xShare

Expanding the European EHRxF to share and effectively use health data within the EHDS

The industry xShare label

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Working paper description

Number and name of working paper: The industry xShare label

Publishable summary: The xShare Industry Label is a voluntary certification developed to help the digital health industry align with upcoming European Health Data Space (EHDS) requirements. It provides a pathway for manufacturers to demonstrate technical compliance with interoperability standards, supporting early readiness for the EHDS and fostering cross-border health data exchange.

Statement of originality

This working paper contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Disclaimer

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List of abbreviations

Please refer to the i~HD Glossary: https://glossary.ramit.be/public/index.cfm

Abbreviation	Term
CE Mark	Conformité Européenne Mark
EEHRxF	European Electronic Health Record Exchange Format
EHDS	European Health Data Space
EU	European Union
GDPR	General Data Protection Regulation
HL7	Health Level 7 International
IEEE	Institute of Electrical and Electronics Engineers
IHE	Integrating the Healthcare Enterprise

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Executive summary

This report presents the design, validation, and sustainability strategy for the experimental xShare industry label, developed under the xShare project to support industry readiness for upcoming obligations under the European Health Data Space (EHDS), with a focus on compliance with the European Electronic Health Record Exchange Format (EEHRxF), and more precisely, the interoperability harmonised components set in the EHDS regulation.

The label has been designed as a voluntary, pre-regulatory tool that helps manufacturers of EHR systems and wellness applications demonstrate their ability to meet upcoming EHDS interoperability requirements, particularly in the areas of data portability, secure sharing, and structured health information exchange. The label supports manufacturers in preparing for formal EU declarations of conformity (Article 39), participation in digital testing environments (Article 40), and future listing in the EU-wide registry for certified EHR systems and wellness apps (Article 49).

The development process included extensive engagement with industry stakeholders, including expert interviews, workshops, and benchmarking of existing labelling initiatives. Findings indicate that the label is seen as a valuable steppingstone toward EHDS compliance, provided it aligns with existing industry practices and regulatory frameworks, reduces duplication with other certification schemes, and provides clear benefits in terms of market visibility and procurement readiness.

The label validation process combines self-assessment, technical testing using tools like Gazelle, and real-world usage demonstrations, with the results published in the xShare database. This database is designed to serve as a preparatory environment for the official EU registry, ensuring manufacturers can familiarise themselves with future EU registration requirements and demonstrate early alignment with EHDS interoperability standards.

The European EHRxF Policy and Standards Hub, established under the xShare project, will ensure the long-term maintenance, promotion, and governance of the label beyond the project's end in 2026. The Hub will provide continuous testing services, stakeholder engagement platforms, and technical support to help the industry adapt to the EHDS Implementing Acts expected in March 2027 and the first wave of mandatory compliance in 2029.

Finally, it offers initial recommendations to the European Commission on how the label's findings and methodologies can inform the design of the EU conformity declaration, digital testing environments, and the EU certification database, providing information for the upcoming implementing acts, positioning the experimental xShare industry label as a practical enabler of EHDS policy implementation and a trusted signal of interoperability readiness across Europe.

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1 Introduction

In the context of xShare, the **xShare Yellow Button**[1] refers to a recognisable user interface element designed to enable individuals to access their health data and perform a **one-time download or secure sharing action**. This functionality aims to simplify the process for patients or data holders to obtain and share their electronic health data in line with the EHDS requirements for data portability and interoperability.

Building on this concept, the experimental **xShare Industry Label** will be awarded to organisations that can demonstrate their technical capability to implement this feature. Specifically, the label will certify that the organisation's solution supports either or both of the following functions:

1. **Download**: Allowing users to securely export their personal health data.
2. **One-Time Share**: Enabling users to share their data once with a specified recipient, following secure and verifiable technical processes.

Certification will be based on compliance with the **technical specifications** outlined and updated in the xShare Yellow Button 1.0 IG available at https://build.fhir.org/ig/hl7-eu/xShare/content.html.

The development of the xShare industry label is aligned with EHDS Regulation and its implementation timeline. Specifically, the label is designed to help industry prepare for key regulatory milestones, including the **adoption of the EHDS Implementing Acts expected in March 2027** and the **first wave of mandatory conformity assessments starting in 2029**. By providing a structured, voluntary pathway for early technical validation and market preparation, the xShare Industry Label offers manufacturers a practical way to align with EHDS requirements ahead of formal enforcement. The following image shows the latest EHDS upcoming dates:

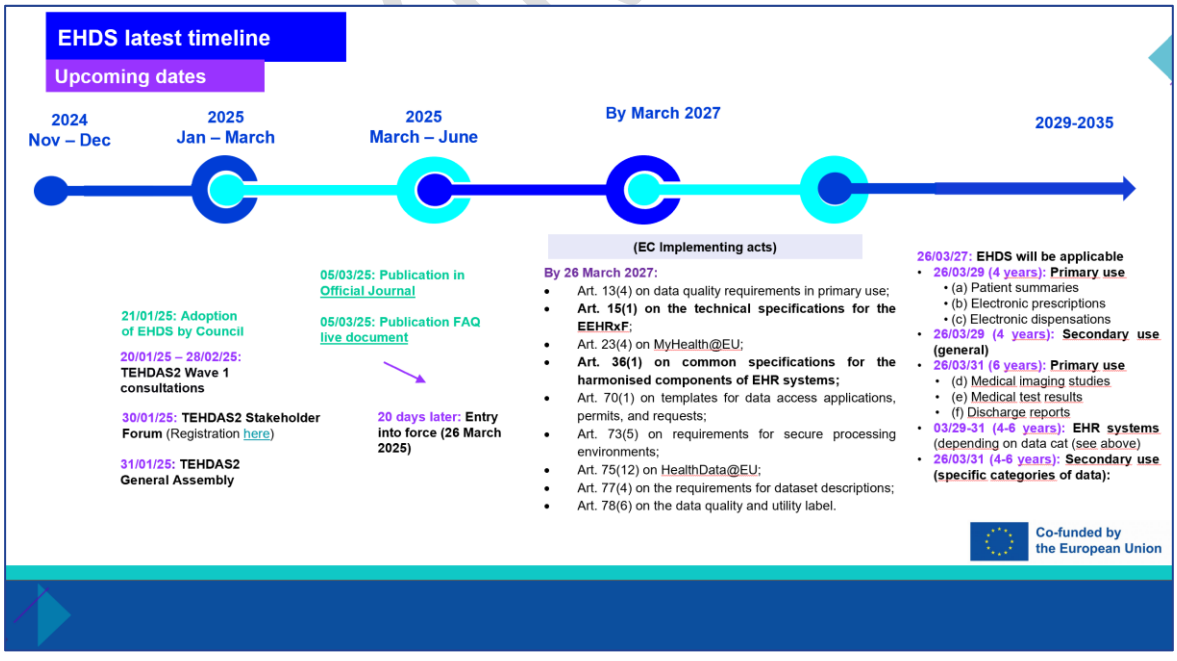

Figure 1 - EHDS upcoming dates

[1] "Yellow Button Information View - xShare Project Yellow Button v0.1.0," accessed April 16, 2025, https://build.fhir.org/ig/hl7-eu/xShare/content.html.

2 Methodology

2.1 Overview of research design

The xShare Industry Label is built on a shared vision of facilitating compliance with the interoperability requirements within the EHDS Regulation, with a particular focus on the EEHRxF.[2] However, while this vision is well established, further discussion and refinements will be needed to define robust evaluation criteria and validate the certification process through collaboration with digital health authorities and industry players to make the label feasible and usable by stakeholders in which are affected by the different Articles of the EHDS. Mainly, the following Articles were the ones that are of imperative to link with the experimental xShare Industry Label, besides Art. 36 listing the priority health data categories:

- **EU declaration of conformity (Article 39)** requires EHR system manufacturers to perform a self-assessment and issue an EU declaration of conformity to ensure their systems meet interoperability and logging requirements under the regulation.
- **Digital testing environments (Article 40):** across Member States for ex-ante assessment of compliance with the requirements
    - To assess compliance of harmonised components with essential requirements
    - Developed by the European Commission, deployed by Member States
- **EU database for registration of EHR systems and wellness applications (Article 49)** introduces a mandatory label for wellness apps that claim interoperability with EHR systems, helping users identify apps that meet EU standards for interoperability and security.

A consideration in this process is ensuring the experimental xShare industry label is both feasible and acceptable to industry stakeholders. Even if the label is technically comprehensive, **its true value lies in its adoption by the industry.** Without acceptance, the xShare industry label risks of becoming an unpractical project output, regardless of how well-crafted and aligned with the EHDS it may be. To use its full potential, it is essential to understand industry needs, evaluate feasibility from their perspective, and identify the factors that could either drive or hinder adoption.

It is important to note that the current assessment of the xShare Industry Label's feasibility does not include a direct financial evaluation, such as calculating return on investment (ROI) or predicting specific economic benefits. At this stage, such assessments would be highly speculative and unlikely to yield meaningful or reliable insights. The financial implications are difficult to forecast without broader implementation data and long-term adoption trends. Therefore, the focus remains on evaluating the conceptual, regulatory, and practical feasibility of the label rather than doing financial estimations.

Having said that, the organization of the IHE Pluggathon (xShare track) in Vienna and the subsequent open calls will provide preliminary input for the long-term sustainability discussion in the context of the European EHRxF Standards and Policy Hub, to be hosted under ESHIA.

[2] "eHealth Network - European Commission," March 28, 2025, https://health.ec.europa.eu/ehealth-digital-health-and-care/digital-health-and-care/eu-cooperation/ehealth-network_en.

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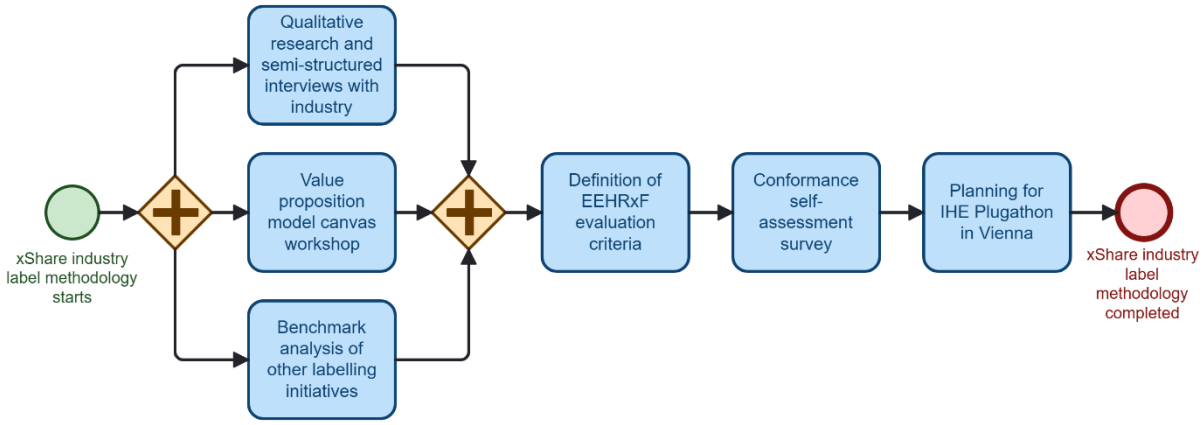

Figure 2 - xShare industry label Creation Methodology Process

2.2 Qualitative research and semi-structured interviews with industry

The project team adopted a qualitative methodological approach, conducting targeted interviews to gather insights from experts representing different segments of the industry to assess the industry needs, perceptions, and priorities for a successful and smooth xShare Industry Label rollout. In this context, the interview questions revolved around four key themes, namely, **(I)** assessing feasibility and practical challenges; **(II)** exploring the business viability and strategic potential of the label; **(III)** designing a scalable and industry friendly certification process; **(IV)** exploring the adoption barriers and enablers.

In this context, **45-minute semi-structured expert interviews** with industry representatives across different segments and levels were conducted. The interviews aimed to explore the feasibility and business viability of an EU-wide xShare industry label for the EEHRxF. Additionally, the interviews aimed to capture various perspectives, needs, and requirements, to shape a more comprehensive and inclusive strategy for the xShare Industry Label adoption.

The interviews were conducted using a semi-structured format, which facilitated a focused yet flexible dialogue, allowing for further probing on key themes arising. Each session, held virtually to accommodate the geographic diversity and time zones of the participants, lasted from 45 to 55 minutes, optimal for engaging in discussions without inducing fatigue in the interviewee. The full list of questions can be seen in the annex chapter: 10.1 Annex A) Collection Instrument for xShare Industry Label Interviews with Industry Representatives. The responses were qualitatively analysed, integrating insights with the findings from **xShare Industry Label User-Centred Workshop held on 22 April 2025** (explained in its own section below) virtually via Microsoft Teams video conference tool and other discussions made within project meetings, especially in WP9 monthly meetings. This approach enabled a comprehensive understanding of the industry's perspective on the xShare industry label's adoption criteria, certification process as well as adoption drivers and barriers.

Data collected from the semi-structured expert interviews and the workshop are thematically analysed to detect recurring themes with the support of ATLAS.ti.[3] The software was used to analyse the interview data with more ease and speed, as the functionalities offered include workflows, sentiment

[3] "ATLAS.Ti | The #1 Software for Qualitative Data Analysis," ATLAS.ti, accessed April 15, 2025, https://atlasti.com.

analysis and identification of common patterns. The synthesis of these insights aims to help in defining a robust evaluation criterion and validate the certification process of the xShare industry label.

The following table shows the industry segment and the country from each interview. Other personal data from participants is occulted as per previous agreement and to also follow GDPR guidelines.

Interview Code	Industry Segment	Country
E01	Health IT/EHR Infrastructure	DE
E02	In Vitro Diagnostics (IVD) & Lab Systems	FR
E03	Medical Imaging & Connected Care	NL
E04	Medical Devices	DE
E05	EHR Software Vendor	NL
E06	Accreditation, Certification, and Risk Management Services	NO
E07	Health IT / Electronic Health Record (EHR) Systems	UK

Table 1 - xShare industry label expert interviews

2.3 Value proposition model canvas workshop

To ensure the development of a meaningful and user-driven xShare Industry Label, the project team also conducted a dedicated **Industry Label User-Centred Workshop** on **22 April 2025**. The objective was to collaboratively validate the **value, feasibility, and usability** of the proposed label with key industry stakeholders and come up with a clear **value proposition.**

The session was designed using the **value proposition model canvas** as a structured facilitation method. This tool enabled participants to systematically explore the benefits, pain points, and requirements associated with the xShare label from their organizational perspectives. Participants represented a diverse range of industry stakeholders, including healthcare providers, IT vendors, standardization bodies, and policy experts. The session had an average of 20 participants during its 1-hour duration.

Using a **collaborative Miro board**, participants co-created the (1) customer segment, right side of the canvas and (2) the value proposition, left side of the canvas, ensuring collective ownership of the results. The outcomes included concrete suggestions to improve the xShare industry label's clarity, feasibility, and relevance for the project stakeholders.

2.4 Benchmark analysis of other labelling initiatives

This chapter was developed through a combination of document analysis and stakeholder consultations. The research started by reviewing previous work, which provided an initial mapping of existing labelling initiatives relevant to health data interoperability and regulation. Building on this foundation, the team conducted targeted desk research to further analyse the scope, adoption, interoperability focus, and regulatory status of these initiatives. To validate and enrich the desk research, the in-depth interviews were carried out to explore practical experiences with existing labels, identified unmet needs, and tested the relevance and feasibility of the proposed xShare Industry Label. The team cross-checked these insights with the requirements of the upcoming EHDS regulation and the EEHRxF. The results were synthesised through a comparative analysis, highlighting gaps and opportunities in the current landscape, and positioning xShare's contribution. The draft findings were

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then reviewed and refined with input from consortium partners and stakeholders to ensure their robustness and practical value.

2.5 Definition of EEHRxF evaluation criteria – conformance self-assessment survey

This survey was prepared based on established technical requirements widely adopted by the industry and informed by ongoing policy discussions involving participants in the xShare project, the current version of the conformance statement survey can be seen here.[4] It underwent internal circulation within the consortium to gather input and ensure alignment with project objectives. The content reflects the principles set out in Article 39 of the EHDS Regulation (EU declaration of conformity)[5], which requires EHR system manufacturers to carry out a self-assessment, testing in an environment provided by the EC to member states, and issue an EU Declaration of Conformity. This declaration ensures that systems meet **harmonised software components for EHR systems** defined under the regulation. While the document provides only an initial outline with a focus on the **interoperability requirements** (as the label does not check for logging requirements), it explores the role in facilitating cross-border health data exchange in the European Union. The preparation process ensured that the document is both technically sound and consistent with regulatory expectations, with contributions validated through collaborative review by the consortium partners.

The purpose of such document is to be able to test the experimental xShare industry label and provide policy recommendations to the European Commission regarding the conformance self-assessment survey that will be coming during the implementing acts in March 2027.

2.6 IHE Plugathon in Vienna (June 23 – 27)

The Gazelle Testing Environment is an open-source platform developed by IHE-Europe to support the testing and validation of healthcare IT systems, particularly for interoperability standards such as HL7.[6] It is widely used in the IHE Plugathon that will take place from the 23rd until the 27th of June 2025 in Vienna.[7] During the Plugathon, the staff from IHE-Europe will help manufacturers to ensure their solutions can be compliant with the interoperability requirements set for the **xShare Yellow Button.**

As explained in chapter **Error! Reference source not found.**, the xShare Yellow Button represents a user-facing functionality that enables individuals to download or perform a one-time sharing of their personal health data. Building on this concept, the experimental **xShare Industry Label** will be awarded to those who can demonstrate their ability to support these functionalities in line with the technical specifications outlined in the table below. These specifications are continuously updated on the xShare Yellow Button IG page.[8]

[4] xShare Project, "xShare Yellow Button Declaration of Conformity," April 2025, https://shorturl.at/12C5S.
[5] European Commission, "Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and Amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (Text with EEA Relevance)" (2025), art. 39, http://data.europa.eu/eli/reg/2025/327/oj/eng.
[6] "Gazelle | IHE Europe," accessed May 16, 2025, https://www.ihe-europe.net/testing-IHE/gazelle.
[7] "The 2025 IHE Plugathon Registration Is Now Open! - xShare," May 9, 2025, https://xshare-project.eu/news/the-2025-ihe-plugathon-registration-is-now-open/.
[8] "Yellow Button Information View - xShare Project Yellow Button v0.1.0. https://build.fhir.org/ig/hl7-eu/xShare/content.html"

9

Priority domains	HL7 FHIR IG
(a) patient Summaries	HL7 International Patient Summary v1.1.0
(b) electronic prescriptions;	HL7 EU ePrescription v0.1.0-ci-build
(c) electronic dispensations;	HL7 EU Medication Prescription and Dispense FHIR IG v0.1.0-ci-build
(d) medical imaging studies	HL7 EU Imaging Report v0.1.0-ci-build
(e) medical test results, including laboratory results	HL7 Europe Laboratory Report v0.1.0
(f) discharge reports.	HL7 Europe Hospital Discharge Report (0.1.0-ci-build)

Table 2 - Technical specifications to prove conformance with are the content specification

When it comes to Gazelle, there are three key advantages that the Gazelle testing environment has. First, Gazelle provides automated and standardised conformance testing against healthcare interoperability profiles. Second, it provides comprehensive test management and reporting tools. Third, it facilitates early detection of integration issues and increase product quality, reducing time as well as cost in product development.

For the experimental xShare Industry Label, three-level certification levels, so-called bronze, silver, and gold levels, are envisioned. All three levels use the same principle and are self-assessed by the manufacturers themselves, with the support of the xShare consortium. This tiered approach allows organisations to choose the level of rigour that best fits their needs. These certificates are independent of each other. These are explained in more detail in chapter 3, where the xShare industry label is explained in more detail. The IHE Plugathon in Vienna will be issuing the testing reports necessary for awarding **Silver level** of the experimental xShare industry label edition 2025.

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3 xShare Industry label feasibility analysis and discussion

3.1 Results of the interviews

Even if the experimental xShare Industry Label is designed to be technically comprehensive, its true value lies in its adoption by the industry. Without widespread acceptance, the label risks becoming obsolete, regardless of how well-crafted its specifications may be. To unlock its full potential, it is essential to understand industry needs, evaluate feasibility from their perspective, and identify the factors that could either drive or hinder adoption.

To support this effort, semi-structured expert interviews were conducted with representatives from various health industry segments, including health IT/EHR infrastructure, lab systems, medical imaging, medical devices, and EHR software vendors. These interviews explored four key themes:

I. **Specific objective 01:** Assessing feasibility and practical challenges
II. **Specific objective 02:** Exploring the business viability and strategic potential of the label
III. **Specific objective 03:** Designing a scalable and industry-friendly certification process
IV. **Specific objective 04:** Exploring the adoption barriers and enablers

3.1.1 Assessing feasibility and practical challenges

This section of the interviews examined how well the xShare technical specifications align with current industry practices, and the practical obstacles companies might face in adopting them. Understanding both current usage patterns and anticipated technical, operational, and organisational challenges offers insight into the readiness and adaptability of different segments across the health industry.

Across interviews, it emerged that none of the participating companies currently use xShare specifications directly, but most are aligned with widely recognised interoperability standards such as HL7 FHIR, DICOM, and IHE profiles. The relevance of these standards, however, varies significantly by sector.

During the interviews, two distinct industry positions emerged. The first group, comprising EHR vendors, health IT providers, and imaging solution manufacturers, commonly uses HL7, FHIR, DICOM, and IHE standards. These companies indicated a willingness to align with xShare industry label specifications if they are harmonized with both national and EU-level requirements. On the other hand, companies outside the traditional EHR or imaging domains such as those in the lab systems and diagnostics sectors, expressed scepticism regarding the xShare industry label's relevance for their domain. For instance, a representative from the in vitro diagnostics (IVD) domain noted that FHIR is virtually unused in laboratory environments. Adopting FHIR in this space would lead to major disruption of validated workflows and regulatory misalignment, particularly under frameworks like ISO 15189. The following table summarises the perspective of the industry on this subject:

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Feasibility / How to make it feasible	Practical challenges
• Alignment with existing standards like HL7 FHIR is feasible and already in use in several regions (e.g., Netherlands). • Alignment with the International Patient Summary (IPS) is essential to ensure global interoperability, especially for sectors like defence. • The label could provide market value if positioned as a voluntary, industry-friendly tool for regulatory alignment. • Using the label as a stepping stone toward EHDS compliance is viewed as positive, provided ongoing industry involvement in updates is ensured. • Existing patient engagement functionalities (e.g., one-click data sharing) are technically achievable if legal frameworks support cross-border rights.	• Lack of clarity on long-term maintenance and versioning of specifications after the initial publication by the European Commission. • The accelerated timeline for finalizing specifications may not allow enough time for technical maturity. • Missing API specifications reduce implementation predictability for developers. • Cross-border legal and governance challenges regarding data exchange remain unresolved. • Potential market fragmentation if member states introduce divergent national extensions or interpretations.

Table 3 - Interviews summary SO1

3.1.2 Exploring the business viability and strategic potential of the label

This section of the interviews has focused on exploring whether companies perceive strategic or commercial value in pursuing the xShare label, especially within a multi-tiered certification model. It also examined their willingness to participate in pilot testing, which reflects early confidence in the initiative's value and structure.

Most companies expressed a cautious openness to pursuing the xShare label depending on alignment with industry needs and regulatory relevance. In this context, some industry representatives were supportive of the label if it builds on existing infrastructure (e.g. MyHealth@EU), such as IHE Plugathon. However, many were critical of bronze-level (self-declared) certification, citing concerns about lack of verification and potential risks to data quality and credibility. Instead, they advocated for external validation to ensure trust and consistency.

Other respondents emphasized the need for clarity before committing to the label, arguing that sector-wide inclusion must be prioritized in the label's design. The tiered model (bronze, silver, gold) was seen as valuable for allowing gradual adoption and for recognizing varying levels of maturity across different types of vendors.

Most respondents were open to participating in pilot or co-creation settings if the testing is integrated into existing structures, remotely capable as well as resource efficient, and if it is not a standalone or duplicative process. For instance, one of the industry experts argued that they would only participate if testing were integrated with events like Plugathons. Similarly, others noted a strong preference for remote environments and lightweight validation methods. Some industry representatives stressed that testing should not be limited to some sectors. All sectors should be represented in the scope and criteria of the label. The following table summarises the perspective of the industry on this subject:

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Business viability	Business challenges
• Cautious openness if the label aligns with industry needs and regulatory frameworks. • Positive value perceived if the label builds on existing structures like IHE Plugathon rather than creating standalone schemes. • Tiered models (bronze, silver, gold) is seen as beneficial for gradual market adoption and reflecting vendor maturity. • Willingness to participate in pilot testing if integrated into existing events (e.g., Connectathons) and not duplicative. • Preference for remote-capable, resource-efficient, and lightweight validation methods to reduce participation barriers. • Strategic interest if the label is designed to represent all manufacturer types and sectors equally, ensuring broad market relevance.	• Strong criticism of bronze-level self-certification due to perceived lack of trust, verification, and data quality risks. • Concerns that standalone or duplicative certification efforts may discourage adoption if not harmonized with existing industry practices. • Risk of low credibility if external validation is not required, potentially undermining the label's industry acceptance. • Fear that testing limited to certain sectors or vendors may create market imbalance and reduce cross-sector relevance. • Need for clear governance, scope, and participation rules before committing to adoption or pilot testing.

Table 4 - Interviews summary SO2

3.1.3 Designing a scalable and industry-friendly certification process

Interviewees emphasised that the certification process must be technically credible, cost-effective, and aligned with existing industry practices. To avoid resistance and promote adoption, it must minimise disruption and leverage familiar tools and infrastructures. In this context, five key design principles, as well as five desired support mechanisms, have been identified across interviews.

Key design principles

- Integration with existing testing events, tools and standards such as IHE Plugathon, Gazelle validation platform, and HL7/FHIR tooling.
  1) Remote and automated testing would reduce cost and logistical burden as well as support scalability.
- The xShare industry label should align with the EHDS requirements, and its role relative to MDR, IVDR, ISO standards must be clarified
  2) New requirements should not jeopardise regulatory compliance.
  3) Certification should deliver procurement advantages, recognition, and customer trust

Desired Support Mechanisms

1) Well-structured implementation guides with examples and walkthroughs
2) Reliable support channels, including helpdesks and peer forums
3) Interactive documentation platforms similar to FHIR IGs or IHE tools
4) Webinars and onboarding workshops for structured orientation
5) Pre-certification sandboxes that allow self-testing and early debugging

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Key aspects to facilitate user friendliness	Key aspects to avoid/ monitor when issuing the label
• Integration with existing events like IHE Plugathon to leverage familiar, recognized validation structures. • Remote-capable testing environments to reduce travel and resource constraints. • Lightweight validation procedures that minimize administrative burden, especially for smaller vendors. • Clear, transparent criteria and governance mechanisms to guide industry participation confidently. • Flexible scheduling and modular validation tracks accommodate different development timelines and product scopes. • Avoidance of sector-specific bias by ensuring cross-industry relevance in process design.	• Risk of fragmented validation environments if not harmonized with other European or international frameworks. • Risk that overly centralised or inflexible procedures could discourage participation. • Absence of a long-term update and maintenance plan could lead to outdated criteria. • Risk**s** that lacks stakeholder oversight could reduce trust in the governance of the label.

Table 5 - Interviews summary SO3

3.1.4 Exploring the adoption barriers and enablers

In this section of the interview, companies shared insights on what would most motivate or deter them from adopting the xShare industry label. While many technical and operational concerns were noted, the strongest motivators were strategic and market driven.

Drivers for the experimental xShare Industry Label:

1) Regulatory alignment. If endorsed by the EU or national governments such as via EHDS, the label would carry strong weight.
2) Procurement relevance. A recognized role in public tenders or procurement processes would create a strong incentive.
3) Market signalling. As a visible badge of compliance and technical maturity, the label could support sales and customer trust.
4) Compatibility with existing standards. Adoption would be easier if the label builds on familiar frameworks such as IHE, HL7, ISO, MDR/IVDR, avoiding redundant certification efforts.

Barriers for the xShare Industry Label

1) Unclear business value or lack of demand and customer interest
2) High resource burden, especially for smaller vendors
3) Duplication with other certification frameworks
4) Immature or evolving specifications that could become obsolete

- Lack of harmonization across the EU which would make implementation inefficient.

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Aspects to facilitate uptake and adoption	Adoption barriers
• Official recognition or endorsement by EU or national authorities, especially in connection with the EHDS, creates a strategic mandate that is highly motivating for adoption. • Inclusion in public procurement as a qualifying or scoring factor would provide a direct commercial advantage, turning compliance into a competitive edge. • Visibility as a market-recognised label that signals technical quality and regulatory readiness, supporting vendor differentiation in competitive markets. • Re-use of existing standards and conformity frameworks (IHE, HL7, ISO, MDR/IVDR) ensure investment protection and minimises rework.	• Lack of real customer or market demand, making the label a non-priority for business strategy. • Perception of low ROI if the label does not translate into market access, customer trust, or procurement advantage. • Potential redundancy with other certification schemes, leading to market fatigue and duplicative compliance costs. • Obsolescence risks if technical specifications are not stable or quickly outdated, undermining long-term value. • Inconsistent adoption across Member States, risking market fragmentation and inefficient implementation efforts.

Table 6 - Interviews summary SO4

3.2 Results of the workshop value proposition model canvas workshop

As part of the feasibility assessment, the xShare consortium organised a dedicated co-creation workshop with industry representatives on 22 April 2025. The objective was to validate whether the proposed xShare Industry Label can provide meaningful support for compliance with the EHDS regulation, while being practical, scalable, and aligned with market needs. Using the Value Proposition Canvas methodology, participants were asked to map both the industry's challenges and the potential value of the label. Based on the **interviews and the workshop,** the main value proposition may be:

Main value proposition of the xShare Industry label
The xShare Industry Label is an experimental, voluntary label designed to help the industry prepare for upcoming interoperability components, mandated by the EHDS. Its main purpose is to support manufacturers in getting ready for EEHRxF compliance by 2029 for primary use and 2031 for secondary use, by offering clear guidance, visibility, and alignment with European standards, without adding unnecessary complexity.

Table 7 - xShare industry label value proposition

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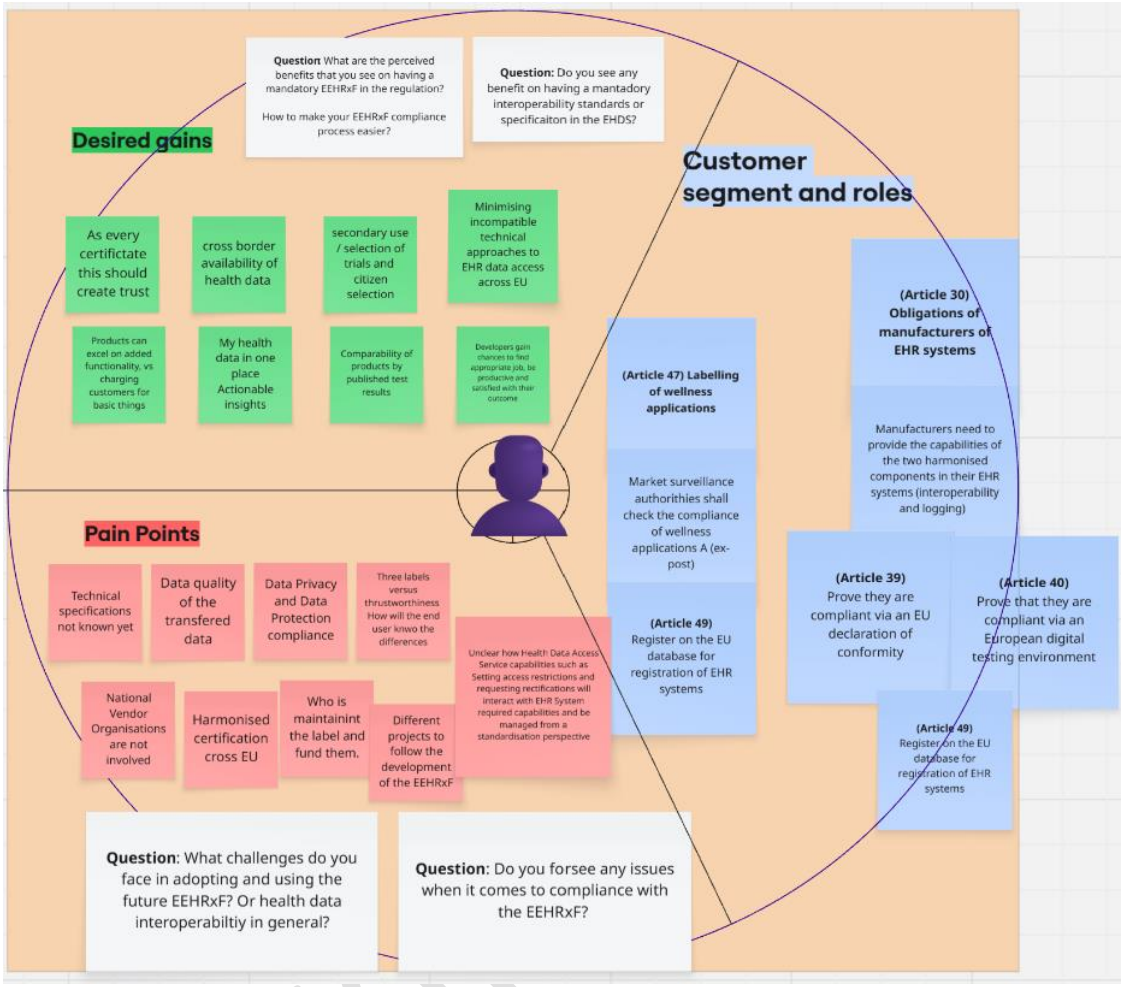

Figure 3 - Customer segment (right side)

On the **customer segment (right side of the canvas)**, industry members expressed several challenges and expectations regarding the adoption of the xShare Industry Label. Some raised concerns about the feasibility and added value of a three-level certification (bronze, silver, gold), fearing it might create unnecessary complexity and confusion, especially if national variations are introduced on top of EU-level requirements. Participants emphasised the need for a harmonised certification process that is recognised across all EU Member States, thereby reducing the risk of fragmented implementations or additional market barriers. Specific pain points included a lack of clarity on the technical specifications that would underpin the label, uncertainties around how data protection and privacy requirements would be addressed, and the absence of mechanisms to ensure comparability and trustworthiness of certified solutions. Participants also highlighted the need to address challenges related to maintaining data quality, supporting cross-border data access, and ensuring that vendors and users are actively involved in the ongoing development of the label.

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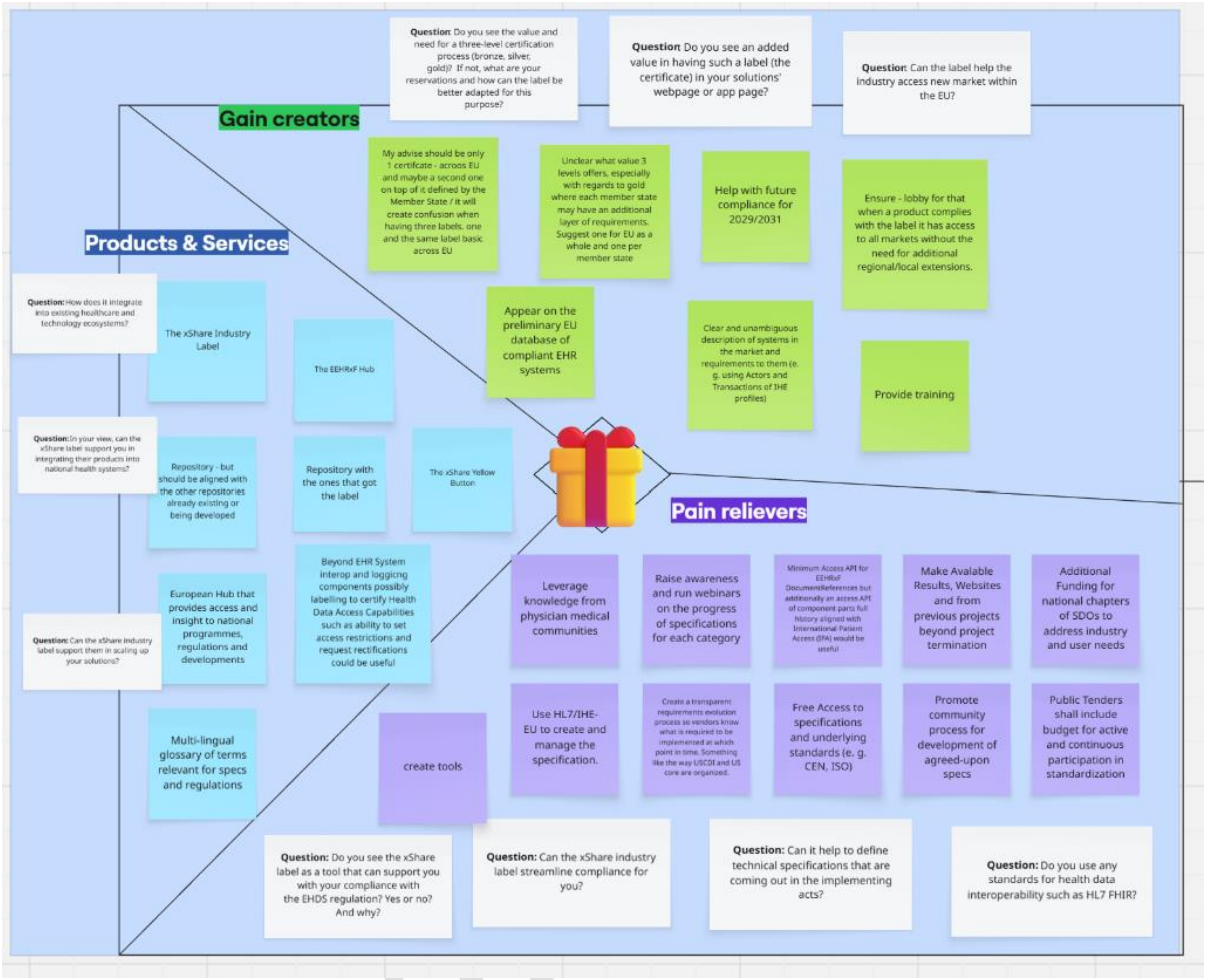

Figure 4 - Value proposition (right side)

On the **value proposition** (**left side of the canvas)**, participants identified key features and services that the xShare Industry Label should offer to create value. They suggested positioning the xShare industry label as a single, EU-wide certification with the possibility for optional national extensions, to ensure coherence while allowing for local flexibility where needed. The label should be backed by clear and publicly accessible technical specifications, as well as a central EU repository that lists all certified solutions to improve transparency and market visibility (and preparation for the EU database as required by the EHDS regulation). Additional support measures were proposed, including multilingual resources, webinars, and training to help organisations navigate compliance requirements. Participants also recommend establishing a transparent process for updating the certification criteria, ensuring that vendors are aware of evolving requirements in a timely manner. Finally, they encouraged leveraging existing European communities, such as HL7 and IHE, and industry associations (DIGITALEUROPE, MedTech Europe) to manage and promote the xShare industry label and called for sustained investment in these activities to ensure long-term success and relevance.

The feedback gathered in the workshop shows that the xShare Industry Label is **both relevant and feasible**, but only if certain conditions are carefully addressed. Participants were clear in their call for **simplicity and clarity**, a single EU-wide certification, backed by clear technical requirements, seems the most promising way forward. They also highlighted the need for **practical support**, such as access to standards, training, and ongoing communication to keep the industry informed as the label evolves.

Equally important is the **need for long-term commitment**: the xShare industry label cannot succeed if it is launched without a clear plan for how it will be maintained, governed, and funded over time. However, if these challenges are taken seriously and addressed in the next stages of the xShare project, participants agreed that the xShare industry label could become a **valuable and trusted tool** to help industry navigate EEHRxF compliance and improve interoperability across Europe.

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4 Benchmarking and gap analysis results

This benchmark analysis describes the other labelling initiatives and their role in the labelling landscape. It aims to address "why the xShare industry label is needed?" and "what is the value proposition of the xShare industry label?" by providing the outline of value proposition and requirements for each label. In other words, it assists the xShare industry label to position itself within the labelling landscape, to also complement the other labels and potentially fill in the gaps on issues that the other labels are not solving.

The section provides analysis of the labels based on:

- Interoperability standards;
- Regulatory compliance;
- Scope of application;
- Adoption and recognition.

4.1 Recap of D9.1 (The Vision for an xShare Industry Label) findings

In the working paper xShare D9.1: The Vision for an xShare Industry Label – Liberating Health Data, the benchmark analysis mapped the diverse landscape of labelling initiatives, including the CE Mark, ENCePP Seal, EUCROF Code of Conduct, Continua Guidelines, IHE CONNECTATHON SEAL, Label2Enable, WiFi (IEEE), QUANTUM, and Blue Button 2.0. Each of these serves distinct purposes within their respective domains.

This analysis identified existing gaps and clarified how the xShare Industry Label could be positioned within the current labelling ecosystem. Specifically, it highlighted how the xShare Label could complement existing initiatives by addressing unmet needs. As a result, building on the xShare vision of everyone having access to their health data at the click-of-a-button in the EEHRxF, four key strategic contributions of the experimental exShare Industry Label have been identified: enhancing interoperability, strengthening regulatory compliance, broadening the scope of application, and increasing adoption and recognition. Based on this analysis, the following conclusions have been drawn:

- First, the xShare Industry Label can enhance interoperability. By aligning with standards such as those developed by Continua and IHE, the label can support high levels of interoperability within specific workflows.
- Second, it can strengthen regulatory compliance. Drawing on insights from labels such as the CE Mark and the EUCROF Code of Conduct, the xShare Industry Label can offer robust frameworks to support compliance with key EU regulations, including the GDPR and the forthcoming EHDS.
- Third, the xShare Industry Label can broaden the scope of application. Unlike labels that target specific domains such as Label2Enable for health apps or Blue Button for patient data access, the xShare Label aims to provide a more comprehensive framework applicable across a wide range of health data uses, including clinical research and digital health services.
- Fourth, it can increase adoption and recognition. By incorporating effective strategies from established labels such as WiFi (IEEE) and the CE Mark, the xShare Industry Label can promote greater trust, visibility, and uptake across the EU ecosystem.
- Fifth, it prepares the industry for formal regulatory processes, ensuring agility and compliance.

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4.2 Gap analysis of existing labelling initiatives

In the evolving landscape of digital health, a variety of labelling initiatives have emerged to promote trust, ensure regulatory compliance, and support interoperability across systems and devices. Each of these labels serves specific objectives ranging from product safety and data protection to interoperability validation and data quality assurance.

This section provides a structured overview of nine prominent labelling frameworks currently in use across Europe and internationally. For each initiative, it summarises the core purpose, interoperability orientation, regulatory status, scope of application, and level of adoption. By analysing both their strengths and shortcomings, this comparative review reveals critical gaps, particularly in cross-border data exchange, semantic interoperability, and alignment with upcoming EHDS requirements.

The xShare Industry Label is a strategic and future-oriented initiative designed to address these gaps. Specifically, it aims to operationalise compliance with the EEHRxF and facilitate the secure as well as structured exchange of health data in line with EHDS Article 36. The following table offers a side-by-side comparison of the xShare Industry Label with existing labelling schemes, outlining its unique contributions and positioning within the broader regulatory and interoperability ecosystem.

Labels	Short Description	Interoperability Standards	Compliance necessity	Scope of Application	Adoption and Recognition
xShare Industry Label	Assesses EHR systems conformance with interoperability requirements of the EHDS.	Focuses on EEHRxF, HL7, SNOMED CT, LOINC, IHE	Voluntary for now, but aligns with upcoming mandatory EHDS rules	Health IT systems, apps, and EHRs for primary use of health data in the EU.	Emerging; intended for wide EU adoption and integration into EHDS ecosystem
CE Mark	Shows that a product meets European safety, health, and environmental requirements.	Defined European standards	Mandatory EU compliance	Broad (various product groups)	High (mandatory for market access)
ENCePP Seal	Identifies studies in the HMA-EMA Catalogue adhering to CoC provisions.	ENCePP methodological standards and governance principles	Adherence to the CoC is mandatory for Seal. CoC is referenced by EMA guidelines.	European, global relevance (all medicinal products)	Recognized and adopted within EMA, but not universally
Code of Conduct EUCROF	GDPR Code for data processors in the clinical research industry.	GDPR; no interoperability standards yet	Compliance to GDPR	Global, open market for adherents	Managed by EUCROF, with supervisory body COSUP

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Continua Guidelines	Ensures interoperability of personal connected health devices.	High interoperability focus	Voluntary guidelines	Health devices and data	Moderate (industry-specific)
IHE CONNECTATHON SEAL	Recognizes a vendor's interoperability capability through IHE profile testing.	High emphasis on technical interoperability	Voluntary participation	Healthcare IT systems	Moderate (within healthcare sector)
Label2Enable	Promotes ISO/TS 82304-2 health app assessment framework for EU quality label for health and wellness apps.	Based on specific ISO standards	Aims for EU-wide quality recognition	Health and wellness apps	Emerging
WiFi (IEEE)	IEEE 802.11 standards underpin Wi-Fi network technology.	Standardization of connectivity	Not directly regulatory (tech standard)	Broad (consumer and enterprise tech)	High (global standard)
QUANTUM	Aims to develop a health data quality label for secondary use of health data in the EU.	Focus on dataset quality	Aims for EU-wide recognition	Secondary use of health data	Emerging
BlueButton 2.0	Aims to allow beneficiaries to share Medicare claims in the US with an Application Programming Interface	Focus on sharing claims data with trusted apps	Focuses on the US	Consumer and service industry	HL7 FHIR

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4.3 Comparative analysis with xShare industry label

The xShare industry label positions itself as a critical component within this ecosystem by addressing gaps and complementing existing labels. Specifically, the xShare industry label aims to:

- Enhance Interoperability: By aligning with standards such as those established by Continua and IHE, the xShare industry label can ensure high levels of interoperability in specific workflows, crucial for seamless health data exchange.

- Strengthen Regulatory Compliance: Leveraging insights from labels like the CE Mark and the Code of Conduct EUCROF, the xShare industry label can provide robust frameworks ensuring compliance with EU regulations, including GDPR and EHDS.
- Broaden Scope of Application: While other labels target specific areas like Label2Enable or Blue Button (e.g., health apps, clinical research), the xShare industry label can offer a more comprehensive approach, covering a wide range of health data applications.
- Increase Adoption and Recognition: By learning from the adoption strategies of established labels like WiFi (IEEE) and the CE Mark, the xShare industry label can implement practices that enhance its recognition and adoption across the EU.

Hence, the xShare Industry Label sets itself apart from other existing labels and certifications through its strategic alignment with the European Health Data Space. In other words, the xShare Industry Label aims to facilitate compliance with the interoperability requirements within the EHDS Regulation and ensures systems to align with EEHRxF. In this context, the xShare Industry Label differentiate itself from the other labels on:

xShare industry label VS CE Marking

While CE Marking under the MDR/IVDR framework ensures the safety, clinical performance, and regulatory compliance of medical devices, the xShare industry label serves as a complementary "addon" initiative focused on digital interoperability and data exchange in healthcare.

CE Marking acts as a mandatory regulatory gateway for market access, with non-compliance carrying legal and commercial risks. It is enforced by authorities and Notified Bodies. In contrast, the xShare Industry Label, governed by industry-led or multi-stakeholder models, promotes strategic alignment with the European Health Data Space (EHDS) by certifying systems for structured, coded, and GDPR-compliant data exchange. Rather than replacing CE Marking, xShare enhances digital trust and transparency by assuring stakeholders that systems are interoperable and ready for future health data regulations.

xShare industry label VS EUCROF GDPR Code of Conduct

EUCROF GDPR Code of Conduct primarily focuses on GDPR compliance for clinical research data processors by taking CROs and data processors as target group. While, xShare offers proactively technical and to a certain degree semantic conformance to HL7 FHIR IGs as EEHRxF specification are emerging, aligning more with data interoperability than privacy governance. It may incorporate codes like EUCROF's but is not limited to legal compliance.

xShare industry label VS ENCePP Seal

ENCePP Seal's primary focus is on scientific integrity and transparency in pharmacoepidemiology targeting mainly research centres and regulators. However, xShare focuses on enabling datath interoperability within and across jurisdictions, rather than scientific conduct.

xShare industry label VS Continua Guidelines

The focus of Continua Guidelines is on device interoperability and data exchange, and they take device and platform vendors as the target audience. On the other hand, xShare extends beyond device-level interoperability to systemic data exchange formats and infrastructure compliance across the EHDS.

xShare industry label VS IHE Connectathon Seal

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IHE Connectathon Seal focuses on IHE profile-based interoperability validation. While both IHE Connectathon Seal and xShare Industry Label validate interoperability, xShare is designed for broad EHDS compliance.

xShare industry label VS Label2Enable (CEN-ISO/TS 82304-2)

Label2Enable ensures the app quality and trust. On the other hand, by supporting compliance with EEHRxF, xShare Industry label adds policy and infrastructure relevance for EHDS.

xShare industry label VS WiFi (IEEE Standards)

The main domain of WiFi (IEEE Standards) is the wireless data transmission by focusing on device and network hardware manufacturers. On the other hand, xShare builds on semantic and syntactic interoperability.

xShare industry label VS QUANTUM Data Quality Label

QUANTUM Data Quality Label focuses on the dataset quality for secondary use under EHDS. While QUANTUM evaluates data sets, xShare evaluates digital health systems as well as apps, testing their ability to exchange data using EEHRxF.

xShare industry label VS Blue Button 2.0

Blue Button 2.0 is a US-specific API for patient data access for Medicare/Medicaid (senior citizens, and disabled). While focusing on the European Union regulations, interoperability across MyHealth@EU and EHR connected to the EHDS systems, the experimental xShare Industry Label is broader as it focuses primarily on patient facing apps and portals for 2025, across private and public health systems.

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5 The xShare industry label and how to attain it

As per the results of the different methods, the experimental xShare industry label represents a voluntary, non-regulatory certification scheme that enables manufacturers to demonstrate their conformance to interoperability requirements under the EHDS. Developed within the xShare project supporting the implementation of the EHDS, the xShare industry label is not intended to replace CE marking or legal conformity assessments. Instead, it functions as preparation and sandbox testing indicating a solution's technical maturity and readiness to engage in health data sharing and exchange within and across jurisdiction, e.g., to help manufacturers be prepared for full compliance by 2029/2031.

This labelling framework is built on three progressive levels—Bronze, Silver, and Gold—each representing an increasing degree of interoperability capability, technical rigour, and ecosystem integration. The goal is to offer a transparent and credible mechanism for recognising technical alignment with EHDS requirements, fostering trust among key stakeholders including healthcare providers, vendors, and patients. Each level is distinct and can be pursued independently, allowing organisations to engage their solutions according to their current technical readiness.

Experimental xShare industry label, labelling icons

Before detailing the different levels of the label, is necessary to highlight that xShare industry label demonstrates if an organisation can indeed implement the Yellow Button. The yellow button enables two core functionalities, namely **(I) download** and **(II) one-time share,** for health data. These functionalities are depicted with the icons below:

Icon	Yellow button functionality
	Download
	One-time share

Table 8 - xShare yellow button functionalities

The data that is then shared is in line with the priority categories of personal electronic health data for primary use of the EHDS (Article 36).[10] E.g., the yellow button functionalities are designed to work across the health priority categories of the EHDS, these are:

- patient summaries (S);
- electronic prescriptions (P);
- electronic dispensations (D);
    - medical imaging studies (I)
- medical test results, including laboratory results (L);
    - discharge reports (R).

In other words, it means that, when clicking the yellow button, an EHR system that is patient facing, will allow the person to **(1) download (yellow button functionality)** its **(2) patient summary - S (category of personal electronic health data).** The xShare industry label is issued then to depict wether

[10] European Commission, Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (Text with EEA relevance), art. 14.

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a system can enact the different functionalities of the yellow button, and for which personal electronic health data, the example below depicts that a system has the bronze level (self-conformance statement) with the yellow button working to download ( ) the patient summary (S) and electronic prescriptions (P) AND to one-time share ( ) the patient summary (S) and laboratory results (L).

Figure 5 - Example of xShare industry label (v2025)

When hovering the mouse on top of the xShare industry label, an hyperlink will be set to the https://build.fhir.org/ig/hl7-eu/xShare/labeling_process.html page, in which these icons and functionalities are more detailed explained to the user. The following chapters explain the main differences of the bronze, silver and gold levels.

5.1 Bronze level

Table 9: Experimental xShare Industry Label v2025,Bronze, indicative template example.

BRONZE
xShare Yellow Button Self-Declaration of Conformance Statement 2025 • Product Name, version, Company • Self Declaration of conformity ☐Download ☐ Upload ☐One-time Share • Supported: ☐PS ☐Laboratory report • Early adopter for: ☐Discharge Report ☐Medicine prescription/ dispensation ☐Diagnostic imaging report Supporting materials: • *xShare Yellow Button Declaration of Conformity insignia* • *xShare industry label database*

The Bronze level was designed with the requirements of Article 39 of the EHDS in mind, which mandates that manufacturers of EHR systems submit an EU Declaration of Conformity demonstrating

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alignment with the essential requirements laid down in Annex II of the regulation. This declaration of conformity also needs to be made available in the language where the EHR system is made available. The self-assessment approach of the bronze label directly supports these needs by offering a structured, standardised way to document conformance. It helps manufacturers clarify what to declare, simplifies verification for national authorities, and promotes consistency across member states, streamlining self-declaration processes and contributing to a more level playing field across the EU digital health market.

The bronze label is the entry point into the xShare labelling system, designed to encourage early-stage engagement by lowering the barriers to demonstrating interoperability. At this level, certification is achieved entirely through a self-declared conformance process. The process to attain this level of the label goes as follows:

- Manufacturers access the EEHRxF Policy and Standards Hub website, where they fill out the xShare Yellow Button Declaration of Conformity Template[11] outlining the functionalities their solution supports, such as the Download function or One-time Share, using the xShare Yellow Button. Additionally, they indicate whether their system operates as a provider (download/One-Time Share), a consumer (Upload/Access SmartHealthLink or QRcode), or both, and which xBundles[12] are implemented (e.g., patient summaries, lab reports, discharge documents).
    1) Upon successful submission of the xShare Yellow Button Declaration of Conformity Form, manufacturers automatically receive the experimental xShare Industry Label (bronze level) by email from the EEHRxF Policy and Standards Hub (industry-forum@ehr-exchange-format.eu), accompanied by clear instructions on how to appropriately use the label in their communication and product materials. This process ensures that manufacturers can quickly leverage the recognition provided by the label without additional procedural steps.
- In parallel, the declared EHR system or wellness application is registered in the xShare database, which also functions as a preparatory environment for the upcoming official EU database mandated by Article 49 of the EHDS Regulation. This step allows manufacturers to familiarise themselves with future EU registration requirements and supports the development of a consistent, transparent registry infrastructure across Europe.

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[11] xShare Project, "xShare Yellow Button Declaration of Conformity Template," v2025, https://shorturl.at/12C5S.
[12] xShare Project, "EEHRxF Priority Domains," accessed April 19, 2025, https://x-bundles.ehr-exchange-format.eu/domains/domains.html.

5.2 Silver level

Table 10: Experimental xShare Industry Label v2025 (IHE Europe Plugathon, Silver, indicative template example.

SILVER

*xShare Yellow Button Self-Declaration of Conformance Statement with external report 2025** • Product Name, version, Company • Self Declaration of conformity ☐Download ☐ Upload ☐One-time Share • Supported: ☐PS ☐Laboratory report • Early adopter for: ☐Discharge Report ☐Medicine prescription/ dispensation ☐Diagnostic imaging report Supporting materials: • Gazelle system report • xShare industry label website • Accessibility report • IHE plugathon website and material *Tested in IHE Europe Plugathon 2025 *xShare track*, report provided by IHE Europe

The Silver label was designed with the anticipated needs of Article 40 of the EHDS Regulation in mind, which mandates the creation of digital testing environments to assess compliance with interoperability, security, and performance requirements. This environment aims to simulate real-world conditions for evaluating digital health solutions before deployment. The Silver level process, through its structured use of the Gazelle platform and the IHE Plugathon for in-depth, scenario-based testing, provides a practical model for these future environments. By incorporating both automated and human-led assessments, Silver-level validation offers a blueprint for how such digital testing environments may function effectively in practice, supporting robust technical evaluations aligned with EHDS objectives.

The Silver label signifies a more advanced stage of interoperability maturity. At this level, systems must demonstrate the ability to both consume and produce EEHRxF-conformant data, establishing bidirectional interoperability and deeper integration into digital healthcare ecosystems. This process involves the use of Gazelle, a testing platform developed by IHE Europe, to validate structured documents such as International Patient Summaries (IPS), using HL7 FHIR and conforming to the xShare implementation guides.

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In this context, the Plugathon will play a role as an educational and validation environment for systems targeting the experimental xShare Industry label at the Silver Level. The Plugathon invites manufacturers to test how their EHR systems interact using standardised APIs in a real-time, collaborative setting. For the xShare label, the focus is primarily on IPS documents, though other types like lab results, ePrescriptions, discharge summaries, and imaging reports may also be tested.

The detailed process and workflow on how IHE-Europe will support issuing the testing report for the Hub to award the experimental xShare industry level at the Silver level, in the plugathon in Vienna and their test cases can be seen in this link (available only for those with access to the xShare internal SharePoint).[13] Prior to the connectathon the process will become public and a leaflet with the content of this section will be communicated to interested parties, including adoption sites and those expressing interest to implement the xShare Yellow Button. In summary, the process will go as follows:

The process to achieve the **Silver Level xShare Industry Label** begins with the **preparation of an IPS document**. Manufacturers are first asked to **select or define a test persona** that includes realistic clinical data such as the **person's name, age, conditions, medications, and allergies**. This information serves as the basis for the IPS, which must be generated in **HL7 FHIR format** using the provided **templates or example instances** as a guide.

For manufacturers who currently hold their IPS in **CDA format**, an **optional step** is available to convert the document to FHIR. This is achieved using the **cda2fhir converter** provided on GitHub, which transforms CDA content into FHIR-compliant IPS resources.

Once the IPS is prepared, manufacturers move on to the **technical validation phase**. They access the **Gazelle Validator platform** and select the **HL7 IPS FHIR IG validator**. Here, they upload their IPS document for **automated compliance testing**. A successful validation is confirmed when the **Gazelle validation report** shows the status **DONE_PASSED**.

Following technical validation, the process continues with a **facilitator-led content review**. In this step, a trained facilitator conducts a **visual inspection** of the submitted IPS. This review checks the **clinical accuracy** of the information, the **clarity of its presentation**, and the **consistency** between the IPS content and the persona's profile. If applicable, the facilitator also verifies the **correct use of standard codes**, ensuring the document meets semantic requirements.

Manufacturers must then **demonstrate the functionality of the xShare Yellow Button**, which allows a **natural person** to download their health data. They do this by **logging into their system as the persona** used to create the IPS and navigating through the **Yellow Button feature**. They must demonstrate that the system supports:

- **Authentication** of a natural person.
- **Search and selection** of the IPS document.
- **Download of the IPS**.

To document this demonstration, manufacturers provide **screenshots** that clearly show:

- The **authenticated user session**.
- The **document selection** process.

[13] xShare Project, "Test Cases - Plugathon 2025," April 2025, https://shorturl.at/oDRmj.

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- The **successful download**, including visible patient details to verify accuracy.

As an **additional extension**, manufacturers may also choose to validate the **One-time Share functionality** using **Smart Health Links**. This involves generating a **secure, revocable link** to the IPS document, demonstrating the ability to **retrieve** the linked document and verifying that the **link can be revoked** if necessary.

Finally, all gathered evidence is **submitted to the facilitators for final review**. If all validation steps are successfully completed, the manufacturer is awarded the **Silver Level xShare Industry Label**, with the specific **validated domain(s)** (such as **IPS**) explicitly listed in the certification.

After the process is completed, the **Gazelle testing environment remains open** to enable ongoing validation activities, allowing manufacturers to **retest or validate new implementations** as needed. Moreover, all successfully certified **EHR systems and wellness applications** are **listed in the xShare database**, which serves as an EU-wide **reference inventory**. This listing supports compliance with **Article 39 of the (EHDS)**, providing a structured and transparent way for manufacturers to demonstrate their conformance with **interoperability requirements**.

At the conclusion of the process, the Gazelle testing environment will remain open as a continuous service, allowing manufacturers to revalidate their implementations or test new versions of their systems at any time. This ensures ongoing access to conformance testing beyond the initial certification event. Furthermore, all EHR systems and wellness applications that successfully pass the silver label validation will be officially listed in the experimental xShare Industry Label database. As mentioned, this database, serves as a reference inventory at the European level, providing visibility to industry stakeholders, policymakers, and national authorities, as mandated by Article 39 of the EHDS.

A similar process will be followed for testing the Laboratory Report priority data categories. In the next version of the label robust testing of all priority data categories listed in Article 36, as well as the experimental categories of IPS+R and careplans, will be included as well as the link option.

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5.3 Gold level

Table 11 Experimental xShare Industry Label v2025, Gold level, indicative template example addon to national / regional health ecosystem -applicable to Catalonia.

GOLD

Country/Region: Catalonia Spain* *xShare Yellow Button Self-Declaration of Conformance Statement with external report 2025 from national ecosystem** • Product Name, version, Company • National Certificate Number • Testing Report (optional) • Self Declaration of conformity ☐Download ☐ Upload ☐One-time Share • Supported: ☐PS ☐Laboratory report Early adopter for: ☐Discharge Report ☐Medicine prescription/ dispensation ☐Diagnostic imaging report Supporting materials: • *Self-declaration form (ZoHO form)* • *Handbook* • *xShare industry label website* • *Label website for REGION* • *FAQs document on REGION* • *Contact info for questions*

The gold level of the label represents the highest level of xShare certification, designed to recognise organisations that are technically and operationally interoperable and embedded within national or regional digital health ecosystems. This level was created to highlight solutions that actively shape and support the broader goals of EHDS through standard-setting, public health collaboration, and advanced use cases such as clinical research and international care coordination. This real-world assessment ensures that the solution functions reliably within a regulated healthcare setting.

The manufacturer will need to engage with an officially recognised regional or national authority, such as Fundació TIC Salut Social in Catalonia, to demonstrate real-world integration into trusted healthcare networks. The national/regional authority may introduce additional tests. For example, in the case of

TicSalut, if the organisation has been validated with the silver level, which is highly recommended, the regional or national validation will be more straightforward, assessing (with a set of criteria) the maturity of the IPS sections –which has not been validated in the silver level. On the contrary, if the organisation applies for validation directly in the region or country, the necessary validation to attain the gold level will be more complete, both using Gazelle to ensure compliance with all requirements linked to the Silver level and assessing the maturity of the IPS sections. Moving forward the intent is to harmonize testing procedures.

In the case of Catalonia, the criteria will assess the level of maturity of the organisation. Level 1 means that the organisation has not included all mandatory sections in the IPS, level 2 includes all the mandatory ones only, and level 3 includes the mandatory ones plus some additional sections. Organisations will have to demonstrate their compliance of the defined set of criteria through evidence.

The process to attain this level of the label goes as follows:

1. The national or regional authority must receive a formal request from the organisation (filling an online Zoho form) accompanied by evidence (technical documentation and functional specifications, typically in machine-readable formats like XML or JSON). The data submitted must cover priority EHDS categories and comply with mandatory EEHRxF requirements. The authority will have available a set of documentation for the organization to consult (handbook, criteria, FAQs, contact information, among others).
- The regional or national authority evaluates the system using its set of defined criteria. In case the authority already has a pre-defined, functioning digital health assessment framework, this set of criteria could be assessed as an add-on in the framework, such as in the case of Fundació TIC Salut Social in Catalonia.[14]
2. If successful, the manufacturer receives a formal assessment report and the gold level label certificate. If any issues (non-conformities and corrective actions) are found, a report outlining shortcomings and recommended improvements is provided instead.
- Upon successful completion, the organisation is awarded the gold label, by submitted the supporting information to the Hub, namely the identification of the national certificate and the testing report for Silver.

Conformant organisations will be a symbol of leadership in interoperability and EHDS conformance and signify authorization to safely access personal health data from the specific jurisdiction. As noted earlier, where testing criteria are available locally, the aim is to harmonize with the interoperability testing procedures available in Gazelle. For those priority data categories where local criteria do not yet exist and the digital health application cannot access the relevant data, the Silver label will be award, assuming successful tests.

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[14] "Certification Services," *TIC Salut Social* (blog), accessed April 27, 2025, https://ticsalutsocial.cat/en/que-fem/digital-assets-for-citizens/certification-services/.

6 Sustainability strategy for the xShare industry label

This chapter presents the sustainability strategy for the xShare Industry Label as a trusted and evolving quality mark for interoperability within EHDS. **The xShare Project is understood as the label to be experimental and to be an evolving asset of the project together with the digital health ecosystem.** With a focus on keeping the label relevant, up to date with regulatory developments, and aligned with market needs, this strategy ensures that the label remains a reliable support mechanism for organisations. It outlines long-term governance, stakeholder engagement, and implementation pathways that collectively ensure the continuity, adaptability, and impact of the label beyond the duration of the xShare project.

6.1 How the Hub supports the long-term sustainability of the xShare industry label

The xShare project is committed to the long-term sustainability and evolution of the experimental xShare industry label as a trusted assurance mark for interoperability within the EHDS. Central to this objective is the establishment and active deployment of the **European EHRxF Standards and Policy Hub** (WP2). The Hub acts as a neutral entity for interoperability and as a strategic enabler of sustainability through its governance, support services, and alignment with evolving regulatory requirements.[15]

The **Hub** plays a role in making sure the experimental **xShare industry label** does not end when the project does. It is designed to keep the label active, trustworthy, and valuable for both **industry** and **regulators** in the years to come until the formal mandatory compliance in 2029/2031. For this purpose the IHE Europe Plugathon, xShare track will provide financial data to explore the financial viability of such a service, and a viable operating model.

First, the Hub takes care of **updating and maintaining the label's criteria and processes**. It works with industry partners, regulators, and standards experts to make sure the label keeps pace with new EHDS implementing acts that will be published in March 2027. The Hub runs regular meetings and consultations through its **Industry and Regulators Forums**, providing a space where all sides can shape future updates together.

Second, the Hub keeps the **testing and support services** running. Companies will still be able to **access the Gazelle testing platform** to validate their systems, even after the project ends. Testing processes will be updated with the update of the IGs, and a second version of the experimental xShare Industry Label will be designed in 2026. It is our hope that the Hub's team will continue to offer guidance and practical help to anyone wanting to improve or renew their label status. This way, the label stays relevant as systems evolve, or new features are added.

Finally, the Hub takes care of promoting the label by maintaining the xShare database of certified solutions. This database is designed to serve as a test bed with the **official EU registry** that will be introduced under Article 39 of the EHDS Regulation. This means that systems earning the label will already be better prepared when it comes to meeting upcoming EU requirements. The testing processes and the experience gained will be shared with the European Commission, in view of the activities under Article 40.

[15] Catherine Chronaki and Robert Stegwee, "The European EHRxF Standards and Policy Hub in a Nutshell: A Policy Brief," 2025, https://ehr-exchange-format.eu/wp-content/uploads/2025/02/European_EHRxF_Hub_nutshell_v2_250121.pdf.

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In short, with the ESHIA/Hub in place there is framework for the xShare Industry Label to continue being a practical and recognised tool for preparing for compliance and promoting interoperability in Europe's digital health market—long after the xShare project itself has ended.

6.2 Stakeholder engagement and feedback

Stakeholder engagement is a pillar of the xShare industry label's development, adoption, and long-term sustainability. To ensure this engagement is systematic, meaningful, and results-oriented, the xShare project deploys two core mechanisms: the **Stakeholder Engagement Matrix** (T8.2) and the **Multi-Stakeholder Community of Excellence** (T8.3). These mechanisms serve to gather insights and to align the label with evolving market dynamics, policy directions, and user needs, ensuring that it is fit for purpose in the European health data landscape.

The Stakeholder Engagement Matrix provides a structured and iterative framework for involving diverse stakeholders across the EHR value chain. A key feature of this framework is the bi-annual EHR Experts Fora, which brings together healthcare professionals, IT vendors, standards bodies, researchers, and public authorities. These sessions are purposefully focused on the practical implementation of the EEHRxF, with emphasis on technical feasibility, compliance readiness, and service integration challenges. Importantly, the feedback collected through these fora directly informs the modifications needed for the experimental xShare industry label. It helps identify barriers to adoption, prioritise refinements to X-Bundles, and uncover country-specific regulatory sensitivities. The Matrix thus acts as a dynamic knowledge base that supports the evolution of the label in line with real-world deployment scenarios and the needs of both procurers and solution providers.

Complementing this is the Multi-Stakeholder Community of Excellence that meets quarterly and includes representatives from national health authorities, standards organisations, civil society, academia, and industry alliances. While the Stakeholder Engagement Matrix facilitates operational feedback loops, the Community of Excellence enables strategic alignment and policy influence.

This community plays a crucial role in shaping strategic outputs by co-authoring policy briefs, position papers, and blog articles that reflect consensus views and forward-looking recommendations. These outputs are fed into key EU policy platforms creating a feedback loop between xShare working papers and the emerging European regulatory framework.

Moreover, the Community of Excellence ensures that the xShare Industry label remains coherent with broader European health data initiatives leveraging shared learnings and promoting convergence on interoperability and data governance best practices. By embedding the label within this ecosystem of strategic partnerships and thought leadership, the xShare project amplifies its visibility and relevance beyond the immediate consortium.

Together, the Stakeholder Engagement Matrix and the Community of Excellence, supported by a high-level advisory board, will form a comprehensive can anchor the xShare label in legitimacy, strengthen its alignment with EU policy, and ensure its technical robustness reflects the lived realities of its users. They also provide an institutional foundation for iterative feedback, which is critical to maintaining the label's relevance as EHDS regulations evolve and new digital health priorities emerge.

6.3 Roadmap for sustainable implementation

The sustainable implementation of the xShare Industry Label will be guided by an adaptive and dynamic roadmap (Task 9.3), synthesising insights from market trends, evolving regulatory frameworks, and stakeholder priorities. This roadmap will delineate adoption scenarios that

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accommodate the diverse political and market conditions across Member States and regions, thereby serving as a strategic compass to guide implementation efforts beyond the project's lifetime.

Informed by continuous inputs from multiple components of the xShare project, the roadmap will integrate operational feedback and real-world performance metrics obtained through WP6 monitoring activities. This evidence-based approach ensures that the roadmap remains grounded in actual deployment experiences and responsive to implementation challenges. The following image depicts the overall roadmap for the label's sustainability:

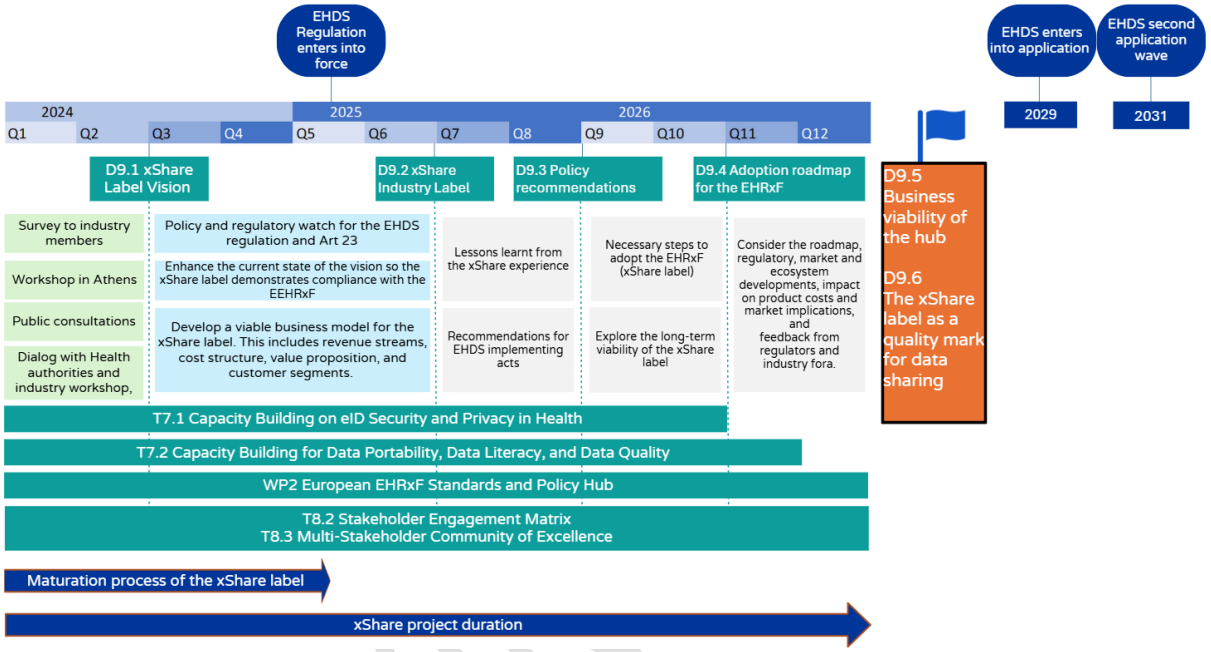

Figure 6 - The xShare label roadmap activities

Critically, the roadmap will remain closely aligned with the evolving regulatory landscape of the European Health Data Space (EHDS), including developments in the EHDS Regulation, implementing acts, and national policies, particularly those affecting conformity assessment and interoperability standards. This will enable the proactive adaptation of the label's governance and technical framework in response to regulatory shifts.

The roadmap will define strategic actions for key stakeholder groups – such as healthcare providers, technology vendors, policy makers, and regional authorities – to promote both the xShare Industry Label and the broader adoption of the European Electronic Health Record Exchange Format (EEHRxF). These actions may include the creation of national or regional endorsement schemes, integration of the label into public funding and procurement frameworks and piloting the label through regulatory sandboxes and real-world evaluations.

To underpin sustainable implementation, the xShare Industry Label will be supported by the project's capacity-building efforts, particularly:

- Task 7.1 – Capacity Building on eID Security and Privacy in Health, and
- Task 7.2 – Capacity Building for Data Portability, Data Literacy, and Data Quality.

These initiatives will deliver targeted training and awareness-raising activities to equip stakeholders with the necessary competencies for implementing and assessing EEHRxF-aligned solutions eligible for

the xShare label. Moreover, the label will benefit directly from capacity-building materials developed by ISCTE, which will include practical guidance and tailored outreach resources. These materials will explain the purpose and operation of the label and outline the procedures for issuing or obtaining it. As such, they will play a vital role in fostering stakeholder understanding and engagement which are key enablers of widespread adoption.

The following table summarises the key activities to be taken from now until the first wave of the EHDS conformance timeline.

Phase	Key Activities	Strategic Outcomes
xShare Project Phase (2025 – 2026)	- Operational rollout of the experimental xShare Industry Label - Piloting and validation with early adopters through Plugathons and adoption sites - Finalisation of capacity-building activities (Tasks 7.1, 7.2) - Development of the first sustainability roadmap (Task 9.3) - Liaising with the Hub and stakeholder forums (Industry and Regulators)	- Establishment of a functioning and user-friendly label framework (v1.0) - Tested and validated label process with different stakeholders - Engaged stakeholder community that has co-develop the xShare industry label - First certified solutions listed in the xShare database **Key Performance indicator:** Awareness of the xShare label among members of the participating industry associations members engaged in digital health >10% in the first year, and >25% in the third.
Transitional Phase – Preparing for EHDS Implementation Acts (2027 – 2029)	- Alignment of the label's technical criteria with EHDS implementing acts (expected March 2027) - Continuous operation of the Hub and Gazelle testing services (open to anyone) - Expansion of stakeholder engagement across Member States - Launch of national/regional endorsement schemes and integration into procurement frameworks	- Label positioned as a trusted pre-conformity assessment tool in supporting the industry for formal compliance in 2029/2031 - Growing market acceptance and recognition by regulators - Database expanded with new validated EHR systems and wellness applications
First Wave of EHDS Application (2029 onwards)	- Full alignment of the label with EHDS conformity assessment procedures - Support for formal recognition of the label at EU and national levels - Expansion of certification services in collaboration with national bodies - Ongoing training, outreach, and capacity building through the Hub - Continuous monitoring of market and regulatory developments	- The label serves as a recognised mark of interoperability and compliance - Integrated into regulatory and market practices - Sustainable operational model secured through the Hub

Table 12 – xShare industry label sustainability strategy

7 Strategic recommendations for the xShare industry label development

This section summarises the key advocacy points developed through the xShare project, its first policy brief and the work done to conceptualise the xShare industry label. The recommendations aim to ensure the xShare industry label supports market needs and provide policy recommendations for the European Commission to draft the implementing acts that will come in March 2027. It is based on what the project team has heard from industry partners, public authorities, and standards experts.

The xShare Industry Label is being developed as an anticipatory tool to support industry readiness for the EEHRxF. Its design is based on one essential principle: flexibility. Given that the EHDS regulation has been adopted but its implementing acts are still forthcoming, the label must be robust enough to provide guidance now, while remaining adaptable to future developments. To achieve this, the label is structured to evolve in **iterative versions**. It serves as a living instrument—capable of reflecting emerging insights, incorporating new technical specifications, and aligning with regulatory clarity as it becomes available. A major update is expected following the publication of the EHDS implementing acts in **March 2027**. This means the label will remain relevant over time and also continue to support manufacturers as they transition from voluntary alignment to formal compliance.

All versions of the label are and will remain openly accessible at https://build.fhir.org/ig/hl7-eu/xShare/labeling_process.html. This site offers a transparent and regularly updated view of the xShare Industry label's structure, criteria, and related implementation guidance.

Each certification level of the xShare industry label offers a step forward in assurance, enabling manufacturers to progressively demonstrate readiness with the EEHRxF. This approach allows room for different levels of maturity and resource availability across industry actors, particularly benefiting small and medium-sized vendors. Though voluntary, the xShare industry label is positioned to complement upcoming legal obligations under the EHDS. It is being designed in close connection with emerging policy instruments such as the EU Declaration of Conformity, the digital testing environments, and the EU-wide EHR certification database. The aim is to ensure that the label does not duplicate formal requirements but instead serves as an **early and reliable support mechanism**, a clear and structured path that industry can follow today while staying aligned with where regulation is heading.

Through its design work and ongoing engagement with the digital health community, the xShare industry label is shaping up as more than just a voluntary tool for the market. It also generating valuable lessons that can inform how the European Commission and Member States implement some of the key obligations set out in the EHDS regulation. These include the self-declaration process, the setup of EU-wide testing environments, and the creation of the official EU database of certified EHR systems. Based on the work conducted in xShare:

- **EU Declaration of Conformity (Article 39):** The xShare industry label's bronze level is being shaped as a structured self-assessment that helps manufacturers verify their compliance with the EEHRxF and interoperability components of the EHDS in a consistent way. This process may directly inform the content and format of the EU Declaration of Conformity that all manufacturers will need to submit under Article 39. The European Commission can help ensure that self-declarations are made more efficient based on the trials conducted in xShare. It is recommended that the European Commission use the xShare industry label's draft materials to help shape the standard declaration template. This would give vendors clarity on

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what they need to provide, make it easier for authorities to verify claims, and create a level playing field across the EU.

- **Digital Testing Environments (Article 40)**: In parallel, the silver and gold levels of the label are being prepared to support more in-depth technical assessments, using real-world test scenarios utilising Gazelle or similar. These assessments focus on the practical ability of systems to exchange health data in line with the EEHRxF specifications. The label will be issued for the different priority health categories. This testing can serve as a valuable blueprint for the digital testing environments that the European Commission will need to establish under Article 40. The feedback and testing environment done in Gazelle can provide valuable insights for the European Commission to develop the upcoming digital testing environment. By leveraging the xShare industry label's testing methods and scenarios, the EU could help manufacturers check their compliance early, before products go to market. This process would reduce risks, speed up adoption, and ensure that all systems meet the same EU-wide expectations. It is important to note that while the xShare industry label currently focuses on interoperability, there is a recommendation to also expand this to include other aspects like the logging component in the future. It is encouraged that the European Commission works with projects like xShare to shape these environments, ensuring they are practical, accessible, and consistent across Member States.
- **EU Database of Certified EHR Systems (Article 49)**: The xShare industry label's design also includes a public registry of labelled solutions, which could provide useful insights for setting up the official EU database of certified EHR systems. This registry is intended to give the market a transparent view of which systems have been tested, what level of compliance they have achieved, and which specifications they support. Building on this experience, the European Commission could define how the EU database should work in practice, what information it should include, how updates should be managed, and how users can trust the data they find there. The xShare experience could also help test the registration process itself, ensuring that it works smoothly for manufacturers and provides real value to health systems and users.

In addition to these contributions, the European Commission can also formally recognise the role of the EEHRxF Policy and Standards Hub as a long-term, neutral coordination and support platform for stakeholders. The Hub brings together industry, standards bodies, regulators, and Member States to provide practical guidance, align technical work, and support the wider community. It is already acting as a bridge between projects and policy discussions, and with proper support, it can continue to serve as a trusted point of contact as the EHDS moves into its implementation phase.

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8 Conclusion

This report presents the work done so far to design and test the experimental xShare Industry Label, a voluntary, pre-regulatory label to help digital health manufacturers get ready for the upcoming EHDS rules. The label focuses on practical aspects of interoperability, such as helping patients download and share their health data in line with the EEHRxF.

Throughout the process, the xShare consortium has worked closely with industry partners, standards organisations, and technical experts to make sure the label reflects real market needs. It was explored how companies see the value of such a label, what challenges they face, and how to make certification both meaningful and practical. From interviews, workshops, and early technical testing, while there is interest in the label, its long-term success will depend on keeping things simple, transparent, and aligned with the official EHDS implementing acts, finalised in March 2027.

The xShare industry label is designed to give companies a head start, helping them build confidence in their solutions, improve market visibility, and prepare for future mandatory certification. It is not meant to replace formal EU requirements, but rather to serve as a helpful stepping stone. The label's development will continue, supported by the Hub, which will ensure the label stays relevant and useful as the European health data landscape evolves.

Eventually, this work aims to make it easier for digital health companies to bring safe, interoperable solutions to the European market, helping healthcare providers, patients, and citizens benefit from better access to their health data across borders.

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10 Annexes

10.1 Annex A) Collection Instrument for xShare Industry Label Interviews with Industry Representatives

Overview

The xShare Industry Label is built on a shared vision of facilitating compliance with the interoperability requirements within the European Health Data Space (EHDS) Regulation, with a particular focus on the European Electronic Health Record Exchange Format (EEHRxF). However, while this vision is well established, further research is needed to define robust evaluation criteria and validate the certification process through collaboration with digital health authorities. The label will be a steppingstone for the systems to align with the EEHRxF. In other words, the xShare Industry Label will assist the industry to comply with the EHDS. It is important to highlight that the xShare Industry Label will be voluntary. Additionally, it focuses on the patient-facing EHR systems and their capacity to support health data downloads in EEHRExF.

A key consideration in this process is ensuring the label is both feasible and acceptable to industry stakeholders. Even if the label is technically comprehensive, its true value lies in its adoption by the industry. Without widespread acceptance, the xShare industry label risks becoming obsolete—regardless of how well-crafted it may be. To unlock its full potential, it is essential to understand industry needs, evaluate feasibility from their perspective, and identify the factors that could either drive or hinder adoption.

To achieve this, we will conduct semi-structured, 45-minute expert interviews with industry representatives across different segments and levels. These interviews will explore the feasibility and business viability of an EU-wide xShare label for the European Electronic Health Record Exchange Format (EEHRxF). We aim to capture multiple perspectives, needs, and requirements, to shape a more comprehensive and inclusive strategy for the xShare Industry Label adoption.

The information gathered from the interviews will contribute to the development of a **(I) handbook document,** which explains the process on how to acquire the label, and **(II) a self-declaration form,** which will certify that healthcare solutions compliance with the EEHRxF through a self-assessment process.

Disclaimer

The insights gathered from these interviews will be analysed and incorporated into a report, visible only for the xShare consortium and the European Commission, on the factors shaping the xShare Industry Label's feasibility, business viability, and industry adoption. While the responses will not be attributed to specific individuals, interviewees should acknowledge that **their input might be utilised to publicly available findings in an anonymised manner.**

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Problem definition

What are the key factors that influence the feasibility, business viability, and industry adoption of the xShare Industry Label for the Format EEHRxF?

General objective

To identify and understand the conditions under which the xShare Industry Label may be feasible, valuable, and widely adopted by digital health industry stakeholders across the EU.

Specific objectives and questions

SO1. Assess feasibility and practical challenges in the current process

- Do you see your organization pursuing the Industry Label at one or more self-certification levels (Bronze, Silver, Gold)? Why or why not?
- What technical, operational, or organisational challenges would you expect in complying with the industry label or EEHRxF?
- Does your organisation currently use any technical specifications to support health data interoperability? If so, which ones?
- How does your current level of interoperability or alignment with EEHRxF affect your ability to pursue the label?

SO2. Explore the business viability and strategic potential of the label

- How do you assess the strategic value of adopting the xShare label (e.g., in terms of partnerships, funding, or visibility) for your products?
- Do you think that by having the label, could it provide your organisation with a competitive advantage in procurement or market positioning? In what context?
- Are there specific products, services, or solutions where the label would strengthen your offering?

SO3. Design a scalable and industry friendly certification process that fosters participation and trust in the xShare label

- From the proposed Bronze, Silver, and Gold certification levels in line with EHDS, which tier would be the most practical starting point for your organisation, and why?
- What features or characteristics would make the certification process credible while remaining cost-effective and time-efficient?
- What kind of guidance or support (e.g. tools, templates, technical documentation, events) would make participation in the certification process more attractive to you?

SO4. Explore adoption barriers and enablers

- What would most motivate your organisation to adopt the xShare industry Label?
- What are the key reasons your organisation might hesitate to adopt the label?
- How do you think the wider industry, including your peers or competitors, would respond to the xShare industry label?

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