



POLICY PAPER

on

Proposing Actions to Promote the Use of Common Standards and Technical Specifications in eHealth Within the EU

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LIST OF ABBREVIATIONS

ACRONYM	DEFINITION
CEF	CONNECTED EUROPE FACILITY
CEN TC215	EUROPEAN COMMITTEE FOR STANDARDISATION, TECHNICAL
	COMMITTEE 215
CEN TC251	EUROPEAN COMMITTEE FOR STANDARDISATION, TECHNICAL
	COMMITTEE 251
CGA	CO-CREATION GOVERNANCE ALIGNMENT
CSA	COORDINATION AND SUPPORT ACTIONS
DOW	DESCRIPTION OF WORK
DSM	DIGITAL SINGLE MARKET
EHEALTHDSI	EHEALTH DIGITAL SERVICE INFRASTRUCTURE
eHMSEG	EHEALTH MEMBER STATE EXPERT GROUP
EHN	EHEALTH NETWORK
eHOMB	EHEALTH ORGANISATION AND MANAGEMENT BOARD
ERN	EUROPEAN RESERACH NETWORKS
EU	EUROPEAN UNION
GDPR	GENERAL DATA PROTECTION REGULATION
GS1	GLOBAL STANDARD ONE
HL7	HEALTH LEVEL 7
IDMP	IDENTIFICATION OF MEDICINAL PRODUCTS
IEEE11073	INSTITUTE OF ELECTRICAL AND ELECTRONICS ENGINEERS
IHE	INTEGRATING THE HEALTHCARE ENTERPRISE
IHTSDO	INTERNATIONAL HEALTH TERMINOLOGY STANDARDS DEVELOPMENT
	ORGANISATION
IMIA	INTERNATIONAL MEDICAL INFORMATICS ASSOCIATION
ISO	INTERNATIONAL STANDARDISATION ORGANISATION
JASEHN	JOINT ACTION FOR THE SUPPORT OF THE EHEALTH NETWORK
MS	MEMBER STATES
MSP	MULTISTAKEHOLDER PLATFORM
NCC	NATIONAL COMPENTENCE CENTRE
NIS	NETWORK INFORMATION SECURITY DIRECTIVE
PHPID	PHARMACEUTICAL PRODUCT ID
ReEIF	REFINED EHEALTH INTEROPERABILITY FRAMEWORK
SDO/NCC	STANDARDISATION DEVELOPMENT ORGANISATION
SNOMED-CT	SYSTEMATIZED NOMENCLATURE OF MEDICINECLINICAL TERMS

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1. Introduction

1.1. Executive Summary

The scope of deliverable D.5.4.2 is to propose a concise set of recommendations to the eHN so that future actions and initiative may be proposed to advance cross border healthcare across Europe.

MS have high-level commitment to the implementation of Cross-border eHealth Service for the patient summaries and electronic prescription/dispensation. 16 MSs have already committed to deploy the services for these use cases with the support of the Connected Europe Facility (CEF) programme. JAseHN, providing the political and scientific support of eHN has to support the *Interoperability priority area* between the eHealth Solution at Cross-Border Level.

The policy paper may be used as a guidance when designing the MSs National Strategies and National Plans for standardization in ehealth projects deployment, even beyond the two use cases of Cross Border Patient Summary and ePrescription Services.

Task 5.4 did a thorough literature review of the current EU Policy and Standardisation for interoperability. The results of this review have integrated in the informative document 5.4.3.1.

Several EU activities have been either completed or are in the process of completion in relation to standards and technical specifications. This policy paper is closely related to the work- in terms of policy recommendations- of other EU projects namely: eStandards, openMedicine and AssessCT. Project eStandards introduced the eStandards compass which is a key tool to be used for building **co-creation**, **governance and alignment (CGA)** into every phase of the development, deployment, and evaluation of standardised artefacts. Co-creation engages all relevant stakeholders to ensure that eStandards meet real needs

In its meeting of November, 2015, the eHN adopted and endorsed the so-called Refined eHealth European Interoperability Framework (ReEIF), on the basis of a document describing this framework. As such the ReEIF is a basic component of many recommendations of this document. In fact, all recommendations have been assessed in relation to their impact on the ReEIF adoption for healthcare interoperability in Europe. All key recommendations proposed abide to some selection criteria as defined below:

- 1. Time relevance
- 2. Relevance to Standards in all levels of the Refined eHealth Interoperability Framework
- 3. Relevance to EU eHealth Policies and EU Directives
- 4. Cross border healthcare enablement

After analysing the various material, T5.4 focused on the following recommendations. Those recommendations propose a set of actions layered into three main group of actors, namely the eHN for policy alignment and awareness, the Member States who are advised to assess

and validate the recommendations on national or regional level, and the EU Commission to better support and expand future activities related to the adoption of standards and technical specifications for interoperability.

- 1. Follow EU Policy Context for EU e-Health Interoperability, Do not reinvent the wheel
- 2. Have an integrated approach on Standards for Interoperability by applying the ReEIF
- 3. Provide better linkage to health professional guidelines
- 4. Put more emphasis on clinical information models
- 5. Encourage the use of standards sets in public procurement within the European context, by the use of sustainable healthcare information exchange and interoperability specifications
- 6. Provide more regulatory clarity on the use of standards and standards sets
- 7. A combined strategy for eHealth and semantic interoperability is a prerequisite for any decision about the adoption and role of terminology resources
- 8. Provide open access tools and testing data for deployment of standards sets, Shaping the way to Certification
- 9. Think about data portability to future ehealth service related to mhealth and cloud computing in healthcare
- 10. Build a stable governance model for Interoperability

As a takeaway for the eHN this document proposes some actions as the result of the adoption of the recommendations proposed in this document. Those in summary are:

- 1. Establish a single point of information concerning basic reference material on standards and technical specifications for interoperablity so that member states and other stakeholders can have a holistic overview of the important documentation
- 2. Reinforce the ReEIF use across member states (i.e. prerequisite for cross border healthcare)
- 3. Align eHN adopted material with the ReEIF
- 4. Propose the use of coherent and harmonised clinical and other standardised guidelines across Europe to enable better healthcare information exchange
- 5. Agree to have an in depth discussion on Health and care information modelling until 2020
- 6. Evaluate the existing MSP approved interoperability specifications to create and adopt a list of agreed standard sets until 2020
- 7. Agree to further support the establishment of an SDO/NCC (national competence centers) collaboration initiative, Propose that SDO/NCC collaboration adopts the CGA methodology
- 8. Promote education on Standards
- 9. Define and adopt an eHealth and derived semantic strategy
- 10. Have an in depth discussion to move from testing to certification Request a policy paper on testing and certification from JAseHN
- 11. Include EU Regulation related to interoperability requirements in future eHN documents

12. Establish a Permanent Interoperability Task Force of experts at a cross border healthcare level under eHOMB

Those actions if adopted will provide a framework for the adoption of standards and technical specifications for cross border healthcare in the years to come.

1.2. Scope of Deliverable

The JAseHN Description of Work (DOW) in 2015 for the objectives of the whole Task 5.4 is the following:

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

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

D.5.4.2 takes up the work relevant to standards and technical specifications that have been proposed in various EU funded actions, building on the results of the Antilope Refined European Interoperability Framework. The scope of the deliverable is to propose a concise set of recommendations for the eHN so that future actions and initiative may be proposed to advance cross border healthcare across Europe.

1.3. Main objective of the Policy Paper

MS have high-level commitment to the implementation of Cross-border eHealth Service for the patient summaries and electronic prescription/dispensation. 16 MSs have already committed to deploy the services for these use cases with the support of the Connected Europe Facility (CEF) programme. JAseHN, providing the political and scientific support of eHN has to support the *Interoperability priority area* between the eHealth Solution at Cross-Border Level. Additional 7 MS applied for funding under CEF in September 2017.

This policy paper will provide an overview analysis on the policy recommendations produced by EU projects related to Cross Border Services in order to finally come up with a list of valuable recommendations for thise body of eHN. The scope is the alignment of the actions that policy makers of eHN will design in their countries to promote interoperability in cross-border services. The ultimate aim is to stimulate their interest to design national strategies for interoperability in cross-border services for the two uses cases included in the JAseHN scope and beyond.

The policy paper may be used as a guidance when designing the MSs' National Strategies and National Plans for standardization in ehealth projects deployment, even beyond the two use cases of Cross Border Patient Summary and ePrescription Services. The mission of the paper would be to make: Policy makers', that recognize the key role of formal standardization in supporting the innovation necessary to enable large-scale eHealth deployment, can strengthen the collaborative efforts striving toward:

- Achieving easy interoperability across eHealth applications
- Increasing accessibility and usability of eHealth standards and specifications
- Reusing knowledge through tooling for eHealth deployment

1.4. Internal Dependencies

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

In addition, this deliverable has a dependency with T5.4 D.5.4.3.1 Report on standardisation developments in eHealth where various EU projects, initiative, stakeholders' initiative and other activities related to interoperability and standards are presented and referenced for further reading. D.5.4.3.1 is a report for information to the eHN as a supportive document.

1.5. External Dependencies

Several activities have been either completed or are in the process of completion in relation to standards and technical specifications. This policy paper is closely related to the work- in terms of policy recommendations- of other EU projects namely: eStandards, openMedicine and AssessCT Those projects include recommendations and policy actions that a review of those is the first step to this paper that have been used as input for the recommendations included in the document. The policy papers propose a methodology in order to organise the information in a more relevant approach to the eHN, in terms of policy recommendations.

2. EU Policy and Standardisation for Interoperability

Task 5.4 did a thorough literature review of the current EU Policy and Standardisation for interoperability. The results of this review have integrated in the informative document 5.4.3.1. In this section we provide a basic catalogue of the reference material included in D5.4.3.1 for the past 5 years. We provide a short description of the main inputs for recommendations included in this policy paper.

- EU document list
 - o Action plan on eHealth,
 - o Digital Single Market (DSM) Rolling plan Overview
 - o eHDSI, overview

¹ eStandards Deliverable 3.1 The case for formal standardization in eHealth deployment: http://www.estandards-project.eu/index.cfm/deliverables/

- EU project report
 - o epSOS,
 - o Antilope,
 - o eHGI,
 - o EXPAND,
 - o HITCH,
 - o Trillium Bridge
- H2020 PHC 34 projects
- Assess-CT
- eStandards
- OpenMedicine,
- ValueHealth
- Ongoing projects and activities
 - o EuroCAS
 - o Trillium II

2.1. eStandards:

Task 5.4 has read all available material from the project eStandard. The eStandards Coordination and Support Actions (CSA)is proposed by HL7, CEN TC251, & IHE, leading Standards Organizations (SDOs), and is supported by the eHealth Network, ISO TC215, GS1, IHTSDO, IEEE11073, and IMIA to advance eHealth interoperability and global alignment of standards with seven objectives:

- 1. Join up with Stakeholders in Europe and globally to build consensus on eHealth standards, accelerate knowledge-sharing, and promote wide adoption of standards.
- 2. Deliver an evidence-based Roadmap for alignment, iterative consolidation, and broad acceptance of eStandards that is endorsed by SDOs, the eHealth Network, the providers, and the Industry.
- 3. Contribute to the eHealth Interoperability Framework use cases focusing on clinical content modelling for different paradigms and embed a Quality Management System for interoperability testing and certification of eHealth systems.
- 4. Collect evidence and provide guidance on the coexistence of competing or overlapping standards in large-scale eHealth deployment nationally and cross-border.
- 5. Participate in EU/US MoU roadmap actions as the international patient summaries standard.
- 6. Explore socio-economic aspects of eHealth interoperability, revisiting the language for user-vendor interaction that embodies 'co-making' in trust, collaboration and long-term engagement.
- 7. Align across PHC-34 to nurture innovation, sustainability & growth under CEF and beyond contributing to Key actions of the Digital Agenda 2020.

Deliverables of eStandards such as "D3.5 r2 Roadmap for a sustainable and collaborative standard development: Recommendations for a globally competitive Europe", "D4.2r2 Interoperability Guideline for eHealth Deployment Projects" are of great value proposing a number of actions content, models, interfaces, services and policy dimensions.

As noted in D3.5.r2, adoption of eHealth at scale calls for broad cooperation among organizations developing standards and specifications, joining policy makers to address the following challenges:

- 1. Provide better linkage to professional guidelines
- 2. Put more emphasis on clinical information models
- 3. Accommodate a reliable mix of patient and provider generated data
- 4. Provide more regulatory clarity on the use of standards and standards sets
- 5. Strive for coherence between terminology initiatives
- 6. Facilitate compliant localization and adaptation of standards and standards sets
- 7. Provide open access tools and testing data for deployment of standards sets
- 8. Encourage the use of standards sets in procurement
- 9. Put in place a governance and maintenance process for standards sets

In addition, the eStandards project proposed its evidence-based eStandards Roadmap which aims to provide a compass to allow those developing or using standards to orient themselves to the unique, but interrelated standardisation perspectives of the health system, the workforce, the citizens, and the market for digital health solutions. The eStandards compass is a key tool to be used for building **co-creation**, **governance and alignment (CGA)** into every phase of the development, deployment, and evaluation of standardised artefacts. Co-creation engages all relevant stakeholders to ensure that eStandards meet real needs. Development and review of an appropriate dynamic and flexible governance system to ensure that eStandards are deployed at scale, referenced by the regulations and practice guidelines that support and govern the implementation of eHealth solutions and services as they are actually used. Finally, the flexibility to adapt and align, as needs and requirements change, nurtures eStandards that remain useable and sustainable within the eHealth ecosystem.

D4.2.r2 provided a practical approach to interoperability successfully applied by various eHealth projects in Europe and internationally. The approach is summarised in seven steps:

- 1. *Identify use cases* from an end-user perspective, including glossary, scenario, actors, privacy requirements and variations.
- 2. Select profiles and standards that support the use case. IHE² and Personal Connected Health Alliance (PCHAlliance) have developed such profiles.
- 3. Refine data content, including document templates, metadata, master files, and terminology. HL7 C-CDA and the openEHR foundation have developed template

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² Commission Decision (EU) 2015/1302 of 28 July 2015 on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement (Text with EEA relevance), http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D1302&from=EN

- repositories to support clinical content profiles, frequently associated with terminology value sets.
- 4. Write interoperability specifications (implementation guides) that describe the standards / profiles selected, the refined data content, and other project specific local needs. This specification enables implementation of the use case across the various IT systems and devices.
- 5. Organise testing by preparing test cases and adopting a test environment for implementers to demonstrate component interoperability and by organising cross-implementer connectivity testing.
- 6. Educate end-users on interoperability: Develop communications materials to familiarise end-users on the benefits and impact of Interoperability. This step may already begin earlier on, once the use case has been identified.
- 7. Support or participate in communities of practice to promote sustainable standards-based implementation and offer feedback to standards and profiling organisations.

2.2. OpenMedicine: Meeting the global challenge of unique identification of medicinal products

OpenMedicine focuses on a cross-border dispensing and administering of a medication item and on the cross-border use of the medication related information within a patient summary.

The project includes³ list of recommendations regarding the medicinal products in cross border ePrescriptions, eDispensing reports and Patient Summaries. In those the linkage of information exchange of pharmaceutical data across Europe is proposed to be based:

- on a **globally unique Pharmaceutical Product ID (PhPID)** which will be ISO/IDMP compatible European Drug Databases- and is proposed to be integrated into the implementations and databases for eP and
- on a unique Pharmaceutical Product ID based on EMA Article 57 substance standard database to support in the short term the needs for the cross-border CEF-based services

Procedures and recommendations regarding information exchange of pharmaceutical data and implementation details are related to Interoperability Levels according to reEIF (that is the integration of PhPID into the cross-border services database, the temporal consistency of information regarding terms and definitions, compliance with EMA and national specifics, the completeness of data, the updated relative databases with new introduced products, the availability of IDMP EU or MS databases, the legal and regulatory context for harmonization on dispending and prescribing products) The project includes ⁴⁵ list of recommendations

³ http://www.who.int/medicines/services/inn/innquidance/en/

 $^{^4 \} http://www.open-medicine.eu/fileadmin/openmed/deliverables/643796_d5.2_substitution_results_and_recommendations_v08.pdf$

regarding the medicinal products in cross border ePrescriptions, eDispensing reports and Patient Summaries (D5.2), as well as a set of recommendations and Implementation Roadmap (D6.3).

2.3. Assess-CT: Assessing SNOMED CT for Large Scale eHealth Deployments in the EU

The ASSESS CT project, integrating a broad range of stakeholders, investigated the fitness of the international clinical terminology SNOMED CT as a potential standard for EU-wide eHealth deployments. In a joint one-year effort, the ASSESS CT consortium:

- addressed this challenge by investigating a number of issues related to the current use
 of SNOMED CT such as concrete reasons for adoption/non adoption of SNOMED
 CT, lessons learned, success factors, type and purpose of use, multilingualism, cultural
 differences, strengths and weaknesses
- reviewed the current state of use of SNOMED CT and the fulfilment of semantic interoperability use cases, known technical and organisational drawbacks, and the way the terminology is improved and maintained, by means of literature review, survey, interviews; focus groups and Workshops.
- employed established evaluation approaches from social science. It will scrutinise
 adoption against two alternative scenarios: to abstain from actions at the EU level, or
 to devise an EU-wide semantic interoperability framework alternative without
 SNOMED CT.
- analysed the impact of SNOMED CT adoption from a socio-economic viewpoint, encompassing management, business, organisational, and governance aspects.

As such, the goal of ASSESS CT was to make a significant contribution to the debate on semantic interoperability of eHealth services in Europe⁶. It came up with a report with five recommendations focusing on the importance on adopting the SNOMED CT as a core reference terminology along with the need for a wider, coherent and priority-driven strategy for optimising the benefits of semantic interoperability in wider, coherent and priority-driven strategy for optimising the benefits of semantic interoperability in health data.

3. Standardisation in view of the ReEIF

In its meeting of November, 2015, the eHN adopted and endorsed the so-called Refined eHealth European Interoperability Framework (ReEIF), on the basis of a document describing this framework. The document can be found here:

https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf

⁵ http://www.open-

medicine.eu/fileadmin/openmed/re_documents/final_d6_3_openmed_recommendations_and_roadmap_after_atr. pdf

⁶ http://assess-ct.eu/fileadmin/assess_ct/final_brochure/assessct_final_brochure.pdf

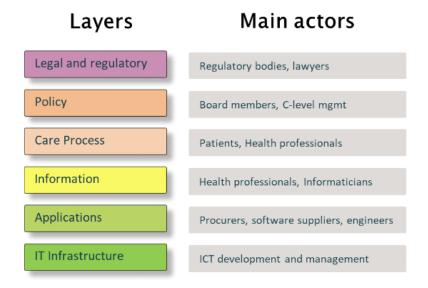


Figure 1 ReEIF Layer

In the ReEIF it is proposed to structure the discussions on eHealth, from policy to technology, along the lines of a six-layer model, showing that every solution needs partial solutions on six significantly different aspects, but in a coordinated manner. Figure 1, taken from the ReEIF document, shows in brief these layers. It is stipulated in the document that the complexity of information solutions in healthcare lies mainly in two facts:

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

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

If we broaden this thinking to *inter*operability the landscape of course consists of two (or more) individual solutions, that should be brought to collaboration, again by applying interoperability thinking on all six layers, as shown in figure 2:

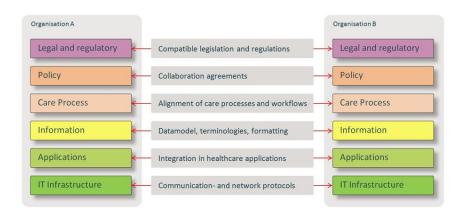


Figure 2 applying interoperability for each ReEIF layer

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

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

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

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

This brings forward the necessity of the vertical integration: six partial solutions only form an over-all working solution when the integration between the layers is done correctly and

consistently. That is the task of every solution provider, and on a national scale often of the NCC. Also here some help is available from internationally operating organisations. These organisations are commonly referred to as profiling organisations after the products they produce: profiles. The profile is a standardised multilayer solution for a specific use case. In other words: a use case is a specific generalised (piece of a) care process, and the profile contains a receipt for the creation of a model solution, suggesting which standards to take on which layer and how.

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

4. Proposed Key Recommendations to the eHealth Network

4.1. Methodological approach

Based on the review of several material and related EU projects this policy paper proposes a number of key recommendations for policy actions to the eHealth Network derived from the review of the materials. All key recommendations proposed abide to some selection criteria as defined below:

1. Time relevance

In the last years many EU documents, EU projects and other initiatives related to the use of Standards in eHealth have been proposed. This policy paper only considered documentation of the last 5 years to provide solid and relevant recommendation to current technological and operational trends across Europe

2. Relevance to Standards in all levels of the Refined eHealth Interoperability Framework (ReEIF) as described shortly in other sections of this document and thoroughly in the references and other JAseHN deliverables (D5.4.1).

3. Relevance to EU eHealth Policies and EU Directives

Many references on the use of standards at a global scale is also available. Nevertheless, this policy paper intention is to focus on EU Policies and support EU Directives adoption, namely the cross border healthcare directive.

4. Cross border healthcare enablement

Recommendations need to be supportive to the mandate of cross border healthcare across the EU ("Bring eHealth on a Higher Level Patient Rights in Cross border Healthcare") following the regulation of the European Union as defined in Article 152 of the Maastricht treaty.

Following this selection process this policy document concluded to propose the following key recommendations. All key recommendations are proposed in the following tabular model, in order to cover all aspects (Why, What, Who, How, for whom, When)

Recommendation Title				
Scope (What)				
Rationale (Why)				
Relevance to Cross Border Healthcare Roadmap				
Cross Border	Information exchange for the patient			✓
Relevance	Information exchange for public heal	th and secondary us	se	✓
	Citizens (as consumers of health services) Direct Indirect		•	
Benefits	Workforce (in the delivery and administration of health services) Direct Indirect I			
Perspective	eHealth Market (where eHealth solutions and services are traded) Direct Indirect In		ctly	
	Health System (where care is delivered and cost, quality, and access deci-sions are made) Indirection		•	
	Legal and Regulatory (legislation and	regulations)		√
Relation to the	Policy (collaboration agreements) Care Process (processes and workflow)		√	
ReEIF	Information (data structures, termino	,		√
	Application (Integration and exchange of medical data)			✓
	IT Infrastructure (communication and	d network protocol	s)	✓
	Collective Level – eHN Decisions			
Proposed Actions	Member State Level			
	EU Commission Level			
Recommendation	High			√
Priority	Medium			√
	Low	Table 1 Recomm		V

Table 1 Recommendation table template

4.2. List of recommendations

After analysing the various material, T5.4 focused on the following recommendations. Those recommendations propose a set of actions layered into three main group of actors, namely the eHN for policy alignment and awareness, the Member states that need to take away the recommendations for National and regional assessment and validation, and the EU Commission to better support and expand future activities related to the adoption of standards and technical specifications for interoperability.

1.	Follow EU Policy Context for EU e-Health Interoperability, Do not reinvent the wheel
2.	Have an integrated approach on Standards for Interoperability by applying the ReEIF
3.	Provide better linkage to health professional guidelines
4.	Put more emphasis on clinical information models
5.	Encourage the use of standards sets in public procurement within the European context, by the use of sustainable healthcare information exchange and interoperability specifications
6.	Provide more regulatory clarity on the use of standards and standards sets
7.	A combined strategy for eHealth and semantic interoperability is a prerequisite for any decision about the adoption and role of terminology resources
8.	Provide open access tools and testing data for deployment of standards sets, Shaping the way to Certification
9.	Think about data portability to future ehealth service related to mhealth and cloud computing in healthcare
10.	Build a stable governance model for Interoperability

Table 2 List of Recommendations

The following schema depicts the correlation of the recommendations amongst themselves and their impact to EU unified vision of the Digital Single Market. In the horizontal axis one can estimate the impact the recommendation may have in the time scale from an impact in the short term to the long term.

Additionally, in the vertical axis an estimation of the impact towards the implementation of the EU cross border healthcare scenarios and towards the vision of the EU for a unified European digital single market.

Finally the recommendation are marked also towards their effects and benefits for 4 major groups of stakeholders namely the patients, the workforce, the eHealth Market and the Health Systems.



Figure 3. Correlation of Recommendations

4.3. Key recommendation tables

Recommendation Title	Recommendation 1. Follow EU Policy Context for EU Do not reinvent the wheel	e-Health Interoperabi	ility	
Scope (What)	*	The scope of the recommendation is twofold: a) make related and existing material available to all and b) enable collaboration of member states in order to learn from each other experience		
Rationale (Why)	Reference material, PHC-34 projects such as eStandards propose to reuse international standards and profiles for eHealth Interoperability as an enabler to cross border healthcare			
Relevance to Cross Border Healthcare Roadmap	EU Policy context for e-Health Interchealthcare operations across Europe	operability is the basis fo	or cross border	
Cross Border	Information exchange for the patient	- citizen	✓	
Relevance	Information exchange for public heal	th and secondary use		
	Citizens (as consumers of health services) Workforce (in the delivery and administration of health		Indirectly	
Benefits	services)		muncetry	
Perspective	eHealth Market (where eHealth solutions and services are traded)		Directly	
	Health System (where care is delivered and cost, quality, and access deci-sions are made)		Directly	
	Legal and Regulatory (legislation and regulations)		√	
Relation to the	Policy (collaboration agreements) Care Process (processes and workflow)		∀	
ReEIF	Care Process (processes and workflow) Information (data structures, terminologies)		√	
	Application (Integration and exchange of medical data)		✓	
	IT Infrastructure (communication and network protocols)		✓	
	Collective Level – eHN Decisions	Adopt the recommendation		
Proposed Actions	Member State Level Recommendation to reuse EU M (ReEIF, MSP, Guidelines, etc)			
	EU Commission Level Create reference mate – make material availa			
Recommendation	High		✓	
Priority	Medium			
	Low		mmendation 1 table	

Table 3 Recommendation 1 table

Recommendation Title	Recommendation 2 Have an integrated appreciate the second	oroach on Standards for Interoperabil	ity by applying the
Scope (What)	ReEIF value is mainly in creating a common vocabulary among different actors, in order to promote the compatibility or alignment of standards. It offers a methodology that enables the definition of specific user needs (reflected into use cases) that can be then analysed into interoperability specifications and integration profiles. It is recommended to explicitly use this methodology also in the development, selection and implementation of standards. The consequence of this is that standardisation happens per layer of the ReEIF followed by integration of the layers.		
Rationale (Why)	https://ec.europa.eu/hea	s adopted the ReEIF since November 20 alth/sites/health/files/ehealth/docs/ev osed so that ReEIF is assessed for adopti	20151123 co03 en.pdf.
Relevance to Cross Border Healthcare Roadmap	level. Quality of data exc	sation is based on the adoption of the Re hange at a cross border healthcare level is nteroperability standards and procedures	s expected to increase
Cross Border	Information exchange fo	r the patient - citizen	✓
Relevance	Information exchange fo	r public health and secondary use	✓
	Citizens (as consumers o	f health services)	Indirectly
Benefits	Workforce (in the delivery and administration of health services)		Indirectly
Perspective	eHealth Market (where eHealth solutions and services are traded)		Indirectly
	Health System (where care is delivered and cost, quality, and access deci-sions are made)		Directly
	Legal and Regulatory (leg	•	✓
	Policy (collaboration agreements)		✓
Relation to the	Care Process (processes and workflow)		\checkmark
ReEIF	Information (data structures, terminologies)		✓
	Application (Integration and exchange of medical data)		√
	11 Intrastructure (comm	1 ,	otos (i.o. promomisito for
	Collective Level – eHN Decisions	cross border healthcare)	
Proposed Actions	Member State Level	Align national strategy with the ReEIF	
	EU Commission Level	ommission Level Align EU Commission strategy with ReE	
D	High		✓
	Medium		
Priority	Low		
Proposed Actions Recommendation Priority	IT Infrastructure (communication and network protocols) Collective Level − eHN Decisions Reinforce ReEIF use across member states (i.e. prerequisite for cross border healthcare) Align eHN adopted material with the ReEIF Member State Level Align national strategy with the ReEIF Provide the ReEIF documents in all EU languages Align EU Commission strategy with ReEIF for ERNs and Reference sites High Medium		eEIF J languages EIF for ERNs and

Table 4 Recommendation 2 table

Recommendation Title	Recommendation 3 Provide better linkage of care processes to health professional guidelines through harmonized information exchange			
Scope (What)	Propose the use of coherent and harmo across Europe to enable better healthca		<u> </u>	
Rationale (Why)	Linked guidelines can streamline the care process at a European level by harmonising information and data inputs and outputs of care processes. Implementation of health professional guidelines enhances quality of data across Europe and especially for handling chronic care diseases that increase cost of care for EU citizens and for the implementation of ERNs for rare diseases in Europe. The lack of coherent and harmonized guidelines already hinders international collaboration. This level is mostly absent in many current cross-border initiatives which tend to focus only on technical specifications. As an illustrative example, the lack of shared operational model or guideline between eHDSI ePrescription participants concerning the substitution of prescribed medicine upon dispensation by alternative strength in comparison to the original prescription. Additionally, the medication related information within a patient summary and eP is a core element, harmonization of the information should be assured when European unique medical data information is provided and integration in national field is assured.			
Relevance to Cross Border Healthcare Roadmap	openMedicine proposed common procedures for cross border ePrescription that allow the information exchange of pharmaceutical data across Europe based on standards such as ISO IDMP. Short term support for the cross-border CEF-based services are also proposed			
Cross Border	Information exchange for the patient - citizen ✓			
Relevance	Information exchange for public health	and secondary use	✓	
	Citizens (as consumers of health service	ens (as consumers of health services)		
Benefits	Workforce (in the delivery and administration of health services)		Directly	
Perspective	eHealth Market (where eHealth solutions and services are traded)		Directly	
	Health System (where care is delivered and access deci-sions are made)	and cost, quality,	Indirectly	
Relation to the ReEIF	Legal and Regulatory (legislation and regulations) Policy (collaboration agreements) Care Process (processes and workflow) Information (data structures, terminologies) Application (Integration and exchange of medical data) I'T Infrastructure (communication and network protocols)			
	Collective Level – eHN Decisions	Adopt the recomme	endation	
Proposed Actions	•		Guidelines at a European and	
	EU Commission Level Propose prescription border healthcare		n guidelines for eP for cross	
Recommendation High				
Priority	Medium		✓	
	Low			

Table 5 Recommendation 3 table

Recommendation	Recommendation 4		
Title	Put more emphasis on health and care information models		
Scope (What)	Propose to member state and EU Codefined sets of health and care inform definition effort.		
Rationale (Why)	Health and care information models ⁷ are building blocks for creating data sets for any use case in health and care. By using those, the data sets of the use cases become mutually consistent and thus enhances interoperability. Some of the key issues of Semantic interoperability are being addressed by adopting this recommendation. However, these should not be developed from scratch but they should be based on already existing specifications. The search for such models from multiple sources should always be carefully performed before suggesting any new specification work.		
Relevance to Cross Border Healthcare Roadmap	Common health and care modelling of patient summaries in emergency and models for rare diseases and chronic and chronic diseases.	pandemic contexts, of comple	ex eprescription
Cross Border	Information exchange for the patient	- citizen	✓
Relevance	Information exchange for public heal	lth and secondary use	✓
	Citizens (as consumers of health services)		Indirectly
Benefits	Workforce (in the delivery and administration of health services)		Directly
Perspective	eHealth Market (where eHealth solutions and services are traded)		Directly
	Health System (where care is delivered and cost, quality, and access decisions are made)		Directly
	Legal and Regulatory (legislation and regulations) Policy (collaboration agreements)		
Relation to the	Care Process (processes and workflow)		
ReEIF	Information (data structures, terminologies)		✓
	Application (Integration and exchange of medical data)		
	IT Infrastructure (communication an Collective Level – eHN Decisions	Agree to have an in depth discussion on	
Proposed Actions	Member State Level Assess Health and Care information model practices and standards		rmation modeling
	EU Commission Level Assess Health and Care information practices and standards		rmation modeling
Recommendation	High		
Priority	Medium		✓
	Low		

Table 6 Recommendation 4 table

⁷ An **information model** in software engineering is a representation of concepts and the relationships, constraints, rules, and operations to specify data semantics for a chosen domain of discourse. Typically it specifies relations between kinds of things, but may also include relations with individual things. It can provide sharable, stable, and organized structure of information requirements or knowledge for a specific domain context, i.e. a clinical building block of information necessary to be orchestrated for clinical use.

Recommendation Title European context, by the use of sustainable healthcare information exchange and interoperability specifications Provide incentives to member states to incorporate EU MSP specifications in their public procurement cycles to enable cross border healthcare as an end result EU Regulation 1025/2012 enables member states to reuse proposed technical specification set for the procurement cycle according the EU procurement rules. Member states need to be aware on existing EU interoperability specification endorsed by the EU MSP Relevance to Cross Border Healthcare Roadmap solution provider at an EU Commission level. Information exchange for the patient - citizen Information exchange for public health and secondary use Citizens (as consumers of health services) Indirectly Workforce (in the delivery and administration of health services) CHealth Market (where cHealth solutions and services are traded) Health System (where care is delivered and cost, quality, and access deci-sions are made) Legal and Regulatory (legislation and regulations) Policy (collaboration agreements) Care Process (processes and workflow) Information (data structures, terminologies) Application (Integration and exchange of medical data) IT Infrastructure (communication and network protocols) Proposed Actions Member State Level Apply interoperability specification based on international standards for ERNs High Medium Low		Recommendation 5:		
Title European context, by the use of sustainable healthcare information exchange and interoperability specifications Provide incentives to member states to incorporate EU MSP specifications in their public procurement cycles to enable cross border healthcare as an end result EU Regulation 1025/2012 enables member states to reuse proposed technical specification set for the procurement cycle according the EU procurement rules. Member states need to be aware on existing EU interoperability specification endorsed by the EU MSP Relevance to Cross Border Relevance arross border level. Those specifications and integration profiles reflect the technical implementation and testing required to adopt the ReEIF uniformly at a cross border level. Those specifications are already adopted by cHealthDSI solution provider at an EU Commission level. Information exchange for the patient - citizen Citizens (as consumers of health services) Indirectly Workforce (in the delivery and administration of health services) eHealth Market (where eHealth solutions and services are traded) Health System (where care is delivered and cost, quality, and access decisions are made) Legal and Regulatory (legislation and regulations) Policy (collaboration agreements) Care Process (processes and workflow) Information (data structures, terminologies) Application (Integration and exchange of medical data) IT Infrastructure (communication and network protocols) Proposed Actions Member State Level Apply interoperability specifications to create and adopt a list of agreed standard sets until 2020 Recommendation Priority Recommendation Priority	Recommendation	Encourage the use of standards sets in public procurement within the European context, by the use of sustainable healthcare information		
Provide incentives to member states to incorporate EU MSP specifications in their public procurement cycles to enable cross border healthcare as an end result	Title			
Provide incentives to member states to incorporate EU MSP specifications in their public procurement cycles to enable cross border healthcare as an end result				
Rationale (Why) Rationale (Why) Relevance to Cross Border Healthcare as an end result EU Regulation 1025/2012 enables member states to reuse proposed technical specification set for the procurement cycle according the EU procurement rules. Member states need to be aware on existing EU interoperability specification endorsed by the EU MSP Relevance to Cross Border Healthcare a cross border level. Those specifications and integration profiles reflect the technical implementation and testing required to adopt the ReEIIF uniformly at a cross border level. Those specifications are already adopted by eHealthD8I solution provider at an EU Commission level. Cross Border Relevance Information exchange for the patient - citizen Information exchange for public health and secondary use Citizens (as consumers of health services) Indirectly Workforce (in the delivery and administration of health services) eHealth Market (where eHealth solutions and services are traded) Health System (where care is delivered and cost, quality, and access deci-sions are made) Legal and Regulatory (legislation and regulations) Policy (collaboration agreements) Care Process (processes and workflow) Information (data structures, terminologies) Application (Integration and exchange of medical data) IT Infrastructure (communication and network protocols) Collective Level – eHN Decisions Member State Level EU Commission Level Member State Level Fullude MSP approved interoperability specifications to create and adopt a list of agreed standard sets until 2020 Apply interoperability specification based on international standards for ERNs				specifications in
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Rationale (Why) Relevance to Cross Border Healthcare Roadmap Cross Border Relevance Information exchange for the patient - citizen Citizens (as consumers of health services) Benefits Perspective Relation to the ReEIF Relation to the Relatio				
Rationale (Why) Relevance to Cross Border Healthcare Roadmap Cross Border Relevance Information exchange for public health as services) Benefits Perspective Benefits Perspective Legal and Regulatory (legislation and regulations) Relation to the ReEIF Relation to the ReEIF Reletion to the Re		EU Regulation 1025/2012 enable	es member states to reuse pr	oposed technical
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Relevance to Cross Border Healthcare Roadmap Benefits Perspective Benefits Perspective Belation to the ReEIF Relation to the ReEIF Relevance Reletion to the ReEIF Reletion to the Reletion	Rationale (Why)	rules. Member states need to be a	ware on existing EU interop	perability
Technical implementation and testing required to adopt the ReEIF uniformly at a cross border level. Those specifications are already adopted by eHealthDSI solution provider at an EU Commission level. Cross Border Information exchange for the patient - citizen ✓				•
Healthcare Roadmap	Relevance to	Proposed interoperability specific	cations and integration profi	les reflect the
Cross Border Relevance	Cross Border		•	
Cross Border Relevance	Healthcare	a cross border level. Those specif	ications are already adopted	by eHealthDSI
Relevance Information exchange for public health and secondary use Citizens (as consumers of health services) Workforce (in the delivery and administration of health services) eHealth Market (where eHealth solutions and services are traded) Health System (where care is delivered and cost, quality, and access deci-sions are made) Legal and Regulatory (legislation and regulations) Policy (collaboration agreements) Care Process (processes and workflow) Information (data structures, terminologies) Application (Integration and exchange of medical data) IT Infrastructure (communication and network protocols) Collective Level – eHN Decisions Collective Level – eHN Decisions Member State Level EU Commission Level Recommendation Priority Indirectly Indire	Roadmap			·
Benefits Perspective Citizens (as consumers of health services) Indirectly	Cross Border	Information exchange for the pat	ient - citizen	✓
Benefits Perspective Health Market (where eHealth solutions and services are traded) Health System (where care is delivered and cost, quality, and access deci-sions are made) Legal and Regulatory (legislation and regulations) Policy (collaboration agreements) Care Process (processes and workflow) Information (data structures, terminologies) Application (Integration and exchange of medical data) IT Infrastructure (communication and network protocols) Collective Level − eHN Decisions Member State Level EU Commission Level Recommendation Priority Workforce (in the delivery and administration of health services) Indirectly Indirectly Indirectly Indirectly Indirectly Directly Dir	Relevance	Information exchange for public	health and secondary use	
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Benefits Perspective eHealth Market (where eHealth solutions and services are traded) Health System (where care is delivered and cost, quality, and access deci-sions are made) Legal and Regulatory (legislation and regulations) Policy (collaboration agreements) Care Process (processes and workflow) Information (data structures, terminologies) Application (Integration and exchange of medical data) IT Infrastructure (communication and network protocols) Collective Level – eHN Decisions Evaluate the existing MSP approved interoperability specifications to create and adopt a list of agreed standard sets until 2020 Proposed Actions Recommendation Priority High Medium Medium		Workforce (in the delivery and ac	lministration of health	7 41 .1
Perspective eHealth Market (where eHealth solutions and services are traded) Health System (where care is delivered and cost, quality, and access deci-sions are made) Legal and Regulatory (legislation and regulations) Policy (collaboration agreements) Care Process (processes and workflow) Information (data structures, terminologies) Application (Integration and exchange of medical data) IT Infrastructure (communication and network protocols) Collective Level – eHN Decisions Proposed Actions Member State Level EU Commission Level High Medium Directly Applications, quality, and cost, quality, and access are delivered and cost, quality, and access are made) Legal and Regulatory (legislation and regulations) Policy (collaboration agreements) Care Process (processes and workflow) Information (data structures, terminologies) Fevaluate the existing MSP approved interoperability specifications to create and adopt a list of agreed standard sets until 2020 Include MSP approved interoperability specification based on international standards for ERNs	Renefite	services)		Indirectly
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Legal and Regulatory (legislation and regulations) Policy (collaboration agreements) Policy (collaboration agreements) Care Process (processes and workflow) Information (data structures, terminologies) Application (Integration and exchange of medical data)		Health System (where care is delivered and cost, quality,		D' 4
Policy (collaboration agreements) Care Process (processes and workflow) Information (data structures, terminologies) Application (Integration and exchange of medical data) IT Infrastructure (communication and network protocols) Collective Level − eHN Decisions Proposed Actions Member State Level EU Commission Level Recommendation Priority Policy (collaboration agreements) Care Process (processes and workflow) Ferminologies ✓ Evaluate the existing MSP approved interoperability specifications to create and adopt a list of agreed standard sets until 2020 Include MSP approved interoperability specifications in national procurement cycles Apply interoperability specification based on international standards for ERNs High Medium ✓				Directly
Relation to the ReEIF Care Process (processes and workflow) Information (data structures, terminologies) ✓ Application (Integration and exchange of medical data) ✓ IT Infrastructure (communication and network protocols) ✓ Collective Level – eHN interoperability specifications to create and adopt a list of agreed standard sets until 2020 Member State Level Include MSP approved interoperability specifications in national procurement cycles specifications in national procurement cycles EU Commission Level Apply interoperability specification based on international standards for ERNs Recommendation Priority		Legal and Regulatory (legislation and regulations)		
Proposed Actions Information (data structures, terminologies) ✓		Policy (collaboration agreements)		
Application (Integration and exchange of medical data) IT Infrastructure (communication and network protocols) Evaluate the existing MSP approved interoperability specifications to create and adopt a list of agreed standard sets until 2020 Member State Level Include MSP approved interoperability specifications in national procurement cycles EU Commission Level Apply interoperability specification based on international standards for ERNs High Medium	Relation to the	Care Process (processes and workflow)		
Proposed Actions Proposed Actions Recommendation Priority IT Infrastructure (communication and network protocols) Evaluate the existing MSP approved interoperability specifications to create and adopt a list of agreed standard sets until 2020 Include MSP approved interoperability specifications in national procurement cycles Apply interoperability specification based on international standards for ERNs High Medium ✓	ReEIF	Information (data structures, terminologies)		✓
Proposed Actions Collective Level − eHN Decisions Decisions Member State Level Evaluate the existing MSP approved interoperability specifications to create and adopt a list of agreed standard sets until 2020 Include MSP approved interoperability specifications in national procurement cycles EU Commission Level Apply interoperability specification based on international standards for ERNs High Medium ✓		Application (Integration and exchange of medical data)		✓
Proposed Actions Proposed Actions Collective Level – eHN Decisions Member State Level EU Commission Level Recommendation Priority Collective Level – eHN Decisions interoperability specifications to create and adopt a list of agreed standard sets until 2020 Include MSP approved interoperability specifications in national procurement cycles Apply interoperability specification based on international standards for ERNs High Medium		IT Infrastructure (communication and network protocols) ✓		✓
Proposed Actions Member State Level EU Commission Level Recommendation Priority Decisions adopt a list of agreed standard sets until 2020 Include MSP approved interoperability specifications in national procurement cycles Apply interoperability specification based on international standards for ERNs High Medium			Evaluate the existing MSP	approved
Proposed Actions Member State Level Include MSP approved interoperability specifications in national procurement cycles EU Commission Level Apply interoperability specification based on international standards for ERNs High Medium ✓		Collective Level – eHN	interoperability specification	ons to create and
Proposed Actions Member State Level EU Commission Level Recommendation Priority Include MSP approved interoperability specifications in national procurement cycles Apply interoperability specification based on international standards for ERNs High Medium		Decisions	adopt a list of agreed stand	lard sets until
Member State Level specifications in national procurement cycles EU Commission Level Apply interoperability specification based on international standards for ERNs High Medium			2020	
EU Commission Level Recommendation Priority Specifications in national procurement cycles Apply interoperability specification based on international standards for ERNs Wedium	Proposed Actions	Mambau Stata Laval	Include MSP approved int	eroperability
Recommendation Priority High Medium		Member State Level	specifications in national p	procurement cycles
Recommendation Priority High Medium Medium		Apply interoperability specification based of		cification based on
Priority Medium		international standards for ERNs		ERNs
Priority	Recommendation	High		
Low		Medium		✓
		Low		

Table 7 Recommendation 5 table

Recommendation Title	Recommendation 6: Provide more regulatory clarity on the use of standards and standards sets		
Scope (What)	Provide clarity to end users and stakeholders on the proper methodology for standards adoption for interoperability in healthcare.		
Rationale (Why)	EU project eStandards defined a Co-Creation Governance Alignment (CGA) Model that proposes a specific rationale on how to align standardisation stakeholders and enable co-creation of standards sets as a response to specific end user needs. Health services and implementers need to guide the co-creation, governance and alignment, and relevant stakeholders are also included in the process.		
Relevance to Cross Border Healthcare Roadmap	The eStandards approach proposed to use the CGA model through four focus areas, leading to the key actions for collaborative development and deployment cross border healthcare. The focus areas chosen are: • unplanned or emergency care • rare disease networks • chronic disease management • common identification of medicines		
Cross Border	Information exchange	for the patient - citizen	✓
Relevance	Information exchange	for public health and secondary use	✓
	Citizens (as consumers	s of health services)	Indirectly
Benefits	Workforce (in the delivery and administration of health services)		Directly
Perspective	eHealth Market (where eHealth solutions and services are traded) Indirectly		
	Health System (where care is delivered and cost, quality, and access decisions are made)		Directly
	Legal and Regulatory (legislation and regulations)		
	Policy (collaboration agreements)		✓
Relation to the	Care Process (processes and workflow)		✓
ReEIF	Information (data structures, terminologies)		✓
	Application (Integration and exchange of medical data)		✓
	IT Infrastructure (communication and network protocols)		✓
Proposed Actions	Collective Level – eHN Decisions	Agree to further support the establishment of an SDO/NCC (national competence centers) collaboration initiative Propose that SDO/NCC collaboration adopts the CGA methodology Promote education on Standards	
	Member State Level	Define natonal priorities and uses cases for healthcare information exchange and interoperability Propose the creation of National SDO/NCC collaboration initiatives that assess the CGA methodology Propose to include Standards in the relevant curricula in the area of health informatics	
	EU Commission Support CEN, CENELEC and ETSI to participate in the establishment and operation of the SDO/NCC initiative		
D	High		
Recommendation Priority	Medium		✓
	Low		

Table 8 Recommendation 6 table

Recommendation Title	Recommendation 7: A combined strategy for eHealth and semantic interoperability is a prerequisite for any decision about the adoption and role		
Scope (What)	Of terminology resources Define eHealth strategies that include semantic interoperability as a core asset to effectively allow information exchange and flow for national, regional and cross border healthcare. Terminology services as common components are key towards healthcare information exchange in the context of quality of care.		
Rationale (Why)	It is important to consider the implementation of a terminological ecosystem in the context of an overall semantic interoperability strategy. There are many complementary elements of an adoption strategy that need to be taken forward at the same time in order to optimise the use of the terminology system and to maximise the benefits from it. This includes determining the priority drivers for advancing semantic interoperability within health care. It is also important to consider whether these drivers are entirely within the border of a single national health system, or whether there are particular areas of Member State co-operation (bilaterally, or at a European scale) that can influence and support the adoption strategy.		
Relevance to Cross Border Healthcare Roadmap	Cross border use cases include not only the support of cross-border patient care but also the sharing and comparing of benchmarks and quality metrics and patient safety intelligence (adverse event reporting, pharmacovigilance, pharmaco-epidemiology, outbreak control).		
Cross Border	Information exchange for the patient		✓
Relevance	Information exchange for public heal	✓	
	Citizens (as consumers of health services)		Indirectly
Benefits Perspective	Workforce (in the delivery and administration of health services)		Directly
	eHealth Market (where eHealth solutions and services are traded)		Directly
	Health System (where care is delivered and cost, quality, and access deci-sions are made)		Directly
Relation to the ReEIF	Legal and Regulatory (legislation and regulations) Policy (collaboration agreements) Care Process (processes and workflow) Information (data structures, terminologies) Application (Integration and exchange of medical data) IT Infrastructure (communication and network protocols)		✓ ✓ ✓
Proposed Actions	Collective Level – eHN Decisions	Define and adopt an eHeal semantic strategy	th and derived
	Member State Level Align eHealth and semantic s it will be Use case based		e strategy. Typically
	EU Commission Level	Adopt the strategy	
Recommendation Priority	High Medium Low		✓
	LOW	T 11 0 D	mendation 7 table

Table 9 Recommendation 7 table

Recommendation Title	Recommendation 8: Provide open access tools and testing data for deployment of standards sets - Shaping the way to Certification		
Scope (What)	Promote the adoption of testing tools and certification processes across Europe		
Rationale (Why)	A series of EU project such as GITB, HITCH, Antilope and EuroCAS are proposing specific guidelines for testing and certification of eHealth Product in Europe based on international standards (IS017025, ISO 17065) to pave the way towards a Single European Digital Single Market. On member state level, there are in some cases even more advanced and operational testing and certification arrangements which must be integrated by any new proposed testing strategies.		
Relevance to Cross Border Healthcare Roadmap	eHealthDSI has adopted a precise testing strategy based on international standards and integration profiles as defined in EU project epSOS.		
Cross Border	Information exchange for the patient - citizen		✓
Relevance	Information exchange for public	√	
Benefits Perspective	Citizens (as consumers of health services) Workforce (in the delivery and administration of health services) eHealth Market (where eHealth solutions and services are traded) Health System (where care is delivered and cost, quality, and access deci-sions are made)		Indirectly Indirectly Directly Directly
Relation to the ReEIF	Legal and Regulatory (legislation and regulations) Policy (collaboration agreements) Care Process (processes and workflow) Information (data structures, terminologies) Application (Integration and exchange of medical data) IT Infrastructure (communication and network protocols)		✓ ✓ ✓ ✓
Proposed Actions	Collective Level – eHN Decisions Have an in depth discussion testing to certification – Requon testing and certification from the Member State Level Adopt eHealthDSI testing struse cases EU Commission Level Adopt eHealthDSI testing struse cases		equest a policy paper from JAseHN strategy for national
Recommendation Priority	High Medium Low		✓

Table 10 Recommendation 8 table

Recommendation Title	Recommendation 9: Think about data portability to future ehealth service related to mhealth and cloud computing in healthcare		
Scope (What)	Prepare to anticipate the future adoption of tools and methodologies to allow data portability across healthcare solutions independently of technological developments, in order to comply with new EU regulations (NIS, GDPR, IDMP, etc)		
Rationale (Why)	ICT is embedded into healthcare. As such new ICT developments need to be assessed on time for adoption into healthcare applications in a fashion that enables interoperability, network security and data portability (mandatory requirement of the GDPR). The goal would be to enforce regulatory actions the enable patient data flow for cross border healthcare.		
Relevance to Cross Border Healthcare Roadmap	eHealthDSI is proposing an interoperability architecture that decouples healthcare data repositories from healthcare procedures based on international standards. Upcoming mhealth solutions need to follow this architecture to reduce and minimise the data silo effect as proposed for example in EU PCP Decipher and other similar projects.		
Cross Border	Information exchange for the patient - citizen		✓
Relevance	Information exchange for public health and secondary use		✓
Benefits Perspective	Citizens (as consumers of health services) Workforce (in the delivery and administration of health services) eHealth Market (where eHealth solutions and services are traded) Health System (where care is delivered and cost, quality, and access deci-sions are made)		Directly Indirectly Directly Directly
Relation to the ReEIF	Legal and Regulatory (legislation and regulations) Policy (collaboration agreements) Care Process (processes and workflow) Information (data structures, terminologies) Application (Integration and exchange of medical data) IT Infrastructure (communication and network protocols)		✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓
Proposed Actions	Collective Level – eHN Decisions Member State Level	documents Assess current and future National / Regional tate Level Health IT systems in the context of new EU regulations Assess current and future eHDSI core	
	services in the context of new EU regulations EU Commission Level Propose a standards an technical specification checkist for interoperability in all new eHealth R&D projects		
Recommendation	High Medium		
Priority	Low		✓
		Table 11 Dee	

Table 11 Recommendation 9 table

Recommendation Title	Recommendation 10: Build a stable governance model for Interoperability		
Scope (What)	Define an interoperability governance model that include all necessary stakeholders.		
Rationale (Why)	Interoperability and standards adoption in e-health is a constant process that needs a stable governance model including prioritizing use cases, selecting open interoperability architecture, defining interoperability specifications and terminology sets, define healthcare information exchange policies and adopt testing tools. All relevant stakeholders need to be involved in the governance model.		
Relevance to Cross Border Healthcare Roadmap	eHealthDSI has incorporated specific governance to enable cross border healthcare (eHMSEG, eHOMB, etc)		
Cross Border	Information exchange for the patient - citizen		✓
Relevance	Information exchange for public health and secondary use		
Benefits Perspective	Citizens (as consumers of health services)		Indirectly
	Workforce (in the delivery and administration of health services)		Indirectly
	eHealth Market (where eHealth solutions and services are traded)		Indirectly
	Health System (where care is delivered and cost, quality, and access deci-sions are made)		Directly
	Legal and Regulatory (legislation and regulations)		√
	Policy (collaboration agreements)		√
Relation to the	Care Process (processes and workflow)		V
ReEIF	Information (data structures, terminologies) Application (Integration and exchange of medical data)		▼
	IT Infrastructure (communication and network protocols)		<i>,</i> ✓
Proposed Actions	Collective Level – eHN Decisions	Request from next Joint Action 2018-2020 to establish a Interoperability Task force of experts at a cross border healthcare level and define an acceptable custodian	
	Member State Level	Establish an Interoperability Task force of experts at a national level	
	EU Commission Level Establish an Interoperability Task force for the eHealthDSI		
Recommendation	High		
Priority	Medium ✓		
	Low	W11 40 B	ommandation 10 table

Table 12 Recommendation 10 table

5. Conclusions and Takeaways

This document proposes a series of recommendations for adoption that would enable to move forward in the domain of the adoption of standards and resulting technical specification (i.e. integration profiles) to promote seamless integration of systems that would enable secure and transparent cross border healthcare scenarios.

Task 5.4 reviewed existing and ongoing projects and initiatives in the European Union that are funded by the EU and promote standards and interoperability at a European level. In order to provide valuable recommendations that would make sense in practical terms, actions are proposed a three levels: the eHealth Network Level (Policy), the member state level (awareness and alignment) and the European Commission (awareness and alignment of current and future EU funded activities).

This deliverable is linked to D5.4.3.1 which provide a more extensive mapping and descriptions of activities. Either of substantial importance at an EU level or currently ongoing and affecting future policy documents and decision making. At the eHN Level some proposed actions are proposed as the result of the adoption of the recommendations proposed in this document. Those in summary are:

- 1. Establish a single point of information concerning basic reference material on standards and technical specifications for interoperablity so that member states and other stakeholders can have a holistic overview of the important documentation
- 2. Reinforce the ReEIF use across member states (i.e. prerequisite for cross border healthcare)
- 3. Align eHN adopted material with the ReEIF
- 4. Propose the use of coherent and harmonised clinical and other standardised guidelines across Europe to enable better healthcare information exchange
- 5. Agree to have an in depth discussion on Health and care information modelling until 2020
- 6. Evaluate the existing MSP approved interoperability specifications to create and adopt a list of agreed standard sets until 2020
- 7. Agree to further support the establishment of an SDO/NCC (national competence centers) collaboration initiative, propose that SDO/NCC collaboration adopts the CGA methodology
- 8. Promote education on Standards
- 9. Define and adopt an eHealth and derived semantic strategy
- 10. Have an in depth discussion to move from testing to certification Request a policy paper on testing and certification from JAseHN
- 11. Include EU Regulation related to interoperability requirements in future eHN documents
- 12. Establish a Permanent Interoperability Task Force of experts at a cross border healthcare level under eHOMB

Those actions if adopted will provide a framework for the adoption of standards and technical specifications for cross border healthcare in the years to come. In order to achieve this a coordination work program that will describe in details who need to perform the needed actions at the eHN, MS and EC levels.