XpanDH

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

D5.2 – Interoperability Enabler Report

WP5 – Growing a pan European XpanDH Ecosystem

28.06.2024

i-HD, Iscte, HL-7, EMP, ARIA, IHE-EUR, EDHA, ASUFC

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What did this document aim to achieve?	This document reports on the activities performed to collect the knowledge needed to understand what is stopping today the wide adoption of the Format by industry and MS at all levels of health care actors and in particular, - What are representative use cases, that leverage the EEHRxF - How have interoperability challenges been or are being tackled. - What barriers in using the Format exist - What needs to be further done
Present the main methodological approaches in bullet point format	The methodological approach has employed two main tools for information collection: Consultations and a Survey. It has been further complimented through desk top research.
What were the main findings or take-away messages? What implications does it have for the XpanDH project?	While the EEHRxF provides a framework for promoting interoperability of EHRs within the EU, its widespread adoption and usage may still be a work in progress, with varying levels of implementation across different regions and healthcare settings. Its adoption and implementation depend on various factors, including national healthcare policies, regulatory requirements, technical infrastructure, and interoperability initiatives within individual EU member states. A number of Recommendations and Calls to Action on accelerating progress will be found in chapter 4.
Which project stakeholder group would benefit the most from the document and why?	**Healthcare Professional** |
	International Adherence Network/Initiative | The deliverable considers current challenges and factors enabling interoperability and makes recommendations for bottom-up actions to be considered by EEHRxF stakeholders
	Investors and Funding |
	Patient Organization | The deliverable considers current challenges and factors enabling interoperability and makes recommendations for bottom-up actions to be considered by EEHRxF stakeholders
	Patient/Caregiver |

	Pharma (Marketing&Sales/Medical Dept./R&D)	
	Public Authority or Policymaker	The deliverable considers current challenges and factors enabling interoperability and makes recommendations for top-down actions to be considered by MS and the European Commission
	Regulatory body	
	Standardization Body/ Open-Source Network Researcher/Academic	The deliverable considers current challenges and factors enabling interoperability and makes recommendations for bottom-up actions to be considered by EEHRxF stakeholders
	Statutory Health Insurance Company	
	Technology & Service Provider	The deliverable considers current challenges and factors enabling interoperability and makes recommendations for bottom-up actions to be considered by EEHRxF stakeholders
	Other	
List any relevant organizations or social media accounts for wider visibility		

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List of abbreviations

Acronym	Description
CEF	Connecting Europe Facility
EEHRxF	European electronic health record exchange format
EHDS	European Health Data Space
eHDSI	eHealth Digital Service Infrastructure
EHR	Electronic Health Record
HDAB	Health Data Access Body
ICT	Information and communication technology
LSP	Large Scale Pilot

Executive summary

The EEHRxF is a key building block for the EHDS. The Regulation is placing the Format in a pivotal position, within the overarching objective to support data portability rights, empower the patients and improve health data outcomes. The use of the Format is expected to also streamline health care processes and enable more efficient and effective care delivery. While the primary objective is to enable data sharing for improving the efficiency and continuity of care, it will also support secondary use of data hence fostering innovation.

Experience, however, shows that adoption and uptake by the industry players and innovation projects has been slow. With the EHDS Regulation, now a reality, it is imperative that adoption and uptake of the Format is accelerated. This document reports on the activities performed to collect the knowledge needed to understand what is stopping today the wide adoption of the Format by industry and MS at all levels of health care actors and in particular,

- What are representative interoperability use cases, tacked today by projects and other innovation initiatives that leverage or could leverage on the EEHRxF
- How have interoperability challenges been or are being tackled.
- What barriers in using the Format exist
- What is missing in order for the Format to be used in the implementation of these use cases.

The methodological approach has employed two main tools for information collection: Consultations and a Survey. The former have been planned and executed over the first half of the Project and has focused mainly on digital health research and innovation activities where the highest level of awareness and adoption would be expected. It has been further complimented through desk research.

The latter has been designed as a general, high-level survey aiming to validate and compliment the findings of the consultations through reaching out to a much larger and diverse audience. It has been prepared on the second half of the project and it is envisaged to be an on-going information collection tool.

Our main findings indicate that -while the EEHRxF framework provides a common format and guidelines for structuring EHR data - its adoption and implementation depend on various factors, including national healthcare policies, regulatory requirements, technical infrastructure, and interoperability initiatives within individual EU member states. Some countries may have made progress in aligning their EHR systems with EEHRxF standards, while others may still be in the process of adoption or may have chosen alternative interoperability frameworks.

Therefore, while the EEHRxF provides a framework for promoting interoperability of EHRs within the EU, its widespread adoption and usage may still be a work in progress, with varying levels of implementation across different regions and healthcare settings. A number of Recommendations and Calls to Action on accelerating progress will be found in chapter 4

1. Introduction

T5.2. is nested within WP5 with the aim to build on T5.1 in order to strengthen the interoperability business cases of EEHRxF in general and more specifically those that are demonstrated in the XpanDH adoption domains and bubbles. It is concerned with collecting and analysing the drivers and potential benefits to different stakeholders and initiatives from adopting and widely using the European Electronic Health Record exchange format. It pursues this through analysing drivers of interoperability success and eliciting related requirements for health care providers and information service providers as well as through developing the understanding for market and user needs in each adoption domain. Based on the enablers elicited before, T5.2 explores how to best capture innovation value from interoperability and develops an understanding on the investment and change needed to enhance adoption and reap these benefits.

The EEHRxF is a key building block for the EHDS. The Regulation is placing the Format in a pivotal position, within the overarching objective to support data portability rights, empower the patients and improve health data outcomes. The use of the Format is expected to also streamline health care processes and enable more efficient and effective care delivery. While the primary objective is to enable data sharing for improving the efficiency and continuity of care, it will also support secondary use of data hence fostering innovation.

The Format has built on the learnings from the epSOS LSP (2008-2012) and has taken the form of implementable specifications, already since 2019, serving primarily cross border sharing of -initially- patient summaries and ePrescriptions by addressing incompatible format issues. It is therefore a reality, at least when it comes to cross border digital services, rather than a goal to be reached. Notwithstanding the fact that the EEHRxF defined in Article 6 of the Regulation needs to be further defined and published in the form of implementable technical specifications, it is clear that it will include

- datasets containing electronic health data and defining structures for the content representation of clinical content and other parts of the electronic health record;
- coding systems and values to be used in datasets containing electronic health data and technical specifications for the exchange of electronic health data, including its content representation, standards and profiles.

The EEHRxF is not a one-time off exercise. It is a dynamic initiative, undergoing several stages of development- innovation/experimentation, formalization and infrastructure deployment, and continuous amendments to ensure the Format remains relevant and requires wide stakeholder collaboration. Despite the fact that additional adoption domains have been added since then and the concept and methodologies to deliver such extensions have been proven in practice, it still has a limited scope, covering a small fraction of clinical data sharing use cases.

Experience shows that adoption and uptake by the industry players and innovation projects has been slow. With EHDS Regulation, now a reality, the new EHR interoperability landscape which leverages on the European EHR exchange Format (EEHRxF) is likely to present the digital health ecosystem stakeholders with new and complex challenges. While the Implementing Acts defining such implementable technical specifications are expected in 2026, adoption and preparation based on what is in place in the form of eHealth Network guidelines, MyHealth@EU interoperability assets and the ISO International Patient Summary standard needs to be now accelerated.

This deliverable focuses on the challenge of understanding the most influential factors that would help accelerate uptake and adoption. More specifically, the work undertaken under this task has been to elicit answers to the following general questions:

- What are representative interoperability use cases, tacked today by EU projects and other innovation initiatives that leverage or could leverage on the EEHRxF
- How have interoperability challenges been or are being tackled
- What barriers in using the Format exist
- What is missing in order for the Format to be used in the implementation of these use cases.

Chapter 2 describes the methodological approach, involving a consultation track and a survey track. Chapter 3 summarises the activities undertaken, the information collected and the main findings and take aways. Based on this, chapter 4 presents a set of recommendations and Calls to Actions addressing the EC, the MS and the stakeholder community.

2. Methodological Approach

The methodological approach has implemented two main tools for information collection: Consultations and a Survey. The former have been planned and executed over the first half of the Project and has focused mainly on digital health research and innovation activities where the highest level of awareness and adoption would be expected. It has been further complimented through desk research.
The latter has been designed as a general, high-level survey aiming to validate and compliment the findings of the consultations through reaching out to a much larger and diverse audience. It has been prepared on the second half of the project and it is envisaged to be an on-going information collection. This report has considered information collection through the survey until its submission; however, the information collection will continue to inform the project activities till the end of the project.

2.1. Consultations

The starting point has been to examine the Adoption Domains nominated by XpanDH itself:

laboratory reports between healthcare organisations and to the patient, and

summary discharge notes between organisations, to the patient and bidirectional exchange with the National Authority.

These provide the initial use cases and potential benefits. However, there are many other European projects, mostly funded by the European Commission, which are developing interoperability assets and demonstrating the value of interoperability with use cases that span a diversity of use cases for adopting the EEHRxF, adding to the Adoption Domains of XpanDH.

To gain an overview of these European projects and leverage on the work being done, empirica screened and collected over 70 European projects working with or on health data in early summer of 2023 as part of T5.1 to prepare for the EEHRxF summit. This resulted in an inventory of these projects and contact points.

We used this inventory and we initially classified these projects in three groups: the core group of projects that contribute directly to the development of the EEHRxF; the group of projects that are using or are potentially using the Format into the use

cases, while building additional interoperability assets to meet needs not covered by the Format and a third group of projects involving those that have an indirect relevance to the Format.

We reached out to these EU projects during August 2023 and invited project representatives from the first two groups into a series of webinars and teleconferences in order to present and explain the EEHRxF and to learn from them their use cases and the areas of interoperability on which they are focusing.

More specifically, we organised in total six meetings of alignment with the projects. We engaged in total with 79 projects. The consultations involved a brief presentation of the Format and the context under which XpanDH was running these consultations, followed by presentation of the projects' main interoperability use cases, challenges and key expected outcomes as well as how the projects perceived their use of and their own potential contribution to the Format. Table 1 summarises the high relevance projects and their mapping in current data categories.

TABLE 1 – PROJECTS AND DATA CATEGORIES ALIGNMENT

Project	eP/eD	PS	Lab.	Disc.	Ima.	Tele.	Exchange
AIDAVA		x	x		x		
eCREAM							x
Gravitate Health	X						
UNICOM	X						
Procure4Health						x	
GenoMed4ALL		x	x		x		
CHAIMELEON					x		
POTENTIAL	X						
SMILE						x	
PATHeD		x					
Xt-EHR	X	x	x	x	x		
xShare	X	x	x	x	x		

A small number of these projects were invited to the **Ghent consultation**.

Aim for the Ghent session has been to kick off a discussion on enlarging the EEHRxF ecosystem in preparation of the December Expert Summit consultation.

The **focus** was on the interoperability challenge and how selected EC projects are leveraging interoperability of core data sets to deliver better continuity of care for

patients, value to health systems, and grow data sets for reuse. Centre stage was the European Electronic Health Record Exchange Format (EEHRxF).

The **main discussion topic** was on how we could scale up the EEHRxF as a major implementation enabler for scaling up the EHDS, through scaling up its ecosystem.

IMMEDIATE TAKEAWAYS

Pool the Expertise at EU level for delivering our EU common good(s); create a knowledge resource that spans across a broad range of knowledge both in system thinking and in subject matter expertise;

Improve **the awareness and the understanding** of the Format itself and the EHDS values, principles, environment and ecosystem;

Define value for Xchangeable data for patients that can result from implementation of the IPS and other EEHRxF data categories;

Integrate the direct patient perspective, into designing for value for patients, exemplified in the xShare button[1];

Encourage and support Communities of Doers, taking a broad view across the full implementation pathway from policy to care and social innovation;

Intensify engagement with industry, national DH **implementation projects** and other EEHRxF implementation initiatives;

Think beyond the EU

A second session of relevance to the acceptance and adoption of the EEHRxF, in the Ghent Conference was the "Patients in the driving seat session"[2], nested within the broader topic of Building Trust in Health Data. **Aim** of this session has been to

[1] A concept developed in the xShare Project, where a patient should be able to share data with a selected party at the click of a button

[2] [2] I~HD Annual Conference AC2023: Building Trust in Health Data, Nov.29-Dec 1st 2023, Ghent Belgium chaired by **Zoi Kolitsi** and **Chistoph Maes**; Speakers: **Karlien Hollanders**, Belgian Federal Public Service Public Health; **Birgit Morlion** Vrije Universiteit Brussel Faculty of Medicine and Pharmacy; **Petra Hoogendoorn**, Leiden University Medical Centre; **Hein Raat**, Erasmus Medical Center Rotterdam Department of Public Health; **Valentina Strammiello**, European Patients' Forum; **Beñat Zubeltzu Sese**, Osakidetza; **Jan Vekemans**, 1patient1record4Belgium; **Carlos Altuna Faus**, European Heart Network; **Dr. Tanja Stamm**, Centre for Medical Data Science, Medical University of Vienna and Ludwig Boltzmann Institute for Arthritis and Rehabilitation, Vienna, Austria

promote DH uptake through leveraging on patient insights and existing and emerging enablers of immersive patient engagement.

The **focus** has been on current successful practices providing trust as well as on the enabling conditions for scaling up what has today shown to provide value and benefit to patients, citizens and society.

Topics for discussion included: What does digital health bring to patients today in terms of innovation and value? What are the game changers introducing the change in the relationship between the patient and the healthcare providers? What is the enabling role of the patient as a curator of its health data and more and more in charge of his/her health prevention, healthcare and treatment?

IMMEDIATE TAKEAWAYS

Patients and their carers are increasingly playing a key role as active participants of data sharing culture change as well as active citizens in the shaping of digital health policies, rethinking health system design for true patient value;

There is untapped potential from **patients as agents of health data value generation** across the continuum from data capture all the way to data curation and quality improvement of their personal health data;

There is furthermore a recognition that such kind of **patient engagement** will improve the **quality of their care** and will simultaneously create conditions for reusability of **quality data for research**;

Recognise the increasingly important role of **Patient Consultants**, i.e., individuals that have become subject matter experts in the course of their health care journey and have system thinking skills in improving the understanding of patient perspectives and guiding the design of DH solutions and services;

Leverage on existing and emerging **enabling solutions and technologies** to support **patient lead communities of doers and initiatives**;

Optimise efficiency of such patient engagement e.g. through automation of processes that do not necessarily require human intervention;

Support **patient choices** of digital health services, **based on Trust conveyed through EU wide, trusted quality Labelling of Apps** and though equipping patients through **targeted information and digital health literacy** interventions.

These conference streams acted as preparatory sessions for the **EEHRxF Expert** Summit, which was held on 12 December 2023 and has provided Task 5.2 with a rich

pool of inputs. The event's detailed minutes have been a valuable source for mining several of the findings reported in the next chapter.

Subsequent work in early 2024 focused on analysing the messages from these two events and in particular the success factors, and barriers to be overcome, to achieve these benefits.

2.2. Learnings from other sources

Besides the current projects reviewed and consulted, we have also leveraged on the contribution of **VALUeHealth**, a project that run between 2015-2017 and had looked at sustainability of what was then the CEF eHDSI. As part of its workplan, the project considered how what was then the technical specifications for ***Patient Summary and e-Prescription cross border eHealth services*** could be extended in a sustainable way and had made recommendations on an EU level entity that would assume responsibility of sustainable operations and scale up. For the purposes of creating a patient centered vision, the project had elaborated Iria's user story, which has been updated to the context of EEHRxF, it is summarised here and included in its extended version in Annex 2. It is brought here as a very powerful illustrator of how the EEHRxF can beneficially impact the lives of citizens and patients, through its wide uptake by and co-ordination within a multistakeholder community that can create synergies and accelerate action.

Iria's story at a glance

Iria Acosta is a financial analyst of 33 years old. She lives in Portugal and for the past 3 weeks, has been working on a short-term assignment for the Portuguese branch of an international bank located in Helsinki. In order to stay fit, Iria enjoys exercising.

Iria has Type 1 diabetes and was diagnosed at the age of 10. She has started using a mobile application to help her manage her diabetes.

Iria experiences an emergency situation while jogging out in cold weather and having left her medication behind.

The smartphone has immediately and automatically transmitted Iria's glycaemia values to her health center, which also provides real-time access to her patient summary contained in her electronic health record (EHR) based in Portugal.

A FI-based on duty emergency physician at a Helsinki clinic near to Iria's location is immediately contacted by the OCC in Portugal. Iria's current glycaemia values are then assessed in relation to her diabetes medical summary, prescriptions and recent care/monitoring data that are on file (all of them are based in Portugal), as well as with the latest European diabetes treatment guidelines.

As Iria is too confused to remember her insulin regimen, thanks to the real-time consultation system enabled by her EHR, the FI physician is able to confirm her last insulin regimen, thus ensuring safe prescribing in accordance with her medication profile in Portugal. The doctor is also able to place an e-referral with Iria's endocrinologist in Portugal asking him to reassess Iria's insulin dosage upon on return to Portugal the following week, in order to reflect her more active life style. Iria is sent home, perfectly fine, an hour later.

Later, back in Portugal, upon filling out Iria's new prescription, her pharmacist checks that both the new insulin dosage and administration schedule are recorded in the patient mobile e-diary that Iria uses to record her daily activities and health status, so that she can also get auto-reminders to refill her prescription. Having provided secure access rights to share her data with her pharmacist, Iria knows that these measures will also contribute to improving her health outcomes.

Another source consulted is the **study on Capacity Building for the Primary Use of Health Data (HADEA/2022/OP/0006), also known as CapacityHD**, which is currently in progress and involves initially the elaboration of a validated Catalogue listing the Capacities that need to be in place in MS for moving forward the Digital

Health agenda in what concerns the primary use of health data for care purposes. This is followed up by MS exchanges on their best practices though study visits, on-line twinning sessions and where needed Masterclasses, including one on the EEHRxF. A very relevant twinning in the context of XpanDH is the one on Digital Health Governance and Strategy, involving initially Norway and Estonia and expanding now to several more MS, including France, the Netherlands, Greece and Hungary.

Early findings from the twinnings indicate that MS that are advancing well with the implementation of their digital health strategies have also compartmentalised their national interoperability activities by separating the demand for specifications supporting their digital health transformation policy activities from the supply of the specifications. An extensive treatment of this aspect is provided in D6.1.

2.3. Survey: How is the EEHRxF impacting your current digital health interoperability use cases?

In previous consultations we explored how selected EC projects are leveraging interoperability of core data sets to deliver better continuity of care for patients, value to health systems, and grow data sets for reuse. Some projects are already using the EEHRxF, others plan to use it while some are working with supplementary data sets for specific use cases.

The purpose of this Survey (Annex I), is to complement findings from consultations with projects, by reaching out to a wide audience representing a wide spectrum of stakeholders with the intension to understand the level of penetration of the EEHRxF as well as how the Format is expected to impact current interoperability use cases, in terms of the most pursued benefits from its use in the short, medium and long term and what are the major barriers to using the EEHRxF today. This is meant to be a high-level survey with the ambition to attract a large volume of responses amongst the X-nets and beyond, in order to verify and further identify main issues and trends. It is not designed to capture details on the different use cases, which would provide richer and more detailed information, but would address a smaller and more EEHRxF savvy audience.

The first group of questions (1-5) aim to synthesize the profile of the responder and organisation of affiliation, the purpose being to correlate responses to specificities of the organisation. Question 6 aims to capture the range and diversity of use cases that have or are being implemented today, the data categories covered and the main beneficiaries addressed. Question 6 and 7 aim to capture basic information on the use cases. The following questions 8-11 focus on the level of awareness and current use of the format, while question 12 elicits information on possible interoperability

assets developed or being developed that could synergistically contribute to the scaling up of the Format.

3. Summary of findings and main takeaways from the consultations

Below we are summarising the main findings from the on-line consultations with projects as well as the two events organised in the end of 2023. They are organised around the following themes:

3.1. Who is working on the Format, on which basis and what scope?

For the purpose of identifying who is working on or with the Format and in what scope, empirica created a mapping of European projects, further described in D7.3. The project mapping heavily supported the invitation process for the EEHRxF Expert Summit which was held on 12th December 2023 in Brussels to ensure the key stakeholders of the ecosystem around the EEHRxF were present. An overview of the project mapping can be seen below.

While we investigated the relevance of over 75 projects and 25 networks (in terms of topic data categories, objectives and start/end dates, among others) we found only a few are directly working on the format and are contributing to it, namely, XpanDH, POTENTIAL, PATHeD and more recently xShare, which are providing inputs to the Joint Action Xt-EHR and through it to the EC and the eHealth Network. There are however several projects that are working on use cases of direct relevance to the EEHRxF. It is not clear that they are all leveraging on the Format in order to implement their use cases; they are however all aware of it and willing to explore these possibilities, if not already using the EEHRxF.

A few examples of such relevant use cases are provided below:

AIDAVA: AI powered Data Curation & Publishing Virtual Assistant are generating a personal health record which is curated, with maximization of automation in "cleaning" and publishing of unstructured and structured, heterogeneous data around breast cancer patient registries and longitudinal health records for cardio-vascular patients, in three languages. AIDAVA's mechanisms are based on a consistent ontology.

eCREAM: enabling Clinical Research in Emergency and Acute care Medicine through automated data extraction will directly extract research data from the

Emergency Departments' electronic health records (EHRs), avoiding dedicated data collection for research

Gravitate–Health: Empowering and Equipping Europeans with health information for Active Personal Health Management and Adherence to Treatment leverages on an international patient expert board to focus on citizens' access to approved electronic product information (ePI) content, and offering a route for patients to access trustworthy, up-to-date information, starting with regulator-approved medicinal product information (e.g. package leaflet content) and EHR-IPS (International Patient Summary).

UNICOM: Up-scaling the global univocal identification of medicines focusing the implementation of the IDMP suite of standards and through this supporting effective pharmacovigilance as well as safe cross-border ePrescription/eDispensation and where safe dispensation may require reliable identification of substances in available products.

3.2. What are the perceived potential (interoperability) benefits of the EEHRxF?

For Patients: The expectation arising from the EHDS Regulation is of course that the Format will enable their portability rights. Beyond cross border interoperability, patients expect to have their portability rights enabled, and have access to own data which should be accurate and provided in an understandable fashion. Language is a challenge in cross border situation but also within a country. The Format is the minimum needed to tackle this problem.

For these expectations to culminate into reality, patients expect that the Format will stimulate a culture of effectively involving patients in the co-design of solutions and the Format itself should be designed together with patients, patient experts and representatives of Patient Organizations.

For healthcare professionals: The overarching expectation and one of the highest priorities is that the Format will contribute to more efficient EHRs made available, that have been co-designed also with healthcare professionals contributing to the vision of one patient one record.

The Format is also expected to contribute to EHRs that are more efficient, structured, relevant, validated, with fields easily identified.

Patient provided data can lead to better care, however it should not be part of the patient summary, but rather exist and be accessed in a separate section.

Similarly, health professionals expect that the Format will stimulate a culture of effectively involving them in the co-design of solutions and the Format itself should be designed together with health professionals.

The use and application of the Format will ensure protection from litigation risk which must be properly addressed.

For Health systems: the Format is expected to address the need for unified clinical documentation. Through enabling interoperability based on a scalable EEHRxF Europe takes a large step - harmonization and convergence.

3.3. What are the unmet expectations?

In a nutshell, a **single EHR is a goal far from being achieved**. Reasons for these were presented during the Summit. EHRs today are slow, they do not facilitate easy flow of information and they are not interoperable. Different systems need to be consulted, from different specialties, diagnosis, management – a health professional is expected to manage with 9-11 different solutions during a 10-minute consultation. In some countries (e.g., Sweden) only the read function is available, hence health data cannot be easily findable nor sorted. In other countries (e.g., Slovenia) a central registry of patients is useful, however health data in provided in pdf format[3].

The current EEHRxF cannot deliver much of its potential value. The EEHRxF provides a spectrum of unreached opportunity: for patient empowerment, providing for the ability to learn from data, for learning Health Systems, to mention a few. Patients can learn from their data. Research, drug development and medical knowledge development could be supported.

Data Quality remains an important outstanding issue. Inside EHR systems physicians need to enter and work with trusted data. There is significant variation across MS in terms of data quality and completeness of records. As a result, the quality of data that is going cross-border is very different from the national level one. Data quality in the IPS is very uneven. IPS is a container, but information is not mandated sufficiently.

The EEHRxF covers **a limited scope in terms of data categories** compared to what is needed in clinical practice.

[3] Sited by the CPME intervention during the Expert summt

Far from delivering on the one patient one record vision

Falls short of delivering much of its potential value

Data Quality remains an important outstanding issue

Limited scope in terms of clinical use case coverage

3.4. What is preventing us from delivering the perceived benefits of the Format?

Lack of Clarity. There is a deficit of clarity at different levels.

- At the societal level, patients and citizens need to understand how this Format is indeed going to help them. The Format itself needs to be easier understandable for patients especially when it comes to interpreting structured info.
- The benefits of standardised data are not broadly known and understood
- The complexity of the technical aspects of interoperability often proliferates into the strategy level, at times resulting in a standstill or unclear policies, strategies and solutions.

Complex IT systems (several layers of software) and insufficient and overloaded technical teams.

Semantic interoperability is an outstanding challenge. It is unclear how the EEHRxF will scale up to the number and heterogeneity of data sources that are relevant to the EHREHR, the projected growth of information, and for making data re-usable for research and innovation purposes.

Limited clinical coverage in combination with **slow implementation of new information data categories/extensions** of the Format is discouraging adoption and uptake.

Immature data quality strategies combined with the need to integrate data from several and diverse data sources with different quality management practices.

Slow and asynchronous implementation by MS. The experience with myHEalth@EU shows that no country can have the full 5-section summary and no country can transfer all content elements. At the same time the Format is undergoing continuous evolution. The EEHRxF related eHEalth Network Guidelines are currently in maintenance phase. Lab and imaging data are being added. There is different pace

of digital health development across MS. Legacy systems and legacy players are hard to keep up with the change.

Implementation support is inadequate, and especially small organisations struggle with the implementation.

User centric design of solutions and digital health services needs to be improved, to increase adoption and minimize resistance by users. Clinicians are highly impacted by administrative burden (estimated 40% of time allocated to administrative tasks).

Industry is yet to provide mature technologies for supporting the implementation of the Format (NLP, AI assisted coding etc).

High complexity and lack of clarity

Slow and effort demanding process of development with Constant evolution of the Format and different pace of updating national EHR systems

Data Quality Heterogeneity across MS

Insufficient implementation support esp. for smaller organisations

Lack of adoption support, especially in small organisations

Immature technology to support implementation of Format

3.5. How are the EHDS and EEHRxF expected to impact the unmet expectations?

The EHDS Regulation places special focus on EHR systems and sets out clear legal requirements for manufacturers of EHR systems and systems connected and exchanging data with them. It also sets out obligations for MS for monitoring market compliance to the common specifications. As such it will place an increased focus on EHR systems by MS.

The latter are envisaged to be implementable specs with high detail with provisions for both structured and unstructured data. Common specifications are to be specified in Delegated Acts, which will encapsulate the consensus of the ecosystem on priority data areas. It will therefore remove much of the current complexity and

will create clarity on technical specifications and conformance criteria for manufacturers to meet.

Implementation of the Format to ascertain predefined scope that will grow with time.

4. Calls to action to enable better health systems adoption of, and benefit from, the EEHRxF

This section forms a proposed response to the challenges outlined in section 3.4. and draws from the consultations with the many EC projects and other initiatives summarised in the previous sections. It presents recommendations, framed as calls to action, to help maximise the value of the EEHRxF for the spectrum of primary and secondary uses to be enabled through the EHDS Regulation. These Calls to Action will be further validated over the remaining course of the project, including during the second summit and may be re-issued upon request.

The middle column in the table below provides recommendations that are primarily the top-down actions that could be taken forward by the EC and by Member States. The right column provides complementary bottom-up actions that could be taken by other stakeholders, often in parallel without needing to wait for the corresponding top-down actions to come into effect.

These actions are mostly in addition to the currently anticipated secondary legislation (implementing acts) that are foreseen in the Regulation.

Challenge 1: Addressing high complexity and Lack of Clarity

TABLE 2 – SUPPORT AWARENESS CAMPAIGNS AND CITIZENS LITERACY PROGRAMMES

EC supports campaigns to improve the awareness and the understanding of the Format itself and the EHDS values, principles, environment and ecosystem and to explain the benefits of	**MS** support and promote such campaigns, and collaborate with patient organisations and other stakeholders to develop and deliver literacy programs for empowering patients and citizens to	**Learned societies and patient organisations** will need to collaborate on delivering appropriate data literacy programmes

standardised data and the role of the Format bringing these benefits to the patients **EC** Supports EU collaboration in designing and delivering patient and citizen literacy programmes	be on the driving seat of their health, through access to and interpretation of their health data	

Challenge 2: Slow and effort demanding process of development, constant evolution

TABLE 3 – SUPPORT THE NECESSARY STANDARDS DEVELOPMENT, DEPLOYMENT AND USE

EC: co-ordinates and provides support, including financial support, for SDO actions to generate the relevant EEHRxF standards, specifications, resources, guides and educational materials. **EC**: supports SDOs and other informatics agencies to develop ontology resources representing the EEHRxF clinical content data categories, as part of the common technical specifications, defining the concepts clearly first for primary use.	**MS**: adopt EEHRxF standards within national policies; finance language translations of semantic standards where necessary; and of guidance materials.	**SDOs**: prioritise the development of EEHRxF standards, specifications, resources and develop guides and educational materials for developers and end users, align across SDOs to smooth end user adoption.

TABLE 4 – ACCELERATE ADOPTION OF EHR SYSTEM UPGRADES

EC: intensifies engagement with industry on good practices and quality standards.	**MS**: incentivise the procurement and support the cost of migration, mostly as system upgrades, to EHDS-certified EHR systems.	**EHR system vendors**: rapidly enable the import and export of data via the EEHRxF, and to better store and process the EHR priority categories of data.
EC: ensures robust but practical assessment criteria for EHR system conformity testing, and alignment of certification across Europe		**EHR system vendors**: optimise user interfaces that encourage better data quality at the point of entry, promote user centric design to maximise data entry efficiency and accuracy and to reduce cognitive load in the use of EHR systems.

Challenge 3: Data Quality Heterogeneity across MS

TABLE 5 – PROMOTE GOOD PRACTICES IN THE QUALITY OF EHR PRIORITY DATA CATEGORIES

EC: supports European healthcare professional organisations and health data organisations to promote good quality data entry within EHR systems.	**MS**: support national healthcare professional organisations, health data organisations and healthcare providers to promote good quality data entry within EHR systems.	**HCP organisations, health data organisations**: develop good practices and educational resources to improve the quality of EHR priority data categories during data entry, and tools to measure data quality. **HCP organisations**: develop guidelines for health professionals to

		clarify accountability for using imported EHR data

Challenge 4: Insufficient implementation support esp. for smaller organisations

TABLE 6 – INVEST IN CAPACITY BUILDING ACROSS MEMBER STATES

EC: collates a categorised pool of expertise at EU level to share experiences and adoption practices, and strategies to overcome challenges.	**MS**: encourage and support communities of achievers, taking a broad view across the full implementation pathway from policy to care and social innovation **MS**: encourage and support communities of achievers, taking a broad view across the full implementation pathway from policy to care and social innovation	**Healthcare providers, clinical research organisations, EHR system and digital health solution developers**: start investing in the data and EHDS related skills in the workforce

TABLE 7 – ESTABLISH FUNDED ACTIONS THAT DEVELOP OR LEVERAGE ADDITIONAL CONTENT WITHIN AN EXTENDED EEHRXF

EC & MS: enlarge the scope of the EEHRxF to cover more stipulated needs by the Regulation proposal e.g. Article 23, with additional business cases leveraging on ePrescription, eDispensation. **EC & MS**: establish pathways for prioritising and developing data set extensions e.g. long-term condition supplements to the IPS, cater better for children's health, cover the data standardisation needs for personalised medicine and genetics e.g. in cancer and rare diseases.

EC & MS: maximise the patient value of the EEHRxF by incorporating the data elements needed for long term condition management, prevention and wellness, and accepting in the EHDS patient generated data beyond remote monitoring devices. **EC & MS**: maximise public health and research value through targeted data set extensions in collaboration with relevant stakeholders. **EC & MS**: establish pathways to capture relevant innovations and evidence from Horizontal Europe projects, e.g. from the Comprehensive Cancer Centres Network (CCCN)

Challenge 5: Lack of adoption support, especially in small organisations

TABLE 8 – TARGET FINANCIAL INCENTIVES

EC: defines, quantifies and collates evidence of value of exchangeable (priority) data for patients and health systems, including health economic value, that can result from implementation of the IPS and other EEHRxF data categories.	**MS**: incentivise adoption of EEHRxF capability (EHR system upgrades, wider data sharing practices), and incorporate non-financial incentives.	**Healthcare providers**: develop business plans that properly valorise the benefits of interoperable and shared EEHRxF data, as a contribution alongside reimbursement towards EHR system upgrade costs and staff training

TABLE 9 – ENCOURAGE THE PROVISION OF HIGH QUALITY EEHRXF COMPLIANT DATA SETS BY DATA HOLDERS

EC: promotes adoption of the data quality and utility label once developed, through open-source labelling tools and education for

data holders, HDABs and data users **EC & MS**: adopts specific industry-acceptable standards and safeguards for IP-protected and trade secret data, for Europe-wide adoption by Health Data Access Bodies (HDABs), to encourage its acceptable use **EC & MS**: agrees guidelines with relevant stakeholders for the protected time for publication and productisation by data holders before data set access becomes obligatory **EC & MS**: specifies data standards for EHR priority categories of data when they are made available as data sets for secondary use.	

TABLE 10 – STRENGTHEN PATIENT ENGAGEMENT AND EMPOWERMENT THROUGH THE EHDS AND EEHRXF

EC & MS: recognise the increasingly important role of Patient Experts/Consultants, with system thinking) in improving the understanding of patient perspectives and guiding the design of Digital Health solutions and services. **EC & MS**: leverage existing and emerging enabling solutions and technologies to support patient lead communities of doers and initiatives. **EC & MS**: optimise efficiency of patient engagement by giving recognition and support to patient organisations in combination and by incorporating Patient Experts in decision making **EC & MS**: supports patient informed decision choices of digital health services, both though improving population health and digital health literacy and quality labelling of patient facing digital health solutions.	**HCP organisations**: facilitate an appropriate trust amongst HCPs of patient generated data using certified apps and devices. **Patient organisations**: develop action plans, or adopt and localise action plans by their umbrella organisations, grow capacity and seek funding to improve the health, digital and data literacy of patient members.

TABLE 11 – ACCELERATE UPTAKE OF DIGITAL HEALTH INNOVATIONS

MS: adapts the regulatory and HTA data categories to encourage and enable early uptake of digital health innovations, with careful oversight, in parallel to the growth of the evidence of its effectiveness and health outcomes impact.
MS: enable reimbursement of transformed care pathways as well as the procurement of digital health solutions.
MS: invest at scale in digital and data literacy education for patients and the public.

Annex 1 – Survey: How is the EEHRxF impacting your current digital health interoperability use cases?

1. Your Name
2. Your Organisation
3. How would you best describe your organisation? When relevant, please indicate size of your organisation
   - Digital Health authority
   - Health care provider
   - Competence center
   - EHR manufacturer
   - DH innovator
   - Research Organization
   - Patient Organisation
   - Other (please define)

4. Please indicate size of your organisation as relevant (Please indicate the size where relevant for example, number of employees, number of beds, geographical coverage (international, national, regional, local), population served of customers or patients. Are you an SME, Large Corporate or Enterprise?)

5. Your Affiliation

6. Name of your Project or initiative

7. What are your interoperability use cases that leverage or could leverage the Exchange Format?
   - Short description of your use case
   - What areas of clinical / health data categories content are the focus?
   - User groups benefitting from achieving this interoperability:

- patients and their carers
- citizens
- health systems
- health professionals
- health care providers?
- EU industry
- researchers/innovators
- other
  - What benefits are being pursued per stakeholder segment?

8. Are you aware of the EEHRxF? Yes/No
   - If yes,
     - How well do you feel you understand the EEHRxF?
     - Through what sources were you informed about the EEHRxF?

- Have you explored the possible application of the Format in your interoperability use cases?
- Have you been using existing EEHRxF interoperability assets where available?

9. How have interoperability challenges been or are being tackled in your use cases? (multiple choice)
    - EEHRxF
    - Solutions reused from other standards and initiatives
    - Own solutions developed to address your specific challenges
    - Other?

10. What are the main barriers or limitations in using the Exchange Format and the available assets for your use case(s)? Are they related to (multiple choice)
    - Stakeholders do not have enough knowledge about the EEHRxF
    - The priority data categories are not relevant or sufficient to cover your clinical data categories use case
    - The needed interoperability assets are not available
    - You have not been able to receive sufficient technical implementation support
    - Cross-functional collaboration to implement the EEHRxF is challenging
    - Mapping from legacy systems and repositories to the EEHRxF is challenging
    - Other please explain

11. What gaps would need to be addressed to enable the Format to be fully implementable in your use case(s) in terms of (multiple choice)
    - Standards
    - Datasets
    - Ontologies
    - Coding systems and values
    - Technical specifications
    - Other please specify

12. If you are you are currently developing any such assets to address your interoperability challenges, please specify
    - Standards
    - Datasets
    - Ontologies (please specify)
    - Coding systems and values
    - Technical specifications

- Other please describe

Annex 2 - EEHRxF Value for Patients: Iria 's story[4]

Iria Acosta is a financial analyst of 33 years old. She lives in Portugal and for the past 3 weeks, has been working on a short-term assignment for the Portuguese branch of an international bank located in the Helsinki Financial District. She was promoted to a senior position in the past year and her job is quite stressful.

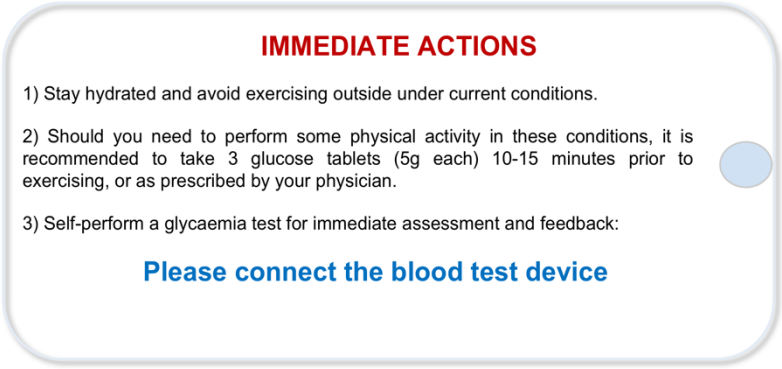
In order to stay fit, Iria enjoys exercising. She is a recreational tennis player, and after finishing work, Iria regularly goes jogging in a beautiful park located near her office. As a senior analyst, Iria is now attending an advanced training seminar on a new financial analytical system, organized at the headquarters of her bank in Helsinki.

Iria has Type 1 diabetes and was diagnosed at the age of 10. She normally takes two injections of insulin per day (she uses Insuman Comb 25, exact units per dose will vary). She has started using a mobile application to help her manage her diabetes. This app was recommended by her physician to empower her to self-manage her chronic condition, and to motivate her maintaining a healthy life style. She has also learned to eat healthily and is quite motivated, thanks to the self-management apps suite installed on her smartphone. Last year, Iria successfully quit smoking, and started jogging (15 minutes 2-3x/week after work). She typically takes one glucose tablet 15 minutes before jogging.

The mobile health solutions have empowered Iria to build her own health profile, and to share her self-monitoring health data (glycaemia levels, weight, etc.) with the health professionals involved in her care plan (endocrinologist, GP, pharmacist and nutritionist) through secured access rights. Iria also uses the personalised e-patient diary on her application which allows her to enter her fitness programme objectives and schedule (for automatic reminders), and to monitor her weight and her adherence to treatment. Iria monitors her glycaemia and regularly does blood tests thanks to a new "lab on a chip" small device connected to the earphone port of her smartphone. This device allows her to get health assessments in real time, to receive personalised alerts regarding potential risks for her health condition in relation to her clinical history, lifestyle, and environmental factors (e.g. exercise, diet, etc.). This feature includes recommended preventive measures based on European clinical guidelines for the management of diabetes. Thanks to her app, and to her healthy choices, Iria's diabetes condition is now managed well with only two injections of insulin per day. She has not experienced any hypo- or hyperglycaemia events in the past 7 months.

[4] This user story has been based on Iria's user story from the ValueHealth Project 2015-2017

Today, Iria is happy to finish her seminar at 4pm which will give her enough time to go jogging at the Festival Gardens Park near her bank's headquarters. After getting ready at her hotel, as she is walking to the park, she receives an alert on her smartphone generated by her diabetes app. Based on her personal health profile and glycaemia values recorded over the past twenty-four hours, she receives the following recommendation:



After checking in her pocket, Iria realizes that she has forgotten her glucose tablets at home. But because she had a healthy lunch at work and has been feeling so good recently, Iria trusts that she will be fine and sufficiently protected if she jogs for no more than 10 minutes. About seven minutes into her run, Iria starts feeling exhausted, and has to stop due to serious shortness of breath, a rapid heartbeat and hand tremors. She starts to have troubles with her vision and feels lightheaded. She then remembers that she can do a blood test using an application provided in the app suite installed on her smartphone. After puncturing her finger with the small device connected to her smartphone, the app displays her glycaemia level (0.45 g/l) and immediately sends her current values to the Living with Diabetes European mHealth (mobile health) platform for real time processing. Seconds later, an alarm rings at the Portugal-based corresponding operational coordination centre (OCC), which is staffed and opened 24 hours a day. The smartphone has immediately and automatically transmitted Iria's glycaemia values to the OCC, which also provides real-time access to her patient summary contained in her electronic health record (EHR) based in Portugal.

Because the self-management mHealth platform has detected that Iria's glycaemia levels are far below the defined thresholds (hence, the risk of a severe hypoglycaemia event is considered high), a FI-based on duty emergency physician at a Helsinki clinic near to Iria's location is immediately contacted by the OCC in Portugal. Iria's current glycaemia values are then assessed in relation to her diabetes

medical summary, prescriptions and recent care/monitoring data that are on file (all of them are based in Portugal), as well as with the latest European diabetes treatment guidelines. This enables the FI physician to make quick, safe and optimal care decisions in real time.

Iria then receives a short text message recommending her to take 3 glucose tablets (or drink 30cl of a fruit drink immediately), and to wait a few minutes for a Helsinki cab to pick her up at the entrance of the park, thanks to the automatic transmission of her GPS coordinates. As she is unstable and shaky, she asks another jogger to help her to the park entrance and to buy a fruit drink for her at the nearby kiosk. Five minutes later, the cab arrives at the park to drive Iria to the nearest emergency unit in Helsinki. On arrival, a couple of minutes later, Iria is examined by the emergency physician on duty. Point of care (POC) diagnostics confirm hypoglycaemia and Iria is then treated for her symptoms. As Iria is too confused to remember her insulin regimen, thanks to the real-time consultation system enabled by her EHR, the FI physician is able to confirm her last insulin regimen, thus ensuring safe prescribing in accordance with her medication profile in Portugal. The doctor is also able to place an *e*-referral with Iria's endocrinologist in Portugal asking him to reassess Iria's insulin dosage upon on return to Portugal the following week, in order to reflect her more active life style. Iria is sent home, perfectly fine, an hour later.

Later, back in Portugal, upon filling out Iria's new prescription, her pharmacist checks that both the new insulin dosage and administration schedule are recorded in the patient mobile *e*-diary that Iria uses to record her daily activities and health status, so that she can also get auto-reminders to refill her prescription. Having provided secure access rights to share her data with her pharmacist, Iria knows that these measures will also contribute to improving her health outcomes. Thanks to Iria's now following closely the instructions from these interoperable mobile health solutions, she has learned how to handle her exercise regime in a more sensible way whenever she is away from her home base.

What we can do today

Iria's health data is captured and recorded electronically in a way that makes it possible to be shared amongst different physicians of different disciplines within Portugal. However, only what is part of her patient summary can be exchanged in a lawful and interoperable way across borders with countries that have joined myHealth@EU. This would still require her physical presence on site, since eIDAS based solutions have been explored but not implemented at this stage.

When at the hospital in Finland, Iria will provide her identification credentials to the health professional. The health professional will initiate a cross border eHealth session, which will allow him to get access to Iria's clinical information. Iria will be also uniquely identified as patient, using her ID credential. This unique identifier will be used to request access to her records in Portugal, using the myHealth@EU cross border infrastructure. Data can be only viewed but cannot be downloaded for local storage. The process is repeated every time the physician needs to consult these records. In the near future, Iria shall be able to access and download her health data and share it with her health professional.

If Iria's treatment abroad included dispensation based on one of her active e-prescription, an e-dispensation message will be sent back to the Portuguese national ePrescription infrastructure and the relevant e-prescription status will be updated accordingly. However, none of the information, referrals and e-prescriptions originating from this encounter will appear in the national systems.

XpanDH and beyond

The EEHRxF will eventually be extended to include the relevant specifications to be used in national implementations making it possible to transcode and translate increasingly larger parts of Iria's medical follow up and share across borders. As part of the use case explored in XpanDH, it will become possible that diabetes laboratory data sets and hospital discharge reports are regularly exchanged with patients and with other health care providers nationally and across EU MS that have ascended the relevant wave of myHealth@EU deployment.

Policy support and incentivisation policies, will see shared care scenarios across Europe, realised by means of new business models supporting mobility of chronic disease patients, and leveraging on (i) the myHealth@EU secure infrastructure and interoperability assets (ii) the empowering legal framework (eIDAS, GDPR, EHDS), and (iii) increasingly harmonised clinical governance models and guidelines.

Such business models may involve connected care communities supported by collaboration platforms, exchanging health data over the myHealth@EU infrastructure thus bringing together an ever-expanding number of HCPs and HPs. Exemplary such communities are today the ERNs where patient data is regularly shared among physicians, members of the network, based on a once-only patient consent and facilitated by a collaboration platform.

In this landscape, an imaginary yet realistic scenario for Iria is that her health data can be shared within such communities of HCPs and health professionals, and Iria

can authorise access to her data to "trusted" health care providers and be notified on her mobile phone every time a member of her care team accesses her data.

Thanks to the EEHRxF and XpanDH diabetes priority adoption domain, X-bundles will be made available facilitating access to laboratory data and hospital discharge reports.

Through an app on her mobile phone, Iria may initiate a process of sharing her medical data with her treating health professional. The app allows her to connect to her national medical EHR service provider to grant access to the requested clinical document by the specific physician, whom she can uniquely identify by scanning a credential e.g. a bar code identifier. The national EHR infrastructure will firstly identify and authenticate her, then forward to the health professional a number that can be used as a one-time/ limited duration passport to her records. The health professional uses this number in his application to request the document in English.

If Iria is unable to perform this task, a break the glass procedure is initiated using Iria's identification details. Iria will get informed through SMS about this emergency access.

A new record is created in FI documenting the findings of the session and containing e-referrals and e-prescriptions by the FI doctor to be executed and dispensed when she is back to Portugal. The information is trusted and is also re-usable because it has been recorded using common semantic interoperability and data quality standards. This information will become available for any subsequent consultation anywhere in Europe. Her PS remains updated and current and as such it can be shared in good confidence with physicians in Portugal and elsewhere in Europe.