xShare

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

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Contact:	chronaki@gmail.com Nathan.carvalho@digitaleurope.org
Contributors:	Nathan Carvalho, DIGITALEUROPE; Catherine Chronaki, HL7 Europe; Alexia Papadimitrou, DIGITALEUROPE; Alper Tanriverdi, DIGITALEUROPE; Elena Petelos, HL7 Europe
Internal Reviewers	Mie Hjorth Matthiesen, MedCom, Luc Nicolas, EHTEL
Editors	Elena Petelos, HL7 Europe; Nathan Carvalho; DIGITALEUROPE

Statement of originality

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List of abbreviations

Abbreviation	Term
AI Act	Artificial Intelligence Act
CDISC	Clinical Data Interchange Standards Consortium
CoC	Code of Conduct
CE Mark	Conformité Européenne Mark
CRA	EU'S Cyber Resilience Act
CEN/TC251	European Committee for Standardization Technical Committee 251
EUCROF	European Contract Research Organization Federation
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

Abbreviation	Term
EEHRxF	European Electronic Health Record Exchange Format
HADEA	European Health and Digital Executive Agency
EHDS	European Health Data Space
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
IPS-R	International Patient Summary extended for Clinical Research
ROI	Return on Investment
SDO	Standards Development Organization
SWOT	Strengths, Weaknesses, Opportunities, and Threats analysis
SNOMED	Systematized Nomenclature of Medicine Clinical Terms
xBundles	Targeted aggregation of interoperability assets that support the connection of health systems in different ways, based on EHRxF specifications
WP	Work Package

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Executive summary

The aim of the is document is to present the vision of the xShare industry label in the EHDS. Starting from the xShare vision ***"to empower everyone to share their health data at-the-click-of-a-button in the EHDS"***, this document positions the xShare industry label among the key elements of the xShare implementation strategy, namely the xShare Button, and the EEHRxF Hub. The comprehensive analysis performed, and methods utilised, to support the development of the xShare industry label in the emerging European digital health ecosystem catalysed by the EHDS are, hereby, presented as a set of capabilities to manage health data of the EEHRxF data categories. A mixed-methods methodological approach comprising review of labelling initiatives in digital health and beyond was adopted, with online questionnaires addressed to xShare partners, and one-to-one interviews with digital health industry leaders to elicit insights and identify key themes and priorities. Questions mapped against the specific objectives established for this process were developed to guide discussion and allow robust evaluation of the main value proposition of the xShare industry label. These preliminary results were, then, used to run a SWOT analysis for the industry label and to identify the next steps paving the way to performing a feasibility study.

Despite the ever-changing landscape and a complex environment of rapid technological, regulatory and market development, consensus was clearly established across stakeholders on the fact the value proposition of the xShare industry label will be stronger when supported by policymakers and the industry, critically, if appropriately linked to procurement. The industry label creates an EHDS ready ecosystem" It allows the development or revisiting of innovative use cases and new types of interactions between the label compliant actors.

1. Introduction

The xShare project (2023-2026) has been funded by the European Union (EU) to foster the aspirations of Europe's DIGITAL DECADE 2030 regarding citizen access to EHR data, boosting key compass indicators in skills, business, and infrastructure. The xShare Workplan helps implementing the vision brought forward by the European Health Data Space (EHDS) and allows people to exercise their data portability rights under GDPR, while bridging across health care, public/population health, and clinical research. A key element of the approach is fostering and expanding the data categories under the European EHR Exchange Format (EEHRxF), so that the EEHRxF can serve as a catalyst for research and innovation in Europe and beyond.

Starting with the five priority data categories outlined in the provisional text of the EHDS regulation, xShare aims to support specifications, implementation support services, and demonstrations of managing new data categories, tied to high-priority business use cases, while ensuring alignment, harmonization, and global standards relevance. To that end, xShare has engaged key standards development organisations, competence centres, government agencies, national programs, and market actors in the real implementation of the EHDS. The EEHRxF Hub created by xShare is meant to be sustainable by design and to serve as a steward and level playing field for development, refinement, and alignment of EEHRxF specification and supporting adoption services.

To prove its relevance and establish the game changer role of the EEHRxF, the xShare "yellow" button featured in portals or apps, allows to share health data safely in a computable EEHRxF format. Deliverable 9.1 "Vision for the xShare industry label, liberating the health data" is the first deliverable of WP 9 "xShare industry label, Policy Recommendations and Business Viability," which aims to analyse the feasibility of creating an industry label for the European EHR Exchange Format (i.e. EEHRxF).

1.1 The xShare project

The vision of xShare is to empower sharing our health data at the click-of-the-button in the EHDS.

1.2 Key elements of implementing the xShare vision

Three are the key elements of the xShare implementation strategy:

- xShare button (the Yellow Button): illustrates the capability to share data in the EEHRxF.
- European EHRxF Standards and Policy Hub brings together global standards with industry and government to create the specifications and accelerate adoption.
- xShare industry label demonstrates commitment of the industry to implement EEHRxF.

Figure I - Key elements of the xShare project.

1.3 The xShare Button

xShare aims to empower everyone to share their health data in the European Electronic Health Record Exchange Format (EEHRxF) with a click-of-a-button, the **xShare Button**. To fully harvest the potential of the **xShare Button**, a sound implementation approach is required. It should take into consideration the heterogeneity and complexity of health systems across the EU, and the needs and preferences of stakeholders across sectors. The xShare button will be featured across health portals and patient apps.

The xShare Button will be featured in eight adoption sites settings, in hospital networks, national portal, regional networks with emphasis in medical tourism and national health portals. Additionally, more than 20 additional adoption sites and clinical research organisations will be funded to demonstrate IPS-R, the international patient summary extended for clinical research, a new proposed data category under EHDS that bridges across patient care, public health, and clinical research. Additional small contracts to implement the xShare button will be awarded in remote Member States.

1.4 European EHRxF Standards and Policy Hub

xShare will establish the European EHRxF Standards and Policy Hub: the "EEHRxF Hub" is a partnership of six standards-developing organisations and market actors, supported by competence centres, nationals and regional authorities, and European SMEs.

- xShare will partner with xt-EHR, a joint action of 25 Member States to support the implementation of the EEHRxF, and XpanDH, which supports the EEHRxF-based digital health ecosystem. xShare will seek engagement also with TEDHAS-2- another joint action which gathers 30 European countries-, focusing on the secondary use of health data.
- The **industry forum in** the EEHRxF Hub will engage market actors directly and through their associations namely DIGITALEUROPE, EUCROF, MedTech-Europe, and COCIR.
- The **regulators forum** will engage with the Digital Health Partnership. The Global Digital Health Partnership is a collaboration of country governments and the World Health Organization formed to support the implementation of worldwide digital health services.[1] Member States competent authorities, digital health agencies, national contact points, and the planned EHDS Board. Six standards organizations, namely CEN/TC251, HL7 Europe, SNOMED, CDISC, IEEE and IHE Europe will be working together to steward specifications and interoperability assets for the EHDS.

[1] Global Digital Health Partnership, 'Global Digital Health Partnership', Global Digital Health Partnership, accessed 30 April 2024, https://gdhp.health/.

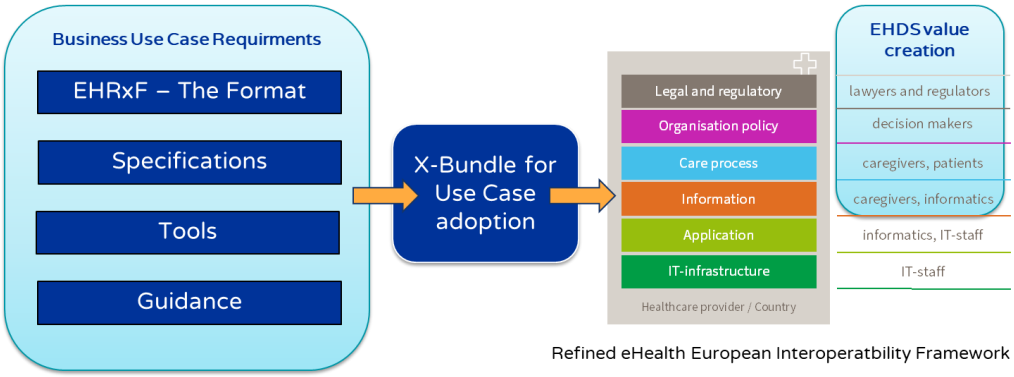

Figure II - Business use cases as a core element in accelerating adoption of the EEHRxF.

Example common specification-related activities under the EEHRxF Hub are:

- Harmonise common specifications by creating or collecting and maintaining xBundles, simply put a collection material to accelerate implementation common data specifications linked to business use cases. They may include FHIR implementation guides, tools and data sets, and other educational or implementation support for key EHRxF health information domains or priority data categories.
- Align a set of common elements across EEHRxF health information domains applicable across EHDS-1 (myHealth@EU and national programs), public/population health and clinical research (healthdata@eu).
- Extend the harmonized IPS specification to include care plans and making it fit for the purpose of clinical research use cases i.e. clinical trial eligibility, real world data, patient reported outcomes, and returning clinical research data to patients.
- Report requirements for change proposals from the EEHRxF community of practice in the context of maintaining specifications and requesting updates to global standards.
- Foster maturing of EEHRxF specification connecting different variants (see Figure III).

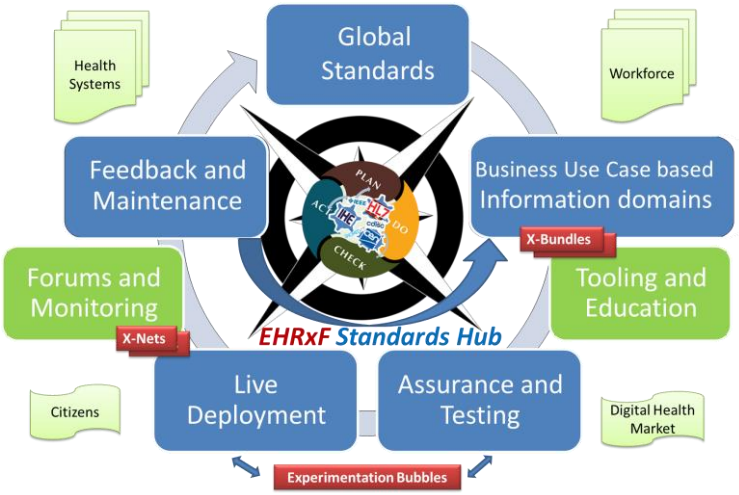

Figure III - A virtuous cycle of maturing business use cases and maturing specification in the EEHRxF Hub.

Example common service-related activities under the EEHRxF Hub are:

- Monitoring adoption of EEHRxF for specific data categories in member states.
- Define business use case repository linked to support services linked to specification xBundles.
- Scope a Digital health product registries that feature products with EEHRxF capabilities.
- Create a registry of EHDS/EEHRxF experts.

1.5 xShare industry label

The xShare industry label guarantees trusted compliance with EEHRxF and demonstrates the capability of producing or consuming structured coded health data. This label serves as a trust mark for citizens and patients, enabling them to share personal health data seamlessly and securely across different platforms. The xShare implementation strategy involves initially demonstrating the xShare industry label through portals and applications of xShare partners. This pilot phase will collect data to develop tools and further accelerate the adoption of EEHRxF Health Information Domains (HIDs).

Figure IV - xShare industry label

Assessing the business viability of the xShare industry label involves coordinated recommendations, sustainability plans, and market feedback. This process examines product costs, market implications, and regulatory impacts. Independent experts and market actors will contribute to evaluating the business aspects of the xShare industry label, ensuring it meets industry and regulatory standards. The methodology also includes aligning with the upcoming EHDS regulation, particularly Article 23, which mandates conformance for EHR systems and related digital medical technologies (Article 14-3). Next actions to develop the xShare industry label will consider feedback from project results, regulatory changes, and ecosystem dynamics. Technical support will be provided to ensure that the xShare industry label facilitates semantic interoperability and advances research and innovation through the EHDS. The development of xBundles, will support interoperability across public health, clinical research, and cross-border health threats.

The next chapter delves into the policy environment that underpins the xShare initiative. It provides an overview of the current policy landscape, including key regulations and legislative frameworks such as the EHDS provisional Article 23, which are crucial for the successful implementation and adoption of the xShare industry label. This chapter also explores the role of various stakeholders, including EU regulatory bodies, national health authorities, and industry associations, in shaping and supporting these policies. Understanding the policy context is essential for aligning the xShare industry label with existing regulations and ensuring its integration into the broader digital health ecosystem.

2. Current policy environment

The EU is pursuing a human-centric, sustainable vision for the digital society throughout the digital decade to empower citizens and businesses. The Digital Decade[2] is a comprehensive framework to guide all actions related to digital transformation, encompassing all aspects of technology and innovation that benefit people. Within this framework, targets and measurable goals have been established along with objectives to guide Member States actions and multi-country projects that will contribute to meeting the digital decade targets. These projects will enable Member States to collaborate and pool resources to develop digital capabilities that they would not otherwise be able to develop. The Interoperable Europe Act[3], which entered into force on April 11, 2024, will facilitate cross-border data exchange and accelerate public sector's digital transformation. Furthermore, the declaration on digital rights and principles[4] promotes a digital transition shaped by European values and has been signed at the highest level by the European Commission, Parliament, and the Council, putting people and their rights at the centre of the digital transformation.

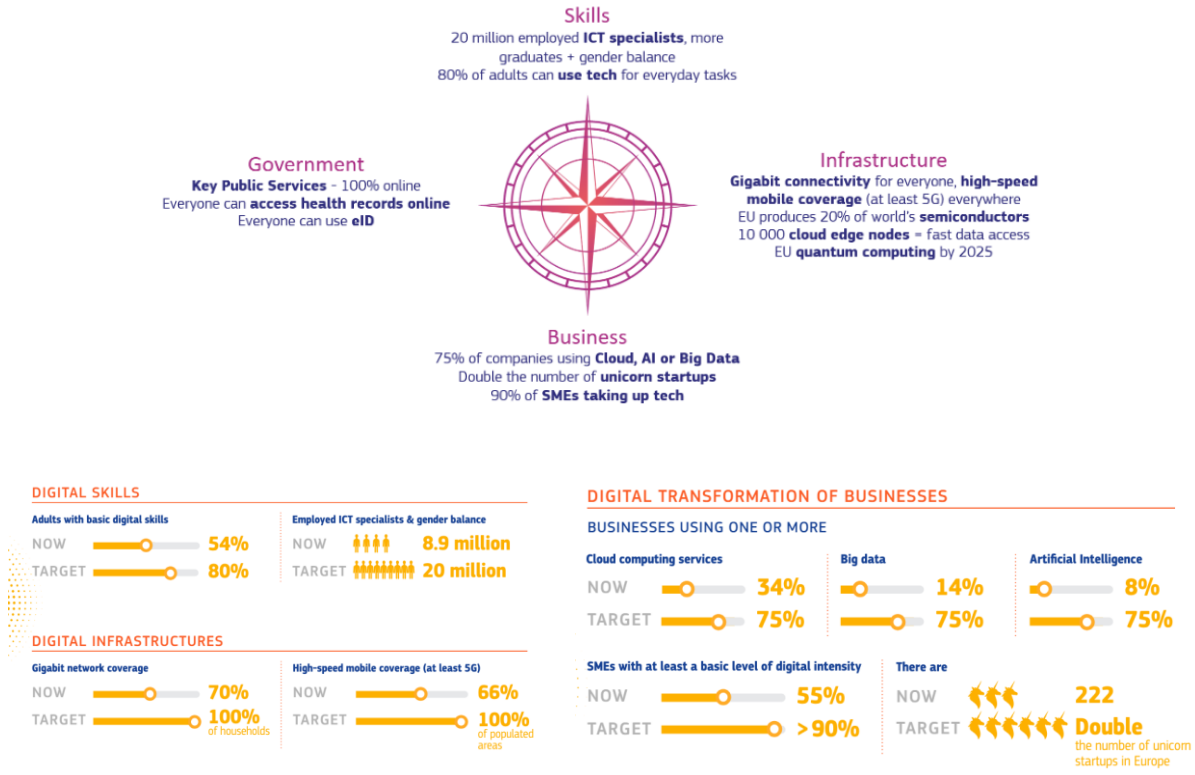

Figure V Cardinal points of the Digital Decade Policy program 2030 and targets

[2] European Commission, 'Europe's Digital Decade | Shaping Europe's Digital Future', Shaping Europe's Digital Future, 4 May 2024, https://digital-strategy.ec.europa.eu/en/policies/europes-digital-decade.

[3] European Commission, 'Interoperable Europe Act Enters into Force for Better Connected Public Services for People and Businesses | Shaping Europe's Digital Future', Shaping Europe's Digital Future, 11 April 2024, https://digital-strategy.ec.europa.eu/en/news/interoperable-europe-act-enters-force-better-connected-public-services-people-and-businesses.

[4] European Commission, 'European Digital Rights and Principles | Shaping Europe's Digital Future', Shaping Europe's Digital Future, accessed 15 May 2024, https://digital-strategy.ec.europa.eu/en/policies/digital-principles.

A dashboard of indicators[5] summarizing the four dimensions of the Digital Decade policy program: digital skills, digital infrastructure, digitalization of business and digitalization of public services has been developed. [6]

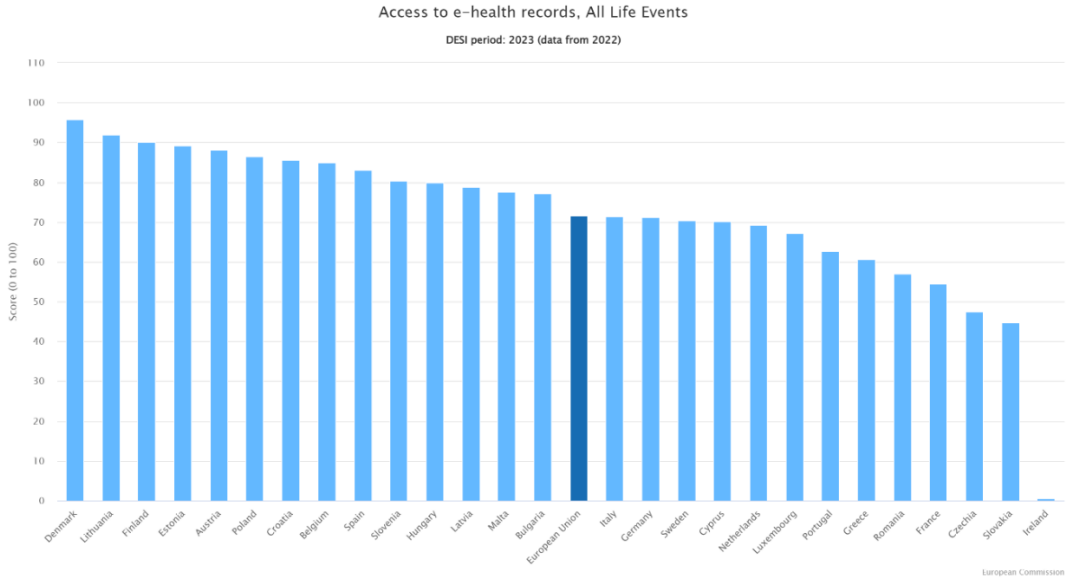

Figure VI - A key indicator of Europe's digital decade is citizens' access to e-health records.[7]

EU policies, legislation, and funding instruments aim to boost research and innovation in Europe, maximizing the potential of EHR data and benefiting European citizens. These efforts support the Digital Compass 2030's goal of 100% EHR access and enhance cross-border digital health services. In line with overarching objectives of the EU and those of the Digital Decade, key EU legislation such as The EHDS Regulation[8], the Artificial Intelligence (AI) Act[9], and the Cyber Resilience Act[10] establish a framework to realise these goals by promoting digital health solutions, leveraging health data and AI, and ensuring public health security. An integral part of all legislative and policy instruments focuses on accelerating innovation and research, improving data interoperability, and enhancing preparedness for future crises, thereby contributing to the robust formation of the European Health Union. The evaluation of eHealth indicators of 2023, suggests that EU27 Member states can be divided into 5 groups (see Figure VI): Leapfroggers, i.e. Denmark, Lithuania, Finland, Estonia, Austria, Progressed, i.e. Poland, Croatia, Belgium, Spain, Pursuers i.e. Slovenia, Hungary, Latvia, Malta, Bulgaria, Laggards i.e. Italy, Germany, Sweden, Cyprus, Netherlands, Luxembourg, and Tail Lights, i.e. Portugal, Greece, Romania, France, Czechia, Slovakia, Ireland.

[5] European Commission, 'Digital Decade DESI Visualisation Tool', Shaping Europe's Digital Future, accessed 15 May 2024, https://digital-decade-desi.digital-strategy.ec.europa.eu/.

[6] European Commission, 'Communication Establishing the Union-Level Projected Trajectories for the Digital Targets | Shaping Europe's Digital Future', Shaping Europe's Digital Future, 27 September 2023, https://digital-strategy.ec.europa.eu/en/library/communication-establishing-union-level-projected-trajectories-digital-targets.

[7] Digital decade e-Health indicators development report, https://op.europa.eu/en/publication-detail/-/publication/78938111-461e-11ee-92e3-01aa75ed71a1

[8] 'The European Health Data Space (EHDS) Regulation', accessed 15 May 2024, https://www.consilium.europa.eu/media/70909/st07553-en24.pdf.

[9] European Commission, 'AI Act | Shaping Europe's Digital Future', Shaping Europe's Digital Future, 23 April 2024, https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai.

[10] European Commission, 'EU Cyber Resilience Act | Shaping Europe's Digital Future', Shaping Europe's Digital Future, accessed 15 May 2024, https://digital-strategy.ec.europa.eu/en/policies/cyber-resilience-act.

2.1 Provisional text of the EHDS Regulation

On April 24, 2024, the European Parliament provisionally approved the EHDS regulation as a health-specific ecosystem comprising rules, common standards and practices, infrastructures, and a governance framework that aims to:

1. Increase individuals' digital access to and control over their electronic personal health data at the national and EU levels.
2. Foster a single market for electronic health record systems, relevant medical devices and high-risk AI systems.
3. Provide a reliable and efficient framework for using health data for research, innovation, policymaking, and regulatory activities (secondary use of data).

The EHDS aims to address challenges in electronic data access, ensure patient autonomy in sharing data with health professionals, and facilitate data sharing both within and across member states. Health records encompass various types of medical information, including diagnostic images, and lack of access can lead to delays and errors in diagnosis or treatment. This issue is particularly critical for individuals in remote areas or far from specialized care centres. Additionally, enhancing data access can support decentralized and hybrid trials, accelerating translational research and clinical development. As clinical practices evolve, routine data and real-world evidence (RWE) are increasingly vital for patient safety and sound regulatory and clinical decisions. However, regulatory fragmentation raises technical and operational challenges, complicating consent processes and deterring data holders from sharing data, even with patient consent.

The elements of the provisionally agreed text that is expected to enter into force in 2026 are:

1. Opt-out in primary use is a voluntary mechanism for Member States, to implement internally;
2. Opt-out in secondary use is a choice of Member States each individual which needs to be notified to the European Commission;
3. Member State are allowed to implement more strict measures in specific data categories;
4. EHR system assessment will follow a mandatory self-certification scheme supported by a digital testing environment;
5. Data localisation is a requirement for storage and processing of secondary use of EHR data.

The provisionally agreed regulation is closely connected to key actions proposed by xShare:

(1) CE marking of conformity means marking by which the manufacturer indicates that the EHR system is in conformity with the applicable requirements set out in this regulation and other applicable union legislation providing for its affixing pursuant to Regulation EC 765/2008
(2) Article 5: priority categories of personal electronic health data for primary use
(3) Article 6: European Electronic Health Record Exchange Format: commonly used, machine readable and allow transmission of personal health data between different software applications, devices and healthcare providers. The format should support submission of structured and unstructured data including the following elements:
    (a) Data sets, defining structures, data fields and groups to represent clinical content
    (b) Coding systems and values to be used in data sets containing electronic health data

(c) Technical interoperability specifications for the exchange of electronic health data including content representation, standards, and profiles.

2.2 myHealth@EU

The provisional text of the EHDS regulation (Art 10) indicates in Article 10 that that each Member State will establish one or more digital health authorities to ensure the implementation of chapter II (primary use of data) and chapter III (EHR and wellness applications). The digital health authorities will make technical contributions, supervise national digital health contact points, and collaborate with other authorities and the European Commission to further the EU's development. According to the provisionally numbered Article 10a, they will submit a biennial report to the EHDS board that includes:

(a) Measures to implement this regulation
(b) Percentage of people with access to different data categories
(c) Information on handling requests by people on exercising their rights.
(d) Number of health providers, pharmacies, hospital, other points of care connected to MyHealth@EU (provisional Article 12)
(e) Volumes of electronic health data shared across borders

Provisional Article 13 refers toSupplementary cross-border digital health services and infrastructures. According to this article national contact points in a third country might be authorized to participate in MyHealth@EU if they fulfil the necessary requirements.

3. Methodology to create the xShare industry label

The xShare industry label aims to become an industry-led response to the EHDS (provisional Article 23)[11] requirement to demonstrate conformance with common technical specifications. To achieve this goal, xShare develops a framework with qualitative and quantitative indicators to measure progress and impact regarding adoption of the EEHRxF in the EHDS.

The EHDS Article 23 empowers the European Commission to further develop specifications through implementing acts. This will first affect EHR systems and devices that claim conformance. However, in the future, these regulations may have an impact on more digital medical technologies and wellness devices that transmit data in the European healthcare systems.

Then, the following xShare industry label methodology forms the baseline for its vision. This baseline vision will create a common ground shared perspective by bringing stakeholders including health industry members, regulators, patients, data users, policymakers, and standard developing organisations (SDEs). Moreover, the methodology also lays the groundwork for the business viability of the label.

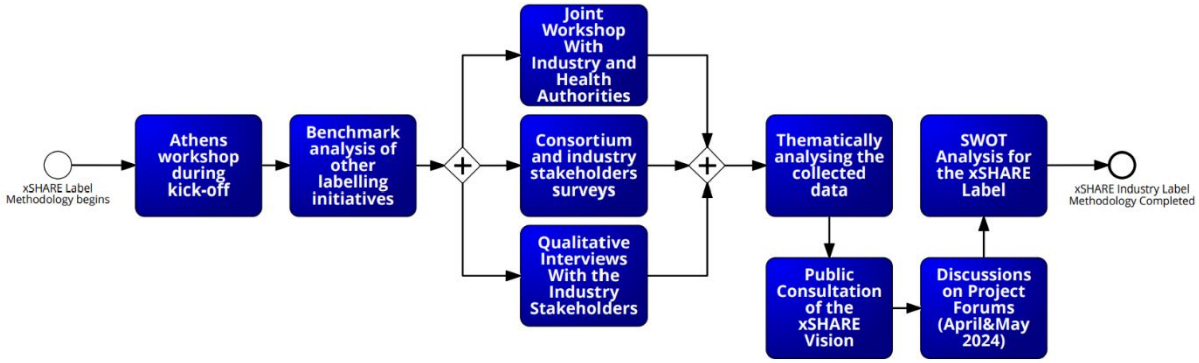

Figure VII – xShare industry label Creation Methodology Process

3.1 Method: Athens workshop during kick-off

DIGITALEUROPE brought together the xShare project consortium partners in Athens in January 2024 as a first step toward reaching an agreement on xShare industry label vision. The goal of the workshop was understanding how project partners representing the health industry, trade associations, data holders and users visualise the label of xShare in relationship with different target groups.

To bring the consortium partners together and create a shared vision for the xShare industry label, several workshop activities focused on organising and managing structured group communication processes to generate insights, were organised. Different questions were used utilising MentiMeter[12], which helped the discussion be more structured and allowed for more effective data collection. The participants were asked to assess different statements concerning the development of a shared xShare

[11] European Commission, 'Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space', § 3 (2022), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52022PC0197.

[12] 'Interactive Presentation Software - Mentimeter', accessed 3 May 2024, https://www.mentimeter.com/.

vision. The questions proposed to support the discussion are listed in Annex I. As a result of the workshop, qualitative data regarding the challenges, strengths, and potential impacts of the xShare industry label were gathered to conduct a thematic analysis.[13]

3.2 Method: Consortium and industry stakeholders surveys

Following the workshop in Athens, the xShare industry label impact and perception survey was circulated twice. Initially to xShare consortium members, and then separately to industry stakeholders, such as the industry members of DIGITALEUROPE, to better understand their perceptions and impact of the label. The complete questionnaire for the survey can be seen in Annex II. To consolidate the data collected at the workshop in Athens, the consortium survey has been shaped around three sub-objectives, which are:

- **Specific Objective I (SO I) - Industry Perception of the xShare industry label:** Evaluating industry and consortium members' perceptions of the xShare industry label's potential effects, exploring expectations, anticipated challenges, and the perceived benefits for organisational operations within the healthcare industry.
- **Specific Objective II (SO II) - Business Viability and Impact of the xShare industry label:** Assessing the impact of the xShare industry label on businesses, including the analysis of financial, technical, and human resource implications, and how these factors contribute to the feasibility and readiness for implementation.
- **Specific Objective III (SO III) - Stakeholder Interpretation of EHRxF Compliance in xSHARE:** Clarify stakeholder interpretations of compliance with the xShare industry label under the European EHRxF (what this compliance means) within the European Health Data Space framework and outline the implications of compliance requisites.

Furthermore, the survey also touched upon assessing the financial, technical, and human resource feasibility of the xShare industry label from the consortium' and external stakeholder standpoints. The data gathered from xShare consortium members and industry stakeholders are then processed and analysed using thematic analysis techniques.[14] Thematic analysis identifies the recurring patterns and themes within data. To identify the recurring themes that will serve as the foundation for the xShare industry label vision, a code set was firstly created by using ATLAS.ti. Afterwards, the coding patterns were used to examine related or unrelated, as well as confirming or disconfirming points or perspectives for the xShare industry label vision.

3.3 Method: Qualitative interviews with industry stakeholders

To develop the xShare industry label vision, industry perceptions, business viability, and impact, the project team adopted a qualitative methodological approach, conducting targeted interviews to gather insights from experts across disciplines to assess the industry needs, perceptions, and priorities, as well as to inform the business viability and the use of the xShare industry label. This process was necessary to determine what would drive the industry to comply with the EHRxF. The qualitative interviews were

[13] Virginia Braun and Clarke, Victoria, 'Using Thematic Analysis in Psychology', *Qualitative Research in Psychology*, 2006, 77–101, http://dx.doi.org/10.1191/1478088706qp063oa.

[14] Chad Lochmiller, 'Conducting Thematic Analysis with Qualitative Data', *The Qualitative Report*, 20 June 2021, 2029–44, https://doi.org/10.46743/2160-3715/2021.5008.

also instrumental in supporting the evaluation of the data from the xShare industry label impact and perception survey.

Name	Occupation	Organisation	Country
Andrea Hull	Global Public Policy	Epic Systems Corporation	UK
Vassil Peytchev	Lead Technical Adviser	Epic Systems Corporation	US
Dipak Kalra	President, Academic, Standards Contributor	I~HD	BE, UK
Mariann Yeager	Chief Executive Officer	Sequoia Project	US
Miroslav Koncar	Global Business Development Director	Philips	HR, NL
Andreas Klingler	Head of Interoperability Competence Centre	Siemens Healthineers	DE
Ben McAlister	Lead Product Regulatory Strategist	Oracle Health	UK
Hans Buitendijk	Director, Interoperability Strategy	Oracle	US
Janos Vincze	IHE Europe Industry Co-chair	GE Healthcare	HU
Yoani Matsakis	Chairman of the Board & CEO	Telemedicine Technologies	FR

Table I - xShare qualitative interview experts

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 30 to 45 minutes—optimal for engaging in discussions without inducing fatigue in the interviewee. The full list of questions can be seen in Annex III. The responses were qualitatively analysed, integrating insights with quantitative data from the xShare industry label Impact and Perception Survey. This approach enabled a comprehensive understanding of the industry's perspective on the xShare industry label's business viability and regulatory impact across European healthcare sectors. The Delphi Method[15] has then been developed to refine the xShare industry label vision through consensus. As a result, experts' opinions were anonymously collated to form a collective stance on the label. Data collected from the survey, interviews, and Delphi stages are thematically analysed[16] to detect recurring themes. The synthesis of these insights aims to shape the xShare industry label vision to meet stakeholder expectations, with the support of analytical tools such as NVivo, ATLAS.ti, and MAXQDA.

3.4 Method: Joint workshop with industry and health authorities

This workshop aimed to refine the xShare industry label vision by discussing the advancement of health data interoperability. In this session, the project team explored and collected data regarding the alignment of national health strategies with industry solutions under the EHDS and EHRxF frameworks. The High-level Digital Health Interoperability Workshop took place on 21 May 2024 at DIGITALEUROPE offices in Brussels.

The high-level Digital Health Interoperability Workshop hosted approximately 80 participants, a combination of health authorities and industry representatives, with attendance both online and in-person (online registration invites were also supplemented via a social media campaign). Each

[15] Julian de Meyrick, 'The Delphi Method and Health Research', *Health Education* 103, no. 1 (1 January 2003): 7–16, https://doi.org/10.1108/09654280310459112.

[16] Lochmiller, 'Conducting Thematic Analysis with Qualitative Data'.

participant was uniquely equipped with specialised knowledge and experience to advance health data interoperability processes through guided exchanges. This hybrid format facilitated a broad and diverse participation and enriched the discussions, ensuring a comprehensive dialogue from various perspectives. The full program and speakers for the workshop can be seen in Annex IV.

Figure VIII - xShare High-level Digital Health Interoperability Workshop

Participants have been invited to the workshop to (1) establish a dialogue between national health authorities and industry; (2) to identify the national strategies for health data interoperability; (3) to examine industry challenges and solutions for health data interoperability. Hence, this joint workshop with industry and health authorities captured the data to understand the challenges and opportunities for the xShare industry label under the EHDS and EHRxF frameworks.

3.5 Method: Public consultation of the xShare vision

In the public consultation phase, the xShare Industry Label vision has been shared internally with a couple of stakeholders for direct feedback. The network of experts is made of Member States representatives and experts from industry, academia, SDOs, national health authorities and more. They have received a short message on what the xShare Industry Label is, the objective and potential impact for applying this label. The xShare consortium took their insights into consideration for the SWOT analysis of the xShare industry label.

3.6 Method: Discussions on project forums (April and May 2024)

The goal of the project forums is to advance xShare's objective. These forums brought together consortium partners, industry representatives, and academia to discuss adoption sites and their EEHRxF business use cases for the xShare Yellow Button. The forums focused on strategic discussions around EEHRxF standards and policies necessary for developing the xShare Industry Label. The xShare project team gathered input from consortium members on establishing the label. By examining real-

world use cases and aligning with European EHRxF Standards and Policy Hub assets, the forums helped shape the criteria and development of the xShare Industry Label.

The project forums were held on 4th April 2024 and 15th May 2024. The April forum highlighted the role of adoption sites. These sites demonstrated the business need for and discussed the implementation of the xShare Yellow Button, directly influencing the criteria and standards for the xShare Industry Label. This forum provided an overview of implementation challenges and the Health Information Domains (HIDs) it supports. The May forum brought together key stakeholders to delve into specific use cases, integrate common assets, and promote EEHRxF campaign strategies to support the broader adoption and recognition of the xShare industry label.

3.7 Method: Benchmark analysis of other labelling initiatives

The benchmark analysis for xShare industry label aimed at developing xShare's value proposition, unveiling its specificity, and explaining how it differentiates from similar initiatives. This was achieved by evaluating different labels against a set of defined criteria. The process involved defining comprehensive criteria, selecting relevant labels, collecting detailed data, and conducting thorough evaluations. The results were compared to identify key differentiators and similarities, highlighting xShare's unique value proposition. The findings were documented in this report with recommendations to enhance the xShare industry label market positioning. The value proposition unveils its specificity and importance and explains how it differentiates from other similar initiatives.

3.8 Method; SWOT analysis

Strengths and weaknesses of the project, as well as the opportunities and threats for the xShare industry label have been identified by the data collected from, firstly, the workshops organised which covered the way for brainstorming and discussions among stakeholders representing different sectors and perspectives. Secondly, the interviews and surveys consist of various question categories such as multiple choice, open-ended, Likert scale, semi-structured, and open-ended to acquire the most relevant information from the participants as elaborately described in the previous sections above.

4. Results of methods applied

The next sub-chapters focus on the results from the surveys and interviews, providing a detailed examination of the perceptions and impacts of the xShare industry label. The survey and interview results offer essential insights necessary to develop and refine the vision of the xShare industry label.

4.1 Results of the consortium and industry stakeholders' surveys

The survey aimed to gather insights on the perceptions and business impact of the xShare industry label, focusing on three specific objectives: evaluating industry and consortium members' perceptions of the label's potential effects, assessing its business viability and impact, and clarifying stakeholder interpretations of compliance with the European EHRxF standards within the European Health Data Space. In the following pages an analysis of the 24 responses to survey results is provided.

SO1: Industry Perception of the xShare industry label: Evaluating industry and consortium members' perceptions of the xShare industry label's potential effects, exploring expectations, anticipated challenges, and the perceived benefits for organisational operations within the healthcare industry.

- **How do you interpret a label such as the xShare industry label's role and purpose across different health data categories or capabilities?**

The survey responses indicate a robust consensus on the multi-faceted role of the xShare industry label in enhancing health data interoperability within the EHDS. Respondents predominantly strongly agree (ratings of 4 and 5) that the label is a tool for identifying applications and systems capable of both sending and receiving data according to European EHRxF standards. This underscores the label's perceived effectiveness in facilitating seamless data exchange, a component for interoperable health systems across the EU. Additionally, there is solid agreement on the label's role in ensuring secure and efficient data portability and interoperability across EU member states, reflecting industry stakeholders' recognition of the importance of standardised data exchange protocols for cross-border healthcare operations. The alignment of healthcare data management with GDPR and other regulatory standards is another area where respondents show strong consensus, highlighting the label's potential in supporting regulatory compliance and enhancing data protection measures.

Furthermore, the label is widely seen as enhancing the credibility and trustworthiness of digital health services within the EHDS, fostering user confidence and adoption of digital health technologies. Lastly, there is significant agreement that the label may facilitate the integration of health data across various sectors, including public health, clinical research, and continuity of care. Respondents emphasised the empowerment of patients as data sources and carriers, which helps in connecting different healthcare providers, and suggested that the xShare industry label could extend the MDR CE Marking to ensure data safety and interoperability, enhancing the ecosystem of medical devices and connected applications.

- **Are you aware of any of these or other existing labels that share objectives or characteristics with the xShare industry label?**

Respondents show awareness of several existing labels, such as the CE Mark, IHE Europe Seal, Continua Guidelines, Label2Enable, BlueButton, and WiFi (IEEE), which share objectives or characteristics with the xShare industry label. The CE Mark is frequently mentioned, reflecting its widespread recognition

in ensuring product safety and compliance within the EU market. Similarly, the IHE Europe Seal and Continua Guidelines are noted for their roles in promoting interoperability and standardisation in healthcare workflows. Label2Enable and WiFi (IEEE) are also acknowledged, indicating a broad awareness of interoperability and certification initiatives that could complement the xShare industry label. The fact that many xShare partners also participate in Label2Enable was taken into consideration. BlueButton 2.0 initially established in 2010 by Veterans affairs and CMS, was revisited in 2018 by the MyHealthEdata program and is linked to a standards-based API that allows beneficiaries to connect their Medicare claims data with apps and services they trust.

Respondents believe that the xShare industry label can synergise with these existing labels by focusing specifically on EHRxF compliance, thus complementing labels that concentrate on other aspects such as safety, privacy, and user-friendliness, as well as utility and trust. It was suggested that the xShare industry label should complement the Medical Device Regulation (MDR) CE Marking in strong alignment with existing procedures, to ensure data safety and interoperability, highlighting its potential role in an ecosystem of interconnected medical device applications. Additionally, respondents noted that the xShare industry label could enable full control of data usage by patients, especially for research based on real-world data, enhancing the overall interoperability landscape.

- **What potential benefits or main added value (value proposition) do you believe the xShare industry label can bring to organisations like yours or others in the healthcare sector?**

The potential benefits and added value of the xShare industry label are regarded by some respondents, who believe it can enhance brand recognition by signalling compliance with premier data sharing and interoperability standards in healthcare. This enhanced reputation is seen as an asset for organisations looking to establish themselves as leaders in health data interoperability. Access to new markets is another benefit highlighted by respondents, who suggest that adherence to the xShare industry label could facilitate easier entry into European markets that prioritise standardised health data exchange. This is particularly relevant for organisations seeking to expand their reach within the EU. Additionally, the label is perceived to provide a potential competitive edge by showcasing compliance with high industry standards, which is important for gaining a market advantage in the increasingly competitive digital health landscape.

The label's role in driving operational efficiency is also noted, with respondents indicating that standardisation could reduce costs and improve service delivery, thereby enhancing overall operational effectiveness. Furthermore, the xShare industry label is expected to boost patient and user confidence by demonstrating a commitment to improved data security and regulatory compliance. Respondents noted that the xShare industry label could significantly enhance the completeness of a patient's electronic health record by integrating various types of health data from different applications, ranging from mindfulness and fitness-related information to purely medical records. This completeness is seen a key enable to support the citizen in an innovative way. This interoperability is viewed as a key value proposition, streamlining and unifying the exchange of health-related data across various sectors within the healthcare industry, ultimately leading to better health outcomes.

- **On a scale from 1 to 5, how ready is the healthcare industry when adopting a label like the xShare industry label, considering the current digital health landscape?**

The readiness of the healthcare industry to adopt the xShare industry label is generally viewed positively, with most respondents rating the industry's readiness at levels 3 to 5. This suggests a moderate level of preparedness among healthcare organisations to integrate the label into their operations. However, some challenges are identified, particularly for organisations that do not extensively use interoperability standards. These organisations may face difficulties in mapping their existing processes and concepts to the new common specifications, which could require significant effort and resources. Additionally, there is a concern that solution providers often implement non-standard integrations due to a lack of experience with standards or a preference for local or proprietary solutions aimed at achieving commercial or economic gains. Despite these challenges, the overall outlook is optimistic, with respondents recognising the potential benefits of adopting the xShare industry label and its importance in advancing digital health interoperability and compliance within the EHDS. It was noted that the readiness of healthcare organisations that do not extensively use interoperability standards might be lower, as the adoption of the xShare industry label could require significant efforts in mapping processes and concepts to the standard.

SO2: Business Viability and Impact of the xShare industry label: Assessing the impact of the xShare industry label on businesses, including the analysis of financial, technical, and human resource implications, and how these factors contribute to the feasibility and readiness for implementation.

- **In your opinion, who should be responsible for covering the costs associated with the xShare industry label, including its implementation, development, assessment, and validation within the healthcare industry?**

Survey responses indicate a range of opinions on who should bear the costs of the xShare industry label. Many respondents believe that government or public health authorities should cover these costs, arguing that the label serves the public interest by facilitating interoperability and innovation across healthcare systems, thereby improving care coordination, and reducing errors. This investment would encourage innovation and align with public health objectives by enhancing healthcare efficiency and outcomes. On the other hand, some respondents suggest a shared responsibility between the organisations directly benefiting from the label and a consortium of healthcare industry stakeholders.

This perspective involves stakeholders to ensure that those who benefit from the label also contribute to its development and maintenance, fostering a sense of shared responsibility and collaboration within the industry. Respondents elaborated that government involvement is crucial due to the label's potential to create an innovative ecosystem of data producers and consumers, enhancing public health outcomes and reducing healthcare costs. Others highlighted that a shared cost approach ensures that all stakeholders are invested in the label's success, reflecting a collaborative effort to enhance healthcare interoperability. However, ensuring fair compliance across different systems is practically challenging. Therefore, the most successful approaches reward the use of label-compliant solutions, providing a generic incentive for the industry to comply and driving overall sector compliance.

What do you perceive as the major challenges or barriers to adopting the xShare industry label for the industry?

- **Technical integration challenges:** Respondents largely agree that integrating the xShare industry label with existing IT infrastructures poses significant challenges. Upgrading or modifying current systems to meet xShare standards could require substantial technical effort

and resources, potentially disrupting ongoing operations. Additionally, respondents noted that these challenges are compounded by the need for extensive mapping of processes and concepts to the EEHRxF format, which can be particularly daunting for organisations not currently using interoperability standards.

- **Compliance with varying certification frameworks:** Respondents noted the significant challenge of adhering to different certification frameworks, often related to national compulsory requirements. These frameworks have varying methodologies and timelines, making it difficult for organisations to achieve consistent compliance. This adds a layer of complexity to adopting the xShare industry label, as organisations must navigate and harmonise multiple certification processes, potentially leading to delays and increased administrative burdens.

- **Cost implications and budget constraints:** There is also a consensus that the financial burden of adopting and maintaining compliance with the xShare industry label is a barrier. The costs associated with implementation, ongoing compliance, and necessary system upgrades may be prohibitive for some organisations, especially smaller entities with limited budgets. This concern reflects the potential financial strain that the label could impose on healthcare providers, making budget allocation a critical issue.

- **Lack of organisational readiness and training:** Respondents highlight the need for extensive training and organisational preparation to effectively integrate the xShare industry label. This includes educating staff about the new standards and ensuring that organisational processes are aligned with xShare requirements, which can be resource intensive. The need for such preparation underscores the importance of building internal capacity to handle the changes brought by the label.

- **Regulatory compliance complexity:** The complexity of complying with the regulatory aspects of the xShare industry label is seen as a significant barrier. Respondents' express concerns about the effort required to understand and implement the necessary compliance measures, which may involve navigating intricate regulatory frameworks. This complexity could potentially delay adoption as organisations work to meet these stringent requirements.

- **Resistance to change and organisational inertia:** Resistance to adopting new standards is noted as a considerable challenge. Organisations may exhibit inertia due to the perceived risks and disruptions associated with change, preferring to stick with established practices rather than adopt the xShare industry label. Respondents also noted that resistance to change often stems from a lack of familiarity with standards and a preference for proprietary solutions that offer commercial advantages.

- **Certification process for xShare industry label: Which of the following methods do you think is most suitable for obtaining the xShare industry label?**

Based on the data provided, the preferred method for obtaining the xShare industry label certification is the **consortium-based certification** (when comparing with a self-certification process or a government authority owning the certification process). Consortium-based certification also goes

beyond EHDS legislative text which suggests self-certification. This method (consortium-based), is where a group of industry stakeholders collaborates to develop and manage the certification process, is highlighted as the most valued due to its capacity to foster collaboration and utilise diverse expertise within the industry. Respondents appreciate this method for its ability to leverage the collective knowledge and resources of various stakeholders, which enhances the applicability of the certification process.

In contrast, government certification and third-party certification are also favoured by some respondents but to a lesser extent. Government certification is noted for providing a high level of credibility and aligning with public health objectives, while third-party certification is recognised for its impartiality and ability to maintain high standards of compliance. However, the consortium-based approach stands out as the most preferred method due to its collaborative and inclusive nature. Finally, responses may need to be considered biased given the number of industry representatives in the xShare consortium.

SO3: Stakeholder Interpretation of EHRxF Compliance in xShare: Clarify stakeholder interpretations of compliance with the xShare industry label under the European EHRxF (what this compliance means) within the European Health Data Space framework and outline the implications of compliance requisites.

- **In order to be compliant with the xShare industry label and the European EHR Exchange Format (EHRxF), which aspects do you believe are essential for organisations to adhere to within the European Health Data Space (EHDS) framework?**

Survey respondents emphasised the importance of several key aspects to ensure compliance with the xShare industry label and the EHRxF within the EHDS framework. These include adherence to specific articles outlined in the EHDS legislation, the implementation of technical and data standards specified by the EHRxF, and meeting data security and privacy requirements beyond basic legal obligations. Respondents perceive compliance with the EHRxF as involving a comprehensive approach that extends **beyond merely meeting the minimum legal standards**. It entails a deep integration of robust technical standards and advanced data security measures, which are essential for safeguarding sensitive health information and ensuring that data exchanges within the EHDS are secure and efficient.

- **Infrastructure Integration: Which priority infrastructure do you believe should incorporate the xShare industry label?**

The survey indicates a preference for integrating the xShare industry label into prominent infrastructures such as public health systems and digital wallets. The myHealth@EU initiative is frequently mentioned as a platform for incorporating the xShare industry label, suggesting a focus on leveraging established health data networks that facilitate cross-border health data exchange within the EU. Respondents elaborate that infrastructure like public health systems should increase the level of data security and information assurance when sensitive data are exchanged. This involves securing the data but also ensuring that the infrastructure can support the complex requirements of the xShare industry label, such as compliance with EHDS legislation and adherence to stringent technical and data standards.

- **Perceived key aspects of compliance and infrastructure needs:**

These aspects are seen as foundational for successfully integrating the xShare industry label within priority infrastructures like public health systems and myHealth@EU. The focus on robust infrastructure integration underscores the industry's commitment to creating a secure, interoperable, and efficient health data environment across Europe. The key point is the adherence to a circle of trust which is indeed the minimum requirements for connecting infrastructures.

4.2 Qualitative interviews with industry representatives

All the industry experts targeted responded positively. Based on targeted methodology selection, they represented different domains across the industry. These experts being recognised leaders within their organisations, play pivotal roles in shaping public policy, business development, product compliance to regulation, and interoperability strategies. Thus, they cound provide insights into the development, adoption, and overall impact of the xShare industry label across different European markets and potentially globally. The structure of the interviews and the method can be seen in chapter 3.3 and the questionnaire can be seen in Annex III: Qualitative-Interview Questions Asked to Industry Stakeholders.

- **SO1: The overall industry Perception of the xShare industry label**

With a focus on evaluating the industry's perceptions of the xShare industry label's potential effects, expectations were discussed along with anticipated challenges, and the perceived benefits for organisational operations within the healthcare industry. There was **consistency** across responses in terms of the importance of recognising the timeliness and space for a label and for this effort.

In terms of what would determine whether the label would be successful and its uptake, the success of label was considered to depend on multiple factors, those consistently identified being: having a **strong value proposition** with clear link to **procurement** and needs of Member States. Furthermore, **sound governance** and **transparency** were also mentioned as part of the expectations within the industry and across sectors. The **regulatory aspect** linked to **acceptance** featured prominently, including in relation to having "**one universal standard**", ensuring strong **branding, self-certification options** and **cost /resource utilisation minimisation**, potentially clear link to CE Mark.
Overall, the development of an xShare industry label ought to build on the trade-off between value proposition and sound business proposition across industry domains.

- **SO2. Business Viability and Impact of the xShare industry label**

An effort was made to synthesise divergent views in terms of what can be the impact of the xShare industry label on businesses. This synthesis included the analysis of financial, technical, and human resource implications, and how these factors may contribute to the feasibility and readiness for implementation or hinder wide uptake. Most respondents pinpointed to the need to raise awareness across different departments, adding that capacity increase and further training may be required to ensure operational readiness. Regulatory, policy and technical aspects were also mentioned as important to incorporate in terms of familiarising an organisation to increase internal awareness with the potential and value of the label.

- **SO3: EHRxF compliance in the xShare industry label and correlation to the EHDS**

All respondents discussed the ambiguity surrounding stakeholder interpretations when it comes to compliance with the xShare industry label under the European EHRxF, i.e., what this compliance would

essentially mean within the EHDS regulation. Also, all mentioned the need to clearly outline the implications of compliance requisites to ensure sound value and business proposition. All respondents noted that currently, there is limited awareness of EEHRxF and EHDS across different departments, sectors, roles, etc., and that there is a need for more visibility of efforts like xShare, including the development of new business cases enabled by the xShare Button, but even more important to harmonise interpretation of EHDS requirements.

Critical input was provided in terms of lessons learned to improve interoperability and current practices, both related to governance and technical aspects, within and beyond Europe were highlighted. More specifically, elaboration on relevance of legislation to drive policies and business strategies was highlighted. The establishment of associations and networks to facilitate or serve as hubs to allow for the necessary processes to be developed and implemented was also mentioned. Key examples from Europe (IHE) and across the Atlantic (dynamic interplay between USCDI-ONC-TEFCA) were mentioned, along with an elaboration on the key elements that were in place to facilitate and guide implementation of standards or harmonization of practices (Rules and Implementation Guide vs. certification/self-certification) were mentioned. The link to future developments and maximising the business viability and positive impact of the label was correlated to performing an impact analysis in relation to the implementation of the EHDS across the health sectors and EU Member States.

- **Stewardship and sustainability: insights and next steps**

The associations were viewed by most as appropriate governance structures to disseminate and manage (and provide the certification) for the xShare industry label. In terms of options, DIGITALEUROPE was supported as one organisation to lead the certification process, the same was mentioned for COCIR and others. Multinational companies with a considerable market share across multiple Member States, as well as potentially many distributors, were identified as optimally placed to garner support and facilitate uptake of the xShare industry label. What was considered important was to balance industry needs vs. implementation provisions. The need to involve Member State-level entities was also discussed, more for establishing trust and relevance in provisions. There was also the opinion that the Hub could be the confluence of different stakeholders industry, authorities/regulators, and standards development that could support and sustain the xShare label.

4.3 Certification process to obtain the xShare industry label

The certification process for obtaining the xShare industry label emerged as a multifaceted theme in the qualitative interviews and quantitative survey data. The primary points of discussion include:

- **Standardisation and interoperability:** There is a consensus among stakeholders on the necessity of a standardised certification process to ensure interoperability across different health data systems. The interviews highlighted that a clear, transparent process is crucial for gaining trust and ensuring widespread adoption. Standardisation would enable different healthcare systems to communicate effectively, reducing errors and improving patient care. Interoperability was frequently mentioned as essential for facilitating cross-border health data exchange, which aligns with the goals of the EHDS.
- **Steps involved:** The process should involve multiple stages, including initial application, rigorous testing of interoperability capabilities, adherence to data security protocols, and

ongoing compliance checks. Interviewees emphasised the need for a robust framework that includes both **technical and administrative evaluations** (a divergent perspective form consortium-based certification)**.** This multi-stage process ensures that systems meet initial standards and continue to comply as technologies and regulations evolve. Regular audits and updates were suggested to maintain high standards.

- **Challenges and barriers:** Key challenges identified include the complexity of harmonising standards across different countries and systems, the financial and administrative burden on smaller organisations, and potential delays in the certification process due to bureaucratic inefficiencies. Smaller entities might struggle with the costs associated with certification, and there were concerns about the time required to navigate the process, which could hinder innovation and adoption.
- **Self-assessment different from self-certification:** A notable distinction is made between self-assessment and self-certification. Self-assessment allows organisations to evaluate their compliance with modular levels, providing a framework for continuous improvement. However, to achieve a higher level of the label, **third-party approval is necessary** to ensure trust and credibility. Self-certification is typically reserved for low-risk products with well-established standards, where manufacturers can ensure compliance without external validation. Given the regulated nature and high stakes of EEHRxF compliance via EHDS implementation, self-assessment is more appropriate for the xShare industry label if it has lower levels of certification (e.g. higher levels of certification should not be self-assessed), ensuring rigorous external evaluation for higher-risk scenarios.

4.4 Ownership of the xShare industry label

The ownership of the xShare industry label is another critical theme with varying perspectives among stakeholders:

- **Centralised ownership:** Many interviewees advocate for a centralised ownership model, preferably under a European a designated entity. A central ownership would ensure consistency, reliability, and impartiality in the certification process. Centralised ownership would also streamline the implementation of updates and changes, ensuring that all participants adhere to the same standards and protocols.
- **Industry involvement:** Some stakeholders suggest a hybrid model where industry associations and professional bodies have a role in governance. This approach can enhance industry buy-in and ensure that the certification remains relevant to technological advancements and industry needs. Involvement from industry experts would provide practical insights and foster a collaborative environment, making the certification process more dynamic and responsive to changes.
- **Governance structure:** The discussions also touched on the governance structure required for managing the label. There is support for a multi-stakeholder governance framework that includes representation from healthcare providers, industry experts, patient advocacy groups, and regulatory authorities. Such a framework would balance the interests of all parties involved, ensuring that the certification process is fair, transparent, and effective in achieving its goals.

4.5 Funding for the xShare industry label

Who should pay for the xShare industry label involves considerations of sustainability and equity:

- **Public funding:** A significant portion of respondents and interviewees believe that the initial funding for the certification process should come from public sources, such as **EU** grants or Member States contributions. This would reduce the financial burden on individual organisations, particularly smaller entities, and non-profits. Public funding would support the development and implementation of the certification framework, making it accessible to all potential users.
- **Private sector contributions:** There is also a strong argument for private sector contributions, especially from larger healthcare organisations and technology companies that will benefit from the industry label associated with EHDS. A tiered fee structure based on organisation size and revenue could be a fair approach. Larger companies, which stand to gain significantly from the interoperability and standardisation, could subsidise the costs for smaller players, fostering an inclusive environment.
- **Cost-sharing model:** A cost-sharing model combining public and private funding is seen as a pragmatic solution. Public funds could cover the development and initial setup costs, while ongoing operational costs could be supported through certification fees from participating organisations. This approach would ensure the sustainability of the certification process, distributing the financial responsibility among beneficiaries.
- **Incentives and subsidies:** To encourage widespread adoption, subsidies or incentives for early adopters and SMEs are recommended. This could include reduced certification fees, grants, or tax incentives. Providing financial support to smaller organisations would mitigate the barriers to entry, ensuring diverse participation and broad implementation of the xShare industry label.

Overall, the certification process for the xShare industry label should be supported by transparent and rigorous governance, ensuring interoperability and data security. Centralised ownership under a European entity is preferred, potentially with industry involvement in governance. Funding should ideally be a mix of public and private contributions, with incentives for smaller organisations to participate. These themes reflect a comprehensive approach to making the xShare industry label a credible and sustainable initiative within the EHDS.

5. Labelling landscape: benchmark analysis

This benchmark analysis is developed to briefly mention the description of other labelling initiatives and what are their role in the labelling landscape. By understanding the value proposition and requirements for each label, it helps 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. This process helps to answer the question on "why the xShare industry label is needed?" and "what is the value proposition of the xShare industry label?".

At the end of this chapter, a table is presented to summarise the results of this analysis. The analyses labels are the CE mark, the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Seal and Code of Conduct, EUCROFs Code of Conduct, the Continua Guidelines, the IHE CONNECTATHON SEAL, the Label2Enable, WiFi, BlueButton 2.0 and QUANTUM. The criteria utilised to analyse each label were the following:

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

5.1 CE marking

CE marking indicates that a medical device complies with the General Safety and Performance Requirements (GSPR) of all applicable European Medical Device Regulations. It is legally required for manufacturers to market their devices within the EU.[17] To understand which requirements a device needs to meet, is necessary to classify the device and identify the appropriate conformity assessment route for a product. This process dictates the required activities to demonstrate conformity. The CE marking certification process is depicted in the image below:

Figure IX - CE marking certification process

- Advantages of CE Marking for the healthcare industry: CE marking serves as a manufacturer's declaration that their medical device meets all relevant requirements set out in the European

[17] 'CE Marking - European Commission', accessed 12 April 2024, https://single-market-economy.ec.europa.eu/single-market/ce-marking_en.

Medical Device Regulation (EU MDR) governing the production and distribution of medical devices in Europe, allowing market entry across the EU and increasing the potential for widespread distribution and rapid innovation uptake.

- Challenges of CE Marking for the healthcare industry: manufacturers must navigate complex classification and conformity assessment routes to demonstrate that their products meet the GSPR, which requires rigorous documentation and can be resource-intensive for some organisations.

5.2 Code of Conduct EUCROF

The European CRO Federation's GDPR Code of Conduct for Service Providers in Clinical Research (EUCROF GDPR Code or Code) is the initiative subsidised and performed by the EUCROF to create a transnational GDPR Code of Conduct for data processors working in the clinical research industry. The EUCROF is the owner of the Code and establishes the supervisory body (COSUP).

Currently in its final stage of approval, when enforced the EUCROF GDPR Code will help to ensure the privacy rights and freedoms of trial participants while promoting the lawful, fair and meaningful use of personal data in the field of Clinical Research. Note that the EUCROF Code has been submitted for approval in March 2021 and has currently passed the co-review and cooperation phases of the approval process. The Code is a sign of the continued progress the organizations and Supervisory Authorities are making toward establishing harmonized standards applied to various industries across the EU related to data protection. Those that adhere to the code earn the right to display a Compliance Mark for 3 years. The Mark signifies the level of adherence.

The GDPR EUCROF Code is a Code of Conduct developed under Article 40 of the GDPR (Regulation). A compliance framework for adhering organisations to demonstrate alignment of their services with the Regulation. It is thus an interpretive guide to the Regulation created and endorsed by multiple stakeholders and opinion leaders in clinical research. An effective governance and accountability mechanism for which the National Commission on Informatics and Liberty (Commission Nationale de l'Informatique et des Libertés (CNIL) is the Competent Supervisory Authority; it is responsible for the approval, establishment and monitoring adherence to the Code. It is a transnational Code, recognized by the 27 Member States EU data protection authorities and approved by the European Data Protection Board (EDPB). The scope of the Code of Conduct includes any data processing activities for the services delivered by CROs and other service providers in clinical research as data processors. GDPR requirements are described in application to 23 classes of services typically delivered by CROs related to personal data of EU study subjects and healthcare professionals processed for interventional and non-interventional studies. The CROs and digital health companies can benefit by adhering to the code of conduct, according to EUCROF as follows:

- To reduce administrative and operational waste caused by conflicting interpretations of the GDPR.
- To obtain the practical instructions on demonstrating and maintaining compliance.
- To exchange practical experience with other Adherents.
- To achieve high efficiency in delivering services to Sponsor of clinical trials.
- To earn the right to display one of the Code's Compliance Marks as the compliance seal.
- To demonstrate compliance and high standards of services to Sponsors conducting clinical trials in the EU.

The code of conduct includes more than a hundred statements that can be audited by an independent body. So far, the statements do not include references to technical standards and associated capability, and we think that this kind of change will be brought over by the EHDS and the European EHRxF. In the xShare context, companies adhering to the code will be eligible to join the innovation community that will receive support to create demonstrators for the European EHRxF.

5.3 ENCePP Code of Conduct and Seal

Research collaboration for multicentre studies had long existed, however, with a fragmented landscape, and a high level of heterogeneity. This heterogeneity was further compounded by systems' level characteristics, uncertainly and critically, differences in population groups, standards of care and clinical practice, as well as prescription patterns. The need to have an expert group to provide clear guidance on best practices was strongly felt, and at the same time, there was a need to capture the rules and principles of quality standards, along with safeguarding scientific independence and transparency. Furthermore, EU-wide legislation came into force on pharmacovigilance, thus, resulting in ENCePP assuming a triple role: [18]

A. To support capacity-building in Europe,
B. To develop common methodological standards, and
C. To establish sound governance principles for the conduct of collaborative studies.

The Code of Conduct also sets interaction standards between investigators, funders, and CROs, promoting best practices and transparency. The Code is referenced in EU pharmacovigilance guidelines and is reviewed regularly. Compliance involves a validation check, public availability of study protocols, and timely reporting. In 2018, a review highlighted limitations in the commitment verification process, leading to a major revision and the introduction of tools to improve awareness, relevance, and process simplification.

5.4 Continua Guidelines

The Continua Guidelines, published by the PCHAlliance, advocate for the global adoption of standards and guidelines to utilise medical-grade data effectively. These guidelines enable rapid integration through commercial-ready software and a conformity assessment program for consistent implementation. [19] They support healthcare providers and insurers in managing populations cost-effectively, help remote care services integrate crucial ICT systems, and assist device and sensor companies in delivering significant data. Unique to Continua, this approach combines open standards, software, and product assurance to reduce integration time, allowing engineers to focus on value-added, market-differentiating applications.

The Continua Design Guidelines establish a standardised framework for interoperability among medical devices, ensuring seamless integration across personal health devices, personal health

[18] Kurz X, Perez-Gutthann S; ENCePP Steering Group. Strengthening standards, transparency, and collaboration to support medicine evaluation: Ten years of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). Pharmacoepidemiol Drug Saf. 2018 Mar;27(3):245-252. doi: 10.1002/pds.4381. Epub 2018 Jan 11. PMID: 29327451; PMCID: PMC5873428.

[19] 'Continua Design Gudelines', Personal Connected Health Alliance, accessed 12 April 2024, https://www.pchalliance.org/continua-design-guidelines.

gateways, health and fitness servers, and health information systems. These guidelines enable devices like blood pressure meters and pedometers to connect through various protocols like Bluetooth and near field communications to gateways and servers, facilitating communication with tele-health services and electronic health records. This system mirrors the mobile industry's connectivity, aiming for widespread scalability in health services. The Continua Design Guidelines also underlines robust security and privacy measures to protect data throughout the network.[20] The architecture is depicted below:

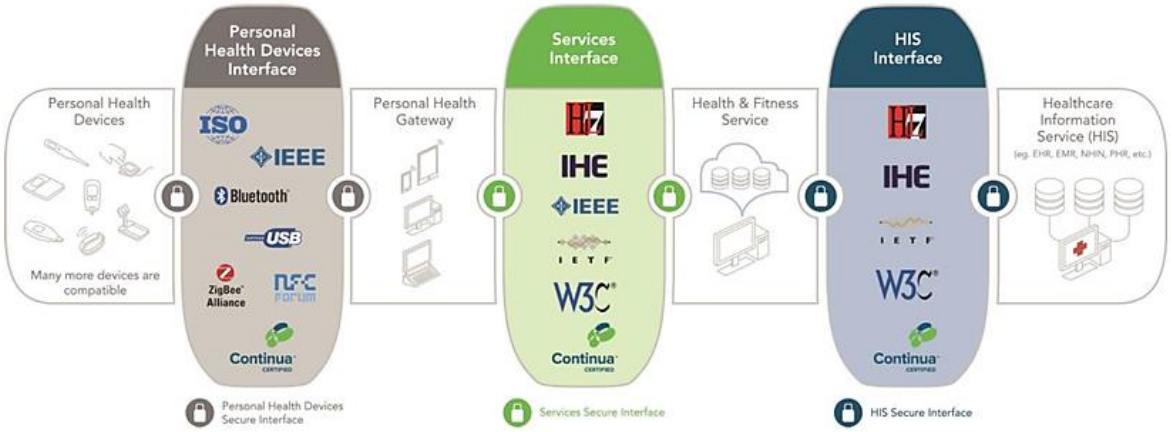

Figure XI - Continua Design Guidelines architecture

- Advantages of the Continua Design Guidelines: The Continua Design Guidelines offer open standards implementation guidance that may considerably reduce integration times from months to days. This process allows manufacturers to quickly implement standards, focusing their engineering resources on developing value-adding features that differentiate their products in the market.
- Challenges of the Continua Design Guidelines: These certified solutions are proposed at a higher price. Also, despite the facilitation of integration, the comprehensive scope of the Continua Design Guidelines requires continuous adherence and updates to stay compliant with evolving standards. This continuity may necessitate ongoing adjustments and re-certifications, potentially increasing the complexity and maintenance burden for participating companies.

While originally, Continua Design Guidelines received significant attention from the industry, the high cost of obtaining the label, lack of regulatory mandate, and in part commoditization of sensors and wearable devices resulted in low uptake and declining interest.

5.5 IHE CONNECTATHON SEAL

The IHE CONNECTATHON SEAL is an official recognition given by Integrating the Healthcare Enterprise (IHE) to vendors who demonstrate their product's interoperability capabilities by successfully testing

[20] Vasco Delgado-Gomes et al., 'Sensor Network Integration for a Medical Device Using CDG', in *2019 IEEE International Symposium on Measurements & Networking (M&N)* (2019 IEEE International Symposium on Measurements & Networking (M&N), Catania, Italy: IEEE, 2019), 1–6, https://doi.org/10.1109/IWMN.2019.8805010.

IHE profiles at an IHE Connectathon event.[21] This seal is a formal confirmation of the vendor's adherence to specific interoperability standards and profiles set by IHE. It is issued by the IHE National/Regional Deployment Committee and is valid for three years, signifying that the vendor has met the rigorous standards for interoperability. The following image depicts the process on how to attain the seal to showcase a system's interoperability capabilities:

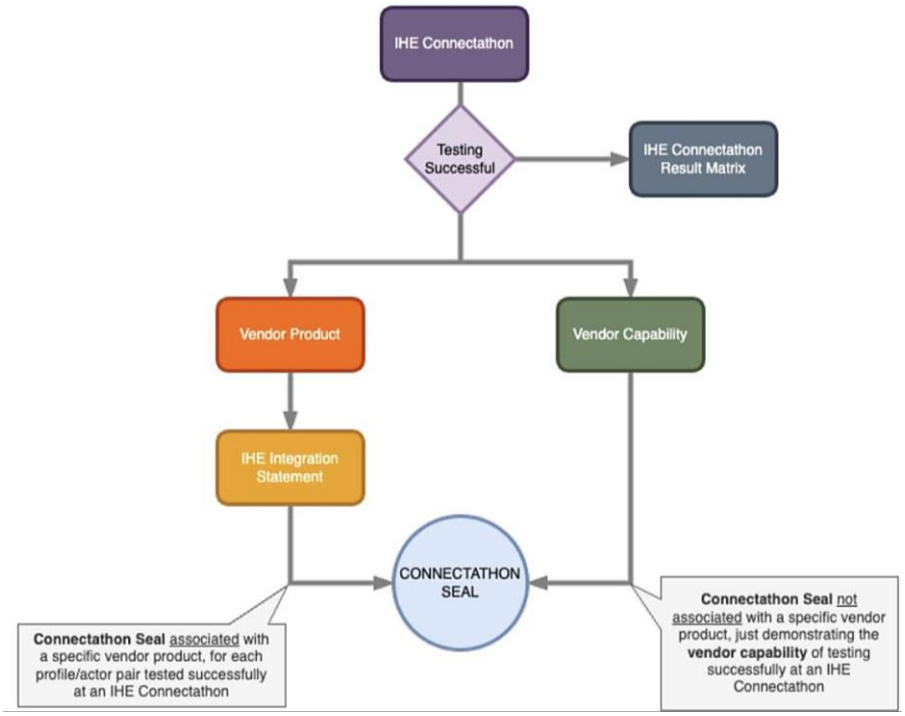

Figure XII - IHE CONNECTATHON SEAL achievement process

- Advantages of the IHE CONNECTATHON SEAL: The SEAL boosts a vendor's market presence by certifying their products as compliant with recognised interoperability standards, enhancing trust and facilitating easier procurement decisions. This seal also has a specific logo that awarded vendors may utilise.
- Challenges of the IHE CONNECTATHON SEAL: Vendors must consistently update and test their products to maintain compliance with evolving IHE standards and regularly participate in Connectathons to revalidate their SEAL, demanding ongoing investment in time and resources. Also, the seal is validity is three years.

Initiated in Japan, the IHE CONNECTATHON SEAL was introduced in IHE Europe Connectathon in 2024.

5.6 Label2Enable

Label2Enable is an EU-funded project to promote the adoption of the CEN-ISO/TS 82304-2 standard and its quality label for health and wellness apps.[22] The project aims to create a digital single market where quality health apps are widely utilised in prevention, health care, and self-care. Label2Enable

[21] 'IHE Connectathon SEAL | Connectathon', accessed 12 April 2024, https://connectathon.ihe-europe.net/ihe-connectathon-seal.
[22] 'About Label2Enable | Label2Enable', accessed 12 April 2024, https://label2enable.eu/about-the-project.

focuses on three main pillars: trust, use, and adoption, each supported by different consortium partners. Currently, the project is testing the label certification scheme with 24 health apps to ensure its effectiveness and applicability. The project seeks to ensure that European standards maintain patient safety, improve health outcomes, and enhance the efficiency of health app manufacturing.

- Advantages of the Label2Enable for the health industry: By developing a certification scheme for health app assessment (ISO/IEC 17065), Label2Enable aims to standardise evaluation methods, ensuring health apps meet high safety, quality, and interoperability standards across Europe. This uniformity helps build trust among consumers and healthcare providers.
- Challenges of the Label2Enable for the health industry: Implementing and maintaining a standard across diverse European markets involves complex coordination among various stakeholders. Additionally, aligning the label with EU legislation and values while considering the financial aspects of app assessment might pose significant regulatory challenges for the industry and smaller developers.

5.7 WiFi (IEEE)

The Institute of Electrical and Electronics Engineers (IEEE) develops and promotes essential global standards in electronics and electrical engineering, significantly impacting the healthcare industry. Key standards like IEEE 802.15.6 for wireless body area networks (WBANs) and IEEE 802.11 (Wi-Fi) are designed to support high-throughput applications, enhance data rates, and reduce latency in dense deployments. These standards are vital for health data interoperability, ensuring the secure, reliable, and timely transmission of critical health data across various medical devices. By establishing uniform protocols for data exchange, IEEE standards facilitate the integration of diverse technologies, enabling continuous patient monitoring and supporting reliable monitoring systems in smart homes and ambient assisted living environments. This standardization helps building a cohesive healthcare system where devices from multiple manufacturers can seamlessly interact, thereby improving patient care and enhancing operational efficiency.[23] The following image illustrates the continuous monitoring of patients in an ambient assisted living environment, showcasing a network of interconnected medical devices like sensors, monitors, and display systems that adhere to IEEE standards. These devices seamlessly exchange real-time health data, ensuring precise and timely healthcare delivery to enhance patient care and safety in a high-tech, supportive living setting.[24]

[23] Gonçalo Marques et al., 'Internet of Things Architectures, Technologies, Applications, Challenges, and Future Directions for Enhanced Living Environments and Healthcare Systems: A Review', *Electronics* 8, no. 10 (24 September 2019): 1081, https://doi.org/10.3390/electronics8101081.

[24] Yazdan Ahmad Qadri et al., 'Preparing Wi-Fi 7 for Healthcare Internet-of-Things', *Sensors* 22, no. 16 (18 August 2022): 6209, https://doi.org/10.3390/s22166209.

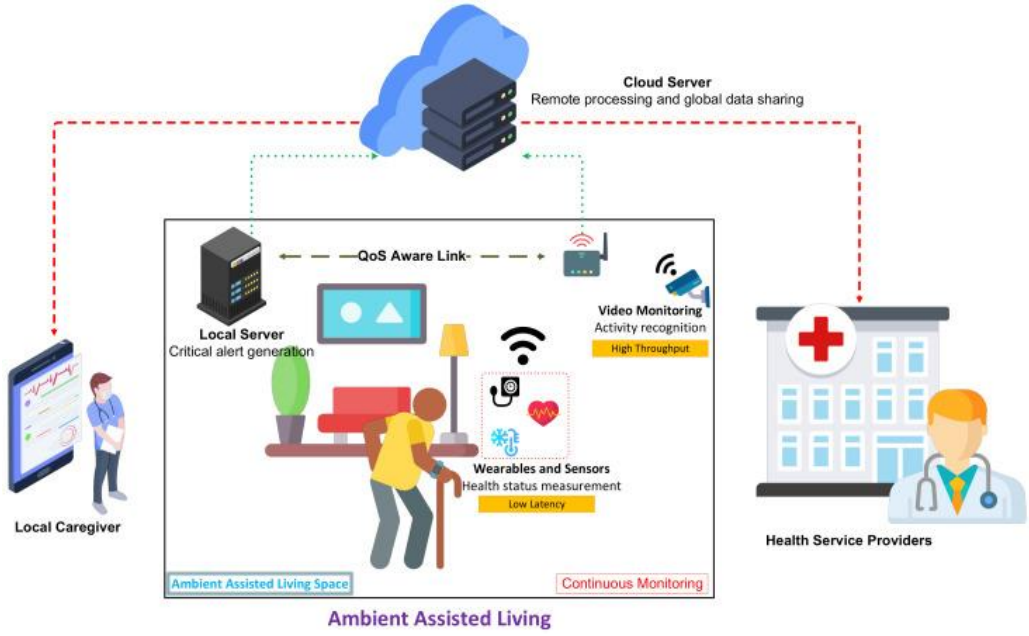

Figure XII - Continuous monitoring of patients in H-IoT: ambient assisted living

For healthcare providers, the IEEE standards extends into enhancing operational efficiencies and improving patient outcomes. These standards ensure that medical devices and systems can communicate effortlessly, reducing errors and delays that can be critical in medical settings. The ability to rely on standardised, high-quality data transmission aids in accurate monitoring, diagnosis, and treatment, facilitating advanced healthcare services such as telemedicine and remote patient monitoring. This process is increasingly vital in an era where healthcare is becoming more personalised and dependent on continuous data from connected medical devices. IEEE standards might be able to support technological interoperability and reinforce the operational effectiveness of healthcare delivery, directly impacting the quality of patient care and the agility of healthcare responses in dynamic environments.[25]

5.8 QUANTUM data quality and utility label

The QUANTUM data quality and utility label, originates from Article 56 of the proposed European EHDS regulation aims to standardise the assessment of health data quality, utility, and maturity within the HealthData@EU ecosystem. This label ensures that data users—such as researchers, policymakers, and innovators—have access to high-quality datasets. The QUANTUM Label may complement the xShare industry label by complementing its objectives of ensuring data quality and interoperability within health data exchanges. While the xShare industry label focuses on certifying the quality and interoperability of data, the QUANTUM label provides a broader framework under the EHDS for assessing data quality and utility across various health data holders. Together, these labels enhance data reliability, interoperability, and efficient use of health data for research and policymaking across Europe.

[25] Yazdan Ahmad Qadri et al., 'The Future of Healthcare Internet of Things: A Survey of Emerging Technologies', *IEEE Communications Surveys & Tutorials* 22, no. 2 (2020): 1121–67, https://doi.org/10.1109/COMST.2020.2973314.

- Advantages of the Quantum Label for the health industry: The Quantum Label offers a standardized framework for data quality and utility assessment, ensuring consistency and transparency across datasets. This standardization facilitates seamless data exchange and integration within the HealthData@EU ecosystem, enhancing data reliability and utility for all stakeholders.
- Challenges of the Quantum Label for the health industry: Implementing and maintaining the Quantum Label involves continuous adherence to evolving standards and regular updates to stay compliant. This process requires significant coordination among various stakeholders and can pose regulatory challenges, especially for smaller data holders.

5.9 Blue Button 2.0

Blue Button[26] was introduced by the Center for Medicate and Medicaid Services (CMS) and the Veteran's administration (VA) in 2010. In 2018 the program was revisited by MyHealthEDATA, and shortly thereafter followed BlueButton 2.0. BlueButton 2.0 is a standards-based application programming interface (API) that delivers Medicare claims for 60 million beneficiaries, allowing them to download via MyMedicare.gove portal a chronology of all their medical procedures, diagnoses, etc. Underpinning the API is a HL7 FHIR-based claims API. As of December 2020, over 60 organizations have Blue Button apps available and over 2500 developers are working on development of applications. Among the use cases suggested for Blue Button 2.0 are plan adjustment, population management, medication adherence, plan matching and gaps in care. Blue Button is focusing on the US and development of the relevant HL7 FHIR implementation guides is supported by accelerators, like the CARIN alliance, and the HL7 DaVinci project.

5.10 Comparison of Labels

Labels	Short Description	Interoperability Standards	Compliance necessity (regulatory/ voluntary)	Scope of Application	Adoption and Recognition
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
Continua Guidelines	Ensures interoperability of personal connected health devices.	High interoperability focus	Voluntary guidelines	Health devices and data	Moderate (industry-specific)

[26] Some Blue Button resources. https://bluebutton.cms.gov/ https://en.wikipedia.org/wiki/Blue_Button

IHE CONNECTATHON SEAL	Recognizes a vendor's interoperability capability through IHE profile testing.	High emphasis on 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 data 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

Table II – xShare industry label benchmark analysis

The benchmark analysis illustrates a diverse landscape of labelling initiatives, each serving unique roles within their respective domains. The xShare industry label could position itself as a critical component within this ecosystem by addressing gaps and complementing existing labels. Specifically, the xShare industry label can:

- 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.

In summary, the xShare industry label, by integrating these elements, can offer a robust, comprehensive, and widely recognised framework that not only ensures data quality and interoperability but also supports the broader objectives of the HealthData@EU initiative.

6. SWOT analysis of the xShare industry label

This SWOT analysis synthesises insights from feedback provided by adoption sites and data gathered from the SWOT workshop conducted with the xShare consortium participants. The workshop was a short one allowing only 15 minutes for each perspective. After discussing the options for each perspective of the SWOT, participants were able to rank the options according to their perceived importance. Aside from the workshop itself, the SWOT analysis was developed with the inputs collected through the qualitative interviews, the xShare survey, the benchmark analysis and the forums.

By detailing the strengths, weaknesses, opportunities, and threats associated with the xShare industry label, this analysis guides strategic decisions to optimise implementation outcomes. Strengths underscore the label's innovative cross-border data sharing capabilities, while weaknesses highlight issues such as digital literacy and the lack of a fully standardised data formats. Opportunities suggest improvements, such as moving beyond PDF data exchanges to more robust EHRxF integrations and harnessing procurement strategies. Meanwhile, threats are related to regulatory and privacy challenges that could hinder the project's success. This analysis, rooted in practical feedback and detailed discussions from key stakeholders, is essential for navigating the complexities of implementing the xShare industry label effectively across various European healthcare settings. It is also worth noting that in the next phases of the project, the SWOT analysis will be further detailed to better reflect the perspective of the different stakeholders involved in xShare, namely national health authorities, industry players, hospitals, patients.

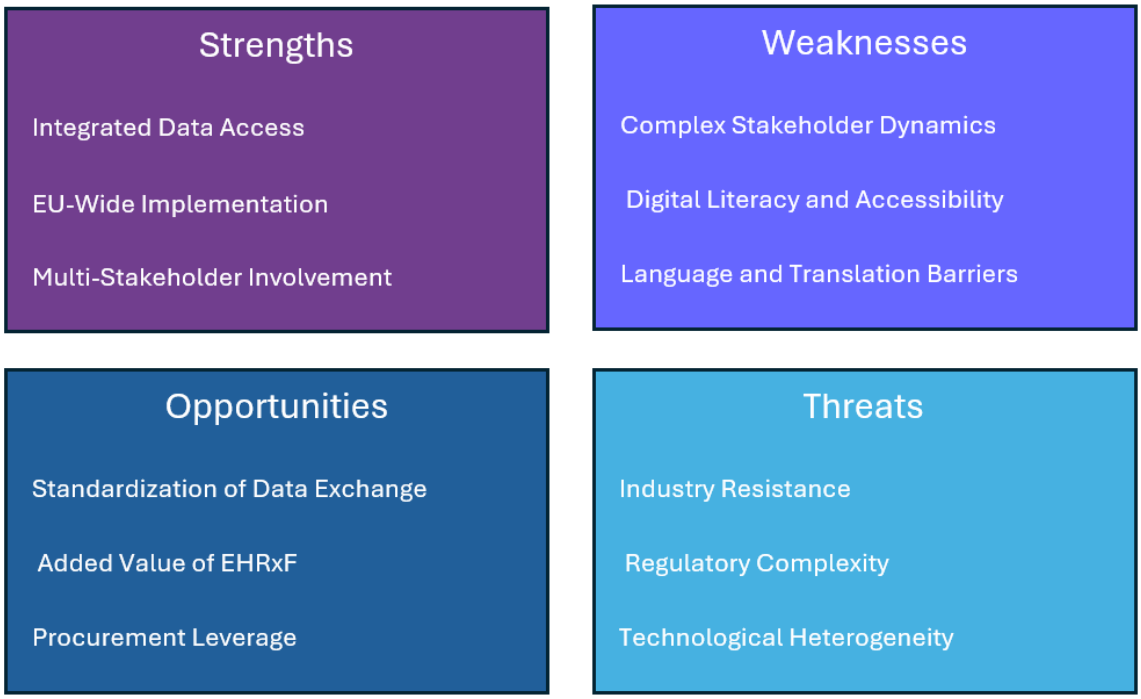

Figure XIII - xShare industry label SWOT

6.1 Strengths

In the SWOT analysis, the strengths section evaluates xShare industry label's unique assets and competitive advantages. By focusing on what makes the xShare industry label stand out and the specific benefits that the labelling mechanism brings, it is possible to pinpoint the core advantages that will drive the project's success. The following images and paragraphs summarise the results taken from the SWOT workshop. The main strengths are:

Figure XIV– *xShare Strengths - SWOT*

Each of these strengths identified by xShare project consortium partners can be transformed into a unique selling point, showcasing the project's distinctive value proposition.

- **Integrated data access (general project strength):** Facilitates centralised access to health data across platforms like mobile apps and patient portals, enhancing user experience and data portability.
- **EU-Wide Implementation (adoption sites feedback):** Adoption across various EU member states creates a unified approach to health data sharing and benefits from diverse implementation insights.
- **Multi-Stakeholder Involvement (general project strength):** Engagement with healthcare providers, IT vendors, regulatory bodies, and patients ensures a comprehensive system design and implementation.

- **Enhanced Interoperability (general project strength):** Promotes interoperability across different health systems and software, facilitating seamless data exchange.
- **Strong consortium and network:** The xShare industry label is supported by a strong team of experts and organisations from different countries, which ensures the representation of key stakeholders from different EU regions. The composition of the consortium itself is an added value, gathering experts from previous outstanding projects in the domain. This brings a legacy of expertise and established working relationships to the project, which can significantly accelerate adoption and implementation of the xShare industry label.
- **Alignment with the EHDS:** The xShare industry label aligns with the proposed EHDS (Article 23), empowering the European Commission to further develop specifications through implementing acts regarding EHR systems and devices that claim interoperability with them.
- **Financial benefits and competitive advantage:** The xShare industry label also promises a competitive advantage in the EU market by lowering development costs, improving efficiency, and supporting research and innovation.

6.2 Weaknesses

The weakness section aims to acknowledge the internal limitations or potential challenges that the xShare industry label will face. This helps mitigating potential issues and enhancing the overall success of the xShare industry label. Among the most frequently mentioned weaknesses, the project consortium identified the following issues:

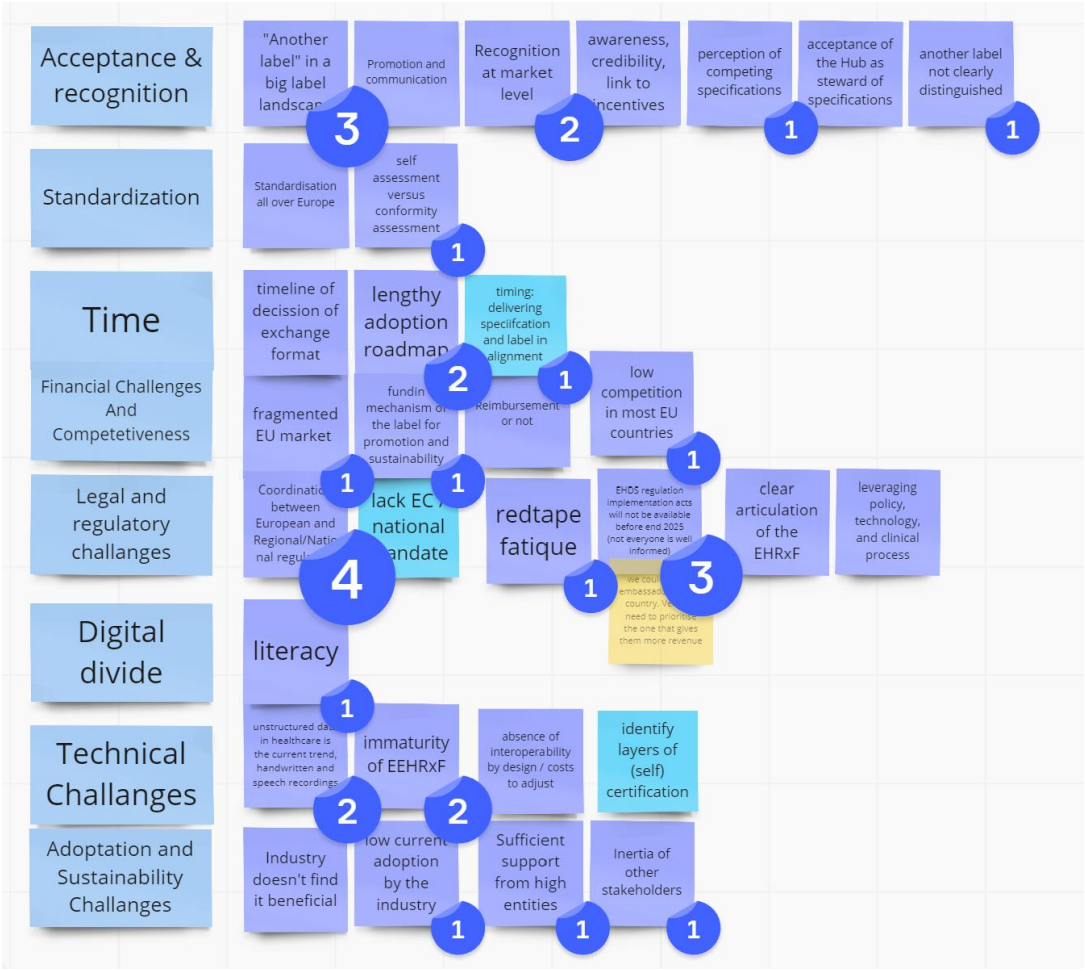

Figure XV – *xShare weaknesses - SWOT*

- **Digital literacy and accessibility (From adoption sites feedback):** Variability in digital literacy among citizens can hinder effective use, potentially limiting reach and impact.
- **Language and translation barriers (from adoption sites feedback):** The need for accurate translation and representation of medical data in various EU languages to facilitate cross-border care. Relying on uncertified tools or lacking common language dictionaries can compromise the continuity of care, leading to potential misinterpretations and clinical errors.
- **Regulatory and privacy concerns (general project concern):** Adhering to GDPR and other privacy regulations poses significant challenges in ensuring both easy and secure data sharing.
- **Dependency on national infrastructure (general project concern):** Effectiveness depends on the underlying digital health infrastructure of each Member State, which can be uneven.
- **Localisation,** inability to read source language, mobile data access, ability and process for HP to receive patients' health data (From adoption sites feedback).
- **Data Standardisation and definition (From adoption sites feedback):** Inadequately defined or non-standardised data formats (X format) can lead to interoperability issues and inconsistency in data handling across systems.
- **Legal and regulatory challenges:** The consortium members emphasized that the EHDS Implementation Acts will not be in effect before 2025. Because of a lack of effective

regulations, there will be information gaps among xShare industry label holders. In a similar vein, a lack of effective regulations leads to disparities and coordination challenges between EU member states, as well as national and local regions.

6.3 Opportunities

The main opportunities identified are related to the actions to be undertaken to influence regulatory standards, empower research, improve services, foster international cooperation, and enhance data for technological advancements:

Figure XVI– *xShare opportunities - SWOT*

- **Standardization of data exchange (From general strategic opportunity and PDF current usage):** Moving from PDFs to EHRxF enhances data usability and accessibility, offering dynamic, retrievable databases.
- **Added Value of EHRxF (explained as a strategic advantage):** Allows real-time data updates, comprehensive analytics, and integration into clinical workflows, improving clinical decision-making and patient outcomes.
- **Procurement leverage (general strategic opportunity):** Utilising procurement processes can drive adoption, with national authorities and health systems as key purchasers.
- **Self-Certification process (suggested in feedback):** Speeds up adoption, reduces costs, and empowers vendors to efficiently demonstrate compliance.

- **Return in investment (ROI) opportunities:** The xShare industry label allows businesses to showcase how much they will receive in return for their investment in the label, as well as how much they will benefit from their investments.

6.4 Threats

When considering the threats, the project partners have identified the external factors that could pose challenges to the success of the xShare industry label, along with mitigation actions to address these potential risks, enhance stakeholders' engagement, and ensure the project's resilience in a competitive environment.

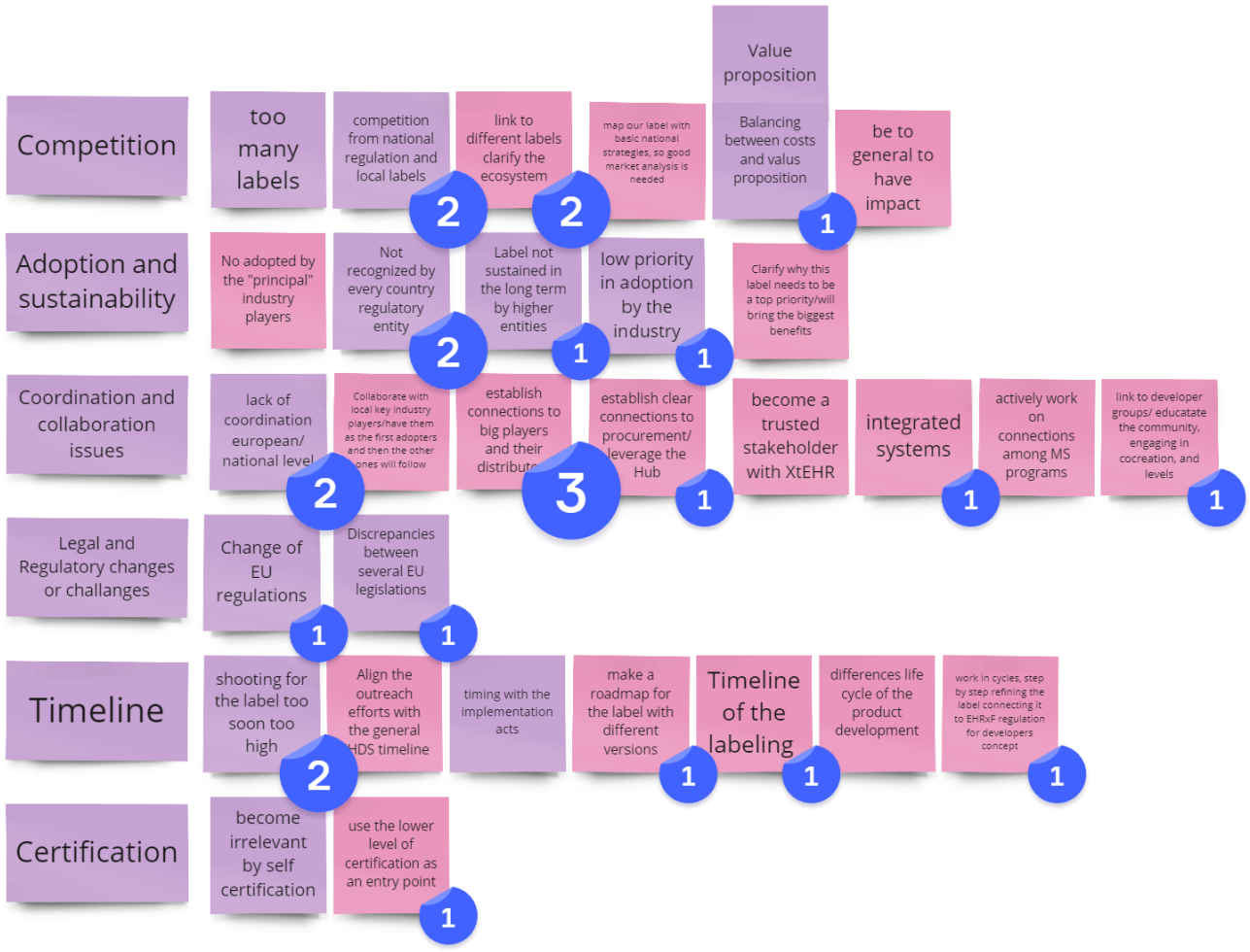

Figure XVII– xShare threats - SWOT

- **Industry resistance (from adoption sites feedback):** IT vendors and healthcare providers may resist integrating a new system that could impose additional costs or require workflow changes.
- **Regulatory complexity (general strategic concern):** The complex regulatory environment across EU countries can delay implementation and increase compliance costs.
- **Technological heterogeneity (general strategic concern):** Diverse technological landscapes and standards across EU member states may complicate uniform implementation.

- **Financial Constraints (general strategic concern):** Budget limitations within healthcare systems and providers may impede the adoption of new technologies like the xShare industry label particularly in less economically robust regions.
- **Society acceptance and adherence (from adoption sites feedback):** Citizens might not be ready to adopt and accept it.
- **Competition:** The xShare industry label faces competition from other EU projects and labels within the EHDS initiative, which could overshadow the xShare industry label.
- **Scalability and adaptability:** The xShare industry label also faces the issue of being potentially too broad and difficult to localize. These issues can also be observed in the spread of the xShare industry label from one EU country to another.

7. Value proposition: The vision for the xShare industry label

The xShare industry label strives to establish a cohesive system to enable individuals to share their personal health data in machine readable format. By adhering to the EEHRxF, it supports the seamless exchange, security, and efficiency of health data. This value proposition delineates the advantages for various stakeholders involved in the xShare initiative, based on thorough qualitative interviews, quantitative surveys, and a comprehensive SWOT analysis.

7.1 Healthcare industry value proposition

- **Pain point:** Health IT vendors and healthcare providers face significant challenges related to the lack of interoperability across different health systems and software. This issue hampers effective communication between systems, leading to fragmented patient care and inefficiencies.
- **Mitigation with xShare industry label:** The xShare industry label addresses this by promoting enhanced interoperability and seamless data exchange. By ensuring compliance with EHRxF standards, the xShare industry label facilitates better patient care through real-time data updates and comprehensive analytics, which are crucial for high-quality healthcare delivery. Additionally, it helps lower development costs by using standardised data formats and protocols, thus translating to higher ROI through reduced redundancy in health data management. The involvement of multiple stakeholders ensures a well-rounded system design, fostering innovation and continuous improvement.

7.2 Industry associations value proposition

- **Pain point:** Industry and professional bodies struggle with the need for standardisation and ensuring their members remain compliant with evolving regulations. This lack of uniformity can lead to inefficiencies and increased compliance costs.
- **Mitigation with xShare industry label**: The xShare industry label provides a robust framework for standardisation and compliance, enhancing interoperability across member organisations. By offering resources and support for implementing and complying with EEHRxF standards, the xShare industry label increases member engagement and support, positioning industry associations as leaders in promoting data security and interoperability. Regular training sessions and informational resources help keep members informed and compliant, thereby reducing inefficiencies and compliance costs.

7.3 Research centers value proposition

- **Pain point:** Research centers often face challenges in accessing comprehensive, interoperable health data sets, which limits the quality and scope of their research.
- **Mitigation with xShare industry label:** The xShare industry label significantly enhances research capabilities by facilitating access to comprehensive health data sets, enabling advanced analytics and data-driven insights essential for innovative research projects. The label promotes collaboration and networking by fostering partnerships between research institutions, healthcare providers, and industry players, creating a dynamic environment for multidisciplinary research. Additionally, aligning with EU funding priorities increases the likelihood of securing grants and financial support for research projects, making competence centers more attractive partners for funding agencies.

8.4 SDOs value proposition

- **Pain point:** SDOs face the challenge of ensuring widespread adoption and implementation of harmonised health data standards across diverse healthcare settings, which can be complex and slow.
- **Mitigation with xShare industry label:** The xShare industry label positions SDOs as leaders in setting global benchmarks for health data interoperability and security by contributing to the development and harmonisation of international standards. The label provides a clear framework for adoption and implementation, driving widespread acceptance and use of harmonised standards. Continuous improvement and updating of standards, encouraged by the xShare industry label, ensure that standards keep pace with technological advancements and remain relevant and effective.

7.4 Governments and national authorities value proposition

- **Pain point:** Governments and national health authorities often struggle with fragmented healthcare delivery systems, which hinder efficient and high-quality patient care. Additionally, ensuring compliance with GDPR and other data protection regulations is a significant challenge.
- **Mitigation with xShare industry label:** The xShare industry label enhances healthcare delivery by promoting interoperable and accessible health data, supporting national health strategies aimed at improving patient outcomes and reducing healthcare costs. By ensuring compliance with GDPR and other data protection regulations, the label safeguards patient data and enhances public trust in digital health initiatives. The label also fosters economic growth by attracting investment and innovation in the healthcare sector, leading to job creation and technological advancements. Providing incentives and support for healthcare providers and IT vendors to adopt and comply with the xShare industry label will further enhance its adoption and impact. Lastly, the label facilitates better population health management through comprehensive and interoperable health data, enabling more effective public health interventions and policymaking.

8. Conclusion and next steps for the feasibility study

The introduction of the xShare industry label is main enabler for the creation of dynamic and innovative health data sharing across Europe. This report draws an initial landscape of the main ideas, benefits, and plans for using the xShare industry label. It uses information from interviews, surveys, and a detailed analysis of strengths, weaknesses, opportunities, and threats (SWOT). The findings highlight the label's potential to solve issues for various players in the healthcare field, such as IT vendors, healthcare providers, industry groups, research centers, standards organizations, and health authorities.

With a clear focus on EEHRxF trusted and secure implementation, the vision for the xShare industry label is to enhance patient care, proactively meet new regulations, encourage new interactions and innovations in healthcare. The label's strong framework for standardisation and compliance will help make processes smoother, reduce waste, and improve the quality and security of health data management.

The next steps involve assessing the xShare industry label by collecting feedback from stakeholders and by conducting a robust feasibility study. This phase will focus on further validating the xShare industry label's framework through stakeholder engagement and deliberation, with a strong focus on the following key elements: regulatory alignment and legal interoperability, technical refinement, economic evaluation, and communication and dissemination. The same channels (meetings, workshops, and surveys) will be used.

This iterative process will ensure that the label meets the expectations and deliver concrete value. Working with regulatory bodies to ensure the xShare industry label complies with current and upcoming regulations, including the EHDS and GDPR, is another vital aspect. Improving the technical and security guidelines will help ensure the robustness and credibility of the xShare industry label. Conducting return-on-investment studies and economic analyses to show the financial benefits of using the xShare industry label and how it can foster better solution-delivery for the society and citizens, will no doubt encourage more healthcare providers and IT vendors to adopt it. Finally, creating comprehensive communication strategies to raise awareness about EHDS, the EHRxF, and the xShare industry label and its benefits among stakeholders, policymakers, and the broader healthcare community will help in its widespread adoption.

The results from this study will be included in the next report, due in M18 of the project. This report will provide a detailed account of the pilot projects, stakeholder feedback, and improved framework for the xShare industry label feasibility study. It will also include a comprehensive analysis of the study's findings, offering practical insights and recommendations for the full implementation of the xShare industry label across Europe. The xShare industry label can address key issues and promote a collaborative, secure data environment for the healthcare industry in Europe.

9. References

'About Label2Enable | Label2Enable'. Accessed 12 April 2024. https://label2enable.eu/about-the-project.

Braun, Virginia, and Clarke, Victoria. 'Using Thematic Analysis in Psychology'. *Qualitative Research in Psychology*, 2006, 77–101. http://dx.doi.org/10.1191/1478088706qp063oa.

'CE Marking - European Commission'. Accessed 12 April 2024. https://single-market-economy.ec.europa.eu/single-market/ce-marking_en.

Delgado-Gomes, Vasco, Fabio Januario, Nuno Vilhena, Maria Marques, and Ricardo Jardim-Goncalves. 'Sensor Network Integration for a Medical Device Using CDG'. In *2019 IEEE International Symposium on Measurements & Networking (M&N)*, 1–6. Catania, Italy: IEEE, 2019. https://doi.org/10.1109/IWMN.2019.8805010.

European Commission. 'AI Act | Shaping Europe's Digital Future'. Shaping Europe's Digital Future, 23 April 2024. https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai.

———. 'Communication Establishing the Union-Level Projected Trajectories for the Digital Targets | Shaping Europe's Digital Future'. Shaping Europe's Digital Future, 27 September 2023. https://digital-strategy.ec.europa.eu/en/library/communication-establishing-union-level-projected-trajectories-digital-targets.

———. 'Digital Decade DESI Visualisation Tool'. Shaping Europe's Digital Future. Accessed 15 May 2024. https://digital-decade-desi.digital-strategy.ec.europa.eu/.

———. 'EU Cyber Resilience Act | Shaping Europe's Digital Future'. Shaping Europe's Digital Future. Accessed 15 May 2024. https://digital-strategy.ec.europa.eu/en/policies/cyber-resilience-act.

———. 'European Digital Rights and Principles | Shaping Europe's Digital Future'. Shaping Europe's Digital Future. Accessed 15 May 2024. https://digital-strategy.ec.europa.eu/en/policies/digital-principles.

———. 'Europe's Digital Decade | Shaping Europe's Digital Future'. Shaping Europe's Digital Future, 4 May 2024. https://digital-strategy.ec.europa.eu/en/policies/europes-digital-decade.

———. 'Interoperable Europe Act Enters into Force for Better Connected Public Services for People and Businesses | Shaping Europe's Digital Future'. Shaping Europe's Digital Future, 11 April 2024. https://digital-strategy.ec.europa.eu/en/news/interoperable-europe-act-enters-force-better-connected-public-services-people-and-businesses.

———. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space, § 3 (2022). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52022PC0197.

Global Digital Health Partnership. 'Global Digital Health Partnership'. Global Digital Health Partnership. Accessed 30 April 2024. https://gdhp.health/.

'IHE Connectathon SEAL | Connectathon'. Accessed 12 April 2024. https://connectathon.ihe-europe.net/ihe-connectathon-seal.

'Interactive Presentation Software - Mentimeter'. Accessed 3 May 2024. https://www.mentimeter.com/.

Lochmiller, Chad. 'Conducting Thematic Analysis with Qualitative Data'. *The Qualitative Report*, 20 June 2021, 2029–44. https://doi.org/10.46743/2160-3715/2021.5008.

Marques, Gonçalo, Rui Pitarma, Nuno M. Garcia, and Nuno Pombo. 'Internet of Things Architectures, Technologies, Applications, Challenges, and Future Directions for Enhanced Living Environments and Healthcare Systems: A Review'. *Electronics* 8, no. 10 (24 September 2019): 1081. https://doi.org/10.3390/electronics8101081.

Meyrick, Julian de. 'The Delphi Method and Health Research'. *Health Education* 103, no. 1 (1 January 2003): 7–16. https://doi.org/10.1108/09654280310459112.

Personal Connected Health Alliance. 'Continua Design Gudelines'. Accessed 12 April 2024. https://www.pchalliance.org/continua-design-guidelines.

Qadri, Yazdan Ahmad, Ali Nauman, Yousaf Bin Zikria, Athanasios V. Vasilakos, and Sung Won Kim. 'The Future of Healthcare Internet of Things: A Survey of Emerging Technologies'. *IEEE Communications Surveys & Tutorials* 22, no. 2 (2020): 1121–67. https://doi.org/10.1109/COMST.2020.2973314.

Qadri, Yazdan Ahmad, Zulqarnain, Ali Nauman, Arslan Musaddiq, Eduard Garcia-Villegas, and Sung Won Kim. 'Preparing Wi-Fi 7 for Healthcare Internet-of-Things'. *Sensors* 22, no. 16 (18 August 2022): 6209. https://doi.org/10.3390/s22166209.

'The European Health Data Space (EHDS) Regulation'. Accessed 15 May 2024. https://www.consilium.europa.eu/media/70909/st07553-en24.pdf.

10. Annexes

10.1 Annex I: xShare industry label Vision Athens Workshop Questions

The xShare industry label Vision workshop in Athens brought consortium partners together to create a shared vision for the xShare industry label. To better understand how project partners representing the health industry, national trade associations (NTAs), data holders, and users perceive the xShare industry label in relation to the various target groups, the following questions were asked:

Breakout Session One

- Perception: How do you perceive what the xShare industry label is?
- Challenges: What are the challenges regarding interoperability and data exchange?
- How do you see the xShare industry label addressing current obstacles in health-data sharing?
- What are the main potential policy impacts of the xShare industry label connected to the EHDS?

Breakout Session Two

- Barriers: Which are the major challenges to adopting the xShare industry label within your organization?
- How do you foresee compliance with the xShare industry label affecting your processes and operations?

10.2 Annex II: xShare industry label Impact and Perception Survey

xShare industry label Impact and Perception Survey aims to gather insight to better understand the perceptions and impact of the xShare industry label among the xShare Project consortium members and industry stakeholders.

10.3 Annex III: Qualitative-Interview Questions Asked to Industry Stakeholders

Qualitative interviews were conducted to gain insight from various experts and assess industry perception, business viability, and the use of the **xShare industry label** to assist the industry in complying with the EHRxF. The following questions were asked during the qualitative interview to develop the **xShare industry label**'s vision, perception, business viability, and impact. Questions were mapped against specific objectives (SOs):

Specific objectives

- **SO1: Industry Perception of the xShare industry Label:** Evaluating industry and consortium members' perceptions of the xSHARE Industry Label's potential effects, exploring expectations, anticipated challenges, and the perceived benefits for organisational operations within the healthcare industry.
- **SO2: Business Viability and Impact of the xShare industry Label:** Assessing the impact of the xSHARE Industry Label on businesses, including the analysis of financial, technical, and human resource implications, and how these factors contribute to the feasibility and readiness for implementation.

- **SO3: Stakeholder Interpretation of EHRxF Compliance to the xShare industry label:** Clarify stakeholder interpretations of compliance with the xShare Industry Label under the European EHRxF (what this compliance means) within the European Health Data Space framework and outline the implications of compliance requisites.

Question (warm-up): What are the products you have? Are you active in the European Market? What is your biggest "main car" product? Are they supported at a specific standard level or through a label for interoperability?

Question 1 (SO1): Are you aware of the **European Health Data Space (EHDS)**, and how do you see initiatives like the EHDS influence your products?

Question 2 (SO1+SO2 consolidated): How would you envision an **industry label**, such as the proposed xShare, contributing to standardization and interoperability within the EU market? Could it influence your products? **What would be the benefits or potential added value (value proposition) of the xShare industry label in terms of procurement for products**? Would the overall impact be negative or positive for your products' competitiveness?

Question 3: Electronic Health Records (EHRs): What **standards** are currently **adopted** by your organization for **exchanging health records**, and how open **is your organization to adopting new ones**? What standards do you currently support for the exchange of EHRs?

Question 4 (SO2): Could you name any **existing industry labels or standards** within or outside healthcare that you think offer **a good example** of how the **xShare industry label** could be structured for maximum impact? What other industry label is a good example for xShare?

Question 5 (SO2): Would your company be **willing to pay** for an **assessment and validation** of a product against the xShare industry label? How should this assessment happen? Should it be an **independent body or a self-assessment**?

Question 6 (SO2): How do you envision the **governance of the xShare Industry Label**? Who should be responsible for maintaining it? Do you see a **role for industry associations** to manage the xShare Industry Label?

Question 7 (SO3): What should be the **role of national authorities** in terms of **supporting or regulating** the xShare Industry Label and/or other labels in support of data exchange standards?

Question 8: Which **digital health solutions** (like EHRs, apps, medical devices, AI algorithms) do you think would benefit most from **aligning with standardized health data exchange formats**?

Question 9: How would the introduction of **a new industry label** focused on health data interoperability might **impact** your organization (e.g**., operational, financial, and training needs**)?

Question 10 (SO2): Considering the role of the **European EHR Exchange Format (EEHRxF),** what **opportunities or challenges** do you foresee for your organization in a more interconnected European health data landscape? The EEHRxF? What is the **biggest opportunity or challenge** for your organization? How would the EEHRxF introduction might **impact** your organization, i.e., **operational, financial and training needs**?

Question 11: Do you think that **industry associations** in Europe can **disseminate and exploit** such a **label** on behalf of its members?

Question 12: Is there someone you think we should definitely interview as they would provide important insights into our efforts towards the xShare industry Label?

10.4 Annex IV: Joint Workshop with Industry and Health Authorities

The High-level Digital Health Interoperability Workshop refined the xShare industry label vision by focusing on the advancement of health data interoperability. The alignment of national health strategies with industry solutions through the EHDS and EHRxF has been explored.