xShare

Expanding the EEHRxF to share and effectively use health data within the EHDS

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Contents

List of abbreviations[1]

Abbreviation	Term
ATC	Anatomical Therapeutic Chemical
BI-RADS	Breast Imaging Reporting & Data System
BUC	Business Use Case
CDISC	Clinical Data Interchange Standards Consortium
CEN	European Committee for Standardisation
CERT	Computer Emergency Response Team
DICOM	Digital Imaging and Communications in Medicine
EDQM	European Directorate for the Quality of Medicines & HealthCare
EHDS	European Health Data Space
eHDSI	eHealth Digital Service Infrastructure
eHN	eHealth Network
EHR	Electronic Health Record
EHRxF	Electronic Health Record Exchange Format
EEHRxF	European Electronic Health Record Exchange Format
EMA SMS	European Medicines Agency, Substance Management Service
EMA SPOR	European Medicines Agency, master data for substances, products, organisations and referentials
EMA PMS	European Medicines Agency, Product Management Service
EMDN	European Medical Device Nomenclature
IDMP	identification of medicinal products.
EU	European Union
GDPR	General Data Protection Regulation
HL7	Health Level Seven
HL7 CDA	Health Level Seven Clinical Document Architecture
HL7 FHIR	Health Level Seven Fast Healthcare Interoperability Resources
Hub	EEHRxF Standards and Policy Hub, commonly abbreviated as "EEHRxF Standards Hub," "Standards Hub," or simply "Hub."

[1] Whenever possible, based on i~HD Glossary: https://glossary.ramit.be/public/index.cfm

Abbreviation	Term
ICD	International classification of diseases
ICF	International Classification of Functioning, Disability and Health
IDMP	Identification of Medicinal Products.
IEEE	Institute of Electrical and Electronics Engineers
IHE	Integrating the Healthcare Enterprise
IPS	International Patient Summary
ISCO	International Standard Classification of Occupations
ISO	International Organisation for Standardisation
KPI	Key Performance Indicator
LI-RADS	Liver Imaging Reporting & Data System
LOINC	Logical Observation Identifiers Names and Codes
MS	Member State
NPU	Nomenclature for Properties and Units
Orphacode	Terminology system for rare diseases, by Orphanet
OID	Object Identifier
RACER	Relevant, Accepted, Credible, Easy, Robust
SDO	Standards Development Organisation
SNOMED CT	Systematic Nomenclature of Medicine - Clinical Terms
SNOMED CT GPS	Systematic Nomenclature of Medicine - Clinical Terms – Global Patient Set
TBD	To Be Decided
TNM	Classification of Malignant Tumors (Tumor, Node, Metastasis)
TRL	Technology Readiness Levels
UCUM	Unified Code for Units of Measure
US	User Story
WP	Work Package
X-Bundles	Targeted aggregation of interoperability assets that support the connection of health systems in different ways, based on EEHRxF specifications
XpanDH	EU project Expanding digital health through a pan-European EHRxF-based ecosystem

Abbreviation	Term
Xt-EHR	Xt-EHR joint action is a project is dedicated to establishing guidelines for the development of a comprehensive, interoperable, and secure EHR systems

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Executive summary

This deliverable describes two monitoring frameworks related to the European Electronic Health Record Exchange Format (EEHRxF). The first framework measures the adoption of the EEHRxF in Member States (MS). The second framework measures the performance of the EEHRxF Standards and Policy Hub (the Hub).

The EEHRxF Adoption Monitoring Framework contains 27 indicators, split into three monitoring areas. Monitoring Area A covers the uptake of Relevant guidelines, standards, and toolsets for Electronic Health Record (EHR) stakeholders. Monitoring Area B focuses on better quality and integrated health datasets within the EHDS for EHR stakeholders. Monitoring Area C tracks the current state and uptake of EHRs, also including indicators on progress in the adoption sites (WP3). *Table 1. Overview of EEHRxF Adoption Indicators* displays all suggested indicators at one glance.

One challenge when developing the indicators for this framework was that Member States do not yet use the EEHRxF itself. Thus, we suggest proxy indicators that we can monitor at this stage and that capture (preparation for) the EEHRxF adoption as accurately as possible.

The main data collection tool for the EEHRxF uptake monitoring framework will be a survey of experts from Member States, Competence Centers, Standards Developing Organisations (SDOs), and industry assessing EEHRxF adoption. Some indicators will be assessed with data from external sources, such as the 2024 Digital Decade eHealth Indicator Study (2024)[2]. The survey will be complemented by interviews with the same target group.

The second framework (*see* ***Fejl! Henvisningskilde ikke fundet.***) measures success in the establishment, operation and intended functions of the EEHRxF Standards and Policy Hub. The most important indicators intend to show the extent of organisational readiness and achievement, stakeholder involvement, and their success in co-creating the assets of the Hub: The Business Use Cases, user stories and specifications in X-Bundles. Beyond these indicators, how far helpdesk activity and costs of bundle assembly can be measured still needs to be established.

Data for this second monitoring framework will be collected in a survey to Hub representatives.

Lastly, we include some suggestions of indicators that we consider including in the updated version of the monitoring framework, due in M24 (i.e. November 2026).

[2] https://op.europa.eu/en/publication-detail/-/publication/c04f6162-3833-11ef-b441-01aa75ed71a1/language-en

***Table 1**. Overview of EEHRxF Adoption Indicators*

Code	Name	Main Measurement Unit	Survey	Prefilled
Monitoring Area A: Relevant guidelines, standards, and toolsets for EHR stakeholders				
i-A-01	Comprehensive standards for patient summaries	Multiple selection list	x	
i-A-02	Comprehensive standards for ePrescription	Multiple selection list	x	
i-A-03	Comprehensive standards for eDispensation	Multiple selection list	x	
i-A-04	Comprehensive standards for medical imaging studies and related imaging reports	Multiple selection list	x	
i-A-05	Comprehensive standards for medical test results, including laboratory and other diagnostic results and related reports	Multiple selection list	x	
i-A-06	Comprehensive standards for discharge reports	Multiple selection list	x	
i-A-07	Member State collaboration with Standardisation Bodies (SDOs)	Qualitative description		x
i-A-08	Member State participation in MyHealth@EU	Binary "Yes" or "No"		x
Monitoring Area B: Better quality and integrated health datasets within the EHDS for EHR stakeholders				
i-B-01	Initiatives to monitor data quality	Binary "Yes" or "No"	x	
i-B-02	Awareness raising efforts to enhance EHR data quality with EHR stakeholders	Binary "Yes" or "No"	x	
i-B-03	Existence of EHR data quality guidelines at national or regional level	Binary "Yes" or "No"	x	
i-B-04	Preparation for key EHDS structures	Multiple selection list	x	
i-B-05	Interoperability support services provided by national Digital Health Authority (or similar)	Multiple selection list	x	
i-B-06	Indicator i-B-06) Preparation for the EEHRxF in national Digital Health Authority (or similar)	Multiple selection list	x	
i-B-07	Protection against cybersecurity risks	Multiple selection list	x	

Code	Name	Main Measurement Unit	Survey	Prefilled
i-B-08	Identification and authentication mechanisms	Binary "Yes" or "No"	x	
i-B-09	Citizen control of their health data sharing	Multiple selection list	x	
i-B-10	Opt-out of EHR data use	Multiple selection list	x	
i-B-11	Anonymisation and pseudonymisation by Health Data Access Bodies (or similar)	Multiple section list	x	
Monitoring Area C: Current State and Uptake of EHRs				
i-C-01	Citizen access to patient summary data	Multiple selection list (percentage)	x	
i-C-02	Citizen access to ePrescription data	Binary "Yes" or "No"		x
i-C-03	Citizen access to eDispensation data	Binary "Yes" or "No"		x
i-C-04	Citizen access to medical imaging reports and images	Binary "Yes" or "No"		x
i-C-05	Citizen access to medical test results, including laboratory and other diagnostic results and related reports	Binary "Yes" or "No"		x
i-C-06	Citizen access to discharge reports	Binary "Yes" or "No"		x
i-C-07	Implementation of yellow button basic functionalities at xShare adoption sites	Binary "Yes" or "No"	x	
i-C-08	Maturity levels of priority data categories at xShare adoption sites	TRL Score 1-9	x	

***Table 2**. Overview of EEHRxF Standards and Policy Hub Performance Indicators*

Code	Name	Main Measurement Unit	Survey	Prefilled
Hub Operation success factors				
ii-A-01	Organisational readiness	Score 1-5	Of a Hub rapporteur	N/A
ii-A-02	Organisational achievement of set goals	Score 1-5	Of a Hub rapporteur	N/A
ii-A-03	Successful stakeholder involvement in business-driven implementation (size and scope of the community)	Score 1-3	Of a Hub rapporteur	N/A
ii-A-04	Hub outcome – creation of specifications for priority categories, based on work in XpanDH (X-Bundles)	Score 1-3	Of a Hub rapporteur	N/A
ii-A-05	Member State involvement in the Hub	Qualitative	Of a Hub rapporteur	N/A
ii-A-06	Industry involvement in the Hub	Numeric	Of a Hub rapporteur	N/A
Business Use Case Registration				
ii-B-01	BUC registrations	Numeric	Of a Hub rapporteur	N/A

Code	Name	Main Measurement Unit	Survey	Prefilled
		Sub-indicators score 1-3		
Helpdesk Management				
ii-C-01	Helpdesk operationalisation	Score 1-3	Of a Hub rapporteur	N/A
ii-C-02	Helpdesk activity	Numeric	Of a Hub rapporteur	N/A
ii-C-03	Helpdesk user satisfaction	Percentage	Of a Hub rapporteur	N/A
X-Bundles				
ii-D-01	X-Bundle costs	Monetary (average per adoption site)	Of a Hub rapporteur	N/A

1. Introduction

This deliverable outlines a first framework to **monitor the European Electronic Health Record Exchange Format (EEHRxF)[3] uptake within the European Health Data Space (EHDS),** presented by xShare *WP6 - EEHRxF adoption monitoring in the EHDS*. The xShare button both relies on and enables this uptake by allowing citizens to share their EHR data with a click-of-a-button.

On European Union (EU) policy level, monitoring the EEHRxF uptake helps communicate how the European Commission is progressing on two important goals of its Health Union and Digital Decade: implementing the European Health Data Space[4] and giving 100% of citizens access to EHR records online[5].

With **two distinct monitoring frameworks**, this deliverable respectively observes the adoption of the **EEHRxF on a national level**, as well as the **advancement of the Standards and Policy Hub**. Within xShare, this monitoring within WP6 provides important primary research to support and accompany the practical implementation of the EEHRxF via the Standards Hub (WP2), in the adoption sites (WP3) and across the three health verticals (WP 3-5).

This benefits both external EHR stakeholders and the project itself. For external stakeholders, it **reinforces awareness of the EEHRxF** and the feasibility for its implementation, reducing uncertainty of those who are still reluctant to prepare for it. Internally, it contributes to **making xShare's results more sustainable** – namely by detecting unexpected findings regarding the EEHRxF uptake early and identifying weak progress in the implementation of the Hub. In doing so, this deliverable links to project objective #4[6]. Figure 1. xShare Intervention Logic contextualises the WP6 monitoring work within the project's intervention logic.

[3] From this point forward, it will be denoted as "EEHRxF" or "the format."

[4] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en

[5] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/europes-digital-decade-digital-targets-2030_en

[6] Monitor the adoption of the EEHRxF in the member states and European regions, assess the Hub's impact, and identify gaps and needs for additional priority data categories (WP6).

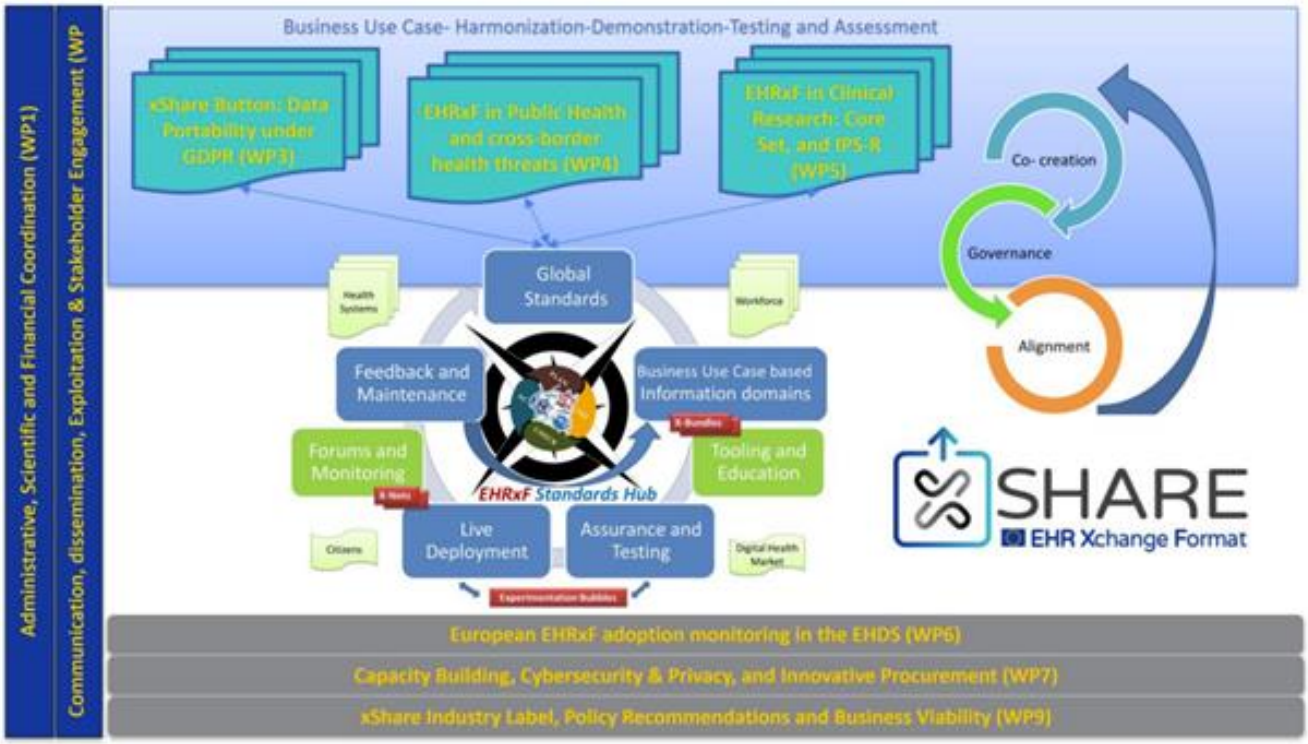

Figure 1. *xShare Intervention Logic*

Thus, this deliverable **tracks progress towards the goal of an adequately adopted EEHRxF across Member States (MS), as well as a solid and sustainable Hub.** It is the first of two monitoring frameworks and will be updated in M24 (i.e. November 2026)[7].

1.1 Structure of the document

This deliverable firstly outlines the methodology for both monitoring frameworks (chapter 2). Chapter 3 goes on to outline the main monitoring framework delivered in T6.1 of xShare – on national EEHRxF Uptake. This framework is subdivided into three monitoring areas, referring to guidelines and standards (A), Better quality and integrated data sets (B), and Citizen-centric data access (C). Chapter 4 presents the second monitoring framework regarding the EEHRxF Standards and Policy Hub. Chapter 5 will outline the data collection process and possible indicators for the updated monitoring framework, due in M24 (i.e. November 2026). Chapter 6 presents conclusions.

1.2 Intended audience

This deliverable addresses diverse EHR stakeholders, primarily policymakers and researchers. It is also directed at xShare consortium members to inform other work packages on the baseline of EEHRxF use.

[7] Monitoring is not intended to extend to activities in other work packages beyond the Standards and Policy Hub, such as co-creation or training activity in adoption sites or beyond (capacity building, WP7).

2. Methodology

This chapter outlines the methodology we used to build both monitoring frameworks. Whenever necessary, we included specific methodological notes in the respective indicator chapters.

2.1 Units of analysis and reporting subjects

Units of analysis for the EEHRxF adoption framework are Member States and Adoption Sites (indicators i-C-07 to i-C-08). Likewise, reporting subjects are Member States and Adoption Site representatives.

For the EEHRxF Standard and Policy Hub, the unit of analysis is the Hub itself. Reporting subjects are Hub/xShare WP2 representatives.

2.2 Instrument design

We used the **European Commission's Better Regulation Toolbox 2023**[8] as guidance to develop this framework. Below, we outline the five-step process, as per Tool #43 "Monitoring Arrangements and Indicators":

1. **Identify what to monitor**

The frameworks monitor the EEHRXF uptake and the Standards and Policy Hub performance. Based on the original call text, we already identified these units of analysis in the technical proposal.

2. **Indicators**

When developing the monitoring indicators for this deliverable, we followed the following criteria:

- Choice of indicators that correspond to the current status quo of EEHRxF and Hub development.
- Precise definition of monitoring objective – especially for proxy indicators.
- Limitation of burden on the data collection process.

Moreover, the indicators in our project are based on RACER, which means:

(1) **R**elevant, i.e. closely linked to the objectives to be reached;
(2) **A**ccepted by stakeholders. The role and responsibilities of the indicator need to be well-defined;
(3) **C**redible for non-experts, unambiguous and easy to interpret;
(4) **E**asy to monitor (e.g. at low cost and with acceptable administrative burden);
(5) **R**obust against manipulation.

3. **Check any existing data and data arrangements**

Since the EEHRxF and the Hub are relatively **novel concepts, limited data** is available on both units of analysis.

[8] https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox/better-regulation-toolbox_en

For the EEHRxF Monitoring Framework, sources with recent data are available for some indicators. This refers to Member State engagement in Standardisation Bodies (i-A-07) and MyHealth@EU (i-A-08), as well as to citizen access to EHR data (i-C-01 - 06). In these cases, we opted to use this updated data instead of survey questions for data collection, respecting the limitation of the data collection burden.

4. Identify data sources

Most of the data outlined in both monitoring frameworks will be **collected through two surveys** in *T6.2 - Data collection on EEHRxF adoption and Hub performance*. The first will be directed at experts from Member States, Competence Centers, Standards Developing Organisations (SDOs), and industry, assessing EEHRxF adoption. Respondents will be asked to report on baseline data for 2024. The second one will refer to the Hub monitoring, directed at Hub representatives from WP2.

The **existing data sources** for the few available and timely data identified above are clearly quoted in the respective chapters: different SDOs' websites[9], MyHealth@EU website and MyHealth@EU Monitoring Framework[10] and the 2024 Digital Decade eHealth Indicator Study[11]. For some indicators in the EEHRxF uptake monitoring framework, the Study on Interoperability of Electronic Health Records in the EU (2020)[12] provides data from 2020. We consider them too outdated to be used as primary data sources but will consider them as baseline data.

5. Constructing a monitoring and evaluation framework

The next chapters outline the monitoring framework based on the considerations above. The Better Regulation Toolbox recommends setting such a framework out as early as possible in an initiative's lifecycle. Launched in M8 (July 2024), this first framework complies early enough to evaluate the project's intervention logic.

Each indicator is described through the following elements, based on the Better Regulation Toolbox:
1) General/Specific/Operational objective: setting out what we intend to measure with the indicator;

2) Definition: how the indicator is defined. Including also a multiple selection list, if applicable;

3) Type of Indicator: quantitative or qualitative;

4) Unit of Measurement: binary, multiple selection, free text, percentage or monetary;

5) Baseline: existing data we can compare the future data with. If no baseline data exists, we inserted "2024" (for the EEHRxF Uptake Monitoring Framework) and "2025" (for the Hub Monitoring Framework) as base year for our data collection in T6.2;

[9] See indicator i-A-07
[10] See indicator i-A-08
[11] https://digital-strategy.ec.europa.eu/en/library/digital-decade-2024-ehealth-indicator-study
[12] https://digital-strategy.ec.europa.eu/en/library/interoperability-electronic-health-records-eu

6) Target: desired indicator value to achieve. For the EEHRxF Uptake Monitoring framework, whenever baseline data existed, we chose a slightly higher value than the baseline as target. For the other indicators, we estimated a desirable and realistic target.

7) Discussion: explains the rationale of choosing a specific indicator, as well as detailing existing baseline data, if applicable.

3. Monitoring framework on national EEHRxF uptake

The first monitoring framework is designed to **measure the progress of EEHRxF uptake within the EHDS across Member States**. It is structured into **three monitoring areas**, based on the priorities in the original call text[13]:

A. Relevant Standards, Guidelines, and Toolsets for EHR Stakeholders
B. Better Quality and Integrated Health Datasets within the EHDS for EHR Stakeholders
C. Expanded Access to and Sharing of Health Data for Citizens

Defining exact measurements for the EEHRxF actual uptake is still challenging, as of this deliverable's due date (End July 2024). The EHDS Regulation has already been approved and contains more information on the EEHRxF, especially in Article 6. Yet, Article 6 reveals that the European Commission will lay down the format's technical specifications via implementing acts[14]. Only then will the format be defined in an actionable way.

Thus, **we consider it too early for indicators that directly assess the use of the EEHRxF** in Member States. This led us to **choose proxy indicators** that are as closely related as possible with (preparation for) EEHRxF use. *Table 3. Content sources for EEHRxF Adoption Indicators* lists the main sources we used to develop these proxy indicators, with the goal of getting as close as possible to a comprehensive and structured evaluation of (preparation for) EEHRxF uptake. We consulted other sources, e.g. to extract definitions that are not contained in the i~HD Glossary.

***Table 3**. Content sources for EEHRxF Adoption Indicators*

Source	Rationale
The Study on Interoperability of Electronic Health Records in the EU (2020)[15]	Providing a reusable survey tool and 2020 baseline data for EHR uptake in Member States
Study for Digital Decade e-Health Indicators Development (2023)[16]	Providing initial methodology and baseline data collection (2022) of EU citizens' access to their EHRs
2024 Digital Decade eHealth Indicator Study (2024)[17]	Providing first follow up data collection (2023) to the first e-Health indicator study
Regulation on a European Health Data Space (2024)[18]	Providing the legal framework on the use of the EEHRxF

[13] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2023-ind-06-02?isExactMatch=true&status=31094501,31094502,31094503&callIdentifier=HORIZON-HLTH-2023-IND-06&order=DESC&pageNumber=1&pageSize=50&sortBy=startDate
[14] The deadline for the completion of these implementing acts is the end of 2026.
[15] https://digital-strategy.ec.europa.eu/en/library/interoperability-electronic-health-records-eu
[16] https://op.europa.eu/en/publication-detail/-/publication/78938111-461e-11ee-92e3-01aa75ed71a1/language-en
[17] https://op.europa.eu/en/publication-detail/-/publication/c04f6162-3833-11ef-b441-01aa75ed71a1/language-en
[18] We used the 2024 compromise version.

Source	Rationale
XpanDH D3.1 X-Bundle Readiness Model[19]	Providing an initial draft to assess organisation's maturity to use the format
eHealth Network Guidelines[20]	Guidelines for the technical implementation of cross-border health services in Member States
xShare D2.2 EEHRxF in a Nutshell[21]	Anticipated definition of the format (to be refined with implementing acts), overview of progress in priority categories of personal electronic health data

The indicators in this framework will consider the **priority categories of personal electronic health data for primary use**, as in Article 5 of the European Health Data Space Regulation – referred to as "priority categories":

Priority category a) Patient Summary
Priority category b) ePrescription
Priority category c) eDispensation
Priority category d) Medical Imaging Studies and Related Imaging Reports
Priority category e) Medical Test Results, Including Laboratory and Other Diagnostic Results and Related Reports
Priority category f) Discharge Reports

The framework will provide the basis for future data collection, which will involve conducting large-scale surveys, subsequent interviews, and using official data sources. Further information on data collection in T6.2 can be found in chapter 5.

[19] Not publicly available yet.
[20] https://health.ec.europa.eu/ehealth-digital-health-and-care/eu-cooperation/ehealth-network_en#ehealth-network-guidelines
[21] Not publicly available yet.

3.1 Monitoring Area A: Relevant guidelines, standards, and toolsets for EHR stakeholders

Since the EEHRxF Recommendation in 2019, SDOs, the eHealth Network (eHN), and other stakeholders have made substantial progress in specifying the technical details of the format. D2.2 *EHRxF in a Nutshell*[22] provides a comprehensive description of this process. **Guidelines and standards play a crucial role** in implementing the format. Consequently, Monitoring Area A evaluates the adoption of the standards outlined in the eHealth Network guidelines for each priority category of health data.

3.1.1 Standards

The indicators in this subsection are designed to monitor the adoption and implementation of standards for each of the six priority categories. For now, we define "adoption" as the use of the mentioned standards as the basis for most health data exchanges in the health system in the respective Member State, as estimated by the respondent. We are aware that this definition leaves room for individual interpretations. However, we consider a more granular definition (leading to more monitoring areas) to be out of scope for this deliverable. As we develop the survey in T6.2, we will further refine and clarify the concept of adoption for data collection. This is especially important to note, as our data collection occur several months after the finalisation of the first version of the monitoring framework in this deliverable, which may result in significant legislative developments and consequently impact the definition of adoption in this context. As a result, the monitoring framework is initially intended to serve as a structure that can be adjusted to the data collection methods while also accounting for developments of this nature.

These indicators are crucial for assessing how the Member States are aligning with the standards that are central to the EEHRxF implementation. This assessment should be performed both in general terms (i.e., preparation for EEHRxF Standards across domains) and specifically for each of the six priority categories of personal electronic health data (referred to as "priority categories" in short).

Each indicator captures three components for each priority data category: **Clinical Information Structures, Content Representation Standards**, **Supporting Standards and Preferred Code System**. These components were chosen based on the Commission Recommendation on a European Electronic Health Record Exchange Format[23] and *D2.2 EHRxF in a nutshell*[24]. While we keep this division for consistency, we might not explicitly name them in the questionnaire for the subsequent data collection. *Table 4. Components of Standards Adoption* provides more detail on how we define and intend to use these components.

***Table 4**. Components of Standards Adoption*

Component	Definition	Comment
Clinical Information Structures	Frameworks and templates used by EHR systems to capture, store, and manage clinical data. They determine how clinical information is documented, categorised, and accessed.	We will use the eHN guidelines for each priority category as a basis to assess Member State progress in clinical information

[22] Deliverable will be publicly available after approval by European Commission.
[23] EC (2019): Commission Recommendation on a European Electronic Health Record Exchange Format. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019H0243
[24] Deliverable will be publicly available after approval by European Commission.

Component	Definition	Comment
	The eHN guidelines offer standardised recommendations on clinical information structures to be used across the European Union.	structures towards the EEHRxF.
Content Representation Standards	Establish technical specifications for formatting, structuring, and encoding clinical information. They ensure consistent interpretation and use across healthcare systems and support interoperability and efficient data exchange.	The content representation standards recommended by the eHN guidelines often overlap with the supporting standards. Thus, in the indicators below, we mention concrete standards from this category as part of the supporting standards component.
Supporting Standards and Preferred Code Systems	Enhance content representation standards by offering additional frameworks, terminologies, and coding systems. Preferred Code Systems are the standards the eHN Guidelines recommend to describe specific fields in data sets for each priority category.	In the interviews that will accompany the survey during the data collection phase, we will query more intensely which preferred code systems the Member States use per data category.

Based on these three components, we query the adoption of specific standards for each priority category. We chose the individual standards based on the eHN Guidelines and after consultation with CEN (within the consortium). We assume that the more of the mentioned standards Member States adopt, the more prepared they are to implement the EEHRxF. For Member States that have adopted fewer standards, we assume a bigger gap in EEHRxF implementation.

3.1.1.1 Indicator i-A-01) Comprehensive standards for patient summaries

- **General/Specific/Operational objective:** Identify the adoption of standards and availability of clinical information for patient summaries.
- **Definition:** This indicator evaluates the use of content representation standards, the availability of patient summary information, and Supporting Standards and Preferred Code Systems.
  Specified Standards and their relevance:
  - Clinical Information Structures:
    - eHealth Network guidelines on Patient Summary[25] (see standard list under "supporting standards and preferred code systems").

[25] https://health.ec.europa.eu/document/download/e020f311-c35b-45ae-ba3d-03212b57fa65_en?filename=ehn_guidelines_patientsummary_en.pdf

        - EN ISO 27269:2021 'Health informatics – International patient summary' – revision in development
        - Current structures used by EHR systems. To be specified by the survey respondent, if possible.
    - Content Representation Standards:
        - HL7 CDA[26]: For ensuring structured clinical documents are standardised for interoperability.
        - HL7 FHIR[27]: For facilitating more efficient and flexible data exchange across healthcare systems.
    - Supporting Standards and Preferred Code Systems:
        - ATC[28]: For therapeutic chemicals.
        - EMA PMS[29]: For identification of pharmaceutical and medicinal products.
        - EMDN[30]: For medical devices.
        - EN ISO IDMP Suite of standards[31] (11615, 11616, 11238, 11239, 11240) for unique identification and exchange of medicinal product information.
        - ICD-10 / ICD-11[32]: For standardised diagnosis coding.
        - ICF[33]: For functional assessment.
        - IHE Profiles[34]: For ensuring interoperability and effective information exchange.
        - LOINC[35]: For observational details.
        - NPU[36]: For observational details.
        - Orphacode[37]: For rare diseases.
        - SNOMED CT GPS[38]: SNOMED CT specifically for Global Patient Set.
        - UCUM[39]: For units of measure.
    - Other(s).
- **Type of Indicator:** Qualitative.
- **Unit of Measurement:** List of standards: Multiple selection list. "Other": Free text.
- **Baseline:** 2024.

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[26] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=496
[27] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=491
[28] https://www.who.int/tools/atc-ddd-toolkit/atc-classification
[29] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/substance-product-data-management-services
[30] https://health.ec.europa.eu/latest-updates/european-medical-device-nomenclature-emdn-questions-and-answers-2021-06-15_en
[31] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview
[32] https://www.who.int/standards/classifications/classification-of-diseases
[33] https://www.who.int/standards/classifications/international-classification-of-functioning-disability-and-health
[34] https://www.ihe.net/resources/profiles/
[35] https://loinc.org/
[36] https://npu-terminology.org/
[37] https://www.orpha.net/en/disease
[38] https://www.snomed.org/gps
[39] https://ucum.org/

- **Target:** Adoption of all relevant standards by at least 40% of Member States.

3.1.1.2 Indicator i-A-02) Comprehensive standards for ePrescription

- **General/Specific/Operational objective:** Identify the adoption of standards and availability of clinical information for ePrescriptions.
- **Definition:** This indicator evaluates the use of content representation standards, the availability of ePrescription information, and Supporting Standards and Preferred Code Systems.
  Specified Standards and their relevance:
  - Clinical Information Structures:
    - eHealth Network guidelines on ePrescription and eDispensation[40] (see standard list under "supporting standards and preferred code systems").
    - EN ISO 17523:2016[41] 'Health informatics – Requirements for electronic prescriptions' – revision in development.
    - Current structures used by EHR systems. To be specified by the survey respondent in a free text field, if possible.
  - Content Representation Standards:
    - HL7 CDA[42]: For ensuring structured clinical documents are standardised for interoperability.
    - HL7 FHIR[43]: For facilitating more efficient and flexible data exchange across healthcare systems.
  - Supporting Standards and Preferred Code Systems:
    - ATC[44]: For therapeutic chemicals.
    - EDQM Standard Terms[45]: For standardising terms for ePrescriptions.
    - EMA PMS[46]: For identification of pharmaceutical and medicinal products.
    - EMA SMS[47]: For substance data.
    - EMA SPOR[48]: For providing substance, product, organisation, and referential data management.
    - EN ISO IDMP Suite of standards[49] (11615, 11616, 11238, 11239, 11240) for unique identification and exchange of medicinal product information.
    - SNOMED CT GPS[50]: SNOMED CT specifically for Global Patient Set.

[40] https://health.ec.europa.eu/document/download/b744f30b-a05e-4b9c-9630-ad96ebd0b2f0_en?filename=ehn_guidelines_eprescriptions_en.pdf
[41] https://www.iso.org/standard/59952.html
[42] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=496
[43] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=491
[44] https://www.who.int/tools/atc-ddd-toolkit/atc-classification
[45] https://www.edqm.eu/en/standard-terms-database
[46] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/substance-product-data-management-services
[47] https://spor.ema.europa.eu/smswi/#/
[48] https://spor.ema.europa.eu/sporwi/
[49] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview
[50] https://www.snomed.org/gps

        - UCUM[51]: For units of measure.
    - Other(s).
- **Type of Indicator:** Qualitative.
- **Unit of Measurement:** List of standards: Multiple selection list. "Other": Free text.
- **Baseline:** 2024.
- **Target:** Adoption of all relevant standards by at least 40% of Member States.

3.1.1.3 Indicator i-A-03) Comprehensive standards for eDispensation

- **General/Specific/Operational objective:** Identify the adoption of standards and availability of clinical information for eDispensations.
- **Definition:** This indicator evaluates the use of content representation standards, the availability of eDispensation information, and Supporting Standards and Preferred Code Systems.
  Specified Standards and their relevance:
    - Clinical Information Structures:
        - eHealth Network guidelines on ePrescription and eDispensation[52] (see standard list under "supporting standards and preferred code systems").
        - CEN ISO/TS 19293:2018 'Requirements for a record of a dispense of a medicinal product' – revision in development.
        - Current structures used by EHR systems. *To be specified by the survey respondent in a free text field, if possible*.
    - Content Representation Standards:
        - HL7 CDA[53]: For ensuring structured clinical documents are standardised for interoperability.
        - HL7 FHIR[54]: For facilitating more efficient and flexible data exchange across healthcare systems.
    - Supporting Standards and Preferred Code Systems:
        - ATC[55]: For therapeutic chemicals.
        - EDQM Standard Terms[56]: For standardising terms for ePrescriptions.
        - EMA PMS[57]: For identification of pharmaceutical and medicinal products.
        - EMA SMS[58]: For substance data.
        - EMA SPOR[59]: For providing substance, product, organisation, and referential data management.

[51] https://ucum.org/
[52] https://health.ec.europa.eu/document/download/b744f30b-a05e-4b9c-9630-ad96ebd0b2f0_en?filename=ehn_guidelines_eprescriptions_en.pdf
[53] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=496
[54] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=491
[55] https://www.who.int/tools/atc-ddd-toolkit/atc-classification
[56] https://www.edqm.eu/en/standard-terms-database
[57] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/substance-product-data-management-services
[58] https://spor.ema.europa.eu/smswi/#/
[59] https://spor.ema.europa.eu/sporwi/

        - EN ISO IDMP Suite of standards[60] (11615, 11616, 11238, 11239, 11240) for unique identification and exchange of medicinal product information.
        - SNOMED CT GPS[61]: For providing comprehensive clinical terminology for consistent coding.
        - UCUM[62]: For units of measure.
    - Other(s).
- **Type of Indicator:** Qualitative.
- **Unit of Measurement:** List of standards: Multiple selection list. "Other": Free text.
- **Baseline:** 2024.
- **Target:** Adoption of all relevant standards by at least 40% of Member States.

3.1.1.4 Indicator i-A-04) Comprehensive standards for medical imaging studies and related imaging reports

- **General/Specific/Operational objective:** Identify the adoption of standards and availability of clinical information for medical imaging studies and related reports.
- **Definition:** This indicator evaluates the use of content representation standards, the availability of medical imaging information, and Supporting Standards and Preferred Code Systems.
  Specified Standards and their relevance:
    - Clinical Information Structures:
        - eHealth Network guidelines on medical imaging studies and reports[63] (see standard list under "supporting standards and preferred code systems").
        - EN ISO 21860:2020 'Health informatics – Reference standards portfolio (RSP) – Clinical imaging'.
        - Current structures used by EHR systems. To be specified by the survey respondent, if possible.
    - Content Representation Standards:
        - EN ISO 12052:2017[64] 'Health informatics – Digital imaging and communication in medicine (DICOM) including workflow and data management' – revision in development.
        - DICOM[65]: For standardising the handling, storing, and transmitting of medical imaging data.
        - HL7 CDA[66]: For ensuring structured clinical documents are standardised for interoperability.

[60] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview
[61] https://www.snomed.org/gps
[62] https://ucum.org/
[63] https://health.ec.europa.eu/document/download/0079ad26-8f8f-435b-9472-3cd8625f4220_en?filename=ehn_mi_guidelines_en.pdf
[64] https://www.iso.org/standard/72941.html
[65] https://www.dicomstandard.org/current
[66] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=496

        - HL7 FHIR[67]: For facilitating more efficient and flexible data exchange across healthcare systems.
    - Supporting Standards and Preferred Code Systems:
        - ATC[68]: For therapeutic chemicals.
        - BI-RADS[69]: For breast imaging.
        - EDQM Standard Terms[70]: For standardising terms for ePrescriptions.
        - EMDN[71]: For medical devices.
        - EN ISO IDMP Suite of standards[72] (11615, 11616, 11238, 11239, 11240) for unique identification and exchange of medicinal product information.
        - ICD-0-3[73]: For oncology data.
        - IHE Profiles[74]: For ensuring interoperability and effective information exchange in medical imaging.
        - LI-RADS[75]: For liver imaging.
        - LOINC[76]: For study procedures performed.
        - OID[77]: For study instance identification.
        - Orphacode[78]: For rare diseases.
        - SNOMED CT[79]: For providing comprehensive clinical terminology for consistent coding.
        - TNM[80]: For tumour classification.
        - UCUM[81]: For units of measure.
    - Other(s).
- **Type of Indicator:** Qualitative.
- **Unit of Measurement:** List of standards: Multiple selection list. "Other": Free text.
- **Baseline:** 2024.
- **Target:** Adoption of all relevant standards by at least 40% of Member States.

[67] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=491
[68] https://www.who.int/tools/atc-ddd-toolkit/atc-classification
[69] https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Bi-Rads
[70] https://www.edqm.eu/en/standard-terms-database
[71] https://health.ec.europa.eu/latest-updates/european-medical-device-nomenclature-emdn-questions-and-answers-2021-06-15_en
[72] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview
[73] https://www.who.int/standards/classifications/other-classifications/international-classification-of-diseases-for-oncology
[74] https://www.ihe.net/resources/profiles/
[75] https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/LI-RADS
[76] https://loinc.org/
[77] http://oid-info.com/
[78] https://www.orpha.net/en/disease
[79] https://www.snomed.org/
[80] https://www.uicc.org/what-we-do/sharing-knowledge/tnm
[81] https://ucum.org/

3.1.1.5 Indicator i-A-05) Comprehensive standards for medical test results, including laboratory and other diagnostic results and related reports

- **General/Specific/Operational objective:** Identify the adoption of standards and availability of clinical information for medical test results, including laboratory and other diagnostic results and related reports.
- **Definition:** This indicator evaluates the use of content representation standards, the availability of medical test result information, and Supporting Standards and Preferred Code Systems.
  Specified Standards and their relevance:
  - Clinical Information Structures:
    - eHealth Network guidelines on laboratory results[82] (see standard list under "supporting standards and preferred code systems").
    - Current structures used by EHR systems. To be specified by the survey respondent, if possible.
  - Content Representation Standards:
    - HL7 CDA[83]: For ensuring structured clinical documents are standardised for interoperability.
    - HL7 FHIR[84]: For facilitating more efficient and flexible data exchange across healthcare systems.
    - LOINC[85]: For standardising the coding of laboratory and diagnostic test results.
  - Supporting Standards and Preferred Code Systems:
    - EMDN[86]: For medical devices.
    - ICD-10 / ICD-11[87]: For essential standardised diagnosis coding.
    - IHE Profiles[88]: For ensuring interoperability and effective information exchange in medical testing.
    - NPU[89]: For observational details.
    - Orphacode[90]: For rare diseases.
    - SNOMED CT[91]: For providing comprehensive clinical terminology for consistent coding.
    - UCUM[92]: For units of measure.
  - Other(s).
- **Type of Indicator:** Qualitative.
- **Unit of Measurement:** List of standards: Multiple selection list. "Other": Free text.
- **Baseline:** 2024.

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[82] https://health.ec.europa.eu/publications/ehn-laboratory-result-guidelines_en
[83] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=496
[84] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=491
[85] https://loinc.org/
[86] https://health.ec.europa.eu/latest-updates/european-medical-device-nomenclature-emdn-questions-and-answers-2021-06-15_en
[87] https://www.who.int/standards/classifications/classification-of-diseases
[88] https://www.ihe.net/resources/profiles/
[89] https://npu-terminology.org/
[90] https://www.orpha.net/en/disease
[91] https://www.snomed.org/
[92] https://ucum.org/

- **Target:** Adoption of all relevant standards by at least 40% of Member States.

3.1.1.6 Indicator i-A-06) Comprehensive standards for discharge reports

- **General/Specific/Operational objective:** Identify the adoption of standards and availability of clinical information for discharge reports.
- **Definition:** This indicator evaluates the use of content representation standards, the availability of discharge report information, and Supporting Standards and Preferred Code Systems.
  Specified Standards and their relevance:
  - Clinical Information Structures:
    - eHN Guidelines on Hospital discharge reports[93] (see standard list under "supporting standards and preferred code systems").
    - Current structures used by EHR systems. *To be specified by the survey respondent, if possible*.
  - Content Representation Standards:
    - HL7 CDA[94]: For ensuring structured clinical documents are standardised for interoperability.
    - HL7 FHIR[95]: For facilitating more efficient and flexible data exchange across healthcare systems.
  - Supporting Standards and Preferred Code Systems:
    - ATC[96]: For therapeutic chemicals.
    - EMA SMS[97]: For substance data.
    - EMA SPOR[98]: For providing substance, product, organisation, and referential data management.
    - EMDN[99]: For medical devices.
    - EN ISO IDMP Suite of standards[100] (11615, 11616, 11238, 11239, 11240) for unique identification and exchange of medicinal product information.
    - ICD-0-3[101]: For oncology data.
    - ICD-10 / ICD-11[102]: For essential standardised diagnosis coding.
    - IHE Profiles[103]: For ensuring interoperability and effective information exchange in discharge reports.

[93] https://health.ec.europa.eu/document/download/cbb2efd4-82b4-4127-ab58-0aaedf662df6_en?filename=ehn_hdr_guidelines_en.pdf
[94] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=496
[95] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=491
[96] https://www.who.int/tools/atc-ddd-toolkit/atc-classification
[97] https://spor.ema.europa.eu/smswi/#/
[98] https://spor.ema.europa.eu/sporwi/
[99] https://health.ec.europa.eu/latest-updates/european-medical-device-nomenclature-emdn-questions-and-answers-2021-06-15_en
[100] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview
[101] https://www.who.int/standards/classifications/other-classifications/international-classification-of-diseases-for-oncology
[102] https://www.who.int/standards/classifications/classification-of-diseases
[103] https://www.ihe.net/resources/profiles/

        - ISCO[104]: For healthcare professional role.
        - LOINC[105]: For standardising the coding of laboratory and diagnostic test results.
        - NPU[106]: For observational details.
        - Orphacode[107]: For rare diseases.
        - SNOMED CT[108]: For providing comprehensive clinical terminology for consistent coding.
        - TNM[109]: For tumour classification.
        - UCUM[110]: For units of measure.
    - Other(s).
- **Type of Indicator:** Qualitative.
- **Unit of Measurement:** List of standards: Multiple selection list. "Other": Free text.
- **Baseline:** 2024.
- **Target:** Adoption of all relevant standards by at least 40% of Member States.

Discussion: These first six indicators offer a robust framework for mapping the standards and practices employed across Member States for each priority data category. It is rooted within the most updated eHN guidelines for each category. Parallelly, this approach gauges progress towards the EEHRxF, aiding in the identification of gaps and areas in need of improvement.

Potential areas for enhancing these first six indicators include:

- Ensuring regular updates to reflect new developments in standards and practices.
- Broadening the scope to encompass emerging technologies and data formats.
- Refining the granularity to capture finer details of adoption and usage across different healthcare settings.

3.1.1.7 Indicator i-A-07) Member State collaboration with Standardisation Bodies (SDOs)

- **General/Specific/Operational objective:** Document the extent of collaboration and engagement of Member States with Standardisation Bodies.
- **Definition:** This indicator monitors the collaboration and engagement of Member States in key standardisation bodies critical to the EEHRxF. Key aspects that can be covered:

[104] https://isco.ilo.org/en/
[105] https://loinc.org/
[106] https://npu-terminology.org/
[107] https://www.orpha.net/en/disease
[108] https://www.snomed.org/
[109] https://www.uicc.org/what-we-do/sharing-knowledge/tnm
[110] https://ucum.org/

  - **Engagement Processes:** Measure the frequency and type of interactions Member States have with standardisation bodies such as CDISC[111], CEN[112], IEEE[113], IHE[114], HL7[115], and SNOMED CT[116].
  - **Impact on Standard Adoption:** Gauge how collaboration and engagement influence the adoption and implementation of standards within Member States.
- **Type of Indicator:** Qualitative.
- **Unit of Measurement:** Description of the engagement activities and corresponding impact.
- **Baseline:** 2024.
- **Target:** Active participation of at least 50% of Member States in at least three SDOs.

Discussion: This indicator will assess whether the Member States are active in the Standardisation Bodies at the heart of the EEHRxF. To avoid overburdening respondents, we suggest not querying it in a survey but using the organisation's geographic member overview for this assessment: CDISC, CEN, IEEE, IHE, HL7, SNOMED CT.

3.1.2 Engagement in EEHRxF-related EU initiatives

The indicators in this subsection could be good proxies for relevance and progress at the national level toward the EEHRxF and fully interoperable EHR cross-border exchange. This monitoring area will be amplified later.

3.1.2.1 Indicator i-A-08) Member State participation in MyHealth@EU

- **General/Specific/Operational objective:** Monitors the degree of Member State involvement in MyHealth@EU initiatives.
- **Definition:** This indicator monitors the level of engagement and operational status of Member States in the MyHealth@EU framework[117]. It focuses on the implementation and functionality of the cross-border eHDSI services.
- **Type of Indicator**: Qualitative.
- **Unit of Measurement:** Status of national participation (Binary "Yes" or "No").
- **Baseline:** 2024 status, as per EU sources.
- **Target:** Active participation of at least 60% of Member States.

Discussion: This indicator assesses the participation **in MyHealth@EU**'s eHDSI services. This is a relevant data point since participation in current EU-level health data exchange initiatives is a proxy indicator of readiness for format uptake.

To avoid survey fatigue among Member State representatives, we will not include this indicator in the questionnaire but elicit this data point based on the official MyHealth@EU website. This resource lists

[111] https://www.cdisc.org/global/region/europe
[112] https://standards.cencenelec.eu/dyn/www/f?p=CEN:5
[113] https://www.ieee.org/communities/geographic-activities/regional-list-region-8.html
[114] https://www.ihe-europe.net/participate/national-initiatives
[115] https://www.hl7.org/documentcenter/public/HL7/HL7%202022%20Annual%20Report%20v3.pdf
[116] https://www.snomed.org/members
[117] https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-health-services_en

the participation in eHSDI services for all Member States[118]. Other KPI are also available via the MyHealth@EU Monitoring Framework[119], although not all report numbers from 2024.

This section should ideally also contain an indicator of the progress of **HealthData@EU**. However, this initiative is still in the piloting phase via HealthData@EU[120] Pilot. Thus, we consider it too early to assess Member State's efforts to build an integrated infrastructure for the secondary use of health data.

[118] https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-health-services_en
[119] https://experience.arcgis.com/experience/77f459be23e545b48f46a79cfaf19423/page/1_1/
[120] https://ehds2pilot.eu/

3.2 Monitoring Area B: Better quality and integrated health datasets within the EHDS for EHR stakeholders

This subchapter aims to set out indicators to measure efforts towards health datasets that with higher data quality and better integration (including security and privacy) within the EHDS. We chose to develop indicators **focused on the EEHRxF context**. High data quality, trust, integrity and security were mentioned as one of the initial requirements of the xShare Yellow Button.

In addition to data quality and integration, we also incorporate data security, protection, and privacy into this monitoring area. The definitions outlined in *Table 55. Definitions: Monitoring Area B* serve as the foundation for the work presented in this chapter.

Table 55. *Definitions: Monitoring Area B*

Concept	Definition
Data quality	As per EHDS Regulation (Art. 2, 2. (ad)): "The degree to which the elements of electronic health data are suitable for their intended primary and secondary use."
Data integration	The process of converting and translating structured and unstructured data to common vocabularies and establishing connections between the data and relevant sources and systems.[121]
Data security	Measures to protect digital data from destructive forces, unwanted actions, or unauthorised users.[122]
Data protection	Measures to keep data safe from unauthorised access.[123]
Data privacy	Data subjects' right to decide who can process their data and for what purposes.[124]

3.2.1 Data quality

Data quality is crucial to enhancing interoperability between healthcare systems. It also exemplifies the EEHRxF's Position as a "broker" at the intersection of primary and secondary use of health data. Understanding how EHR data for primary use is structured is important for work in secondary use.

Although the EHDS Regulation refers to data quality more in the context of secondary than of primary use, it also sets out the EEHRxF as basis for registration and exchange of health data that fulfil data quality requirements (EHDS Regulation, Recital 20). While the exact nature of these quality requirements is foreseen to be laid out in implementing acts, Article 56 (3) of the EHDS Regulation sets out the following quality elements (the context of the data quality and utility label): data

[121] This is our own definition, which is based on TEHDAS D6.3 Recommendations on a Data Quality Framework for the European Health Data Space for secondary use.
[122] https://en.wikipedia.org/wiki/Data_security#cite_note-1
[123] https://gdpr.eu/data-privacy/
[124] Refer to footnote 122 above.

documentation[125]; technical quality[126]; data quality management[127]; coverage[128]; access and provision[129]; data modifications[130]. Since the data quality and utility label is a tool for secondary use of health data, we do not consider all these elements important for the monitoring of EEHRxF uptake. Thus, our indicators will refer only to data quality management.

We also acknowledge that data quality is highly linked to the use of standards since standardised data collection and transmission tend to result in more high-quality datasets. Thus, Member States scoring well in the indicators of measurement area A might also score better in measurement area B.

3.2.1.1 Indicator i-B-01) Initiatives to monitor data quality

- **General/Specific/Operational objective:** Discover if there are initiatives on Member State level to monitor the quality of EHR data. Aiming to assess the level of maturity of the data quality management processes.
- **Definition:** Existence of initiatives at Member State (or regional) level to ensure that EHR data follows certain quality standards – e.g. completeness, uniqueness, accuracy, validity, timeliness, and consistency
- **Type of indicator:** Qualitative
- **Unit of Measurement:** Binary "Yes" or "No"
- **Baseline:** Study on Interoperability of Electronic Health Records in the EU (2020)
- **Target:** at least 50% of Member States answering "Yes"

Sub-indicators

- If "Yes": please describe these initiatives (including URL link)

Discussion

This indicator aims to assess whether Member States are currently undertaking actions to improve the quality of EHR data in their country. It relates to the data quality element of data quality management (EHDS Regulation, Article 56 (3c)).

The baseline measurement from the Study on Interoperability of Electronic Health Records in the EU (2020) a) focuses only on auditing of clinical content of EHRs; b) reveals a quite low level of Member State action here (36% "Yes"). Although the data collected with this indicator will not be totally comparable with the baseline, they will be an important proxy for the readiness of Member States to undertake measures for EHR data quality for the implementation of the EEHRxF.

[125] Including meta-data, support documentation, data dictionary, format and standards used, provenance, and, when applicable, data model.
[126] Including completeness, uniqueness, accuracy, validity, timeliness, and consistency of the data.
[127] Including the level of maturity of the data quality management processes, including review and audit processes, bias examination.
[128] Including time period, population coverage and, when applicable, representativity of the population sampled, and average timeframe in which a natural person appears in a dataset.
[129] Including the time between collecting electronic health data and adding them to the dataset and the time to provide electronic health data following approval of an electronic health data access application.
[130] Including merging and adding data to an existing dataset, including links with other datasets.

To make this clearer, the related survey question will contain an explanation of the data quality elements we refer to (see EHDS Regulation, Article 56 (3c)).

3.2.1.2 Indicator i-B-02) Awareness raising efforts to enhance EHR data quality with EHR stakeholders

- **General/Specific/Operational objective:** Discover whether the Member States employ awareness-raising campaigns with EHR stakeholders to enhance data quality, especially regarding machine readability.
- **Definition:** Whether Member States undertake efforts to raise awareness among EHR stakeholders for the importance of high EHR data quality, including the use of appropriate standards.
- **Type of indicator:** Qualitative.
- **Unit of Measurement:** Binary "Yes" or "No".
- **Baseline:** 2024.
- **Target:** at least 50% of Member States answering "Yes".

Discussion

This indicator assesses the data quality management dimension by assessing whether Member States value EHR data quality enough to clearly communicate to EHR stakeholders why this topic is important. While it does not directly assess EEHRxF data, it assesses awareness-raising efforts on a related topic.

We found no baseline data for this indicator. Yet, the MonitorEHR study surveyed Member States' awareness-raising campaigns on the benefits of access to and the exchange of EHR data, to which 82% of responding countries replied affirmatively.

We aim to include an information box in the survey that gives examples of these awareness-raising campaigns and their intended target groups.

3.2.1.3 Indicator i-B-03) Existence of EHR data quality guidelines at national or regional level

- **General/Specific/Operational objective:** Assess whether Member States have already undertaken steps to harmonise the quality of EHR data.
- **Definition:** Existence of quality guidelines for EHR data on the national or regional level – especially for healthcare professionals and providers. This does not have to be a proprietary national data quality framework but can also be from a third party.
- **Type of indicator:** Qualitative.
- **Unit of Measurement:** Binary "Yes" or "No".
- **Baseline:** 2024.
- **Target:** At least 30% of Member States answering "Yes".

Discussion

This indicator assesses whether Member States already have existing quality guidelines for EHR data on the national or regional level. It relates to the maturity of data quality management processes and aims to assess past efforts in harmonising EHR data quality.

There is no exact baseline data for this indicator. The Study on Interoperability of Electronic Health Records in the EU (2020) asked whether the country trains staff to perform data usability evaluations to improve data quality, to which 29% of Member States responded affirmatively.

We estimate that Member States who have already undertaken efforts in this regard are more likely to adopt the EEHRxF faster.

3.2.2 Data integration

Data integration is essential to making EHRs interoperable and integrating digital technologies into health and care.[131] It is also an important requirement for system readiness to use the EEHRxF and is also addressed in the XpanDH Readiness model (WP3) and Artefacts (WP2). Data integration also links to the related requirements set out by the EHDS Regulation.

3.2.2.1 Indicator i-B-04) Preparation for key EHDS structures

- **General/Specific/Operational objective:** Assess Member State's state of preparation for key structures set out in the EHDS regulation.
- **Definition:** Existence of preparations of key structures for the EHDS.
  Key structures:
  - Established/ Designated Digital Health Authority (EHDS, Art. 10);
  - Established/ Designated Health Data Access Body (EHDS, Art. 36);
  - Started preparing for European Interoperability component for EHR systems (EHDS, Art. 13a);
  - Started preparing for European logging component for EHR systems (EHDS, Art. 13a);
  - Participates in EU Capacity Building Activities/ Community of Practice for Primary Use;
  - Participates in EU Capacity Building Activities/ Community of Practice for Secondary Use;
  - Other.
- **Type of indicator:** Qualitative.
- **Unit of Measurement:** Mechanisms: Multiple selection list. "Other": Free text.
- **Baseline:** 2024.
- **Target:** At least 50% of Member States answering "Yes" to at least two options.

Discussion

Preparation for the most important Member State level structures set out in the EHDS Regulation is important to measure. The structures quoted in the answer options all aim to promote data integration. Thus, we assume that Member States who have started preparing for many of these structures are also more advanced towards data integration.

Since the EHDS concepts are novel, no baseline data exists here yet.

3.2.2.2 Indicator i-B-05) Interoperability support services provided by national Digital Health Authority (or similar)

- **General/Specific/Operational objective:** Assess whether the national digital health authorities provide specific tools and services to implement interoperability.

[131] EC (2019): Commission Recommendation on a European Electronic Health Record Exchange Format. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019H0243

- **Definition:** Existence of support from national digital health authorities to implement interoperability.
  Support mechanisms:
  - National terminology server.
  - National IDMP data base.
  - Implementation guidelines, toolboxes.
  - Capacity building on interoperability (e.g., training, certification programmes, *connectathons*, etc.).
  - Consultations.
  - Other.
- **Type of indicator:** Qualitative.
- **Unit of Measurement:** Mechanisms: Multiple selection list. "Other": Free text.
- **Baseline:** 2024.
- **Target:** At least 50% of Member States answering "Yes" to at least two options.

Discussion

To complement the assessment of use of standards in the first monitoring area, this indicator measures whether the national health agencies provide support to healthcare providers in applying these standards. This is important since the involved actors will likely adopt the EEHRxF more rapidly if they receive support in applying standards in practice – leading to better-integrated data.

There is no exact baseline data for all answer options of this indicators. Study on Interoperability of Electronic Health Records in the EU (2020) queried about existence of terminology serves, to which 46% of Member States replied “yes”.

3.2.2.3 Indicator i-B-06) Preparation for the EEHRxF in national Digital Health Authority (or similar)

- **General/Specific/Operational objective:** Assess whether national digital health authorities are already taking steps to prepare for the EEHRxF.
- **Definition:** Existence of steps taken to implement the EEHRxF – e.g. working groups established, guidelines on national adaptation published, experts consulted, involvement in capacity-building activities.
  Preparation mechanisms:
  - Established working group.
  - Published guidelines on national adaptation.
  - Consulted experts.
  - Involved in capacity building activities.
  - Developed training.
  - Other.
- **Type of indicator:** Qualitative.
- **Unit of Measurement:** Mechanisms: Multiple selection list. "Other": Free text.
- **Baseline:** 2024.
- **Target:** At least 50% of Member States answering "Yes".

Discussion

This indicator assesses whether digital health authorities in the Member States have started preparing for the EEHRxF. The indicator is relevant since Member States with existing awareness and preparation

are more likely to manage a faster EEHRxF adoption. The answer options query different presumed types of preparation and also leave space for more information.

Since the concept of EEHRxF is novel, no baseline data exists yet. Study on Interoperability of Electronic Health Records in the EU (2020) assessed only Member States' interpretation of the Recommendation[132].

3.2.3 Data security and protection

Since data security and protection are very similar and often mentioned together, they will be assessed in the same subarea of this measurement framework.

A downside of better EHR interoperability is that it might make cybersecurity attacks on EHR systems more attractive since data commonly structured via the EEHRxF is also more accessible to illegitimate users. Thus, it is crucial to monitor measures against cyber-attacks and unauthorised access.

3.2.3.1 Indicator i-B-07) Protection against cybersecurity risks

- **General/Specific/Operational objective:** Detect whether there are measures in place to protect EHR data protection against cybersecurity risks.
- **Definition:** Check whether EHR systems are built to detect cyber-attack attempts before they occur through an integrated security approach.
  Measures queried:
  - Use of updated software, including latest patches and security versions.
  - Existence of a CERT structure (or similar) to handle cybersecurity incidents.
  - Data on secondary memory (data at rest) is encrypted.
  - Other.
- **Type of indicator:** Qualitative.
- **Unit of Measurement:** List of measures: Multiple selection list. "Other": Free text.
- **Baseline:** Study on Interoperability of Electronic Health Records in the EU (2020).
- **Target:** At least 70% of Member States answering "Yes" to at least two options.

Discussion

This indicator measures whether Member States take a proactive role in protecting their EHR data against cyber-attacks. This indicator is relevant to the EEHRxF given the likely increased value of well-structured EHR data for cyber-criminals (see above). The specific measures queried were chosen in consultation with consortium partner CERTH. If possible, points of entry for hacking attempts in EHR systems are identified through regular monitoring; the Member States are also more likely to wisely incorporate EEHRxF in their systems without compromising cyber-security.

The Study on Interoperability of Electronic Health Records in the EU (2020) assessed this indicator in 2020, with 68% responding to Member State representatives answering affirmatively.

3.2.3.2 Indicator i-B-08) Identification and authentication mechanisms

- **General/Specific/Operational objective:** Existence of national rules of identification/ authentication for EHR access.

[132] EC (2019): Commission Recommendation on a European Electronic Health Record Exchange Format. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019H0243

- **Definition:** Existence or not of national rules on how health professionals identify and authenticate themselves and on who is allowed to set up and access EHRs.
- **Type of indicator:** Qualitative.
- **Unit of Measurement**: Binary "Yes" or "No".
- **Baseline:** Study on Interoperability of Electronic Health Records in the EU (2020).
- **Target:** >90% of Member States answering "Yes".

Discussion

This indicator assesses whether national law stipulates that only authorised users can access and create EHRs. This is relevant for the EEHRxF since those actors allowed to access EHR data are likely to be identical to those allowed to receive and send EHR data via the format.

When the Study on Interoperability of Electronic Health Records in the EU (2020) assessed this indicator in 2020, 89% of Member States replied positively.

3.2.4 Data privacy

This monitoring sub-area measures the degree of control that citizens have over who can access their EHR data – in line with both GDPR[133] and EHDS Regulations. We chose to indicators, focussing on health data sharing functionalities and opt-out options.

3.2.4.1 Indicator i-B-09) Citizen control of their health data sharing

- **General/Specific/Operational objective:** Measure to which degree citizens control their own health data sharing.
- **Definition:** This indicator measures whether citizens can control certain aspects of their own health data sharing.
    - Citizens can insert information into their EHR (EHDS, Art. 8b);
    - Citizens can have their EHR records rectified (EHDS, Art. 8c);
    - Citizens can share their health data with healthcare providers of their choice (EHDS, Art 8d);
    - Citizens can restrict access to their EHR data (EHDS, Art. 8e);
    - Citizens can share their health data with other natural persons (EHDS, Art. 8g);
    - Citizens can be informed on who accesses their health data (EHDS, Art. 8f).
- **Type of indicator:** Qualitative
- **Unit of measurement:** Multiple selection list.
- **Baseline:** Study on Interoperability of Electronic Health Records in the EU (2020)[134].
- **Target**: At least 70% of Member States answering "Yes".

Discussion:

The xShare Yellow Button enables citizens/patients to share health data easily with a healthcare provider of their choice, as well as other functionalities. Also, the EHDS Regulation, Art. 8, sets out ample rights for natural persons regarding data sharing. Thus, it is crucial to assess the status quo of these aspects through monitoring.

[133] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0679
[134] https://digital-strategy.ec.europa.eu/en/library/interoperability-electronic-health-records-eu

The Study on Interoperability of Electronic Health Records in the EU (2020) offers some baseline data on three items.

On a similar, but not identical question than answer option one, 64% of respondents replied that patients/citizens are able to decide and specify which health-related data from their national EHR can potentially be shared with healthcare professionals other than their own General Practitioner.

Regarding EHR record rectification, 68% replied that patients/citizens can request their own health related EHR data be corrected or correct it themselves, if inaccurate.

The study also asked whether citizens can delete health-related data from their EHR, to which only 11% (n=3) replied “yes”.

3.2.4.2 Indicator i-B-10) Opt-out of EHR data use

- **General/Specific/Operational objective:** Assess whether citizens can opt out of EHR data sharing for primary and secondary use.
- **Definition:** Existence of citizen's right to opt out of EHR data sharing – for primary and/or secondary use.
  Opt-out modalities:
  - Yes, primary use;
  - Yes, secondary use;
  - No.
- **Type of indicator:** Qualitative.
- **Unit of Measurement**: Multiple selection list.
- **Baseline:** 2024.
- **Target:** At least 50% of Member States answering "Yes" (either primary or secondary).

Discussion

The EHDS regulation does not foresee a mandatory opt-out right for the primary use of health data but leaves it up to Member States to implement this. Opt-out is introduced in all Member States for secondary use. These opt-out rights for primary and secondary use are of different relevance for EEHRxF adoption and for xShare.

Firstly, the EHDS regulation sees the EEHRxF primarily as a tool for the primary use of health data.

Secondly, of the three health data use verticals in xShare, health data portability (WP3) relates to primary use, while population health (WP4) and clinical research (WP5) relate to secondary use. Considering the EHDS Regulation stipulations on opt-out, we can assume that more citizens will be given the right and choose to opt out of secondary than of primary use. Thus, the use case for health data portability – such as in the adoption sides – will likely have larger and more complete data available than the other two. It makes thus sense to assess a baseline regarding national legislation.

Since the concept is novel, no baselined data exists yet.

3.2.4.3 Indicator i-B-11) Anonymisation and pseudonymisation by Health Data Access Bodies (or similar)

- **General/Specific/Operational objective:** Assess whether Health Data Access Bodies (or similar) provide anonymised and/ or pseudonymised data.

- **Definition:** Provision of data by Health Data Access Bodies (or similar) in anonymised and/or pseudonymised format.
  Options:
  - Yes, anonymised.
  - Yes, pseudonymised.
  - Neither anonymised nor pseudonymised.
- **Type of indicator:** Qualitative.
- **Unit of Measurement**: Multiple selection list.
- **Baseline:** 2024.
- **Target:** At least 50% of Member States answering "Yes" (either a or b).

Discussion

Anonymisation and pseudonymisation of electronic health data are crucial techniques to preserve citizens' privacy in secondary use. The EHDS Regulation sets out that Health Data Access Bodies should make health data available per default in anonymised format (Art. 44, 2) and only exceptionally in pseudonymised format (Art. 44, 3). Since xShare considers to include an anonymisation filter in the Yellow Button, it is interesting to assess which Member States are already applying these techniques.

While no comprehensive baseline data exists for this indicator, HealthData@EU Pilot conducted a landscape analysis of the legal framework of eight Health Data Access Bodies in 2023[135]. One Health Data Access Body offers download of pseudonymised data, while three offer download of anonymous data.

3.3 Monitoring Area C: Current state and uptake of EHRs

This monitoring area aims to provide an overview of the current status and utilisation of, and citizens access to, EHRs within the national healthcare system, encompassing various dimensions of access, adoption, cross-border exchange, and adoption site deployment. These indicators aim to build upon the findings of both the initial[136] and the follow-up[137] studies on the Digital Decade eHealth Indicator, published in 2023 and 2024, respectively.

3.3.1 Citizen-centric data access

The indicators in this subsection link directly to Article 8a in the EHDS Regulation, regarding the right of natural persons to access their personal electronic health data - at least in the priority data categories and in the EEHRxF. It also links to the Digital Decade target of 100% of EU citizens having

[135] https://ehds2pilot.eu/wp-content/uploads/2023/07/Website-publication_2023_WP7-landscape-analysis_rev-1-1.pdf?_gl=1*18i2l1t*_up*MQ..*_ga*OTU3ODUwNzY1LjE3MDIwNTE2MDU.*_ga_NPY4Z26JQR*MTcwMjA1MTYwNC4xLjEuMTcwMjA1MTY2Mi4wLjAuMA

[136] https://op.europa.eu/en/publication-detail/-/publication/78938111-461e-11ee-92e3-01aa75ed71a1/language-en

[137] https://op.europa.eu/en/publication-detail/-/publication/c04f6162-3833-11ef-b441-01aa75ed71a1/language-en

access to their EHRs by 2030[138]. It captures the accessibility and usability of EHRs from the citizens' perspective. More specifically, the indicators should assess if citizens can access their EHR data in the priority data categories.

Indicators i-C-01 to i-C-07 refer to 2024 Digital Decade eHealth Indicator Study (2024) both for indicator development and as a baseline date. The eHealth Indicator Study relies heavily on composite indicators, differentiating between non-access, non-timely access and timely access or grouping different priority data categories together.[139] For the xShare monitoring framework, we chose to not use a composite indicator, to maintain the same methodology throughout the three measurement areas and keep it simply. Thus, for baseline data, we rather consider the number/percentage of Member States confirming access to a certain data category, according to the eHealth Indicator Study.[140]

We do not differentiate between timely and non-timely access. Also, in case of discrepancy, we will consider the priority categories of health data as measuring units according to the EHDS Regulation, Article 5.

3.3.1.1 Indicator i-C-01) Citizen access to patient summary data

- **General/Specific/Operational objective:** Monitor the availability of patient summary data to citizens.
  Definition: This indicator measures the percentage of patient summary data categories that are available to citizens through the electronic health records data online access service.
  For this framework, the specific data categories within the patient summary comprise:
  - Personal information (e.g., name, date of birth, gender).
  - Allergies (e.g., description and type of allergy, severity, agent).
  - Current problems (e.g., description and onset).
  - Medical devices and implants (e.g., device ID, implant/explant date).
  - Procedures/operations (e.g., description, body site, date).
  - Current and relevant past medicines (e.g., reason, use, brand name, ingredients, dosage.
  - Other(s).
- **Type of Indicator:** Quantitative.
- **Unit of Measurement:** Percentage of data categories available for patient summaries. For "Other": Free text.
  Additionally, there should be a free text option for the respondent to provide **details on the actual format**, such as PDF or text, through which citizens can access this priority data category.
- **Baseline:** 2024 Digital Decade eHealth Indicator Study (2024)[141].

[138] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/europes-digital-decade-digital-targets-2030_en

[139] The average score for data availability is calculated as follows: not available (0%), available but not timely (50%), and available and timely (100%). This results in an average percentual maturity score across Member States — e.g., 85% for ePrescriptions.

[140] The study explicitly mentions the number of Member States, and we calculate the percentage.

[141] https://op.europa.eu/en/publication-detail/-/publication/c04f6162-3833-11ef-b441-01aa75ed71a1/language-en

- **Target:** At least four data categories (as listed above) are available for at least 50% of the Member States.

Discussion

The data categories available in the latest eHealth Indicator Study are not the same as those described for patient summaries as per the EHDS Regulation, Article 5. Nonetheless, leveraging these data categories enables cross-study analysis between the eHealth Indicator Study results (from its two iterations), the ones of this monitoring framework, and any future studies, thereby producing a comparable and robust analysis sample to assess the development of citizen access to patient summary data across Europe.

3.3.1.2 Indicator i-C-02) Citizen access to ePrescription data

- **General/Specific/Operational objective:** Monitor the availability of ePrescription data to citizens.
- **Definition:** This indicator measures the availability of ePrescription data to citizens through online access services.
- **Type of Indicator:** Qualitative.
- **Unit of Measurement:** Binary "Yes" or "No".
  While we may give preference to employing data pre-filling for this indicator, it is imperative to also include a free text option for the respondent to provide **details on the actual format, such as PDF or text,** through which citizens can access this priority data category.
- **Baseline:** 2024 Digital Decade eHealth Indicator Study (2024)[142].
- **Target:** Available in at least 90% of Member States.

Discussion

ePrescription data has been repeatedly identified as the most mature data category regarding health data exchange. In the 2024 e-Health indicator study, 89% of (n=24) Member States reported availability[143].

Since data from 2023 is available through the study and to avoid survey fatigue, we will not query this indicator in the survey but prefill it with the study results.

3.3.1.3 Indicator i-C-03) Citizen access to eDispensation data

- **General/Specific/Operational objective:** Monitor the availability of eDispensation data to citizens.
- **Definition:** This indicator measures the availability of eDispensation data to citizens through electronic health records online access services.
- **Type of Indicator:** Qualitative.
- **Unit of Measurement:** Binary "Yes" or "No".

[142] https://op.europa.eu/en/publication-detail/-/publication/c04f6162-3833-11ef-b441-01aa75ed71a1/language-en

[143] Calculation: Each data type had three different answer options with varying impacts: not available (0%), available but not timely (50%), available and timely (100%)

While we may give preference to employing data pre-filling for this indicator, it is imperative to also include a free text option for the respondent to provide **details on the actual format, such as PDF or text,** through which citizens can access this priority data category.

- **Baseline:** 2024 Digital Decade eHealth Indicator Study (2024)[144].
- **Target:** Available in at least 90% of Member States.

Discussion

Like ePrescription, eDispensation has been repeatedly identified as one of the most mature data categories for sharing. In the 2024 e-Health indicator study, 85% (n=23) of Member States replied positively[145].

Since data from 2023 is available through the study and to avoid survey fatigue, we will not query this indicator in the survey but prefill it with the study results.

3.3.1.4 Indicator i-C-05) Citizen access to medical imaging reports and images

- **General/Specific/Operational objective:** Monitor the availability of medical imaging reports and imaging to citizens.
- **Definition:** This indicator measures the availability of medical imaging reports and images to citizens through electronic health records online access services.
    - Medical imaging reports (reports with summaries of diagnostic imaging procedures of any kind).
    - Medical images (made available to citizens in digital formats, e.g., .png, .jpeg or .pdf).
- **Type of Indicator:** Qualitative.
- **Unit of Measurement:** Binary "Yes" or "No".
  While we may give preference to employing data pre-filling for this indicator, it is imperative to also include a free text option for the respondent to provide **details on the actual format, such as PDF, .png, or even text,** through which citizens can access this priority data category.
- **Baseline:** 2024 Digital Decade eHealth Indicator Study (2024)[146] (separate indicators for images and reports).
- **Target:** Medical images and/or reports available in >30% of Member States.

Discussion

Medical images and imaging reports are considered a category with rather low levels of access.[147] The 2024 eHealth indicator study assess this priority data category in two separate indicators. Medical images (made available to citizens in digital formats, e.g., .png, .jpeg or .pdf) were available in merely 26% of Member States (n=7). Significantly better for Medical Imaging reports (reports with summaries

[144] https://op.europa.eu/en/publication-detail/-/publication/c04f6162-3833-11ef-b441-01aa75ed71a1/language-en
[145] Calculation: Each data type had three different answer options with varying impacts: not available (0%), available but not timely (50%), available and timely (100%).
[146] https://op.europa.eu/en/publication-detail/-/publication/c04f6162-3833-11ef-b441-01aa75ed71a1/language-en
[147] Quote XpanDH, xShare, MonitorEHR.

of diagnostic imaging procedures of any kind), the study recorded availability in 78% (n=21) Member States.

The xShare indicator will consider these two elements as one single indicator to reflect the wording of priority data category d) in the EHDS Regulation, Article 5.

Since data from 2023 is available through the study and to avoid survey fatigue, we will not query this indicator in the survey but prefill it with the study results. To take into account the split into two indicators in the eHealth Indicator Study, we will consider the answer to the question as positive if either Medical Imaging Reports or Medical Images itself are available.

3.3.1.5 Indicator i-C-04) Citizen access to medical test results, including laboratory and other diagnostic results and related reports

- **General/Specific/Operational objective:** Monitor the availability of medical test results, including laboratory and other diagnostic results and related reports.
- **Definition:** This indicator measures whether citizens can access electronic laboratory test results through the electronic health records data online access service.
- **Type of Indicator:** Qualitative.
- **Unit of Measurement:** Binary "Yes" or "No".
- While we may give preference to employing data pre-filling for this indicator, it is imperative to also include a free text option for the respondent to provide **details on the actual format, such as PDF, .png, or even text,** through which citizens can access this priority data category.
- **Baseline:** 2024 Digital Decade eHealth Indicator Study (2024)[148].
- **Target:** Available in at least 90% of Member States.

Discussion

Laboratory results are also considered one of the most mature data categories. In the 2024 e-Health indicator study, 89% (n=24) of Member States replied positively.[149]

Since data from 2023 is available through the study and to avoid survey fatigue, we will not query this indicator in the survey but prefill it with the study results.

3.3.1.6 Indicator i-C-06) Citizen access to discharge reports

- **General/Specific/Operational objective:** Monitor the availability of discharge reports to citizens.
- **Definition:** This indicator measures the availability of discharge reports to citizens through the electronic health records data online access service.
- **Type of Indicator:** Qualitative.
- **Unit of Measurement:** Binary "Yes" or "No".
  While we may give preference to employing data pre-filling for this indicator, it is imperative to also include a free text option for the respondent to provide **details on the actual format, such as PDF, .png, or even text,** through which citizens can access this priority data category.

[148] https://op.europa.eu/en/publication-detail/-/publication/c04f6162-3833-11ef-b441-01aa75ed71a1/language-en

[149] Calculation: Each data type had three different answer options with varying impacts: not available (0%), available but not timely (50%), available and timely (100%).

- **Baseline:** 2024 Digital Decade eHealth Indicator Study (2024)[150].
- **Target:** Available in at least 80% of Member States.

Discussion

Discharge reports have also been considered a challenging data category.[151] The eHealth Indicators Study defined this category as "hospital discharge reports (reports with summaries of ward episodes or ambulatory care)". The 2023 data found that 78% (n=21) of Member States provided access.

Since data from 2023 is available through the study and to avoid survey fatigue, we will not query this indicator in the survey but prefill it with the study results.

3.3.2 Status quo of adoption sites

xShare features eight adoption sites, developing business use cases for the Yellow Button across Europe and in business (n=1), national (n=4), regional (n=2), and hospital network (n=1) contexts. *D3.1 xShare Data portability business use cases, validation process, and localisation requirements* explain the co-creation process of the business use cases in the adoption sites in more detail.

The indicators in this subsection capture the implementation progress of the xShare yellow button in these adoption sites. The insights generated should help future implementation. Unlike the remaining indicators, these indicators are targeted at the adoption sites directly.

In addition, the monitoring results from the remaining indicators will provide a baseline for adoption sites to evaluate their performance compared to the overall EU scenario.

A crucial point about this subsection relates to the fact that xShare monitors units, such as the Adoption Sites and the Hub (the latter one to be discussed in later chapters), which are creations of the xShare project itself. With regards to Adoption Sites, their monitoring indicators follow the same premise as the overall monitoring framework: They provide a basis for both updating and adapting to the available data collection method. Therefore, WP6 members will hold bilateral meetings with active experts on the Adoption Sites to refine indicators that are both internally and externally valid.

3.3.2.1 Indicator i-C-07) Implementation of yellow button basic functionalities at xShare adoption sites

- **General/Specific/Operational objective:** Monitor the implementation of the xShare Yellow Button basic functionalities (download, one-time share, linked options) for each priority data category in adoption sites.
- **Definition:** This indicator measures the implementation of basic functionalities in xShare adoption sites for each priority data category. Basic functionalities refer to:
    - Download: Allowing users to download their health data.
    - One-time share: Enabling users to share their health data once.
    - Linked option: Connecting EHR systems to apps or to each other.

  Subsequently, the priority data categories referenced here (as defined in this whole monitoring framework) are:
    - Priority category a) Patient Summary.
    - Priority category b) ePrescription.

[150] Refer to footnote 146 above.
[151] Quote XpanDH, xShare, Monitor HER.

  - Priority category c) eDispensation.
  - Priority category d) Medical Imaging Studies and Related Imaging Reports.
  - Priority category e) Medical Test Results, Including Laboratory and Other Diagnostic Results and Related Reports.
  - Priority category f) Discharge Reports.
  - Other(s). *To be added by survey respondents in case pertinent*.
- **Type of Indicator:** Qualitative.
- **Unit of Measurement:** The implementation of each basic functionality for every priority category at a given adoption site. Implementation is to be described binarily ("Yes" or "No"), with an optional text field for more details. Here is an example of how this would be structured in the data collection phase for a priority data category.

Priority data category	Basic functionalities		
	Download	One-time share	Linked option
Priority category a) Patient Summary	$Implementation = \{Yes, No\}$	$Implementation = \{Yes, No\}$	$Implementation = \{Yes, No\}$

  Additionally, there should be a free text option for the respondent to **specify the actual format or method, like PDF, text, or through an online portal**, that allows users to access the basic functionalities of the button for a given priority data category.
- **Baseline:** 2025.
- **Target:** Full implementation of all basic scenarios in all adoption sites by 2025.

Discussion:

Describing the basic scenario implementation via binary terms allows for cross-study comparisons with other analyses and reporting focused on xShare's adoption sites. This strengthens the robustness of the data gathered on their progress. Additionally, the reason for using a binary description for this indicator (i-C-07) is that the following one (i-C-08) covers the complexity of the implementation level using a framework widely employed in the EU (the technology readiness framework).

3.3.2.2 Indicator i-C-08) Maturity levels of priority data categories at xShare adoption sites

- **General/Specific/Operational objective:** Monitor the maturity levels of each priority data category at the xShare adoption sites in terms of technology readiness.
- **Definition:** This indicator monitors the maturity levels of each priority data category at the xShare adoption sites based on their Technology Readiness Levels (TRL) framework. The TRL framework evaluates the maturity of a technology from initial concept to operational use. The TRL framework[152] defines the levels as follows:
  - TRL 1: Basic principles observed.
  - TRL 2: Technology concept formulated.
  - TRL 3: Experimental proof of concept.
  - TRL 4: Technology validated in lab.

[152] https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-g-trl_en.pdf

  - TRL 5: Technology validated in relevant environment.
  - TRL 6: Technology demonstrated in relevant environment.
  - TRL 7: System prototype demonstration in operational environment.
  - TRL 8: System complete and qualified.
  - TRL 9: Actual system proven in operational environment.

  Subsequently, the priority data categories referenced here (as defined in this whole monitoring framework) are:
  - Priority category a) Patient Summary.
  - Priority category b) ePrescription.
  - Priority category c) eDispensation.
  - Priority category d) Medical Imaging Studies and Related Imaging Reports.
  - Priority category e) Medical Test Results, Including Laboratory and Other Diagnostic Results and Related Reports.
  - Priority category f) Discharge Reports.
  - Other(s). *To be added by survey respondents in case pertinent*.
- **Type of Indicator:** Quantitative.
- **Unit of Measurement:** Maturity level scores based on the TRL (1-9) framework for each priority category. Here is an example of how this would be structured in the data collection phase for a priority data category.

Priority data category	Maturity
Priority category a) Patient Summary	$TRL\ Score = \{1, \dots, 9\}$

- **Baseline:** 2025.
- **Target:** Achievement of the target TRL stages for each adoption site, as defined in D3.1[153].

Discussion:

This indicator measures the progress of the TRL levels for each priority category in each adoption site. D3.1 already sets out the baseline and desired TRL level in each case.

[153] Deliverables will be publicly available after approval by European Commission.

4. Framework 2 – Monitoring EEHRxF Standards and Policy Hub performance

One of the main ways xShare plans to achieve advancement in standards for digital health data is by creating 'the Hub'. This EEHRxF Standards and Policy Hub will promote the adoption and development of digital health under the upcoming EU regulation on the EHDS. It will act as a steward for EEHRxF specifications and related interoperability tools, speeding up implementation and alignment across Europe.

The work planned by the Hub is established through a series of consecutive Annual Work Plans set up by the project's WP2. The main goal of WP2 is to set up the EEHRxF Standards and Policy Hub and make it an independent and sustainable organisation by 2025. The Annual Work Plan 2025[154], the first in this series of yearly plans for the EEHRxF Standards Hub, has already been drafted. In 2024, the xShare project will start co-creating, establishing core services and tools for The Hub, and gaining initial support from stakeholders.

This monitoring is intended to provide a documentation of the Hub performance and monitor whether its self-set goals can be attained.

Existing data

Since the Hub is a creation of the project, no data exists yet.

Dimensions of monitoring and measurement areas

In line with the Description of Action, we suggest the indicator framework reflects the three thematic areas to be covered, plus a general monitoring of the organisational implementation of the Hub's proceedings. Therefore, the dimensions of monitoring will be organised as follows:

a. Hub operation
b. Use case generation
c. Helpdesk
d. Cost

4.1 Hub Operation success factor indicators

This section is supposed to suggest indicators of successful Hub operation. It should measure whether the Hub has taken on its work and addresses the functions it needs to engage.

The Annual Work Plan for 2024 states the following:

"Creating the EEHRxF Standards and Policy Hub as a self-sustainable entity involves a multifaceted approach, focusing on delivering a solid value proposition, ensuring robust content management, establishing transparent governance and processes, and identifying responsible individuals to lead the initiative. "[155]

Establishment of the Hub and initiation of its processes can be measured in an indicator of organisational readiness, and later organisational achievement. As of this moment, the Hub is still being developed and can be understood as a virtual organisation which is being established via a Letter of Intent and an Alliance. As of July 2024, 21 organisations have already expressed their interest to be

[154] Deliverables will be publicly available after approval by European Commission.
[155] xShare: Annual EHRxF Standards and Policy Hub Work Plan 2024. Deliverable 2.1 (not public yet). p.18.

Members of the Hub and other organisations are still engaged in a discussion concerning their membership.

For this first monitoring framework, we measure the organisational readiness of the Hub using the following characteristics: a values proposition (or: a mission statement), a content management structure, a governance structure, and responsible individuals in charge of these functions. Based on further experience once the Hub is operational, we will likely update the second monitoring framework with more characteristics.

4.1.1 Indicator ii-A-01) Organisational readiness

- **General/Specific/Operational objective:** Measure organisational readiness as prerequisite for proper working of the Hub
- **Type of indicator:** Quantitative
- **Definition:** Arithmetic average of 7 measurements on 1-5 scales (very low – very high), expert assessment on ordinal scale
- **Unit of measurement:** numeric (Likert scale)
- **Baseline:** 2025
- **Target:** 3

Sub-indicators:

- Mission Statement
  - (1) In finding/definition process / (2) / (3) Draft waiting for ratification by all members/ (4) / (5) Fully adopted
- Governance structure
  - (1) Hub is in planning phase/pre-founding phase / (2) / (3) Hub is legally founded and starts working / (4) / (5) Hub is fully operating
- Content management structure
  - (1) ill-defined/ad-hoc / (2) / (3) content management functions and responsibilities are drafted / (4) / (5) operational processes, management and support functions are fully agreed and allocated
- Personnel and functional set-up
  - (1) ill-defined / ad-hoc / (2) / (3) roles and responsibilities are taken up provisionally / (4) / (5) operational, management and support functions are fully allocated
- Resource identification and gap analysis
  - Identification of all critical resources necessary for the Hub's operations, spanning personnel and technological infrastructures, as described per workplan 2025 (D2.1), chapter 5.2.: (1) not (2) delayed (3) fully
- Financial stability for continuation of operations after xShare funding has stopped.
  - (1) not / 2) / (3) in progress / (4) / (5) fully financially sustainable.
- Recruitment and resource acquisition strategy

- Established recruitment initiatives for attracting essential talent, and strategies for procuring necessary technological tools, as described per workplan 2025 (D2.1[156]), chapter 5.2.: (1) not / (2) / (3) delayed / (4) / (5) fully

Reporting units:

- Hub as a whole – a rapporteur will give a qualified assessment and assign the scores 1-3 on each of the six sub-indicators. It is accompanied by a short written justification.

4.1.2 Indicator ii-A-02) Organisational achievement of set goals

- **General/Specific/Operational objective:** Measure how the Hub is achieving work plan goals
- **Type of indicator:** Quantitative
- **Definition:** Arithmetic average of 4 measurements on 1-5 scales (low – high), Expert assessment on ordinal scale
- **Unit of measurement:** numeric (Likert scale)
- **Baseline:** 2025
- **Target:** 3

Sub-indicators:

- **Milestones and deliverables**
  - Milestones and deliverables in the workplan of the hub are produced: (1) not/ (2) / (3) delayed / (4) / (5) fully on plan
- **Hub website launched**
  - (1) no / (2) / (3) in development / (4) / (5) yes
- **Process mapping and analysis**
  - Mapping of all essential processes related to the Hub's operations as described per workplan 2025 (D2.1), chapter 5.2.: (1) not / (2) / (3) delayed / (4) / (5) fully
- **Process documentation**
  - Comprehensive documentation of all operational processes as described per workplan 2025 (D2.1), chapter 5.2.: (1) not / (2) / (3) delayed / (4) / (5) fully

Reporting unit:

- Hub as a whole – a rapporteur will give a qualified assessment and assign the scores 1-3 on each of the six sub-indicators. It is accompanied by a short, written justification.

[156] Deliverable will be publicly available after approval by European Commission

4.1.3 Indicator ii-A-03) Successful stakeholder involvement in business-driven implementation (size and scope of the community)

- **General/Specific/Operational objective:** Measure the involvement of stakeholders in the working of the Hub and the achievement of co-creation as a "joint effort to achieve the adoption of standard sets and tooling for local specification through collaboration of the stakeholders" (D2.1., Ch 5.3)
- **Type of indicator:** Quantitative
- **Definition:** Arithmetic average of measurements on 1-3 scales (low – medium – high), Expert assessment on ordinal scale
- **Unit of measurement:** numeric (ordinal scale)
- **Baseline:** 2025
- **Target:** 3

Sub-indicators:

- Involvement of adoption sites in co-creation
  - a) rarely b) some c) significant
- Involvement of other relevant projects like XT-EHR, TeHDAS2 etc. (please name)
  - a) rarely b) some c) significant
- Involvement of industry in co-creation
  - a) rarely b) some c) significant
- Involvement of regulatory entities in co-creation
  - a) rarely b) some c) significant
- Involvement of other stakeholders (patients, consumer & data protection orgs) in co-creation
- a) rarely b) some c) significant

Ideally, concrete target figures can be agreed on with the Hub to define in each case what a), b) and c) mean. This is yet to be done, once the Hub is operational.

Reporting unit:

- Hub as a whole

4.1.4 Indicator ii-A-04) Hub outcome – creation of specifications for priority categories, based on work in XpanDH (X-Bundles)[157]

- **General/Specific/Operational objective:** Measure the creation of specifications
- **Type of indicator:** Quantitative
- **Definition:** Arithmetic average of measurements on 1-3 scales (low – medium – high), Expert assessment on ordinal scale
- **Unit of measurement:** numeric (ordinal scale)
- **Baseline:** 2025

[157] Every X-Bundle can cover various priority categories of health data.

- **Target:** 3

Sub-indicators:

- **X-Bundle availability for the xShare Button**
  - Coverage of architecture ecosystem: a) One b) two or more c) all
  - Coverage of priority categories : a) One b) two or more c) all
  - Usage of X-Bundles: X-Bundle for the xShare Button has been used by a) one b) two or more c) ten or more instances.

- **X-Bundles creation**. X-Bundles created per priority category – coverage of priority category processes
  - Number of X-Bundles - a) up to 33% b) up to 67% c) more than 67% of target number
- % coverage of priority categories - a) up to 33% b) up to 67% c) more than 67% of target numbers
- **X-Bundle maturity**
  - a) drafted and in first stakeholder consultation, b) published and disseminated, c) taken up in pilots/ in adoption sites
- **X-Bundle standardisation**
  - a) X-Bundle drafts are processed in SDOs, b) X-Bundles are in standardisation "pipeline", c) X-Bundles reference a standard
- **X-Bundle regulation**. X-Bundles are part of national regulation
  - a) not b) expected c) yes

Reporting unit:

- Hub as a whole

4.1.5 Indicator ii-A-05) Member State involvement in the Hub

- **General/Specific/Operational objective:** Measure the involvement of each Member States with the Hub
- **Type of indicator:** Qualitative
- **Definition:** Short (maximum half page) report about each Member State summarising their interaction with the hub.
- **Unit of measurement:** free text
- **Baseline:** 2025
- **Target:** No target
  - Hub as a whole

4.1.6 Indicator ii-A-06) Industry involvement in the Hub

- **General/Specific/Operational objective:**
- **Type of indicator:** Quantitative
  - **Definition:** Number of EHR vendors involved in the Hub

- **Unit of measurement:** numeric
- **Baseline:** 2025
- **Target:** open

Discussion

The indicators are meant to measure the success of setting up the EEHRxF Standards and Policy Hub and its operations. They are the core indicators to measure whether the project's mission is on track. As such, setting up the framework has been aligned with work in WP2. To gain more insights on the Hub's engagement, we will also monitor the degree of Member States and industry (especially EHR vendor involvement). The measurement of these indicators is reliant on the operational knowledge and insight, expert assessment, and honest reporting of the Hub representative acting as a rapporteur vis-à-vis the monitoring task.

4.2 Business use case registration and its indicators

The annual workplan 2024[158] (D2.1) mentions that "*The Business use cases and requirements are co-created with WP3, WP4 and WP5, as well as with the initiatives that respond to the open call(s) to be issued by the xShare project. Based on the assets collected in the Hub, X-Bundles will be co-created with the adoption sites and additional settings, based upon their business use cases and requirements.*" To this end, and in the scope of WP3, eight Business Use Cases (one for each adoption site) together with a set of User Stories, were co-created with the Adoption sites, supported by the SDOs. The result of this exercise is a set of common and adoption sites specific requirements for the adoption of the xShare Yellow Button, considering the way its usage is envisaged on each (see deliverables[159] D3.1 and D3.2). This set of business use cases is thus expected to grow beyond the number of adoption sites over the lifetime of the Hub and is expected to cover the data priority categories and the specifications ecosystems.

4.2.1 Indicator ii-B-01) BUC registrations

- **General/Specific/Operational objective:** Measure the registration of business use cases
- **Type of indicator:** Quantitative
    - **Definition:** *Number of registered business use cases*
- **Unit of measurement:** numeric
- **Baseline:** 2025
- **Target:** open

Sub-indicators:

- **Operationalisation of the Business Use Case Registry**
    - a) pilot implementation b) terms of reference and governance in place c) full operation/ production use
- **Adoption site Business Use Case (BUC) readiness**. Adoption site BUC's are considered
    - a) vague b) largely ready with X-Bundle in place c) ready and published, with reference to X-Bundle

[158] Deliverable will be publicly available after approval by European Commission.
[159] Deliverables will be publicly available after approval by European Commission.

    - arithmetic average across all adoption sites
- **BUC User Story (US) completeness**. BUC US's are considered
    - a) vague b) largely complete c) complete and published
    - arithmetic average across all adoption sites
- **Richness of X-Bundles to support BUC adoption.** The X-Bundles accompanying the BUCs are considered
    - a) immature (few or no assets available to support users) b) medium (some assets available to support users) c) rich
    - arithmetic average across all adoption sites

Reporting unit:

- Hub as a whole

Discussion

The registration of business use cases shall be measured by these indicators. The targets for what a good coverage of adoption sites, user stories, application areas and specification ecosystems might be still to be determined.

4.3 Helpdesk Management Indicators

The helpdesk will support partners in the generation of the business use case repository.

4.3.1 Indicator ii-C-01) Helpdesk operationalisation

- **General/Specific/Operational objective:** Measure the level of operationalisation of the helpdesk
- **Type of indicator:** Qualitative
- **Definition:** Operational readiness of the helpdesk; 1-3 scales (low – medium – high), Expert assessment on ordinal scale
- **Unit of measurement:** numeric (ordinal scale)
- **Baseline:** 2025
- **Target:** open

4.3.2 Indicator ii-C-02) Helpdesk activity

- **General/Specific/Operational objective:** Measure the activity of the helpdesk
- **Type of indicator:** Quantitative
- **Definition:** Number of queries handled, and number of queries handled successfully to solve an issue
    - **Unit of measurement:** numeric
- **Baseline:** 2025
- **Target:** open

4.3.3 Indicator ii-C-03) Helpdesk user satisfaction

- **General/Specific/Operational objective:** Measure the satisfaction of users of the helpdesk
- **Type of indicator:** Quantitative
- **Definition:** Average rating by users, satisfaction rating 1-5

  - **Unit of measurement:** numeric (ordinal scale)
- **Baseline:** 2025
- **Target:** average of 4

Discussion

The activity of the helpdesk should be measured by these indicators. The activity and operations of the helpdesk are as yet only vaguely defined, therefore there is still scope for improvement in terms of operationalisation of these indicators.

4.4 Costs of implementing priority data category (or HID) specifications with X-Bundles

4.4.1 Indicator ii-D-01) X-Bundle costs

- **General/Specific/Operational objective:** Measure the cost of adoption sites implementing an X Bundle, including the creation and taking into account the maturity (of the X-Bundle)
- **Type of indicator:** Quantitative – cost
  - **Definition:** Amortized cost of X-Bundles – cost divided by number of adoption sites which have adopted this. Add up costs of adoption sites and cost of initial creation and divide by number of adoption sites.
- **Unit of measurement:** monetary
- **Baseline:** 2025
- **Target:** open

Discussion

We are considering this – depending on the evolution of the implementation acts this section may be subject to change.

Sub-indicators may be considered for priority categories and by architecture ecosystems.

The cost measurement has not been an issue of discussion yet and therefore this indicator should be considered a placeholder for future concretisation. Also, it is heavily dependent on context, maturity and implementation level, so quantifying meaningful values might be challenging.

5. Outlook

This chapter briefly outlines the next steps following the submission of this monitoring framework.

5.1 Data collection in T6.2

This framework will be a basis for two surveys that we will develop in T6.2 — Data collection on EEHRxF adoption and Hub performance. The first will be a large-scale survey of experts from Member States, Competence Centers, SDOs, and industry assessing EEHRxF adoption. The second will refer to Hub monitoring, directed at Hub representatives from WP2.

To contribute to a high survey response rate, we will time the survey to less than 15 minutes and pilot it beforehand via the industry and regulators forum and Xt-EHR. Data collection will take place in two periods (M18 – March 2025; M30 — May 2026), using the same survey and target group to measure progress in uptake.

The survey results will be complemented with expert interviews conducted in parallel with the survey response periods. As per the project key performance indicator (KPI), we aim to conduct around eight interviews in each collection period. This additional qualitative information will help us contextualise survey answers, detect unknown challenges and potentials, and gather input for future monitoring frameworks and surveys. They will also allow us to gather more details that would have been too cumbersome in the survey (such as detailed questions on preferred code systems when querying standards – see 3.1.1)

Representatives of the Hub will reply to the Hub monitoring survey. WP6 lead will carry out a ca. 3-monthly interview with WP2 representatives to assess the Hub performance, to gather some preliminary data in between data collection periods.

In this context, it is important to highlight again that xShare monitors specific units, such as Adoption Sites and the Hub, which are integral components of the xShare project. Additionally, some members of WP6 are involved in either of these project components. This not only requires engaging in bilateral meetings with active experts on the Hub and Adoption sites to refine indicators and their subsequent data but also necessitates monitoring that involves external and self-assessment. Proper allocation and structuring of these elements are crucial for effective monitoring.

5.2 Updated monitoring framework

This first framework iteration exists in a dynamic EEHRxF uptake landscape prone to change soon. Thus, we identified several indicators that are potentially useful only in the second framework iteration, due in M24 (i.e. November 2026).

Fejl! Henvisningskilde ikke fundet. below lists the indicators we consider including in the second iteration monitoring framework.

***Table 6**. Potential Additional Indicators for Updated Framework*

Indicator name	Short description	Rationale for transferring to the updated monitoring framework
EEHRxF Adoption Monitoring Framework		
Adoption of implementing acts queried in all indicators in sub-area 3.1.1	Query whether the Member States are adopting the implementing acts related to certain priority category.	The implementing acts have not been published yet.
Type of data architecture used in EHR systems	Query which type of data architecture Member States use in their EHR systems	xShare is barely initialising work on data architecture. Thus, it is too early to assess this.
MS participation in HealthData@EU	Evaluate whether Member States are actively participating in HealthData@EU.	It is too early to assess this since HealthData@EU is still in the pilot stage.
Scalability of EEHRxF measures in Member State	Evaluate how far the efforts Member States undertake to implement the EEHRxF are scalable.	It is unlikely to detect many measures yet, so it does not make sense to measure scalability.
Readiness of National Institutions for EHDS Implementation	Measure whether the MS has undertaken steps to build the structures required for EHDS.	This may be too far beyond the scope of this monitoring framework.
Use of xShare Yellow button on Market	Measure how far the market is taking up the xShare Yellow Button	Too early to measure this, since the button is not fully implemented yet.
EEHRxF Standards and Policy Hub		
Time to implement X-Bundles	Duration from finalisation of the Bundle to implementation.	It is too early to monitor, given that X-Bundles are still under development.
Size of the community	Size of the community served by the Hub.	It is too early. At this point, we limit our focus to determining

Indicator name	Short description	Rationale for transferring to the updated monitoring framework
		whether key stakeholders are involved.
Training	Number of trainings conducted by the Hub for X-Bundle users.	It is too early. Unclear at this point how the Hub will carry out training.
Multistakeholder visibility	How are decision-makers approached.	Concept is unclear at the moment.
Helpdesk activity and user satisfaction	Indicators ii-C01 and ii-C02 are to be defined once helpdesk activity is imminent.	To be adapted to the planned help desk activity.
X-Bundle costs	Indicator ii-D01 to be defined.	Feasibility of cost measurement is unclear.

6. Conclusions

A solid monitoring framework provides a crucial basis for advancing the EEHRxF within the EHDS – with the xShare Yellow Button and the EEHRxF Standards and Policy Hub as its main driving forces.

Our first iteration of indicators to monitor the EEHRxF uptake in the Member States and the EEHRxF Standards and Policy Hub performance provides an essential first step but is still to be updated. The units of analysis of both frameworks will still change. Consequently, this circumstance represents the most significant limitation of the monitoring framework.

The first framework contains indicators that monitor the (preparation for) EEHRxF uptake as precisely as possible as of 2024. However, it lacks the certainty of EEHRxF specifications to be delivered via the EHDS implementing acts and first outcomes from Xt-EHR.

The EEHRxF Standards and Policy Hub monitoring framework is based on the envisioned operation, as set out in its first annual work plan (D2.1). Nevertheless, more specific monitoring indicators can be developed after the Hub starts in mid-2025.

Thus, we will develop both monitoring frameworks further as xShare and EEHRxF efforts progress. This ongoing work will contribute to a sustainable expansion of the EEHRxF within the EHDS.