

The European EHRxF Standards and Policy Hub in a nutshell: a policy brief

The European EHRxF Standards and Policy Hub is an initiative of the xShare project (2023-26) to deliver robust health interoperability assets in support of the European Health Data Space.

This document is a description of the Hub, the purpose, functions, and its future after the xShare project, for broad dissemination among potential partners and stakeholders.

Introduction

The European EHRxF Standards and Policy Hub (“the Hub”) is a joint initiative of standards development organisations (SDOs) with the digital health industry, policymakers, regulators, research organisations and other stakeholders, to support the European Health Data Space (EHDS) via **the xShare project**. The project will incubate the Hub and build a legal entity, and xShare partners will make it sustainable beyond the duration of the project.

The **xShare project** is a research and innovation action funded 2023 -2026 by the European Commission’s Horizon Europe programme. xShare is led by HL7 Europe and Medcom (DK), and convenes SDOs, industry associations, public authorities, stakeholders and experts. The SDOs involved are CDISC, CEN/TC 251, HL7 Europe, IEEE, IHE-Europe, and SNOMED International.¹

The EHDS regulation is expected to enter into force in the spring of 2025. Among its core objectives is to advance health data interoperability for the provision of healthcare (primary use) and for research and innovation (secondary use), by empowering the European Commission to lay down the underlying technical specifications (the **European Electronic Health Record Exchange Format**, or EEHRxF) through a series of implementing acts.²

The **Hub's objective** is to support the development, harmonisation, maintenance, extension and the adoption of these interoperability specifications. The Hub will serve as a **one-stop-shop and accelerator for European EHRxF specifications** and thus as a critical resource for regional, national and European authorities and regulators to implement the EHDS regulation, and for manufacturers of EHR systems and other digital health solutions to comply with it.

The Hub is to start operations in winter 2024/25 and will operate with full funding as part of the xShare project until the end of 2026. As part of the **sustainability plan**, a plan for a legal structure, charter and governance will be in place in mid-2025. The vision for the Hub’s governance is democratic, collaborative, and inclusive, encompassing international SDOs as well as European stakeholder and research organisations, with engagement mechanisms for authorities and industry, and a business model to ensure its lasting support for the EHDS. The Commission and other international organisations will be invited as observers.

Contact

Robert Stegwee
Chair, CEN/TC 251 Health Informatics
xShare Hub WP2 leader
robert@trace-health.nl

Catherine Chronaki
Secretary General, HL7 Europe
xShare scientific coordinator
chronaki@hl7europe.org

¹ Project website at www.xshare-project.eu; info at <https://cordis.europa.eu/project/id/101136734>

² See EHDS regulation Article 6.

The European EHRxF Standards and Policy Hub

PURPOSE AND FUNCTIONS

Expressed from a functional point of view, the three principal roles of the Hub include: (1) stewardship of the European EHRxF interoperability assets, (2) delivering a neutral and supportive environment for co-creation and design-thinking, and (3) enabling and promoting European EHRxF adoption (see Figure 1: Functions of the Hub).

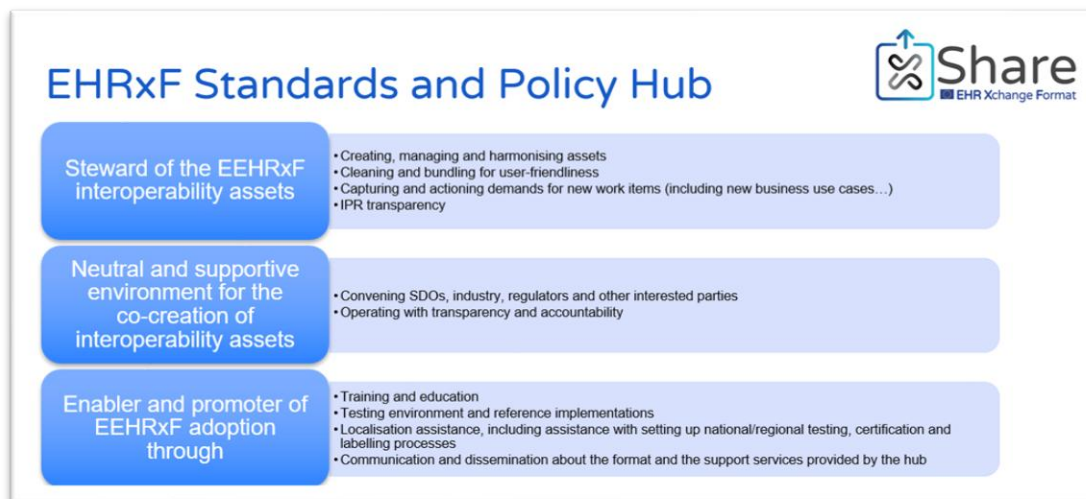


Figure 1: Functions of the Hub

Asset stewardship

The core added value of the Hub is its functionality to direct and support (potential) users of the assets that are relevant to achieve interoperability for their business use cases and needs. This value has to be delivered without losing the bigger picture of the European EHRxF, its future extensions to support also secondary use, and its added value across the board around the globe.

To facilitate the availability of the relevant information and related assets, a public [website on the European EHRxF and Hub](https://ehr-exchange-format.eu) has been launched linking to an [online registry](https://x-bundles.ehr-exchange-format.eu) providing references to the assets as well as an [online repository](https://usecase-repository.ihe-europe.net/xshare-use-cases) showcasing the various business use cases.³ The website and the linked registry and repository, provide the platform for the Hub's objective to be a single point of reference and information on the European EHRxF. By providing information without the need for extensive knowledge beforehand, the website is easily understandable and informative for all relevant audiences ranging from the health care professional to the

The **European EHR Exchange Format** is a set of requirements and technical specifications, as well as endorsed support materials, targeted at ensuring the interoperability of electronic health record systems following the EHDS Regulation and other applicable laws. It is designed to enable the exchange of personal electronic health data between two or more EHR systems or other digital health applications or medical devices in a meaningful way. All elements belonging to the Format are called “**assets**”.

³ URLs are (respectively): <https://ehr-exchange-format.eu> (website); <https://x-bundles.ehr-exchange-format.eu> (registry); <https://usecase-repository.ihe-europe.net/xshare-use-cases> (repository).

regulators, EHR-providers and individual citizens. Thus, creating awareness on the European EHRxF with a low threshold.

With the release, updates and amendments of the EHDS and implementing acts, the specifications, assets and relevant business use cases relevant for the European EHRxF will evolve over time. Therefore, these resources and platforms will be updated continuously by partners and associated members ensuring up to date information and relevance for all audiences.

Co-creation environment

The Hub aspires to serve as a neutral ground, a level playing field that will steward common specifications for the EHDS that are agreed upon between industry and regulators with support from Standards Development Organisations (SDOs) and competence centres. Industry, regulators and policymakers have much more to gain by the creation and growth of the Hub, as a means to achieve alignment and co-ordination, while offering interoperability assets and services for specific business use cases in support of individual adopters and implementers of the European EHRxF.⁴

Development of standards, their adoption, and implementation can be seen as a continuous execution of Co-creation, Governance and Alignment as depicted in Figure 2⁵. Co-creation involves all actors – health systems, the workforce, the market and citizen – and includes co-designing and -delivering services. Governance enables maintaining the strategic direction, detecting changes in the ecosystem, and establishing accountability mechanisms. Alignment covers the continuous nature of the process and allows for feedback systems to monitor adoption experience and external developments. The three steps are closely intertwined and can be considered as a continuous activity. The Hub will facilitate this process engaging initially in the exploratory phase with the xShare adoption sites.

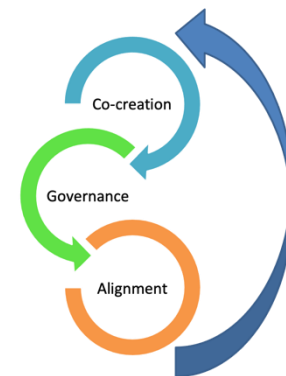


Figure 2: Co-creation, Governance and Alignment

Even though the Hub will be established as an independent entity in its own right, the creation of the content that is relevant for the Hub will always be community driven. Maintenance of an adoption dashboard initially developed in xShare will show case the level of EHDS adoption across Europe.

Promoting implementation

Collaboration with the community of practice starts with understanding their business use cases and matching them, where possible, with existing business use cases, (for instance, the use cases incorporated in the eHealth Network guidelines and the EHDS⁶). Then they need to be matched with the relevant EHRxF specifications, tools, and supporting materials. Together with the implementers, the X-Bundles for these business use cases are assembled, supporting

⁴ The functioning of the Hub, the co-creation mechanism, and the alignment process are discussed in detail in the deliverable D2.1 Annual EHRxF Standards Hub Work Plans-Y1 (2024-2025).

⁵ Taken from “The case for eStandards”, a document adopted by the eHealth Stakeholder Group In February 2019: https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=58930

⁶ The eHealth Network Guidelines are published as https://health.ec.europa.eu/ehealth-digital-health-and-care/eu-cooperation/ehealth-network_en

the adoption of the EEHRxF and the best practices for interoperability, security, education, and implementation. The Hub will advance a learning health system paradigm, accelerating adoption of the EHDS and harnessing its benefits for European health systems and businesses.

During the lifetime of the xShare project, the creation of assets will be facilitated in the xShare adoption sites, additional implementation settings, retreats, and in the industry and regulators forum. Beyond the xShare project, it is expected that the community collaboration will continue to be based on the value proposition provided by the Hub as a level playing field bringing together the industry with SDOs, competence centres, and decision makers.

Accelerating and facilitating large scale adoption of EHDS requires that members and contributors strive to maintain structure and consistency across the assets of the Hub. Clear processes and agreements need to be in place that are adhered to by all contributors and market actors across Europe or even globally. Therefore, the future legal entity will need to be specific about the objectives and overall governance of the Hub, as well as the more detailed process descriptions for the co-creation, governance and alignment of the assets of the Hub.

ENGAGEMENT WITH EUROPEAN EHRXF STAKEHOLDERS

The xShare project has built mechanisms to engage with critical constituencies for EEHRxF experimentation and exploration: industry and regulators, experts and practitioners:

- Through the **industry forum**, the Hub will support the healthcare industry in aligning with EU standards governance by providing a structured environment for engagement and collaboration that goes beyond individual SDOs, projects, and trade associations. The forum will serve as a critical touchpoint, offering stakeholders access to the latest updates, tools, resources and quality measures related to the EEHRxF. It will also facilitate direct communication with policymakers and regulatory bodies, ensuring that the industry's needs and challenges are addressed, promoting a coherent approach to health data interoperability and compliance within the EU. Initial activities for establishing the industry forum started in May 2024 exploring the exact functions of the industry forum, in the Hub creation and exploratory phase.
- The **regulators forum** brings together public authorities, policy makers and regulatory bodies in national and regional health systems, which are critical drivers of the EHDS implementation. Similarly to the industry forum, the regulators forum will serve as a critical touchpoint of the Hub, offering stakeholders access to the latest updates, tools, and resources related to EEHRxF assets. The forum kicked off in October 2024 and will continue to serve as a platform to share information about the progress towards EHDS implementation and for alignment of national practices.
- In part by building on the Industry and Regulators Fora, xShare is building a **community of excellence** on the topic of EHDS and the European EHRxF. In contrast to the fora where members represent their organisations, the community of excellence is a network of experts representing industry, government, research organisations and SDOs, to create synergies and establish a lasting coalition of partners dedicated to enabling policies and advance European EHRxF implementation.⁷ This community will grow with engagement with more educational institutions and professional associations, and the European Pact for Skills.

⁷ Terms of reference and a facility to join the community are available on the xShare website at <https://xshare-project.eu/community-of-excellence/>

GLOBAL ALIGNMENT

In the standards development process, the global alignment of standards and tools that are referenced by or used in the EHDS is an important task, to ensure that state-of-the-art standards for health informatics are reflected in the EEHRxF and vice versa. This will be advanced mostly by SDOs and their respective stakeholder communities that are well versed in the consolidation of requirements across the globe. The first step in this journey will start with experimentation across the xShare adoption sites and those adoption sites responding to the xShare open calls across healthcare, public/population health, and clinical research.

The European Standards and Interoperability Alliance

The European Standards and Interoperability Alliance (ESIA) is the proposed name of the legal entity that will carry forward the Hub. The three pillars of a successful ESIA are:

- Serving as the institutional home of **the European EHRxF Standards and Policy Hub**
- A **governance model** ensuring democratic stakeholder support, transparency, and neutrality, and
- A **sustainable partnership** built on collective knowledge and collaborative practices.

The expectation is that building on these pillars will help establish ESIA as a recognised and reputable supporter for the European Health Data Space, ensuring its organisational and financial sustainability. We discuss these three pillars below.

THE HUB

During the initial creation and exploratory phase of the Hub (established and supported by the xShare project, 2023-2026), the Hub will facilitate the creation of easy-to-use interoperability assets and adoption kits, engaging with the xShare adoption sites and building the industry and regulators fora for the Hub customers. After the end of the xShare project, the Hub will need to function without being embedded in the xShare project’s governance, and without the financial support from the xShare project’s funding by the European Commission.

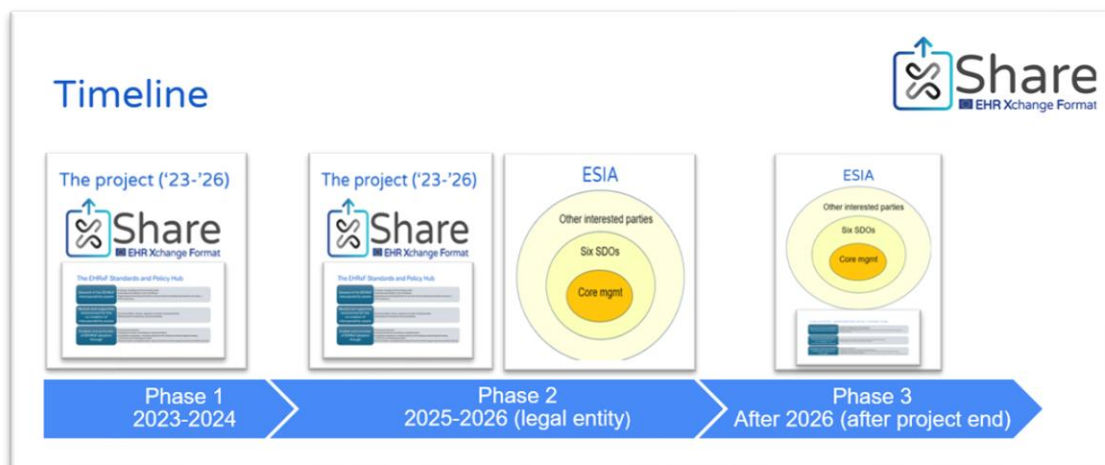


Figure 3: Timeline for the Hub and ESIA

Establishing the European EHRxF Standards and Policy Hub as an entity to advance standards driven innovation in the EHDS is a key objective of the xShare project and its key performance indicator #1 when the proposal was submitted in early 2023. The xShare project started in December 2023, and the establishment of a legal entity is planned for May 2025.

Delivering a sustainable governance and funding model will fall on the Hub's new legal entity: the "EHDS Standards and Interoperability Alliance" or "ESIA". The model of an alliance or membership structure was chosen to maintain the project's multistakeholder governance. Developing a legal entity early in the project would enable the Alliance already to engage in initiatives and contractual arrangements, beyond the scope of the xShare project, that would facilitate the Hub's transition from a project-based initiative to an independent and neutral service provider after the end of the project. The timeline is depicted in Figure 3.

GOVERNANCE MODEL

The xShare project has delivered the Hub's governance within the wider xShare project governance for the duration of the project, enshrined in the xShare consortium agreement and ensuring democratic processes through the

- partnership council as the ultimate decision-making body,
- an executive committee, and
- a project office supporting the collaboration in the work packages and project wide.

The xShare project has also made provisions for general stakeholder outreach and specifically the creation of two for a for two key constituencies of the Hub: regulators (understood to be Member States' public authorities) and industry. ESIA will follow the xShare governance model in some critical aspects:

- **Multi-stakeholder:** ESIA will be developed as a nonprofit international membership association, with the legal instrument of an AISBL (an "*association internationale sans but lucratif*") that has been chosen by many European stakeholder associations registered in Belgium. The AISBL has strict compliance rules in regard to democratic processes and transparency rules, but within these rules gives its members considerable latitude. As a membership association, ESIA will have SDOs at its core (beginning with the six SDOs in the xShare consortium) and will be open to all European stakeholder organisations as well as academic and research organisations.
- **Democracy, neutrality, transparency:** ESIA will ensure democratic decision-making processes conducted in full internal transparency, including the general assembly of all members the critical decisions, membership elections for the Board of Directors, and the Board of Directors supervising the chief executive and secretariat. The proceedings will be recorded and made open in full accordance with Belgian requirements and good governance practices. The principle will be consensus: no single organisation, or group of organisations, will be able to push through a particular agenda or issue. This will also go for the Hub: specifications will be delivered through consensus and collaboration.
- **Engagement with industry and regulators:** National and regional authorities ("regulators") and industry are constituencies with a special interest in the Hub as a provider of a neutral collaborative environment for co-creation and of EEHRxF-related specifications and services. To ensure the impartiality and neutrality of the Hub and of ESIA, both groups will not be eligible to join ESIA as members; instead, ESIA will seek to build consultative and advisory bodies akin to the xShare regulators and industry fora. These advisory boards would be managed and periodically convened by the ESIA Board members for information sharing and strategic discussions. For both groups there will be mechanisms to seek their involvement, engagement and support.

These aspects will be adapted to the requirements of a membership association under Belgian law. ESIA will seek to engage with the European Commission and its DGs (alongside with other

international bodies, such as the WHO, OECD, the Global Digital Health Partnership) in informal ways; options include periodic consultations, invitations to board of directors meetings, and other arrangements.

To build support and interest among members of the xShare consortium in ESIA, the project considered the Hub's value proposition in a workshop in March 2024. In May 2024, all consortium members were invited to express their interest to support this Alliance through a formal letter of intent. By the end of 2024, 21 of the 37 consortium members signed the letter and will join the discussions of the bylaws and internal rules of ESIA, membership conditions and fees, and the development of a business model with robust revenue streams.

A SUSTAINABLE PARTNERSHIP

For ESIA, the key members will be the SDOs. The field of digital health standards and specifications appears fragmented, with a plethora of public and private organisations with arcane abbreviations that can be confusing for customers and users. Turning this diversity of standards and specifications into a one-stop-shop for EEHRxF specifications will be a key innovation of the Hub and ESIA, and will deliver a critical value proposition to the field.

SDOs and stakeholder organisations have been building collaborative habits through years of EU-funded projects to advance digital health interoperability. These projects go back at least to the epSOS project (2008-2014) and include HITCH, Trillium Bridge, Antilope, EXPAND, eStandards, X-eHealth, and XpanDH, among others. SDOs have occasionally sought to give such collaborations a more lasting structure, including the Joint Initiative Council.

The Hub, the European EHRxF and the European Health Data Space will be the shared purpose binding the SDOs, stakeholder associations and the academic/research organisations together. ESIA as an institution will provide a more lasting basis and an institutional home for:

- The European EHRxF interoperability assets
- The collective knowledge of co-creation, testing, assessment
- The collaborative habits among SDOs
- The resolution of conflicts through deliberation and consensus
- The source of technical assistance and training around EEHRxF specifications.
- The industry label for the European EHRxF

With a clear and shared mission, a robust and transparent governance, and a compelling value proposition for EHDS implementation, ESIA will fill a clear need and function in the emerging EHDS ecosystem.