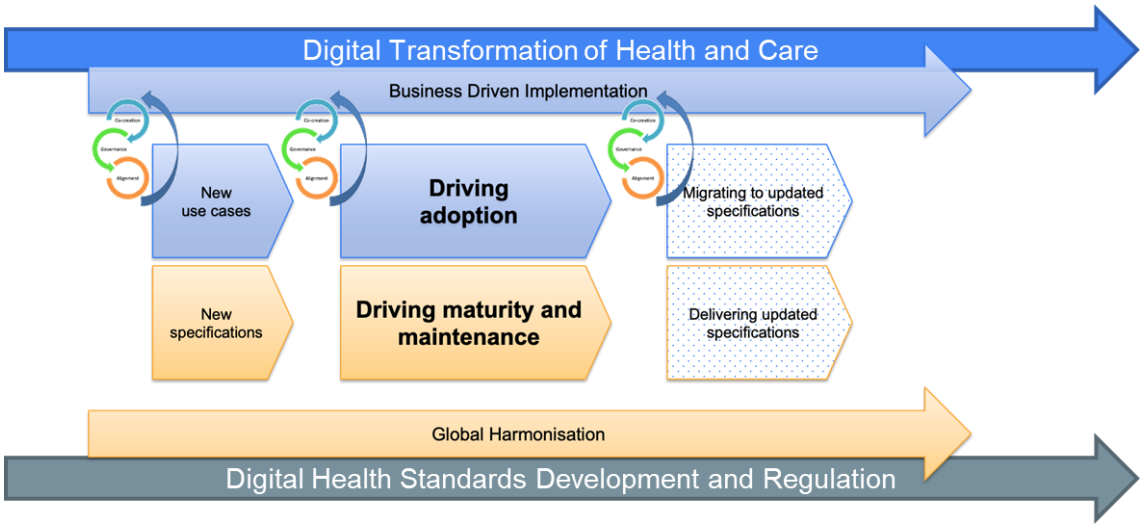


Figure 19: Developing new business uses cases considers existing data elements and specifications, in an integrated business driven way in a spirit of global harmonization.

Common service components. Accelerating adoption of the Format requires reliable high-quality services be offered by the Hub. These services can be mediated in the wider digital health ecosystems and be attested by the Hub and the collaborating community. Service components could include besides tools also

[63]Smart-on-FHIR: https://scholar.harvard.edu/jmandel/publications/smart-fhir-standards-based-interoperable-apps-platform-electronic-health and https://blog.interfaceware.com/top-7-best-smart-fhir-apps/

services including consulting and be covered under alternative business models and licencing rules. What is important is that the Hub serves as the place to learn about the quality of services offered, through recommendations in the community of doers. Based on current experience and previous projects, a set of services that are needed to aid implementation have been identified. These include: business analysis, testing and assurance, sandbox, sample or synthetic data and technical support to implementation, as well as knowledge services such as a glossary.

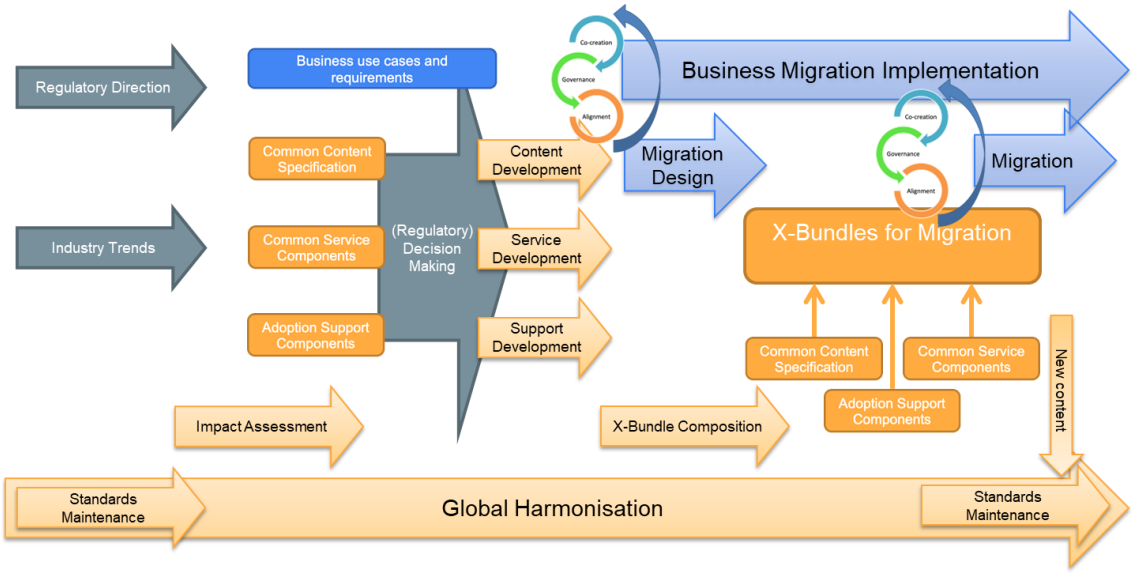


Figure 20: Sustainability of the Hub, requires addressing shifts in the technology and standards supporting business migration.

Adoption support components. As early as in the Semantic Health roadmap of 2009, the importance of socio-economic guidance in advancing interoperability was noted. Indeed, successful adoption, implementation, and evolution of the Format across the communities, includes firstly educational framework and materials (e.g., EHRxF in a capsule). Secondly it includes an organization readiness model that allows to assess the time and effort required to proceed with an adoption strategy. This readiness model can take the form of an Adoption maturity model self-assessment as the one developed in WP3. It may also take the form of a commitment as in the case of the Hospitals-on-FHIR X-Net HL7 FHIR adoption maturity framework. Lastly, webinars guiding implementation, procurement or just case studies of best practices or errors to be avoided offered in industry roundtables or community engagement meet ups can be of great help to newcomers. Once again, an important element is that the Hub provides the framework, the level-playing field for stakeholders to meet and learn from each other. Thus, brokering services and creating operational plans that are sustainable and advance interoperability every step of the way, through better tools and maturing specifications, and a knowledgeable community.

With each and every business-driven implementation of a use case, the relevant X-Bundles are incorporated from the state of adoption planning in cycles co-creation and dynamic governance, fostering a spirit of alignment (see Figure 21), welcoming

change requests from the community. Thus, with each adoption site, the X-Bundles for a particular business use case, are maintained, advancing in maturity. Content specifications are updated in a spirit of harmonization that is carried out to global standards, while the business use cases repository becomes richer with new user stories, testimonials, and examples.

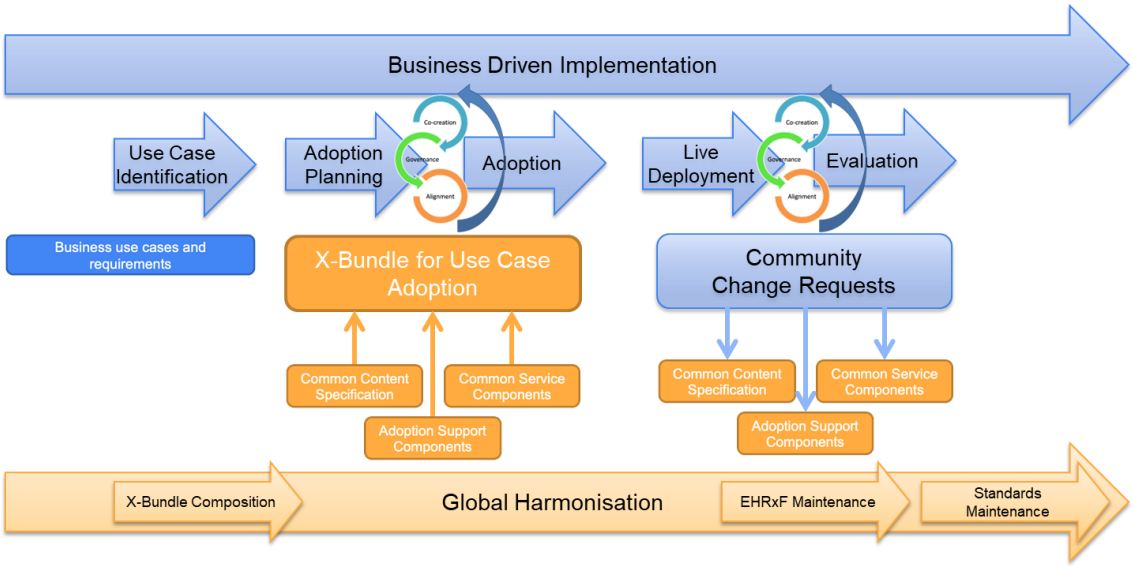


Figure 21: The X-Bundles for business use case adoption evolve with every new deployment, as community change requests arrive and are addressed.

5.1. Standards Hub governance and coordination.

Establishing, managing and operating the European EHRxF Standards Hub requires to create, maintain, and periodically adjust its processes and governance structures. The intent is to provide sustainability by design, as the Hub needs to support the EHDS with a widely adopted set of Formats for priority health data categories. To this end, intense collaboration is needed with a variety of stakeholders, which will be organized addressing among other issues:

a. Policy alignment processes recognizing the Hub as an independent organisation endorsed by policy makers and the European Commission.
b. Content, Service, and Standards alignment processes
c. Governance structure, sustainable by design ensuring development of Annual work plans approved by its stakeholder community.

Industry Forum: The Hub success relies in part on the robust involvement, input, and support from health information technology industry, driven particularly by those companies that manufacture the products that will need to demonstrate compliance with the EEHRxF, but also including other interested players. To this end, the Hub will host an open industry working group that will be consulted on key Standards Hub initiatives including governance, specifications, services, and the sandbox. The following organisations and initiatives will be approached to build engagement:

a. Industry trade associations including COCIR, DIGITALEUROPE, MedTech Europe and their national member associations.
b. Regional and local digital health ecosystems
c. SDOs with industry members such as IHE, HL7, CDISC, IEEE
d. The X-Nets built in XpanDH

Regulators working group. The Hub needs to be aligned with the regulatory domain for personal electronic health data. This is triggered besides the EHDS regulation, also by related regulations on medical devices, in-vitro diagnostics, as well as horizontal regulations on data, interoperability, and artificial intelligence. The work, however, carries on all the way into the detailed set up of testing and assurance as organised within the member states. To connect the very high-level European legislation with the operational activities within countries, an intricate web of stakeholders will form, which will influence the requirements and operations of the Standards Hub. This task will make sure these influences are clarified early on and working relationships as well as mutual understanding are fostered with the regulatory stakeholder community. To this end, this task will:

a. Engage with the Joint Actions on the EHDS that are being carried out across the member states (PATHeD, Xt-EHR, and other [future] actions).
b. Engage with the eHealth Network, the European Commission (esp. DG SANTE and DG CNECT) for policy alignment.
c. Engage with the central and local operators and management bodies of the two EHDS infrastructures: MyHealth@EU and HealthData@EU.
d. Engage with the national eHealth competence centres in the member states.
e. Co-create an agenda for regulatory engagement in establishing and managing of the Hub also as part of the adoption process for the Annual workplan.

5.2. Creating and Maturing X-Bundles

The Hub will extend the Business Use Case repository first developed in the Antilope project to accommodate business use cases of the EEHRxF. Since different business use cases may be using the same specifications for priority health information domains, we could envision grouping of business use cases, or a hierarchical structure supported by appropriate metadata.

Each business use case can be associated with one of more X-Bundles that include specifications and supporting services to accelerate implementation.

6. Discussion

The last 15 years we have seen the contribution of European funded research to standards being channelled through standards organizations with increasing investment on collaborative actions. The creation of a multistakeholder entity to support and sustain this cooperation across time has been discussed at least since the eStandards project seen as a counterpart of an eHealth agency. Now that the need to increase capacity for experts engaged in developing and maintaining X-Bundles this need increases.

The international patient summary is an illustrative case for the need for collaboration. Starting from the Oslo agreement signed by HL7 and CEN/TC251 to collaborate on developing standards for the International Patient Summary on November 19, 2016, within the frame of the eStandards project, several SDOs joined, and the topic was elevated to the Joint Initiative Council. However, the engagement of multiple SDOs and the need of multiple standards to work together raised the issue of maintenance. For its standards ISO/TC215 already announced a maintenance agency, while the JIC itself operates a currently ad hoc committee to deal with xSDO alignment.

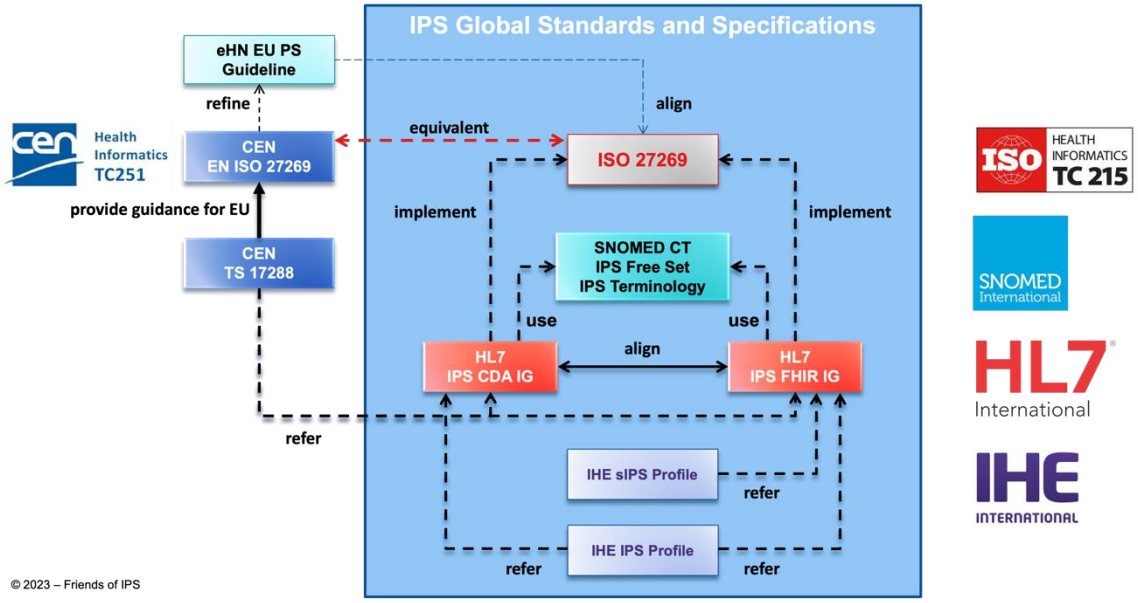


Figure 22: Collaboration of SDOs in the International Patient Summary

At the same time the InternationalPatientSummary.net website was formed, managed by SDO experts in volunteer capacity. The associated page in LinkedIn monitors the interest of the wider community in IPS related developments. The importance of these activities is high, as IPS developments within MyHealth@EU and at GDHP are limited to experts associated with government or donor driven initiatives.

Health IT and standards literacy and organizational readiness are an essential part of the Hub. Already organizational readiness is tackled in WP3-Organisational Readiness, while the community of doers is part of WP5-Growing Digital Health ecosystems along with X-nets. Within the hospitals on FHIR X-net we see that the journey to FHIR maturity scale is quite high level and needs to be instantiated to individual business use cases or groups thereof, as discussed in the previous section.

In 2009, CALLIOPE first identified the need for a multistakeholder forum, and the follow-up Joint Action and eHealth Governance Initiative used it to start on the guidelines for patient summaries and ePrescription, developing structures that matured under myHealth@EU, without formally engaging competence centres or SDOs, unless experts were identified by participating ministries of Health in personal capacity. This situation is a barrier to the sustainability and wide adoption of the format, an issue that can be addressed by the Hub. Over the years, there have been doubts about the viability of such an entity. However, projects like UNICOM have shown that this collaboration can work.

6.1. Moving from standards to interoperable services

The Hub can make a reality what individual disjoint organizations are unable to do. For instance, there are several versions of the International Patient Summary that differ slightly in semantics and optional contents. A systematic cross-SDO process can keep them aligned as illustrated in the JIC white paper: "The future of the IPS as a Common Good"[64]. And going beyond the IPS, projects across public/population health, clinical research, as well as health and care, create "Common Data Models" or ontologies. So how do we go about aligning and harmonizing these models as we pave the way towards interoperable services? Perhaps with the Hub it will be possible to use the IPS as the baseline for data models, providing a set of elements that are supported with value sets that are consistently defined, globally.

The answer is that we focus on the message, the content. This is what the AIDAVA white paper: "A roadmap for data interoperability" 63 argues for high level ontology that would allow to tap into Large Language Models and benefit from AI, in creating standards and in using them. Quite thought provoking it argues that: "To solve the problem of interoperability and quality of health data, we need a structured roadmap, involving individuals as active stakeholders. "This no doubt means bringing people together creating learning health communities. That is way the EEHRxF as an integral part of the EHDS regulation, being mandated for EHRs has the potential to push the envelope for interoperability: aligning data models and bridging across initiatives and projects. Exploring systematically the maturity of FHIR resources and

[64] JIC White paper. "The future of the IPS as a Common Good"
http://www.jointinitiativecouncil.org/images/pdf/JIC%20Discussion%20Paper%20-%20The%20Future%20of%20IPS%20as%20a%20Global%20Public%20Good.pdf

identifying those top-level ones that are more mature and widely used, can really help. This is especially when we stop being content agnostic in the exchange and become content transparent sharing the specification along with the message. This is how the Master Value Catalogue and the inspirational European Semantic Strategy were developed, and we need more!

7. Conclusions and Next Steps

The Digital health compass for the application of EEHRxF looked into the results of the past projects on eHealth that dealt with interoperability standards, revisiting some of the key roadmaps starting from Semantic Health, CALLIOPE, TrilliumBridge and eStandards. In parallel we looked at large scale pilots and cross-border services connected to EHDS. The effort has not been exhaustive due to time and space limitations. It was complemented by the efforts supporting and the Joining the Dots conference organized by i~HD and the EEHRxF expert summit held in December 2023 organized by XpanDH and the European Commission and hosted in the EC facilities bringing together more than 150 experts in this area.

For the next steps, the success of XpanDH depends on the extend and strength of EEHRxF "Format" ecosystem to be formed, and the X-Bundles that will be handed over to xShare/Xt-HER as well as recommendations for Xt-EHR lead efforts of the formalization of the Format.

Next, this report will be considered by WP6-Sustainability and Future Action, which will reflect on the ongoing results of experimentations, in strong synergies with complementary initiatives. It should also be useful for the forthcoming implementation projects (under DEP - Digital Europe Program), much like projects pre-2014 helped the implementation projects (under CEF – Connecting European Facility) that lead to MyHealth@EU services. The new projects (such as i2X, or MyHealth@MYHands will benefit from not reinventing the wheel in artefacts, concepts and frameworks that have proven valuable in the past initiatives and benefit from a functional EHRxFormat Standards and Policy HUB as outlined and proposed in this document.