



D1.8 – (D1.6) – Report on Policy Dialogue activities and achievements

WP1 – Coordination

31.01.2025

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| What did this document aim to achieve? | This document aims to summarize notable achievements resulting from Policy Dialogue activities, such as: <ul style="list-style-type: none"> • successful collaborations or partnerships with policy makers • milestones reached in engaging with Ministries of Health, Social Affairs and digital health authorities. • impact on the development and adoption of the EEHRxF format | |
| Present the main methodological approaches in bullet point format | Report based on the project interactions with key digital health stakeholders. | |
| What were the main findings or take-away messages? What implications does it have for the XpanDH project? | The XpanDH project has advanced policy dialogue and engagement for the EEHRxF, ensuring alignment with the EHDS. Key achievements include bridging policy and technical domains, multi-level stakeholder engagement, and supporting regulatory alignment, laying a solid foundation for EEHRxF adoption. | |
| Which project stakeholder group would benefit the most from the document and why? | Healthcare Professional | |
| | International Adherence Network/Initiative | This group focuses on global adherence to standards and initiatives. The document could help them understand how the project aligns with international standards and fosters adherence. |
| | Investors and Funding | |
| | Patient Organization | |
| | Patient/Caregiver | |
| | Pharma (Marketing&Sales/Medical Dept./R&D) | |
| | Public Authority or Policymaker | |
| | Regulatory body | |
| | Standardization Body/ Open-Source Network Researcher/Academic | |
| | Statutory Health Insurance Company | |
| | Technology & Service Provider | |
| | Other | |
| List any relevant organizations or social media accounts for wider visibility | | |

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List of abbreviations / Glossary

| Acronym | Description |
|--|---|
| EC | European Commission |
| Catalogues (to find reusable resources) | Help administrations find reusable resources (e.g. services, data, software, data models). Various types of catalogues exist, e.g. directories of services, libraries of software components, open data portals, registries of base registries, metadata catalogues, catalogues of standards, specifications and guidelines. Commonly agreed descriptions of the services, data, registries and interoperable solutions published in catalogues are needed to enable interoperability between catalogues ¹ |
| CDA | Clinical Document Architecture |
| Common eHealth assessment framework | The defined Common eHealth assessment framework serves as a basis for preparing the set of harmonisation and interoperability guidelines and standards for the Eastern partner countries in line with relevant EU norms |
| Common harmonisation and interoperability guidelines and standards (CHIGS) | A document dedicated to the Eastern partner countries as a deliverable of eHealth stream in the project “EU4Digital: Supporting digital economy and society in the Eastern Partnership”, carried out by an EY led international consortium |
| Connecting Europe Facility (CEF) | A key EU funding instrument to promote growth, jobs and competitiveness through targeted infrastructure investment at European level |
| DHE | Digital health Europe |
| Digital Health | An umbrella term for a wide range of digital technologies associated with health, healthcare, living, and society to improve healthcare delivery and support personalised and precision medicine |
| Digital Health governance | Governance for digital health aims to strengthen the capabilities and skills needed for countries to promote, innovate and scale up digital health technologies |
| Digital Service Infrastructure (DSI) | A term describing foundational services that are necessary to the information technology capabilities of a modern society |
| Digital Single Market | A definition where the free movement of persons, services and capital is ensured and where the individuals and businesses can seamlessly access and engage in online activities under conditions of fair competition, and a high level of consumer and personal data protection, irrespective of their nationality or place of residence ² |
| Digital Transformation of Health and Care | A part of Digital Single Market empowering citizens and building a healthier society |
| Eastern partner countries | The term stands for the six Eastern neighbourhood countries: Armenia, Azerbaijan, Belarus, Georgia, Moldova, and Ukraine |
| eDispensation (eD) | Represents the act of electronically retrieving a prescription and giving the medicine to the patient. Once the medicine has been dispensed, a report on the items dispensed is sent to the prescriber in a structured format |
| EEHRxF | European electronic health record exchange format |

| | |
|--|---|
| EHDS | European health data space |
| FHIR | Fast Healthcare Interoperability resources |
| eHDSI | eHealth digital service infrastructure |
| eHDSI Member State Expert Group (eHMSEG) | Composed of Technical, Semantic or Organisation Experts according the configuration, nominated by the participating Member States. It performs the operational impact assessment |
| eHealth | The World Health Organisation defines eHealth as the use of information and communication technologies (ICT) for health ³ |
| eHealth Digital Service Infrastructure (eHDSI) | The term used for the generic and core services for the cross-border health data exchange under the Connecting Europe Facility financing |
| eHN | eHealth Network |
| eIDAS, eIDAS 2.0 | eIDAS (Electronic Identification, Authentication and Trust Services) is a European Union (EU) regulation implemented in 2014 to ensure secure and reliable electronic identification and trust services across the EU. The regulation facilitates electronic interactions between businesses, citizens, and public authorities within the EU by establishing common standards for electronic identification, authentication, and trust services. eIDAS 2.0 is the latest and updated version of that rule and aims to solve its shortcomings. The technical infrastructure which connects the national eID schemes. The first eIDAS 2.0 draft was introduced in 2018 (and has been developed since). This update builds upon the original eIDAS law and aims to enhance the security and reliability of electronic identification and trust services within the EU. |
| Electronic Health Record (EHR) | A collection of longitudinal medical records or similar documentation of an individual in digital form. This set of health information based on the principle one EHR per patient in a country |
| Electronic Health Record Exchange Format (EHRxR) | Seeks to facilitate the cross-border interoperability of EHR, currently being developed by EC, the recommendation released in 2019 |
| LOINC | Logical Observation Identifiers Names and Codes |
| ePrescription (eP) | A tool to generate prescriptions electronically. It is generally understood as a prescriber's ability to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point-of-care. ePrescription is also used by nurses to administer medicines and by pharmacies to review orders and manage the supply of medicines |
| EU4Digital Facility | A three-year programme promoting key areas of the digital economy and society, in line with EU norms and practices |
| European Commission (EC) | A group appointed by agreement among the governments of the EU, which initiates Union action and safeguards its treaties. |
| European Interoperability Framework | A part of the Communication (COM(2017)134) from the European Commission adopted on 23 March 2017. The framework gives specific guidance on how to set up interoperable digital public services. It offers public administrations 47 concrete recommendations on how to improve the governance of their interoperability activities, establish cross-organisational relationships, streamline processes supporting end-to-end digital services, and ensure |

| | |
|---|---|
| | that both existing and new legislation do not compromise interoperability efforts ¹ |
| European Reference Network (ERN) | A virtual network comprised of healthcare professionals spread around Europe. Their objective is to tackle complex or rare diseases and conditions that necessitate highly specialised treatment and a concentration of knowledge and resources ⁴ |
| GDPR | general data protection regulation |
| Health Care Provider (HCP) | An individual healthcare professional or a healthcare institution licensed to provide medical care |
| Health Level 7 (HL7) | A framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems |
| Information Society | Describes a society where a significant degree of activity focuses on the creation, distribution, use and reuse of information. This activity takes place using what is known as information and communication technologies (ICTs) |
| Integrated Public Services | In the public sector context, integrated services refer to the result of bringing together government services so that citizens can access them in a single seamless experience based on their wants and needs. Integration enables public agencies to share their objectives across organisational boundaries, whereby information and services can be shared among ministries and government entities in a way that avoids data redundancy, boosts up the efficiency of internal processes and ultimately provides citizens with high quality services and improved levels of governmental interaction ¹ |
| Integrating the Healthcare Enterprise (IHE) | An initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information |
| International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10) | The purpose of the ICD is to permit systematic recording, analysis, interpretation and comparison of mortality and morbidity data collected in different countries or areas and at different times. The ICD is used to translate diagnosis of diseases and other health problems from words into an alphanumeric code, which permits easy storage, retrieval and analysis of the data ⁵ |
| Interoperability | The ability of different systems, organisations or countries to exchange health information and use it meaningfully. That means the participants must be able to understand and interpret the shared information correctly, which basically means using the same standards and processes to provide an eHealth service |
| i~HD | The European Institute for Innovation through Health Data |
| Legislative framework | The body of policies, legislation and regulations, at national, regional and local level, governing a particular area |
| Logical Observation Identifiers Names and Codes (LOINC) | A terminology for laboratory and clinical observations to send clinical data electronically |
| Mobile health (mHealth) | The practice of healthcare supported by mobile devices |
| National Contact Point (NCP) | Independent organisations (Ministries, Academies of Science, |

| | |
|--|---|
| | Research agencies) that act as information providers to European Research Council applicants in their native language |
| National Contact Point for eHealth (NCPeH) | Independent organisations (Ministries, Academies of Science, Research agencies) that act as information providers to European Research Council applicants for eHealth in their native language |
| National eHealth Strategy (NeHS) | A national level strategy setting out a range of measures for the increased use of digital technologies to support delivery of healthcare services |
| OHDSI | Observational Health data Sciences and Informatics |
| OpenNCP | epSOS pilot-based component available as NCP software, available to public |
| Patient Summary | A standardised set of basic medical data that includes the most important clinical facts required to ensure safe and secure healthcare. This summarised version of the patient's medical data gives health professionals the essential information they need to provide care in the case of an unexpected or unscheduled medical situation (e.g. emergency or accident) |
| Public Key Infrastructure (PKI) | A set of roles, policies, hardware, software and procedures needed to create, manage, distribute, use, store and revoke digital certificates and manage public-key encryption |
| ReEIF | refined eHealth European interoperability framework |
| Refined eHealth European Interoperability Framework (ReEIF) | Provides a common framework of terms and methodologies that serves as a key instrument to address eHealth interoperability issues |
| Regulatory Authority | A public authority or government agency responsible for exercising autonomous authority over a specific area of activity in a regulatory and/or supervisory capacity. Regulatory authorities are commonly set up to enforce safety and standards, and/or to protect consumers in markets where there is a lack of effective competition |
| The Eastern Partnership | The Eastern Partnership is a joint initiative of the European External Action Service of the European Union together with EU, its Member States, and six Eastern European Partners governing its relationship with the post-Soviet states of Armenia, Azerbaijan, Belarus, Georgia, Moldova, and Ukraine |
| The European Interoperability Framework (EIF) principles | <u>The fundamental behavioural aspects to drive interoperability actions. There are 12 principles relevant to the process of establishing interoperable European public services. They describe the context in which European public services are designed and implemented!</u> |
| The Systematized Nomenclature of Medicine (SNOMED) | Medical terminology covering most areas of clinical information such as diseases, procedures, pharmaceuticals etc. |
| Trans European Service for Telematics between Administrations system (TESTA) | The private IP-based network of the European Union |

Executive summary

This report describes the comprehensive Policy Dialogue activities conducted by the XpanDH consortium within WP1 – Coordination. The document outlines methodologies employed in engaging relevant policy spaces, establishing the Policy Board and coordinating with policy makers. Notable achievements, collaborations, and milestones in the adoption of the European electronic health record exchange format (EEHRxF) are spotlighted. The signature of a MoU with the Xt-EHR Joint Action signified the productive collaboration that was evident during 2024, and that ended with the handover of key recommendations but also ongoing efforts such as some Communities of Doers and some X-Nets. The interactions with the EC were regular and fruitful culminating with the 2 Summits jointly organized. The project further interacted with the eHealth Network, particularly with its technical and semantic sub-groups. The report clarifies the implications of these activities for the XpanDH project, providing valuable insights into its alignment with international standards and contributions to the broader digital health landscape.

Use text of the “deliverable abstract”

1 Introduction

Striking a balance between the **technical development** of the EEHRxF and its **policy-driven adoption** is vital for the successful deployment and sustainability of digital health infrastructures. While technical advancements provide the foundational framework for interoperability, adoption relies on strategic policymaking, regulatory alignment, and stakeholder commitment. Government leadership ensures that these technical innovations are embedded into national healthcare strategies while fostering ecosystem maturity and securing political buy-in.

XpanDH has recognised this need from its outset, actively engaging with Member States' **Ministries of Health (MoH)** to build a foundation of support. This engagement has resulted in formal expressions of support from eight Member States and informal consultations with representatives from five others before the project's core activities commenced. Additionally, the Spanish MoH joined XpanDH as an Associated Partner during the project lifetime, in alignment with XpanDH's principle of open consortium. Instead of relying on a dedicated policy board as an intermediary, XpanDH has moved to pursuing **direct engagement with the European Commission (EC) and the Joint Action (JA) on the EHDS** and with other policymakers, ensuring streamlined interactions and faster regulatory alignment.

Policy dialogue has been a key focus throughout the project, complementing XpanDH's technical activities and ecosystem activation efforts. These interactions ensure that digital health solutions align with the **evolving regulatory and governance landscape**, ensuring that the EEHRxF is not only technologically viable but also **politically and legally feasible**.

A pivotal area of focus has been the implementing acts introduced under the **European Health Data Space's (EHDS)** framework. These acts represent significant shifts in governance, policy, and technical requirements, transitioning from non-binding guidelines under the **Cross-Border Directive (CBD)** to **binding regulations with legal obligations** for Member States. The implementation of these acts will have long-term effects on **data governance, standardisation, and cross-border health data exchange**.

Table 1 – Before/after EHDS comparison

| | Then (under Cross-Border Directive) | Now (adoption of EHDS) |
|---------------------------|-------------------------------------|------------------------|
| Nature of document | Non-binding guidelines | Mandated regulation |

| | | |
|-----------------------------------|--|---|
| Governance | eHealth Network with eHOMB and eHMSEG | Overseen by EHDS Board, consultation process |
| Policy | Included in generic guidelines | In EHDS Regulation |
| structure | Generic guidance supported by domain-specific specification | Intention to produce implementation act outputs by article |
| Infrastructure requirement | Specification for cross-border exchange of data, but no requirement within national borders | Mandated requirements with significant implications within each Member State |
| Detailed requirements | Draft specification with optionality, but enough detail to be able to agree, subject to later change | Each Implementing Act will have to be implemented, each with its own timescale and conformance criteria |
| Timing | Each MS could propose their implementation plan, for agreement with eHN | Time period for development and implementation (two years for primary use, four years for secondary |

The need for a **Global EHR** has been increasingly recognised as digital health initiatives expand beyond the European Union (EU). XpanDH's policy engagements have incorporated perspectives from **Latin America, North America, and other international regions** where digital health interoperability is evolving. Emerging regional frameworks, such as those developed in **Latin America**, are considering EEHRxF principles in their own digital health transformation strategies. The **cross-border challenges faced by non-EU countries** highlight the broader relevance of XpanDH's work in shaping global EHR adoption strategies.

Beyond formal policy documents, XpanDH has engaged in **extensive direct interactions** with policymakers at both national and EU levels. Key aspects of this engagement include:

- **Close collaboration with the European Commission (DG SANTE, DG CNECT)** to align EEHRxF with EHDS regulations.
- **Member State consultations** through the eHealth Network and direct ministerial discussions.
- **Strategic input and handover of material and findings into the JA**, ensuring that EEHRxF implementation aligns with the regulatory roadmap.
- **Engagement with industry and patient representatives** to incorporate practical insights into policy frameworks.

The introduction of the EHDS has necessitated **significant policy and structural changes**. The implementing acts will drive **detailed requirements**, ensuring uniform conformance across Member States and fostering greater **interoperability at both national and cross-border levels**. These regulatory shifts will have lasting impacts on **health data governance, patient rights, and industry compliance**, supporting the broader goals of the XpanDH project in establishing a **pan-European digital health ecosystem**.

2 Scope

This document outlines the policy dialogue activities and achievements within the XpanDH project, focusing on the interactions between the project's technical and policy components, which have been a primary source of the changes addressed throughout the report. It reflects the strategic efforts made to align the project's outcomes with the evolving European regulatory framework, particularly in the context of the EHDS.

The scope of this report encompasses the range of engagements between XpanDH and key European and national policy actors, including the European Commission, Member States' Ministries of Health, and other regulatory bodies. Additionally, it describes the critical interactions with technical groups, highlighting how these engagements have driven policy and governance changes. The document also covers the project's collaboration with external stakeholders beyond the EU, showing how XpanDH has both influenced and responded to international policy developments.

Central to this report are the recommendations aimed at informing the EHDS Implementing Acts and associated policy regulations. These recommendations, which are summarised at the end of the document, provide a roadmap for addressing governance, regulatory, and technical transformations necessary for the successful implementation of the EHDS. They reflect the lessons learned from the project's interactions with the policy landscape, offering guidance for future initiatives in the European digital health space.

The development of this document has been supported by numerous interactions with key stakeholders, including the European Commission, XpanDH Work Package leaders and partners, and external entities such as Member State health regulators. Through these collaborative efforts, the report offers a comprehensive view of how XpanDH has engaged in policy development and proposes actionable insights for sustaining the growth of digital health ecosystems across Europe.

3 Policy Dialogue Methodology

XpanDH employed a **multi-tiered policy engagement strategy**, ensuring the effective involvement of policymakers, industry stakeholders, and standardisation bodies. The methodology focused on:

- **High-Level Stakeholder Meetings:** Engaged directly with the European Commission (DG SANTE, DG CNECT), national ministries, and regulatory bodies to align EEHRxF adoption strategies with EHDS policies.
- **Consultations with Standardisation Organisations:** Close collaboration with HL7 Europe, CEN/TC 251, IHE-Europe, and other key standardisation entities to ensure technical alignment with global and European interoperability standards.
- **Workshops & Webinars:** Interactive discussions with industry leaders, patient organisations, and healthcare providers to address practical implementation challenges.
- **Participation in EU-Led Initiatives:** Active involvement in EHDS development forums, MyHealth@EU consultations, and Digital Health Governance discussions to align project outputs with broader European digital health strategies.

To ensure that policy recommendations were grounded in robust evidence, XpanDH employed multiple data collection techniques, including:

- **Stakeholder Interviews & Considerations:** Capturing insights from policymakers, industry representatives, and healthcare professionals to assess policy adoption challenges and opportunities.
- **Desk Research on Policy Frameworks & Digital Health Initiatives:** Review of EU health data regulations, other related regulations, international EHR frameworks and existing interoperability policies.
- **Analysis of Regulatory Developments & Policy Papers:** Systematic evaluation of EHDS-related policy documents, national digital health strategies, and legal frameworks to anticipate policy trends and implementation challenges.

This structured approach ensured that XpanDH's policy engagement activities were not only **responsive to the evolving regulatory landscape** but also **contributory to shaping future digital health policies** at both national and European levels.

4 European Commission

Since April 2023, XpanDH has held several alignment meetings with the European Commission (EC) to coordinate efforts around the European Electronic Health Record Exchange Format (EEHRx) and the XpanDH experimentation bubbles. These interactions have been instrumental in ensuring that the project aligns with broader EU policy objectives, contributes meaningfully to the development of the EHDS, and engages key stakeholders in the European digital health landscape.

Throughout these meetings, XpanDH has worked closely with the EC to discuss the structure and strategic planning of an event dedicated to the EEHRx and its real-world implementation. A key focus has been on ensuring that this event serves as a platform for multi-stakeholder collaboration, knowledge sharing, and ecosystem-wide engagement. Critical considerations included the timing of the event, its alignment with the broader eHealth Network agenda, and ensuring it does not overlap with other major digital health forums.

In these engagements, representatives from the EC, including DG SANTE and DG CNECT, have reiterated the importance of fostering alignment between ongoing projects, enhancing stakeholder collaboration, and consolidating efforts within the EEHRx ecosystem. Discussions have also covered the technical and governance aspects of the EEHRx, highlighting the need for practical implementation support and greater clarity on the evolving regulatory landscape.






















| | |
|---|---|
|  | 20230426_EC & XpanDH alignment |
|  | 20230503_EC & XpanDH alignment |
|  | 20230512_EC & XpanDH alignment |
|  | 20230518_EC & XpanDH alignment (internal) |
|  | 20230526_EC & XpanDH alignment |
|  | 20230629_EC & XpanDH alignment |
|  | 20230703_EC & XpanDH alignment (internal) |
|  | 20230711_EC & XpanDH alignment (internal) |
|  | 20230713_EC & XpanDH alignment |
|  | 20231004_EC & XpanDH alignment |
|  | 20231020_EC & XpanDH alignment |
|  | 20231027_EC & XpanDH X-bubbles |
|  | 20231031_EC & XpanDH Summit |
|  | 20231107_EC & XpanDH Summit |
|  | 20231127_EC & XpanDH Summit - Bubbles |
|  | 20231205_EC & XpanDH Summit |
|  | 20240311_EC & XpanDH - Bubbles |
|  | 20240711_EC & XpanDH Summit - Developments |
|  | 20240723_EC & XpanDH Summit - Readiness Model etc |
|  | 20240902_EX & XpanDH_D1.8 & Bundles |
|  | 20241014_EC & XpanDH Results |

Figure 1: XpanDH drive folders containing material from EC alignment meetings

Overall, XpanDH has conducted more than a dozen structured interactions with the European Commission, addressing themes such as EEHRxF governance, alignment with the EHDS regulatory framework, and the need to accelerate adoption across Member States. These discussions have reinforced the project's role as a key contributor to shaping the European interoperability landscape and fostering cross-border health data exchange.

Through these engagements, XpanDH has successfully positioned itself as a vital partner in the implementation of the EHDS, ensuring that policy dialogue translates into concrete actions that support Member States, industry players, and healthcare providers in adopting the EEHRxF effectively.

5 eHealth Network

5.1 eHN plenary meetings

XpanDH has been discussed at various **eHN plenary meetings**, most notably during the **26th eHN meeting on 19–20 June 2024**. In this session, Member States inquired about **formal collaboration** between XpanDH and eHN regarding electronic exchange formats. It was clarified that ongoing **knowledge-sharing** was taking place, particularly through the **Subgroup on Semantics**.

Joint Meeting – 5 November 2024

In a dedicated **joint session**, the **XpanDH coordinator** presented the project's key challenges and engaged stakeholders in discussions on policy alignment. Key aspects included:

- An overview of **Bubbles Feasibility Assessments**, evaluating EEHRxF adoption against eHN guidelines.
- Open discussions with policymakers and technical experts to identify **priority areas for implementation support**.
- Addressing concerns regarding **technical constraints** and standardisation approaches (e.g., testing via **Gazelle** vs. direct point-to-point exchanges).

Through its continuous engagement with the eHN and its subgroups, XpanDH has played a vital role in ensuring that EEHRxF development aligns with the broader European **digital health interoperability agenda**. These interactions have provided **valuable insights for the next phases of EEHRxF standardisation**, helping bridge gaps between **technical frameworks, national policies, and real-world healthcare needs**.

5.2 Subgroup on semantics

f XpanDH has actively engaged with the eHealth Network (eHN) Subgroup on Semantics to align the project's work on **X-Bubbles** with the existing **eHN guidelines on health data exchange**. These interactions focused on the **collaborative review and verification** of eHN guidelines in relation to the **Laboratory Reports** and **Hospital Discharge Reports (HDR)**.

First Meeting – 10 April 2024

During the first meeting, XpanDH representatives presented the project's methodology and discussed key areas of alignment between the X-Bubbles approach and existing eHN guidelines. The discussion centered around:

Laboratory Reports:

- Alignment with the **eHN guidelines on laboratory results exchange** under the Cross-Border Directive.
- Review of dataset elements, terminology standards (**LOINC**, **NPU**, **SNOMED CT**), and technical requirements (**FHIR for content representation and transmission**).
- Identification of gaps and opportunities, particularly the lack of technical specifications for implementation and the challenge of defining an appropriate **subset of value sets** from the extensive **LOINC and SNOMED CT** catalogues.

Hospital Discharge Reports (HDR):

- Identified as less mature in terms of structured data representation.
- Noted that most healthcare organisations still rely on **free text** for discharge summaries, posing a challenge for structured interoperability.
- Discussion on whether **specialty-specific subsets** of data fields would improve usability.

Challenges Identified:

- The need for **better clarity on EEHRxF implementation** within Member States.
- Emphasising the importance of **data exchange** and the contexts of use.
- Defining specific use cases, including **primary and secondary use** of health data.
- Balancing **existing national coding systems** with international interoperability frameworks.

- Engaging a diverse set of stakeholders, including **clinicians, IT professionals, and policymakers**.

Further Collaboration:

- XpanDH committed to working closely with the **eHN Subgroup on Semantics** to refine data exchange standards.
- Planned engagement between **XpanDH WP4** and the subgroup to address outstanding technical challenges.
- Contribution to **Xt-EHR** for aligning EEHRxF content with future Implementing Acts.
- Participation in the **Joint Meeting on Semantics, EEHRxF, and Interoperable Communities** on 21 May 2024.

Second Meeting – 25 June 2024

During the second meeting, XpanDH presented findings from its **Bubbles Feasibility Demonstrators**, showcasing:

- Real-world testing of EEHRxF components.
- Implementation challenges and lessons learned.
- Further alignment opportunities with eHN guidelines.

6 eHealth Member State Expert Group

XpanDH has actively engaged with the **eHealth Member State Expert Group (eHMSEG)** to align its work on **EEHRxF adoption** with the broader **MyHealth@EU** agenda and the evolving governance framework under the **EHDS Regulation**. The **31st eHMSEG meeting on 15 October 2024** marked a key moment in this engagement, with XpanDH representatives presenting findings and contributing to discussions on digital health interoperability.

Key Themes of Discussion

During its engagement with eHMSEG, XpanDH focused on several core areas:

- **EHDS Regulation and Implementation:**
 - Updates from the European Commission on the finalisation and formal adoption timeline for the EHDS Regulation.
 - Clarifications on the role of the EHDS Board, the governance structure of **MyHealth@EU** and **HealthData@EU**, and their implications for Member States.

- Discussions on the transition from **voluntary frameworks** under the Cross-Border Directive to **mandatory compliance** under EHDS.
- **XpanDH Contribution to EEHRxF Adoption:**
 - Presentation of **XpanDH's Readiness Model and Community of Doers** as a mechanism for **structured adoption of EEHRxF** across Member States.
 - Introduction of the **X-Bubbles**, with an emphasis on feasibility demonstrators for **Laboratory Results, Hospital Discharge Reports, and Medical Imaging**.
 - Exploration of how **XpanDH's X-Bundles** could be leveraged to support Member States in aligning national systems with EEHRxF specifications.
- **Technical and Semantic Alignment:**
 - Discussion on alignment efforts between **eHN guidelines and EEHRxF technical specifications**.
 - Identification of challenges related to **semantic interoperability**, particularly **data structuring in discharge reports and lab test standardisation**.
 - Potential **contributions from XpanDH to the Xt-EHR project**, particularly regarding implementation support and validation of specifications.

Challenges and Areas for Further Collaboration

XpanDH's engagement with eHMSEG identified several key challenges:

- **Bridging Policy and Technical Adoption:**
 - Need for a clear roadmap from **policy guidance to technical implementation**, ensuring EEHRxF is both **regulatory-compliant and operationally feasible**.
 - Continued support for **Member States in national implementations**, with knowledge transfer from XpanDH's work in experimentation bubbles.
- **Addressing Fragmentation in National Implementations:**
 - Variability in **Member State readiness and digital maturity levels**, requiring tailored support.

- Potential **use of X-Bundles as standardised assets** to help Member States comply with EEHRxF.
- **Ensuring Long-Term Sustainability:**
 - Strategies for ensuring that XpanDH's outputs (e.g., **X-Bundles, X-NETs, X-Bubbles**) remain available and relevant **beyond the project's lifespan**.
 - Need for sustained engagement between **XpanDH, eHMSEG, and the EHDS governance structures** to ensure continuity of efforts.

Outcomes and Next Steps

As a result of XpanDH's participation in eHMSEG, the following steps were agreed upon:

- Strengthened collaboration with **eHN subgroups and Xt-EHR** to ensure alignment of EEHRxF technical specifications with **Member State needs**.
- Agreement to contribute **lessons learned from X-Bubbles** to **support MyHealth@EU's roadmap** for new services such as **Laboratory Results and Discharge Reports**.
- Plans to participate in further **joint meetings and technical workshops** to ensure that **XpanDH's work is effectively integrated into the EHDS framework**.

Through its engagement with eHMSEG, XpanDH has reinforced its role as a key **policy and technical contributor** to the development of the European **digital health interoperability ecosystem**, ensuring that EEHRxF adoption is not only a regulatory obligation but a practical and implementable reality for Member States.

7 Joint Action (Xt-EHR)

XpanDH has established a structured and collaborative relationship with **Xt-EHR**, ensuring the continuity of efforts towards the implementation and adoption of **EEHRxF** within the **EHDS framework**. This collaboration has been formalised through a **Memorandum of Understanding (MoU)** signed by the coordinators of both projects, marking a commitment to sustained alignment and knowledge transfer.

Coordination and Alignment Activities

Throughout 2024, XpanDH and Xt-EHR engaged in multiple coordination and handover activities to ensure the seamless integration of project findings and outputs. Key activities included:

- **10 July 2024** – Coordination alignment meeting to establish **collaborative mechanisms and shared objectives**.
- **17 July 2024 (13:00–15:00 CET)** – **Handover Workshop 1**, focusing on the **structural alignment of EEHRxF specifications and technical documentation**.
- **28 August 2024 (17:00–18:00 CET)** – **Joint alignment meeting with the European Commission**, ensuring that both projects support the **EC's strategic goals** for digital health interoperability.
- **13 September 2024** – **Second Coordination Alignment Meeting** to review progress and refine the roadmap for handover processes.
- **15 October 2024 (09:30–12:00 CET)** – **Handover Workshop 2**, diving into **implementation frameworks and operational strategies** for EEHRxF integration.
- **5 November 2024 (14:30–16:00 CET)** – **Handover Workshop 3**, finalising recommendations for Xt-EHR and discussing governance and sustainability plans.

European Digital Health Interoperability Days

A significant milestone in the XpanDH-Xt-EHR collaboration was the **European Digital Health Interoperability Days (16–19 December 2024, ISCTE, Lisbon)**. This event served as the **final dissemination platform** for XpanDH's results, with approximately **half of the agenda dedicated to knowledge transfer** to related initiatives such as xShare and Xt-EHR. Sessions covered:

- **Key findings from the XpanDH experimentation bubbles.**
- **Final alignment strategies for EEHRxF adoption within Xt-EHR.**
- **Long-term governance mechanisms and sustainability planning.**
- **Technical showcases and interoperability demonstrations.**



Figure 2: Photo of the Joint Action Xt-HER during the European DHI Days @Iscte

Participation in a panel discussion during the European Digital Health Interoperability Days @Iscte in Lisbon on 18 December 2024. (Participants from left to right in the picture: Simon Lewerenz – Iscte; Duarte Sequeira – UpHill; Anderson Carmo – Iscte, Andreas Neocleous – NeHA, Xt-HER and Chloé Lefèvre – TechForLife; Zoltan Lantos – ESZFK attending online the panel)

Ensuring Long-Term Impact

The structured handover activities between XpanDH and Xt-EHR aimed to:

- **Ensure that EEHRxF technical assets and policy insights remain relevant beyond the XpanDH project lifecycle.**
- **Support the ongoing work of Xt-EHR in formalising interoperability governance under EHDS.**
- **Provide actionable implementation strategies for Member States and industry stakeholders.**
- **Reinforce the importance of cross-initiative alignment in building a robust European digital health ecosystem.**

Through this collaboration, XpanDH has successfully established a pathway for its findings to directly contribute to the **next phase of EEHRxF implementation**, ensuring that technical and policy advancements continue to evolve under the **Joint Action Xt-EHR framework**.

8 Forums, events and other initiatives

8.1 Through Deliverable 5.2 work

As part of the work related to **Deliverable D5.2**, XpanDH has actively engaged with other EU-funded projects to **raise awareness, align efforts, and enhance collaboration** within the European digital health ecosystem. A total of **six structured meetings** were conducted with representatives from key EU initiatives to discuss interoperability, data exchange strategies, and alignment with **EEHRxF and EHDS objectives**.

These interactions were part of a broader effort to scale up the EEHRxF ecosystem and leverage the work of existing European projects that contribute to the **development, adoption, and integration** of interoperability frameworks. As highlighted in **D5.2**, an extensive screening and inventory of over **70 European projects** working on health data was conducted, resulting in a classification of projects into three key groups:

- **Core projects directly contributing to the development of EEHRxF.**
- **Projects adopting or potentially integrating EEHRxF into their use cases while building complementary interoperability assets.**
- **Projects indirectly relevant to EEHRxF through related digital health innovations.**

Following this classification, project representatives were engaged in **webinars and consultations**, discussing how their work aligned with EEHRxF and where further collaboration was possible.

Key Areas of Engagement

The interactions with these initiatives primarily focused on:

- **Interoperability Alignment:** Understanding how different projects are leveraging **EEHRxF** and addressing key interoperability challenges in their respective domains.
- **Knowledge Exchange:** Sharing findings and methodologies developed under XpanDH, particularly around **X-Bundles and X-Bubbles**, to facilitate a common approach to data sharing.
- **Regulatory and Policy Considerations:** Identifying policy barriers and discussing alignment with the EHDS regulatory framework to **accelerate adoption** across Member States.

Highlighted Collaborations

In total, 79 projects were engaged with, within which several **high-impact projects** were identified as particularly relevant for advancing EEHRxF adoption. These included:

- **POTENTIAL** – Addressing **cross-border digital health infrastructure challenges** and leveraging EEHRxF for **primary and secondary data use**.
- **PATHeD** – Focusing on **data exchange for personalised healthcare and patient-driven data governance**.
- **xShare** – Exploring **mechanisms for data portability and patient empowerment** within the EHDS framework.
- **Xt-EHR** – Ensuring a structured **handover of EEHRxF knowledge and implementation strategies** from XpanDH.
- **UNICOM** – Contributing expertise on **medication data standardisation and cross-border ePrescription interoperability**.
- **Gravitate-Health** – Investigating the role of **patient-facing digital health solutions and structured data access**.

A summary of **projects mapped against relevant EEHRxF data categories** is presented in **Table 1 of D5.2**, which highlights the alignment of projects across domains such as **lab results, discharge reports, medical imaging, and telehealth**.

Scaling Up EEHRxF Adoption

The **Ghent Consultation**, held as part of this engagement strategy, brought together key EC-funded projects to discuss how to **scale up the EEHRxF ecosystem** in preparation for the **December Expert Summit consultation**. Discussions centered on:

- **How EEHRxF can be expanded as a key implementation enabler for EHDS.**
- **Interoperability challenges and how selected projects are driving adoption.**
- **Scaling EEHRxF to enhance continuity of care, value to health systems, and secondary data reuse.**

More details on the key takeaways from these consultations and the alignment of EU projects with EEHRxF can be found in **Deliverable D5.2**.

Through these engagements, XpanDH has helped establish a **cohesive and collaborative environment** that fosters **long-term impact** in European digital health policy and interoperability adoption.

8.2 i~HD conference

Scaling Up the European Health Data Space

As part of its policy and ecosystem engagement activities, XpanDH convened a dedicated session on the **European Electronic Health Record Exchange Format (EEHRx)** during the **Annual Conference of the European Institute for Innovation through Health Data (I~HD)**, held in **Ghent, Belgium, from 30 November to 1 December 2023**. This session was embedded within the broader “**Building Trust in Health Data**” event, which gathered key European projects, industry leaders, and policy stakeholders to discuss the challenges and opportunities of scaling health data use and reuse across Europe.

This session played a crucial role in **preparing for the December 12 Expert Summit**, where XpanDH aimed to consolidate its policy alignment efforts and further refine its strategy for EEHRx adoption. Following preliminary consultations with EEHRx-related projects, the session served as an interactive forum to examine:

- **How EU-funded projects are applying EEHRx** and developing complementary interoperability assets.
- **Interoperability challenges** in leveraging structured health data for continuity of care, health system efficiency, and data reuse.
- **Barriers to EEHRx adoption** and how to address them in the short, medium, and long term.
- **Expanding the EEHRx** to serve additional domains and use cases, including clinical research.

Session Agenda & Key Discussions

The session was chaired by **Dr. Zoi Kolitsi (Digital Health Policy and Strategy Lead, i~HD)**, with co-chair **Carola Schulz (Senior Research Consultant and Project Manager, empirica)**. Key presentations included:

- **Introduction to the EEHRx** by **Kyriacos Hatzaras**, outlining its role within the EHDS as a patient-level data exchange standard.
- **XpanDH's role in fostering broader EEHRx collaboration**, presented by **Dr. Anderson Carmo**, highlighting ecosystem activation strategies and the X-Bubbles initiative.
- **Use case presentation: Re-using emergency department (ED) data for clinical research**, by **Dr. Guido Bertolini (eCREAM Project Coordinator)**.
- **Automating health data interoperability**, presented by **Dr. Isabelle De Zegher (Clinical Coordinator, AIDAVA Project)**.

- **Vision for expanding EEHRxF within the Joint Action Xt-EHR**, delivered by the **JA09 Xt-EHR Coordinator**.

A **panel discussion followed**, where project representatives and stakeholders debated strategies to **scale EEHRxF across multiple domains** and how EU digital health initiatives can align their use cases with interoperability frameworks.

Outcomes and Next Steps

- **Consensus on scaling EEHRxF adoption:** The session reinforced the need for **structured support and funding** for projects aiming to implement EEHRxF within **EHDS-compliant frameworks**.
- **Bridging policy and technical implementation:** Stakeholders stressed the importance of **ensuring regulatory clarity** while maintaining the **technical flexibility** needed for real-world deployment.
- **Expanding the EEHRxF ecosystem:** The discussion highlighted opportunities to **extend EEHRxF use cases**, particularly in **research, imaging, and emergency care data reuse**.
- **Alignment with upcoming regulatory frameworks:** The session provided a valuable opportunity to anticipate potential **policy shifts within EHDS Implementing Acts**.

8.3 IHE Experience Days

8.3.1 IHE Experience Days 2023 – Rennes

XpanDH actively participated in the **IHE Experience Days 2023**, held in **Rennes, France, on September 26, 2023**. The event provided a significant platform to engage key stakeholders in discussions about **EEHRxF adoption, co-creation, and alignment with European health data strategies**.

The workshop focused on **raising awareness** about the EEHRxF and supporting its broader adoption by equipping participants with practical tools and methodologies for interoperability implementation. It served as an opportunity to directly engage with healthcare providers, policymakers, and industry leaders, facilitating a structured dialogue on the **strategic vision of EEHRxF within the European Health Data Space (EHDS)**.

A core component of the workshop was the **interactive engagement** with stakeholders, aiming to explore **the readiness of different ecosystems to adopt EEHRxF**. Discussions centred on the key challenges and opportunities in implementing interoperability frameworks, particularly addressing:

- The role of **co-creation in interoperability frameworks** and how stakeholders can actively contribute to refining EEHRxF specifications.
- **Policy activation strategies** to drive the adoption of EEHRxF, with a focus on aligning with national and EU-level digital health priorities.
- **Practical implementation considerations**, including the importance of structured data governance, semantic alignment, and regulatory compliance.
- The **scalability of EEHRxF** across various healthcare domains and its role in facilitating cross-border health data exchange.

Participants also explored **mechanisms to engage in the XpanDH ecosystem**, including:

- The **X-Bubbles initiative**, demonstrating real-world use cases and feasibility testing of EEHRxF components.
- The **Readiness Model**, outlining key steps for organisations to assess and enhance their EEHRxF adoption strategies.
- The **Community of Doers and X-Nets**, highlighting the importance of collective engagement and stakeholder-driven governance.

An interactive session concluded the workshop, allowing stakeholders to share their perspectives on **the next steps for EEHRxF adoption** and how **ongoing EU projects** can align their interoperability assets with the evolving EHDS framework. This engagement provided valuable insights into the practical challenges of EEHRxF implementation and reinforced the need for continued dialogue between **technical, clinical, and policy stakeholders**.

8.3.2 IHE Experience Days 2024 – Trieste

Building on the success of its engagement in 2023, XpanDH participated in the **IHE Experience Days 2024**, held in **Trieste, Italy**. This event provided a critical forum for presenting **project findings across various work packages (WPs)** and discussing their relevance to the ongoing evolution of **EEHRxF and EHDS implementation**.

During the event, XpanDH representatives showcased **key achievements and lessons learned**, emphasizing how the project has contributed to advancing interoperability frameworks, stakeholder engagement, and policy alignment within the EU digital health landscape. The presentation highlighted:

- **Findings from experimentation bubbles** and how they inform EEHRxF scalability.
- **Challenges and successes in stakeholder-driven interoperability adoption.**
- **Practical insights into how EEHRxF can be embedded into Member States' digital health strategies.**
- **Policy implications** and recommendations for fostering further alignment between **technical developments and regulatory requirements.**

A key component of XpanDH's participation was a **panel discussion alongside representatives from the European Commission**. This dialogue provided an opportunity to:

- **Engage directly with policymakers on the next steps for EEHRxF adoption.**
- **Address questions regarding regulatory frameworks and alignment with EHDS.**
- **Discuss strategies for ensuring sustainability and long-term impact of EEHRxF initiatives.**



Figure 3 Photo of XpanDH (Anderson Carmo-Iscte) at the IHE Experience Days 2024 in Trieste

The event reinforced the need for **continued collaboration between EU projects, industry stakeholders, and policy leaders** to ensure a **cohesive approach to digital health interoperability**. XpanDH's active role in these discussions solidified its **position as a key enabler of EEHRx implementation**, bridging the gap between **technical innovation and policy activation**.

8.4 Madeira Digital Transformation Week

XpanDH played an active role in the **Madeira Digital Transformation Week**, engaging both in a **workshop with national authorities** and an interactive **Community of Doers (CoD) session**. The event provided a platform for structured discussions on **best practices in EEHRx adoption**, fostering knowledge exchange among Member States and digital health stakeholders.

The **workshop with national authorities** facilitated a comparative dialogue on how different countries were implementing digital health policies. Each country presented its experiences, followed by an open discussion that aimed to **identify best practices, exchange insights, and generate solutions to shared challenges** in EEHRx adoption.

Towards Individual Empowerment Over Health Data: The Role of EEHRx

Held on **27 June 2024**, the **XpanDH-led workshop** focused on the role of **EEHRx as a fundamental enabler of secure health data exchange across Europe**, emphasising its relevance in the broader **EHDS framework**. The workshop was structured into two parts:

Part I: Xpanding EEHRx

- **The EEHRx as a building block for EHDS**, positioning it as a **key enabler for patient data accessibility and interoperability**.
- **Advancing the implementation ecosystem**, identifying essential governance and policy steps for Member States.
- **Assessing maturity and evolving digital health strategies**, discussing methodologies for evaluating EEHRx adoption readiness.
- **Bubbling around the format**, presenting results from XpanDH's feasibility studies and pilot projects.
- **Interactive exercise**, where participants collectively **identified further efforts, challenges, and barriers** to widespread EEHRx implementation.

Part II: Enabling Secure Health Data Exchange

- **The xShare Yellow Button**, showcasing its potential as a tool to facilitate **secure, patient-centric data sharing** in alignment with EHDS requirements.

- **From vision to reality: Adoption sites**, presenting insights from **real-world implementations of secure data-sharing solutions**.
- **Interactive session**, gathering additional feedback from participants to further refine **data governance and security mechanisms**.
- **Key Takeaways and Policy Implications**
- **Cross-country collaboration was identified as essential** for harmonising EEHRxF implementation pathways.
- **Stakeholder engagement required reinforcement**, with stronger industry, policy, and healthcare provider involvement in EEHRxF ecosystem-building efforts.
- **Technical and policy alignment progressed in parallel**, ensuring that regulatory frameworks supported real-world interoperability needs.
- **The role of individual empowerment in digital health was underscored**, with participants advocating for enhanced **patient access to health records and self-sovereign data exchange mechanisms**.
- **Targeted Attendees and Contributors**

The event attracted **academia, industry leaders, researchers, healthcare professionals, health IT experts, and citizen representatives**, reflecting the **broad-based support needed for EEHRxF success**.

Key speakers included:

- **Henrique Martins** (ISCTE-IUL)
- **Carola Schulz** (empirica)
- **Jürgen Brandstätter** (IHE-Europe)
- **Maria Marques** (UNINOVA)
- **Alexander Berler** (Gnomon Informatics)
- **Orsolya Becze & Gergely Heja** (OKFŐ – Hungary)
- **Maria Manuela Salazar, Cesar Quintas & Juliana Sá** (ULS SA – Portugal)
- **Eva Sabajová** (National Health Information Centre, Slovakia)
- **Michael Johansen** (MedCom, Denmark)
- **John O'Neill** (HSE Ireland)
- **Andreia Pimenta** (Secretaria Regional de Saúde e Proteção Civil, Madeira)
- **Theodoros Solomou** (University of Cyprus)

- **Charlotte Cameli** (Telemedicine Technologies)
- **Fábio Januário & Vasco Delgado-Gomes** (UNINOVA)

Outcomes and Lessons Learned

- Lessons learned from the Member State presentations were integrated into XpanDH's policy recommendations.
- Insights from interactive exercises informed the refinement of EEHRx implementation strategies.
- Engagement with national authorities contributed to the identification of concrete steps for EEHRx adoption.

8.5 MedTech Europe

XpanDH engaged with **MedTech Europe**, culminating in a keynote presentation and discussion session between the two on 3 September 2024. MedTech Europe is a leading European trade association representing the **medical technology industry**, to present the project's findings and discuss the **implications of EHDS and EEHRx for industry stakeholders**, particularly **EHR vendors and health IT solution providers**. MedTech Europe's broad network, including more than **48,000 online followers** and extensive industry representation, provided a unique opportunity to **align industry perspectives with evolving EU digital health policies**.

The discussions built upon **previous engagements with industry players**, extending XpanDH's policy outreach to ensure that **technical, business, and regulatory dimensions of EEHRx adoption** were addressed. The session included:

- **An overview of XpanDH's final outcomes**, including the results of its policy dialogues and technical experimentation.
- **A discussion on the EHDS framework**, focusing on how medical technology and EHR vendors could **align their systems with new regulatory requirements**.
- **An exploration of legacy initiatives**, such as **xShare and the Joint Action Xt-EHR**, ensuring continuity in the **advancement of interoperability assets**.
- **Tailored recommendations for MedTech Europe and industry collaboration**, including potential areas for **further engagement in interoperability standardisation efforts**.

A key outcome of this engagement was the **active participation of MedTech Europe members in the XpanDH Industry X-Net**, a dedicated working group within the project that facilitated ongoing dialogue with **private sector stakeholders**. This collaboration culminated in the publication of a **position paper** titled:

“**Medical Technology Industry’s Input to the XpanDH Industry X-Net**”¹, which outlined:

- **The need for use-case-driven guidance** for interpreting requirements across digital health product categories.
- **Scaling testing frameworks** for EHDS interoperability to ensure practical and replicable validation mechanisms.
- **Ensuring the separation of exchanged content and transport transactions** within a simplified interoperability architecture, allowing for more flexible and scalable implementations.

Through this engagement, XpanDH successfully **integrated industry perspectives into its final recommendations**, ensuring that the **private sector remains a key driver of EHDS adoption and digital health transformation** across Europe.

9 Member States

At the **Member State level**, XpanDH facilitated dialogue and policy engagement to support the **adoption and integration of EEHRxF** within national digital health ecosystems. The project actively engaged with stakeholders through structured consultations, workshops, and **multi-stakeholder focus groups**, leading to concrete recommendations on accelerating EEHRxF implementation.

9.1 Multi-stakeholders focus group

XpanDH organised two **Multi-Stakeholder Focus Groups**, engaging **Member States, industry representatives, healthcare providers, patient organisations, and policy stakeholders** to discuss EEHRxF adoption challenges and opportunities. These sessions provided a forum for structured dialogue, identification of key barriers, and formulation of policy recommendations.

First Multi-Stakeholder Focus Group – 20 March 2024

The **first focus group**, held online on **20 March 2024**, convened diverse stakeholders to explore the **potential impact of EEHRxF on different sectors**. The session was structured around key thematic questions, including:

¹ The XpanDH Industry X-Net position paper was published at:
<https://www.medtecheurope.org/wp-content/uploads/2025/01/2501-xpandh-industry-xnet-input-cocir-mte-v2.pdf>

- **How EEHRxF would change stakeholder interaction with the health system**, focusing on data portability, interoperability improvements, and research enablement.
- **Use cases where EEHRxF could deliver tangible benefits**, such as patient mobility, continuity of care, personalised medicine, and cross-border healthcare.
- **Challenges in communicating EEHRxF concepts**, including digital literacy concerns, regulatory clarity, and alignment with existing IT systems.
- **Expectations for an EEHRxF Readiness Model**, assessing the preparedness of healthcare providers and national authorities.
- **Approaches to feasibility testing**, ensuring that technical, organisational, and governance aspects were properly evaluated.
- **Evidence required to drive EEHRxF adoption**, including interoperability validation, economic benefits, and trust-building measures.

The session highlighted key concerns regarding **technical readiness, governance structures, and the need for a phased implementation approach**. The importance of **vendor engagement, patient inclusion, and regulatory clarity** was underscored, reinforcing the necessity of continued collaboration among stakeholders.

Second Multi-Stakeholder Focus Group – 25 September 2024

Building on insights from the first session, the **second focus group**, held on **25 September 2024**, aimed to **translate discussions into actionable recommendations**. This meeting focused on producing a structured set of **policy recommendations** to accelerate EEHRxF adoption. Key discussion points included:

- **Stakeholder priorities and mobilisation strategies** for ensuring effective EEHRxF implementation.
- **Regulatory and governance enablers** necessary to align national digital health strategies with EHDS mandates.
- **Technical support and capacity-building mechanisms**, ensuring smaller healthcare providers and Member States with limited resources could effectively engage with EEHRxF.
- **Proposed actions for fostering industry and policy collaboration**, strengthening the role of standardisation bodies in facilitating adoption.
- **Drafting of written recommendations**, capturing stakeholder input and refining a final set of proposals for circulation.

Outcomes and Final Recommendations

Following these discussions, a **set of final recommendations was developed and circulated among participants**, consolidating key insights from both focus groups. These recommendations included:

- **Developing sector-specific guidance** to assist various stakeholders (e.g., healthcare providers, researchers, and industry) in aligning their digital health systems with EEHRxF.
- **Enhancing interoperability testing frameworks**, ensuring scalability and ease of validation for EEHRxF implementations.
- **Ensuring a clear distinction between content and transport transactions**, simplifying the interoperability architecture and reducing complexity in deployment.
- **Reinforcing Member State engagement**, particularly in shaping the regulatory trajectory of EEHRxF within EHDS.

The **written recommendations served as a key input to XpanDH’s final policy outputs**, ensuring that the project’s insights were integrated into ongoing policy dialogues and standardisation efforts. These focus groups provided a structured, evidence-driven foundation for **future EEHRxF implementation pathways**, ensuring that adoption efforts were **stakeholder-driven, technically feasible, and aligned with real-world healthcare needs**.

9.2 Regulators

Regulators’ Forum (28 October 2024). The Regulators Forum’s kick-off meeting (online) was organised using XpanDH network of networks and contacts, which is the reason why it is reported hereby. Yet, the Regulators Forum is aimed to become an integral part of xShare’s Standards and Policy Hub. This was made clear to the participants from the beginning in their invitation letter. Therefore, whilst the first meeting was organised under the auspices of XpanDH project, the following meetings are all planned to be organised by xShare, once the relevant network and ecosystem resources have been handed over from a project to another, for example the XpanDH X-Net of Health Managers & Regulators was one of the parts used to bring together this Regulators Forum first gathering. Ultimately, starting off strong foundations and ensuring continuity of network building increases the strength of alliances of people such as the Regulators Forum.

Key Discussion Topics

The discussions focused on the **regulatory implications of EEHRxF within the EHDS**, considering both **technical and governance aspects**. Participants explored the **expected trajectory of EEHRxF implementation**, including its integration into **national health strategies and European regulatory frameworks**.

A key element of the dialogue was the **harmonisation of digital health policies across Member States**, addressing challenges in **compliance, interoperability, and governance structures**. Participants exchanged insights on **standardisation efforts**, the **alignment of EEHRxF with existing digital health legislation**, and the **need for coordinated approaches to regulatory oversight**.

The forum also examined the **role of industry-regulator collaboration**, ensuring that policy measures **align with technological advancements and market realities**. Discussions highlighted the **importance of testing frameworks**, certification pathways, and **structured compliance mechanisms** to facilitate EEHRxF adoption.

Outcomes and Future Directions

- **Regulators acknowledged the need for ongoing structured dialogue** to support the implementation of EEHRxF and EHDS mandates.
- **Consensus was reached on the necessity of an industry-regulator interface**, allowing for clearer alignment of market solutions with evolving policies.
- **Commitment to continue engagement under xShare's governance**, ensuring continuity in discussions and refinement of regulatory guidance.
- **Emphasis on the importance of testing frameworks and policy implementation strategies**, particularly in defining interoperability compliance mechanisms.

This inaugural **Regulators Forum laid the foundation for a sustained regulatory engagement model**, ensuring that the **EEHRxF remains a key enabler of digital health transformation** within EHDS policy and implementation frameworks.

9.3 Technical interactions

XpanDH organised two **Member State-focused technical workshops**, aimed at discussing **EEHRxF adoption from a national health system perspective rather than individual component-level technicalities**. These interactions were essential in shaping Member State approaches to implementing EEHRxF in alignment with **national infrastructures and the EHDS framework**.

First Workshop: EEHRxF Experimentation in Member States (21 November 2023)

This initial workshop served as an **introductory session**, where XpanDH presented an overview of **EEHRxF experimentation**, outlining its potential impact and practical considerations for Member State adoption. Discussions focused on:

- **Understanding national priorities** for EEHRxF integration.
- **Initial challenges and opportunities** in aligning EEHRxF with existing digital health infrastructures.

- **Feasibility of implementation**, including regulatory and technical constraints.
- **Expected next steps** in terms of national roadmap alignment and policy considerations.

Participants highlighted the **need for further technical exchanges and policy clarification** to support smooth EEHRxF implementation within national systems.

Follow-up Workshop: National Agencies Technical Workshop (4 November 2024)

The second workshop was designed as a **follow-up session**, allowing participating countries to present their **progress in EEHRxF adoption** and share insights from their respective implementation journeys. Unlike the first session, this workshop was more interactive, with **Member States leading discussions** by presenting their national strategies and lessons learned.

Eight countries participated in this workshop: **Hungary, Spain, Germany, Finland, Czech Republic, Cyprus, Ireland, and Norway**. The main highlights from the presentations included:

- **Hungary**: Discussed the transformation of national health data formats to EEHRxF, particularly for **laboratory reports and patient summaries**, while identifying challenges in structuring **hospital discharge reports**.
- **Spain**: Highlighted progress in implementing **National Contact Points (NCPs)** for patient summaries and ePrescriptions across different autonomous regions, with ongoing work to improve structured data exchange.
- **Finland**: Presented efforts to align national coding systems with EEHRxF and the implementation of **FHIR-based interoperability solutions**.
- **Czech Republic**: Explained the challenges of integrating **patient summaries across hospital networks**, with ongoing efforts to map proprietary national specifications to EEHRxF.
- **Cyprus**: Provided insights on early-stage **NCP development** and engagement with healthcare providers to ensure alignment with EHDS priorities.
- **Germany**: Reported on **vendor collaboration** in adapting national EHR solutions to EEHRxF standards and upcoming NCP deployment.
- **Ireland**: Outlined the transition from **unstructured legacy systems** towards structured EEHRxF-compliant data exchanges.
- **Norway**: Shared results from a **gap analysis** comparing Norwegian eHealth solutions with EEHRxF specifications and steps towards harmonisation.

Outcomes and Policy Implications

- **Member States demonstrated varied levels of readiness**, with some already integrating EEHRxF into their **national infrastructures**, while others faced **significant technical and regulatory hurdles**.
- **Patient Summary and ePrescription/eDispensation were the most mature domains**, while **Hospital Discharge Reports posed challenges due to limited structured data availability**.
- **National Contact Points (NCPs) were a major implementation focus**, with several countries working towards their deployment to enable cross-border data exchange.
- **Stakeholders emphasised the need for clear technical guidelines and training**, particularly for healthcare professionals responsible for structured data entry.
- **Collaboration with semantic experts was deemed critical**, ensuring consistent use of terminologies across Member States.

The discussions revealed **significant disparities in national readiness** for EEHRxF adoption, highlighting the importance of continued **technical collaboration, regulatory alignment, and capacity-building efforts**. The need for **training healthcare professionals and IT teams**, as well as **finalising technical specifications and implementing acts**, emerged as key enablers for a successful transition to EEHRxF.

These workshops played a key role in bridging the gap between **policy discussions and technical implementation**, helping Member States align their **national digital health strategies** with evolving EHDS requirements. By providing a structured forum for knowledge exchange, XpanDH **facilitated practical engagement** with EEHRxF adoption and helped shape **future regulatory and technical harmonisation efforts** at the European level.

10 Global context

XpanDH engaged in **policy activation activities** with the **United Kingdom**, leveraging its historical collaboration with **pre-Brexit health data and interoperability initiatives**. The “**XpanDH Comes to the UK**” event, held in **London on 20 May 2024**, provided a platform for UK policymakers, industry leaders, and healthcare stakeholders to explore the **implications of the European Health Data Space (EHDS) and EEHRxF** for the UK’s evolving digital health ecosystem.

Event Overview

The event brought together representatives from **academia, healthcare, industry, and regulatory bodies** to discuss:

- **The latest EU regulations on EHDS and EEHRxF**, presented by XpanDH representatives.
- **The role of EEHRxF in enabling cross-border health data exchange** and its potential relevance to the UK's health system.
- **Challenges and opportunities for UK health interoperability** in the context of EHDS alignment and international collaboration.
- **The potential for a Global EHR**, including industry challenges and technical requirements for interoperability beyond Europe.

Key Discussions and Takeaways

- **Strategic alignment with EHDS:** While the UK is no longer bound by EU regulations, participants acknowledged the **importance of maintaining interoperability with EU frameworks**, particularly for cross-border healthcare services and multinational health research projects.
- **Interoperability priorities for the UK:** The country's **current digital transformation efforts** were discussed, with a focus on **record-sharing programmes, SNOMED CT standardisation, and structured data exchange**.
- **Industry perspectives:** UK-based health IT vendors and innovators explored **potential collaborations with European counterparts**, with an emphasis on aligning **technical standards** to facilitate cross-border health data use.
- **Future cooperation pathways:** The discussion highlighted possible avenues for **continued UK-EU engagement** in digital health, including participation in **pan-European research initiatives** and joint policy dialogues.

Speakers and Panelists

The event featured contributions from experts in **digital health policy, interoperability standards, clinical research, industry, and healthcare service providers**. These included professionals involved in **policy development, standardisation efforts, EHR implementation, and patient data governance**.

Outcomes and Next Steps

- **The UK remains a key collaborator in global digital health interoperability**, with strong industry and academic engagement in **interoperability standardisation and governance frameworks**.

- **Potential future engagement with XpanDH legacy initiatives (xShare, Xt-EHR)** was discussed, ensuring knowledge exchange on **EHR exchange models** and EHDS regulatory developments.
- **A follow-up event was proposed at a UK-based institution** in July 2024 to continue discussions on **UK-EU cooperation in digital health**.

11 First EEHRxF Expert Summit (2023)

The EEHRxF Expert Summit, held as part of the XpanDH project, brought together key stakeholders, policymakers, industry leaders, and digital health experts to co-create a shared vision for the European Electronic Health Record Exchange Format (EEHRxF). Organised in collaboration with the European Commission (DG CNECT and DG SANTE), the event provided a structured space to discuss policy, technical, and governance aspects of EEHRxF implementation.

Key Themes and Discussions

The summit focused on several core themes, including:

- **Policy and regulatory alignment:** Ensuring that EEHRxF supports the broader objectives of the European Health Data Space (EHDS) and aligns with national digital health strategies.
- **Stakeholder perspectives:** Engaging representatives from patients' organisations, healthcare professionals, industry groups, and Member State authorities to gather insights on barriers and opportunities.
- **Technical implementation and interoperability challenges:** Addressing the semantic, syntactic, and organisational hurdles in cross-border health data exchange.
- **EEHRxF adoption models:** Exploring different approaches to piloting, testing, and scaling the Format across Europe.

Summit Outcomes and Next Steps

- **Recognition of EEHRxF as a critical enabler for EHDS**, requiring continued co-creation and alignment with evolving EU legislation.
- **Stronger commitment from Member States and industry** to advance EEHRxF technical and policy adoption efforts.
- **Clearer definition of next steps**, including the development of a roadmap for regulatory and technical alignment.
- **Increased emphasis on stakeholder engagement and testing frameworks**, ensuring that EEHRxF remains practical, scalable, and implementable across diverse healthcare systems.

For a detailed account of the EEHRxF Expert Summit, including session discussions, panel insights, and policy recommendations, please refer to the EEHRxF Expert Summit Flash Report, a policy brief of the XpanDH project reporting back on this event.

12 Second EEHRxF Expert Summit (2024)

The Second EEHRxF Expert Summit was convened on 13 November 2024 in Brussels, building upon the achievements of the first summit. This event brought together key stakeholders from Member States, industry, patient organisations, and European institutions to evaluate progress, enhance ecosystem collaboration, and explore strategies for EEHRxF implementation within the EHDS framework.

Key Themes and Discussions

The discussions focused on:

- Regulatory progress and policy alignment, with emphasis on the timelines for implementing acts and how the EEHRxF would be integrated into national and industry-led EHR systems.
- Technical advancements, particularly in standards development for laboratory and hospital discharge reports, which were identified as critical components for interoperability.
- Stakeholder engagement strategies, ensuring that EEHRxF adoption involves multi-level collaboration among healthcare providers, industry actors, and patient representatives.
- Patient empowerment, highlighting tools such as the xShare “Yellow Button” to support data accessibility and usability.
- Global perspectives on interoperability, exploring how EEHRxF could serve as a model for international health data exchange initiatives.

Summit Outcomes and Next Steps

- Legal and technical alignment: Stakeholders gained clarity on regulatory timelines and necessary steps for implementation.
- Scaling up EEHRxF adoption: The discussions underscored the importance of harmonised approaches to interoperability across Member States.
- Strengthening patient-centric solutions: Recommendations focused on enhancing data accessibility and ensuring patient trust in digital health systems.

- Fostering continuous collaboration: The summit reaffirmed the need for sustained engagement between policymakers, industry representatives, and healthcare providers.

For a detailed account of the Second EEHRxF Expert Summit, including session discussions, breakout group insights, and action points, please refer to the Second EEHRxF Expert Summit Flash Report².

13 Challenges and lessons learned

Throughout the XpanDH project, several challenges emerged regarding **EEHRxF adoption, policy alignment, and stakeholder engagement**. Addressing these challenges has provided valuable lessons that can inform future interoperability efforts within **EHDS and beyond**.

Mapping Expert Networks for Sustainable Interoperability

A key challenge identified in the project was the **need for structured mapping and coordination of expert networks**. Facilitating access to expert knowledge is essential for ensuring that policymakers, implementers, and healthcare providers can easily find and consult relevant expertise when needed.

Accessing and Understanding EEHRxF Information

Stakeholders across various sectors raised concerns regarding **how to find relevant and up-to-date information about EEHRxF**. This challenge was particularly evident among Member State representatives, industry players, and technical experts seeking to align their systems with the evolving regulatory framework. **WP3 of XpanDH** took on the task of improving access to EEHRxF-related resources, reinforcing the need for a **centralised and regularly updated information hub** such as the xShare project-led Standards and Policy Hub. Future initiatives should ensure that **EEHRxF-related documentation, technical specifications, and regulatory updates** are easily accessible to all relevant stakeholders.

Next Steps

Many of these challenges have been explored in detail in D6.4, which presents a comprehensive methodology, key implementation challenges, and recommendations for the European Commission, Member States, and other stakeholders. Next steps include:

² Accessible at: https://xpandh-project.iscte-iul.pt/wp-content/uploads/2024/12/20241205_XpanDH_2nd-EEHRxF-Expert-Summit-Flash-Report_VO.2.pdf

- Ensuring that findings from XpanDH’s work on expert network mapping inform future European digital health coordination efforts.
- Tracking the evolution of EEHRx and ensuring that national and EU-level updates remain accessible and transparent.
- Continuing structured communication between EU and Member States to support the alignment of EEHRx with national digital health infrastructures, ensuring sustained knowledge exchange across Europe.

Towards a Global EHR

The discussions and lessons learned from XpanDH also highlighted the relevance of EEHRx beyond Europe. Several stakeholders emphasised the potential for scaling EEHRx as a model for global EHR interoperability, aligning with broader international efforts to facilitate secure and standardised health data exchange. Ensuring interoperability at a global level will require continued collaboration between EU institutions, international organisations, and national digital health authorities worldwide.

The insights gathered through XpanDH can serve as a foundation for future initiatives that aim to expand digital health interoperability beyond Europe, reinforcing the need for a global EHR vision that ensures seamless, secure, and patient-centric health data exchange worldwide.

14 Conclusion

The XpanDH project has played a **pivotal role in advancing policy dialogue and engagement** for the **European Electronic Health Record Exchange Format (EEHRx)**, ensuring its alignment with the evolving **European Health Data Space (EHDS)**. Through structured interactions with policymakers, regulators, Member States, industry, and technical experts, the project has laid the groundwork for **sustained collaboration and coordinated adoption efforts**.

Key Achievements

- **Bridging policy and technical domains:** XpanDH has demonstrated how policy activation must accompany technical standardisation to enable **meaningful EEHRx adoption**.
- **Multi-level stakeholder engagement:** The project has successfully facilitated dialogue across **Member States, European institutions, industry, and patient communities**, fostering consensus on interoperability priorities.
- **Supporting regulatory alignment:** By interacting with **the European Commission, eHealth Network, and national regulators**, XpanDH has

contributed to shaping the **governance structures and implementation pathways** of EEHRxF within EHDS.

- **Strengthening technical and policy readiness:** XpanDH's experimentation bubbles, industry collaborations, and national-level workshops have helped **validate EEHRxF feasibility and identify barriers to adoption.**

Future Directions and Sustainability

While the XpanDH project has formally concluded, its impact extends beyond its duration. Several **critical areas will require continued attention:**

- **Regulatory Evolution and EEHRxF Implementation:** Ongoing engagement between **Member States and the European Commission** will be crucial to ensure **consistent updates, alignment with evolving EHDS regulations, and implementation support.**
- **Sustaining Policy Dialogue:** The transition of engagement platforms—such as the **Regulators Forum and stakeholder networks—to xShare and Xt-EHR** will ensure that the **momentum generated by XpanDH continues.**
- **Global Implications for Digital Health Interoperability:** The project's work has reinforced the importance of **interoperability at an international scale,** laying the groundwork for further **collaboration towards a Global EHR.**

XpanDH has successfully **bridged the gap between policy intent and technical feasibility,** providing a **solid foundation for EEHRxF adoption within EHDS.** The project's contributions will continue to **inform regulatory discussions, industry practices, and Member State strategies** as Europe advances towards a **more integrated, interoperable, and patient-centred digital health ecosystem.**