Extended EHR@EU Data Space for Primary Use - Xt-EHR Joint Action

Call: EU4H-2022-JA-IBA/Joint Actions 2022, Topic: EU4H-2022-JA-09
Type of Action: EU4H-PJG/EU4H Project Grants, Proposal number: 101128085

D5.1 – Technical Requirements for Electronic Health Record (EHR) systems and key system interfaces

D5.2 – Technical Requirements for European Electronic Health Record Exchange Format (EEHRxF) metadata

Stakeholder Consultation
Briefing Supporting Document

2025, 24 March

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1 Stakeholder Consultation Target Groups

As part of Xt-EHR strategy, selected deliverables will undergo stakeholder consultation. This document intents to engage stakeholders with knowledge on the following topics:

- EHR systems manufacturers (vendors)
- Experts on EHR systems interoperability, security, and logging
- Legal experts (e.g., knowledge in GDPR and EHDS)
- Data and metadata experts
- Data scientists working with primary health data

This work is undergoing within the scope of the European Health Data Space (EHDS) regulation[1], specifically with its Annex II when it comes to the Electronic Health Record (EHR) systems requirements.

2 Overview of Work Package 5

WP5 – *General and security and logging requirements for EHR systems and system interfaces*, focuses on formulating general and technical requirements for EHR systems to ensure secure, interoperable, and efficient exchange of personal electronic health data. It also determines the metadata for structured and unstructured representation of data including common administrative data elements for all types of priority categories of personal health data under the EHDS regulation (Article 14).

More specifically, WP5 aims to provide:

1) Detailed requirements framework designed for EHR systems vendors, healthcare providers, and regulators to achieve compliance with the EHDS regulation. This framework is based on the list of

[1] https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng

essential requirements laid down in Annex II of the EHDS regulation and it details technical, functional, and security requirements for EHR systems and their interfaces.

2) Metadata framework in the context of European Electronic Health Record Exchange Format (EEHRxF) that addresses the basic requirement to align metadata across diverse data exchange scenarios, supporting key objectives: findability, interoperability, access control, reusability, and compliance monitoring.

To achieve these above-mentioned aims, two reports will be developed:

- D5.1 – *Technical Requirements for Electronic Health Record (EHR) systems and key system interfaces*
- D5.2 – *Technical Requirements for European Electronic Health Record Exchange Format (EEHRxF) metadata*

This document focuses on the stakeholder consultation for both D5.1 and D5.2.

3 Overview of Deliverable 5.1 – Technical Requirements for Electronic Health Record (EHR) systems and key systems interfaces

D5.1 – *Technical Requirements for Electronic Health Record (EHR) systems and key system interfaces* lays down the technical, functional, and security requirements for EHR systems and their harmonized components, the "European interoperability software component" and the "European logging software component". It emphasizes compliance with the EEHRxF and provides a list of baseline requirements for vendors on implementing interoperable, secure, and user-focused systems.

The list of requirements stems from the Annex II of the EHDS regulation which lays down the essential requirements for EHR systems and their harmonized components which are divided into three groups:

- **General Requirements** – cover systems performance, access and control rights of natural persons, safety, security and the integrity and instructions for supply, installation, and operational procedures.
- **Interoperability Requirements** – specify the design and technical capabilities needed for the secure exchange and receipt of personal electronic health data, including structured data entry and prevention of undue access or export restrictions.
- **Security and Logging Requirements** – define robust mechanisms for identification and authentication of health professionals, comprehensive logging of access events, and the tools necessary for log review and analysis.

These groups of requirements are accompanied by the cybersecurity requirements and set of recommended technical standards:

- **Cybersecurity Requirements** – provide references to relevant provisions ensuring cybersecurity resilience that are part of other EU legislation such as Regulation (EU) 2024/2847 on horizontal cybersecurity requirements for products with digital elements.
- **Technical Standards** – provide a curated list of recommended technical standards (e.g., HL7 FHIR, DICOM, ISO/IEC 27001) that support and enhance compliance with the EHDS regulation requirements.

The scope of the deliverable mirrors the order of the essential requirements as outlined in the Annex II of the EHDS regulation, and it is structured followingly:

1. General Requirements
   1.1. Performance and Patient Safety
   1.2. Design and Instructions for Supply, Installation, and Operational Integrity
   1.3. Interoperability, Safety and Security Features Upholding Rights of Natural Persons
   1.4. Interoperability and Compatibility with other Products
2. Interoperability Requirements
   2.1. Interface for Access in EEHRxF
   2.2. Capability to Receive Data in EEHRxF
   2.3. Provision of Access to Data in EEHRxF
   2.4. Granularity and Structured Data Entry
   2.5. Prohibition of Access or Sharing Restrictions
   2.6. Prohibition of Expert Restrictions for System Replacement
3. Security and Logging Requirements
   3.1. Identification, Authentication and Authorization of Health Professionals and Other Users
   3.2. Comprehensive Logging of Access Events
   3.3. Tools for Log Review and Analysis
   3.4. Support for Retention Periods and Access Rights
4. Recommended Technical Standards for harmonized Components

Each sub-chapter of the above outlined requirements is structured followingly:

Functional Requirement	Provides description of the required functionality for the EHR system or its harmonized components in line with the relevant part of the Annex II of the EHDS regulation.
Technical Requirements	Outlines selected technical requirements that shall be met in order to ensure the required functionality of the EHR system and/or its harmonized components.
a. Objective	Describes the aim of given technical requirement.
b. Requirements	Describes requirements that are mandated by the EHDS regulation and must be incorporated into EHR systems claiming compliance with the EHDS regulation.
c. Additional Requirements	Outlines requirements that are not directly mandated by the EHDS regulation but were selected by the experts based on the best practices and current state-of-the-art implementation of EHR systems.
Details	Several requirements include more detailed information regarding their aim, content, or functionalities.

4 Overview of Deliverable 5.2 – Technical Requirements for European Electronic Health Record Exchange Format (EEHRxF) metadata

The deliverable outlines a comprehensive metadata framework designed to support the European Electronic Health Record Exchange Format (EEHRxF) for all potential datasets to be used within the EHDS. It aims to facilitate the alignment of metadata across diverse data exchange scenarios, ensuring findability, interoperability, access control, reusability, and compliance monitoring.

Key Objectives

1. **Findability**: Enabling efficient search and retrieval of health data across different systems.
2. **Interoperability**: Ensuring that health data can be seamlessly exchanged and understood across various platforms and jurisdictions.
3. **Access Control**: Implementing robust mechanisms to manage and control access to sensitive health data.
4. **Reusability**: Promoting the reuse of standardized metadata to reduce redundancy and improve efficiency.
5. **Compliance Monitoring**: Facilitating the monitoring and enforcement of regulatory and policy requirements related to health data.

The Metadata Architecture

The metadata framework is structured into three layers.

1. **Business Layer**: High-level concepts and assets independent of specific use cases or technical implementations.
2. **Logical or Semantic Layer**: Structured and technically detailed components, such as logical data models, which define data elements, relationships, and constraints.
3. **Technical or Physical Layer**: Components tied to specific technologies, such as HL7 FHIR profiles, which realize the logical models in practical implementations.

Core Components

Glossary: A collection of business concepts with definitions to ensure consistency across different specifications and use cases.

Data Model: A technology-agnostic logical representation of data, consisting of elements, relationships, and cardinalities.

Data Element: A foundational component of a profile or data model, mapped to a concept in the glossary to ensure consistent naming and definitions.

Profile: A technology-dependent model with additional constraints to ensure data quality and interoperability.

Value Set: A set of possible values for a coded data element, typically a subset of a code system, used to validate data and communicate the aim of a data element.

Implementation and Adoption

The metadata framework is implemented using HL7 FHIR, a widely adopted standard for healthcare interoperability. FHIR provides a robust ecosystem for managing and exchanging healthcare data, including tools for authoring, testing, and validating metadata. The framework supports collaborative authoring, version control, and lifecycle management to ensure the quality and governance of metadata assets.

Governance and Compliance

The framework emphasizes the importance of structured metadata management to achieve effective governance. Key components include clear ownership and stewardship responsibilities, metadata access and discoverability, resource allocation, and continuous improvement through training and awareness programs. The framework also supports compliance with data governance policies, regulations, and industry standards.

By providing a structured and standardized approach to metadata management, the framework supports interoperability, access control, and compliance within the EHDS. The adoption of this framework is expected to enhance the efficiency and effectiveness of health data exchange across Europe.

5 Stakeholder feedback requested for D5.1

To ensure that description of requirements and their mandatory aspects comply with the market standards and EHR system vendors can implement them when EHDS regulation comes into force, WP5 seeks specific feedback from the participants regarding mainly 1) the technical requirements mandated by the EHDS, 2) additional requirements, as well as 3) recommended technical standards for harmonized components of the EHR systems. Therefore, the following areas are the main focus for the stakeholder consultation process:

01 Technical requirements (sub-chapters 1.1 – 3.4)

The document lays down 14 sub-chapters and each of them includes several technical requirements which were identified by the experts participating in the WP5 as necessary to fulfil the functional requirement.

1	Feedback Requested
	• Are there any technical requirements that are essential to fulfil the given functional requirements that are missing? ○ If yes, provide the description of such technical requirement in the following structure: a) its objective, b) description of its mandatory aspects in relation to the Annex II of the EHDS regulation and/or 3) additional requirements that should be implemented. • Are there any technical requirements that 1) are NOT necessary to fulfil the functional requirement, 2) are too excessively described or 3) are misplaced (= should be placed in other sub-chapter)?

02 Requirements mandated by the EHDS (sub-chapters 1.1 – 3.4)

Every technical requirement outlined in the document is composed of requirements mandated by the EHDS regulation (Annex II). EHR system that aims to comply with the EHDS must be designed in line with and to meet these requirements based on the intended purpose and functionalities of such EHR system. Feedback related to these specific requirements that are listed in each chapter under letter "b)" is therefore essential.

2	Feedback Requested
	• Are these requirements clearly and appropriately described? ○ If not, what improvements would you like to propose to increase the clarity and/or the content of the requirement? • Is it feasible to implement given requirement within the process of manufacturing of the EHR system? • Can you detect any aspects of the requirements that would have negative impact on putting the EHR system into service and/or placing it on the market? • Is there any important aspect that is missing?

03 Additional requirements (sub-chapters 1.1 – 3.4)

Most of the technical requirements outlined in the document also include a list of additional requirements. These requirements are not directly mandated by the Annex II of the EHDS regulation but were identified by the experts as important complementarities of the EHR systems that should be included to meet the current interoperability, security and logging standards and ensure intended performance. These additional requirements are listed under the specific technical requirement under letter "c)".

3	Feedback Requested

	• Are these requirements clearly and appropriately described?
	  ○ If not, what improvements would you like to propose to increase the clarity and/or the content of the requirement?
	• Are there any other additional requirements that should be considered?
	• Do you think any of the outlined additional requitements should be removed?
	  ○ If yes, please elaborate the reasoning.

04 Recommended technical standards for harmonized components of the EHR systems

The chapter 4) of the D5.1 presents a curated list of commonly used standards within the EU. Although the EHDS regulation does not explicitly mandate particular standards, their adoption helps ensure that EHR

systems meet the principles of interoperable sharing of health data, technical and semantic interoperability, robust safety and security, and comprehensive auditability.

4	Feedback Requested
	• Is it clearly and appropriately described how these standards ensure the technical and/or semantic interoperability? ○ If not, please provide additional description. • Are there any other standards that are commonly used within the EU and should be added to the list?

6 Stakeholder feedback requested for D5.2

To ensure that the metadata framework described in the deliverable "Technical Requirements for EEHRxF metadata" aligns with market standards and can be effectively implemented by EHR system vendors, we seek specific feedback from stakeholders. This feedback will help refine the document to meet the requirements of the EHDS regulation and support harmonized metadata components across EHR systems. The main focus areas for stakeholder consultation are the following:

01 Metadata Framework Components

The document outlines a metadata framework that includes several key components such as glossaries, data models, value sets, and profiles. These components are essential for ensuring interoperability, access control, and compliance within the EHDS.

1	Feedback Requested

	• Are there any essential metadata components missing from the framework?
	  ○ If yes, please describe the missing components and their importance.
	• Are all the described components relevant and clearly defined for their intended use in EHR systems?
	  ○ If not, which components need further clarification or are not relevant?

02 Implementation and Governance

The metadata framework emphasizes the importance of structured metadata management, including ownership, version control, and lifecycle management. Effective governance ensures the quality and consistency of metadata across different systems and jurisdictions.

2	Feedback Requested
	• Are the proposed governance practices for metadata management feasible and sufficient for ensuring data quality and interoperability?

- If not, what additional practices or modifications would you suggest?
- Do you foresee any challenges in implementing the proposed metadata framework within existing EHR systems?
  - If yes, please describe these challenges and suggest potential solutions.

03 Compliance and Interoperability

The framework aims to support compliance with the EHDS regulation and facilitate interoperability across different healthcare systems. It provides guidelines for metadata standardization and harmonization to ensure consistent data exchange.

3 Feedback Requested

- Does the metadata framework adequately address the compliance requirements outlined in the EHDS regulation?
  - If not, what additional measures or adjustments are needed?
- Will the proposed framework effectively support interoperability between different EHR systems and healthcare providers?
  - If not, what improvements or additional standards should be considered?

7 Contacts for questions

- **For questions related to the organisation of the consultation**: please ask the representative from your country who shared the information and documents on the stakeholder consultation.
- **For questions related to the content of D5.1 and D5.2**: please reach out to the following Xt-EHR WP5 representatives:

  WP5 Leaders
  Vysočina region (**D5.1**): pitrcermak@gmail.com; vanja.pajic@gmail.com; jirakova.k@kr-vysocina.cz
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