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

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# D7.3 Discharge reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems

## Stakeholder Consultation
## Briefing Supporting Document

**2025, 24 July**

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# 1 Introduction

The European Health Data Space (EHDS) Regulation (EU) 2025/327 aims to enhance citizens' access to and control over their electronic health data, while also enabling its secure use for secondary purposes, such as research, policymaking, health crisis response and personalise cared, among other examples. It also intends to strengthen the EU single market by creating a common legal and technical framework for Electronic Health Record (EHR) systems, supporting a resilient European Union.

The Xt-EHR Joint Action contributes to the implementation of the EHDS Regulation by laying the groundwork to support the drafting of the future implementing acts related to the primary use of health data. In this context, Work Package 7 (WP7) focuses on defining the baseline requirements for both the European Electronic Health Record Exchange Format (EEHRxF) and EHR systems that process key categories of personal electronic health data, namely i) medical imaging studies and related imaging reports; ii) medical test results, including laboratory and other diagnostic results and related reports; and ii) discharge reports.

Deliverable 7.3 (D7.3) contributes to this objective by offering a comprehensive implementation guide for discharge reports. It includes the functional and technical requirements for EHR systems regarding the generation, exchange, and use of Discharge Reports (DRs) within the EHDS framework, a logical data model, reference to appropriate international terminologies and standards, and provides alignment with both Article 6 and Article 23 of the EHDS Regulation.

# 2 Purpose of the Stakeholder Consultation

As part of Xt-EHR strategy, selected deliverables will undergo stakeholder consultation.

The purpose of this stakeholder consultation is to gather feedback on the proposed structure, content, and recommendations provided in D7.3. Your input is essential to ensure the guidance is robust, applicable across Member States, and fit for implementation within real-world health information systems.

This document intents to engage stakeholders with knowledge on the following topics:

- EHRs interoperability standards and frameworks;
- Clinical and administrative procedures related to discharge reports;
- Regulatory compliance with the EHDS, GDPR, and eIDAS;
- Cross-border healthcare services and infrastructures, particularly those involved with MyHealth@EU;
- Technical implementation and deployment of health data exchange solutions, including system integration and semantic interoperability.

Therefore, this consultation aims to engage stakeholder such as:

- 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
- Semantic experts
- FHIR experts
- Health professionals
- Data scientists working with primary use of health data

This targeted stakeholder consultation is intended to:

- Validate the **use case and business requirements** defined for exchanging discharge reports in compliance with the EEHRxF;
- Evaluate the **logical data model** developed, including cardinality, data elements, and reuse of models;
- Assess the alignment of D7.3 with the **eHN Guidelines**, existing standards such as HL7 FHIR;
- Gather stakeholder insights on the **practical feasibility of implementation**, including expected benefits and potential challenges;
- Ensure consistency with the broader **EHDS objectives and legal framework**.

## 3 Overview of Work Package 7 – *New services for EHR systems towards EHDS*

WP7 – *New services for EHR systems towards EHDS* focuses on the technical and functional requirements for three critical domains: i) discharge reports, ii) medical test results (including laboratory and other diagnostic-related reports), and iii) medical imaging studies and related imaging reports. For this purpose, WP7 will bring together experts from Member States with the aim of:

- Defining detailed **functional, technical, and semantic requirements** aligned with the EHDS Regulation, particularly Articles 14, 15, 36, and Annex II.

- Develop comprehensive and practical **implementation guides** for seamless interoperability as a baseline for the EEHRxF.
- Support secure and efficient clinical data exchange, significantly enhancing continuity of care across Member States.

Within WP7, Deliverable D7.3 specifically focused on defining the requirements for the interoperable and secure exchange of discharge reports, which play a critical role in continuity of care both nationally and across borders.

Building upon the work from the X-eHealth[1] and xShare[2] projects, as well as the eHealth Network Guidelines on Hospital Discharge Report[3] and MyHealth@EU assets, T7.3 identified key interoperability challenges and reviewed existing European and international initiatives. The resulting D7.3 offers:

- Consolidated **use cases and business requirements** for discharge reports;
- **Logical data model** for discharge reports, including structure, cardinality, data types, and code system preferences;
- Specification of relevant **standards** (HL7 FHIR) and **terminologies** (SNOMED CT, LOINC, ICD, ATC, etc.);
- **Implementation considerations** and other technical recommendations
- Overview of **interoperability components** and alignment with EHDS and the eHN guidelines.

Importantly, all priority categories as defined in Article 14 of the EHDS regulation share common data elements. Therefore, the relevant Xt-EHR Joint Action deliverables setting out the requirements across these domains have been aligned to address these elements collectively, promoting harmonization across domains and ensuring consistency in the implementation of the requirements. As such, all stakeholder consultations impacting these common elements will also be addressed through a collective approach, ensuring coherence and alignment.

# 4 Overview of Deliverable 7.3 – Discharge reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems

Deliverable D7.3 outlines the necessary requirements, standards, and specifications to enable EHR systems to effectively support the creation, exchange, and interoperability of **discharge reports** within the framework of the EEHRxF. D7.3 supports the implementation of the EHDS Regulation by providing detailed technical and functional elements that facilitate both national and cross-border scenarios for discharge reporting.

[1] D5.5 Hospital Discharge Reports Guideline and Functional Specifications: [available here]
D5.5 Hospital Discharge Reports Logical Information Models [available here]
[2] XpanDH Hospital Discharge Report FHIR Implementation Guide [available here]
[3] eHealth Network Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Hospital Discharge Report Release 1.1, November 2024 [available here]

Key aspects include:

- **Purpose and Scope**: The deliverable defines clear, interoperable, and practical requirements for discharge reports, explicitly addressing the needs of both **cross-border** and **national** use cases under the EHDS framework. It aligns with regulatory obligations, including those set out in **Articles 6, 14, 15, 23**, 36 and **Annex II** of the EHDS Regulation.
- **Use Cases**: The document presents representative clinical and administrative scenarios, such as:
  - **Cross-border scenarios**, where a patient receives treatment in another Member State and requires follow-up care upon returning home.
  - **National scenarios**, aimed at improving interoperability and continuity of care between healthcare providers within the same Member State.
- **Gap Analysis**: A systematic analysis of current shortcomings related to semantic alignment, technical standards, metadata harmonisation, regulatory compliance, and the variability of data content across Member States. This includes identifying barriers to standardisation and implementation at scale.
- **Semantic Specifications**: The deliverable promotes the adoption of controlled vocabularies such as **SNOMED CT**, **ICD-10**, and **LOINC**, with clear recommendations for the semantic labelling of key data elements within the discharge report (e.g. diagnoses, procedures, medications, and encounter details).
- **Logical Data Model**: A comprehensive model is proposed to define the structure of discharge reports. This includes data elements, cardinalities, datatypes, and binding to terminology systems. The model aims for reusability and modular design.
- **Technical Specifications**: The report includes concrete technical recommendations, notably:
  - Use of **HL7 FHIR** for data exchange,
  - API-level interoperability guidance and profiles,
  - Secure communication channels (e.g. **TLS**, **VPN**),

- **Logical Models**: Deliverable D7.3 is complemented by a dedicated Logical Information Models for Discharge Reports, available online at: https://build.fhir.org/ig/Xt-EHR/xt-ehr-common/useCaseHospitalDischargeReport.html including the Discharge Report FHIR Implementation Guide, here: https://build.fhir.org/ig/hl7-eu/hdr/
  This guide provides hands-on resources for developers and implementers, including FHIR profiles, value sets, capability statements, and example instances.

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**Further details covered in the deliverable include:**

| | |
|---|---|
| Use Case and Business Requirements | **The discharge report is positioned as a critical clinical document issued at the conclusion of a patient's inpatient care. It encompasses clinical details such as diagnoses, procedures performed, discharge medication, clinical observations, and follow-up recommendations.**<br>**D7.3 defines primary use case**s for the structured exchange **of discharge reports** to enable the right of natural persons to access their personal electronic health data.<br><br>**<u>Core business requirements include:</u>**<br>○ **Supporting clinical decision-making during follow-up;**<br>○ **Enabling structured and automated data import into EHRs;** |

| | |
|---|---|
| | ○ **Promoting semantic consistency via standardised terminologies;**<br>○ **Enhancing patient safety and reducing the risk of information loss.** |
| Logical Data Model | The data model introduced in D7.3 employs a **normalised, modular approach**, allowing the reuse of data components across different domains (e.g., name, address, contact, medication). Each data element is explicitly defined with:<br>○ **Cardinality** (e.g. 0..1, 1..*),<br>○ **Data type** (e.g. code, string, reference),<br>○ **Description**, and<br>○ **Preferred terminology system**.<br>Sections such as patient demographics, diagnoses, interventions, discharge medications, and instructions are individually described. The model aligns with HL7 FHIR and enables consistent implementation across EU contexts. |
| Standards and Terminologies | D7.3 proposes the adoption of well-established health informatics standards and code systems, including:<br>○ **HL7 FHIR** as the principal exchange framework,<br>○ **SNOMED CT GPS** and **ICD-10** for diagnostic concepts,<br>○ **LOINC** for laboratory and observation data,<br>○ **ATC** and **EDQM** for medication classification.<br>The document provides guidance on terminology binding, specifying which controlled vocabularies are recommended or mandatory for each data element. |
| Interoperability and EHDS Alignment | The proposed discharge report structure and exchange mechanisms are mapped to EHDS provisions, particularly:<br>○ Article 14 – Priority categories of personal electronic health data for primary use<br>○ Article 15 – European electronic health record exchange format<br>○ Article 36 – Common specifications<br>○ **Annex II**, which specifies essential requirements for interoperability, performance, security, and logging.<br>Moreover, the specification is designed to ensure **backward compatibility** and **forward scalability** within the MyHealth@EU/eHDSI infrastructure. |

# 5 Stakeholder feedback requested for D7.3

In the context of Deliverable D7.3 — *Discharge Reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems* — stakeholders are invited to provide feedback on the structure, relevance, feasibility, and completeness of the proposed models, use cases, technical standards, and implementation guides. Feedback is particularly important for ensuring that the proposed artefacts can be implemented both nationally and in cross-border scenarios, with minimal ambiguity and maximum alignment with real-world practice.

We welcome input on the following topics:

D7.3 provides relevant definitions that are essential for understanding the structure and objectives of the discharge report specification. It defines the DR, EHR, and the role of semantic and technical specifications (e.g., structured data models, terminologies), though these are mostly contextual rather than listed in a glossary. Key terms include:

- **Discharge Report**: Electronic health data related to a healthcare encounter or episode of care and including essential information about admission, treatment and discharge of a natural person.
- **EHR System**: Any software product used to access or process personal electronic health data as part of health services.
- **EEHRxF**: The Commission Recommendation on a European Electronic Health Record exchange format of 6. February 2019 sets out a framework for the development of a European electronic health record exchange format in order to achieve secure, interoperable, cross-border access to, and exchange of, electronic health data in the Union.
- Terminology and semantic components, such as **SNOMED CT**, **ICD-10**, **LOINC**, **ATC**, and **HL7 FHIR**, are also defined.

### *1. Scope, Terms and Definitions*

**Relevant Sections:**

- "Terms and Definitions" (pp. x–xii)
- "I. Aim of this Document" and "II. Scope and Interdependencies" (pp. xiii–xv)

| 1 | **Feedback Requested** |
|---|---|
| | • Are the definitions of key terms such as DR, EHR system, and EEHRxF clear, complete, and correctly contextualised?<br>• Are there terms that require additional clarification or alignment with national interpretations?<br>• Does the stated scope match real-world clinical and administrative expectations? |

### *2. Methodology and Alignment with existing Frameworks*

- Chapter 2: "Methodology"
- Chapter 3: "Analysis of Existing Guidelines, Specifications and Standards"

| 2 | Feedback Requested |
|---|---|
| | • Are all relevant frameworks (e.g. eHN Guidelines, MyHealth@EU, HL7 FHIR, OpenEHR) appropriately referenced and integrated?<br>• Does the document sufficiently identify and address gaps in current practice? |

### *3. Functional Requirements and Use Cases*

- **Relevant Sections:**
- Chapter 4.1: *Business and Functional Specifications*
  - esp. subchapters 4.1.1 – 4.1.15

| 3 | Feedback Requested |
|---|---|
| | • Are the described use cases (generation, transmission, retrieval, viewing, etc.) comprehensive and aligned with national and cross-border workflows?<br>• Are the functional workflows and statuses realistic and practical?<br>• Are any use cases missing (e.g. secondary use, citizen access, etc.)?<br>• Are the **actors** and roles listed in Chapter 4.1 appropriate and sufficient for the full end-to-end process?<br>• Are there actors missing that should be considered for specific national implementations (e.g., health data intermediaries, national registries)?<br>• Do the actor-role mappings correspond with existing national architectures, and are they easily adaptable? |

### *4. Semantic Specifications and Code Systems*

**Relevant Sections:**

- Chapter 4.2: “Semantic Specifications (Code Systems and Values)”
  (esp. subchapters 4.2.3 and 4.2.6)

| 4 | Feedback Requested |
|---|---|
| | • Are the proposed code systems (ICD-10, SNOMED CT, ATC, LOINC, EDQM, SPOR SMS, Orphacode, etc.) suitable for your national context?<br>• Are any important semantic resources missing?<br>• Are the value sets and binding guidance practical and sufficiently detailed? |

### *5. Technical Requirements and Exchange Protocols*

**Relevant Sections:**

- Chapter 4.3: “Technical Specifications”
  (incl. data exchange, APIs, security, identity management)

| 5 | Feedback Requested |
|---|---|

- Are the technical requirements (e.g. FHIR use, APIs, encryption standards) clear and implementable?
- Are there any concerns with the proposed transport protocols (e.g. VPN, TLS)?
- Does the document adequately address integration with existing national infrastructures?

### *6. Data Models and Dataset Specifications*

**Relevant Sections:**

- Chapter 4.4: “Data Models”
  (subchapters 4.4.1–4.4.6)

| 6 | Feedback Requested |
|---|---|

- Are the logical data models clearly structured and comprehensive?
- Does the dataset cover all necessary data elements?
- Are the datasets and their elements described with sufficient clarity and detail?
  - If any descriptions are vague or unclear, please specify.
- Are the suggested code systems appropriate for these datasets?
- Are there any important code systems that have been omitted?
- Would you recommend additions, changes, or restrictions?
  - Is the proposed logical data model clearly defined, practical, and feasible for use in clinical and administrative settings?
  - Are data elements, their cardinalities, and data types clearly defined and practical?
  - Are all critical clinical and administrative data adequately represented?
  - Is the proposed model easily implementable within your existing healthcare IT infrastructure?
  - Are there additional or redundant data elements identified?
  - For which data elements would you recommend more precise or restricted terminology bindings, and what specific terminology systems or codes would you propose?

- Could structuring the data as proposed introduce any risks?
- Might this approach create additional administrative workload for health professionals?
- Are the search parameters outlined in the metadata suitable for the dataset?
- How would the existence of multiple proposed code systems for a single data element impact implementation in your national context?
- Are there specific advantages or risks associated with allowing more than one coding system per data element?
- Please provide your opinion on whether a single preferred code system should be mandated, or whether multiple options (with prioritisation or fallbacks) should be maintained.
- Do the datasets support both cross-border and national needs?

### *7. Conformity and Implementation Considerations*

**Relevant Sections:**

- Subchapters 4.1.16 (“Conformity Requirements”) and 4.1.15 (“Functional Requirements”)
- Cross-references with WP8 conformity assessment and WP5 general EHR requirements

| 7 | **Feedback Requested** |
|---|---|

- Is the recommended use of HL7 FHIR suitable and practical for your organizational and technical environment?
- Are there any foreseeable challenges with implementing the recommended standards (e.g. FHIR API)? Which version of the FHIR API should be implemented (e.g., R4 or R5)?
- Should additional standards or data exchange protocols be considered?
- What additional narrative guidance would you expect to see in the implementation guide?
- Is the mapping from logical models to FHIR profiles useful?
- Are the following correctly mapped in the IG:
  - preferred code systems,
  - Cardinalities,
  - proposed logical model and data elements,
  - conformity requirements.
- Are the interoperability requirements clear and aligned with EHDS expectations?
- Are there national considerations that require further elaboration to ensure local system integration?

### *8. FHIR Implementation Guide*

**Relevant Reference:**

- External link to the FHIR IG (https://build.fhir.org/ig/Xt-EHR/xt-ehr-common/useCaseHospitalDischargeReport.html)

| 8 | Feedback Requested |
|---|---|

- Are these implementation guides sufficiently detailed, clear, and practical to support real-world deployment?
  - Is the mapping from D7.3 to the FHIR Implementation Guide complete and accurate?
  - Are the included profiles, code bindings, cardinalities, and structure correct?
  - Are additional implementation examples or clarifications needed?
- Are there aspects of implementation that need additional clarification or examples?
- Are there additional tools, resources, or practical recommendations that could further enhance usability and implementation readiness?

## Data Exchange Protocols

Deliverable D7.3 describes detailed technical standards for data capture, storage, and transmission to ensure seamless interoperability.

D7.3 adopts HL7 FHIR as the basis for structuring and transmitting discharge reports. It supports secure communication via TLS, VPN, and existing eHDSI/MyHealth@EU transport services.

The deliverable links directly to the FHIR Implementation Guide (IG): Xt-EHR Discharge Report FHIR IG

| 4 | Feedback Requested |
|---|---|

- Is the recommended use of HL7 FHIR suitable and practical for your organizational and technical environment?
- Are there any foreseeable challenges with implementing the recommended standards (e.g. FHIR API)? Which version of the FHIR API should be implemented (e.g., R4 or R5)?
- Should additional standards or data exchange protocols be considered?

## Interoperability and Integration Requirements

D7.3 maps the discharge report to requirements under the **EHDS Regulation**, specifically Articles 6 and 23 and Annex II. It supports the EEHRxF structure and reuses IPS-aligned content.

# 6 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 D7.3 content**: please reach out to the following Xt-EHR Task 7.3 representatives:
    - T7.3 Leaders (Kraj Vysočina): Vanja Pajić (vanja.pajic@gmail.com), Klara Jirakova (Jirakova.K@kr-vysocina.cz)