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

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D7.1 - Laboratory results and reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems

Stakeholder Consultation
Briefing Supporting Document

2025, August 01st

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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 personalised care, 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 iii) discharge reports.

Deliverable 7.1 (D7.1) contributes to this objective by offering a comprehensive implementation guide for medical test results and test result reports, including laboratory result reports. It includes the functional and technical requirements, as well as specific conformity rules, for EHR systems regarding the generation, exchange, and use within the EHDS framework. It includes a logical data model, references 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 D7.1. 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 medical testing including most of the types of laboratory testing and result reporting;
- 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 stakeholders 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 medical test result reports in compliance with the EEHRxF;
- Evaluate the **logical data model** developed, including cardinality, data elements, and reuse of models;
- Assess general alignment of D7.1 with the **eHN Guidelines** and 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:

- Developing requirements to support the elaboration of the implementing acts under EHDS that establish the requirements and specifications for EEHRxF for medical images and reports, medical test results (including laboratory and other diagnostic-related reports), and discharge reports.

- Developing implementation guides for implementing acts defining common specifications for EHR systems to process the defined data sets.

- Analysing common specifications among these services to ensure alignment and coherence.

Within WP7, Deliverable D7.1 focuses specifically on defining the requirements for the interoperable and secure exchange of medical test results and result reports. Building upon the foundations laid by the X-eHealth project and the eHealth Network (eHN) guidelines and in collaboration with the eHN and eHDSI communities and SDOs, Deliverable D7.1 follows a principle of reusing existing building blocks to build a comprehensive set of technical requirements to support key articles such as 14, 15, 36, and Annex II of the EHDS regulation, with the aim of facilitating the exchange of medical test results and result reports through the EEHRxF.

Relevant terminologies and standards will be described in detail in D7.1, which will be based on widely adopted international standards such as HL7 FHIR, and IHE MHD profile, LOINC, NPU, SNOMED CT and other relevant international code systems.

4 Overview of Deliverable 7.1 – Laboratory results and reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems

Deliverable D7.1 outlines the necessary requirements, standards, and specifications to enable EHR systems to effectively support the creation, exchange, and interoperability of medical test results, including laboratory test results and exchange of related reports within the framework of the EEHRxF. D7.1 supports the implementation of the EHDS Regulation by providing detailed technical and functional elements that facilitate both national and cross-border scenarios for results reporting.

Key aspects include:

- **Purpose and Scope**: The deliverable defines clear, interoperable, and practical requirements for result 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 14,15, 23**, **36** and **Annex II** of the EHDS Regulation as well as **Articles 3, 4, 7, 10, 11, 12 and 13**: on patient rights, health professional access to services, the right to data portability for natural persons, obligations of Member States regarding medical test results, including laboratory and other diagnostic-related reports accessibility and governance.
- **Gap Analysis**: A systematic analysis of current shortcomings related to semantic alignment, technical standards, metadata harmonisation, regulatory compliance, coverage for different types of the laboratory observations (e.g. for microbiology), and non-laboratory medical test results. This includes identifying barriers to standardisation and implementation at scale.
- **Use Cases**: The document presents basic scenarios covering the main phases of the result report lifecycle, such as:

  - Creation of the report
  - Sending/providing report
  - Storing (persisting) report and its content
  - Searching/querying and receiving a report
  - Using a report and its content
- **Semantic Specifications**: The deliverable promotes the adoption of controlled vocabularies such as **SNOMED CT**, **ICD-10**, **NPU**, **LOINC and HL7**. The selection of coding systems follows the recommendations contained in the related eHealth network guidelines endorsed by Member States as well as the interoperability requirements related to the HL7 FHIR standard.
- **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**: A comprehensive model is proposed to define the structure of laboratory result reports. This includes data elements, cardinalities, datatypes, and binding to terminology systems. The model aims for reusability and modular design. The model is also available online at: https://build.fhir.org/ig/Xt-EHR/xt-ehr-common/useCaseLabReport.html
- **Laboratory Report FHIR Implementation Guide**: https://build.fhir.org/ig/hl7-eu/laboratory. This guide provides hands-on resources for developers and implementers, including FHIR profiles, value sets, capability statements, and example instances. The model and FHIR IG will be continuously refined and supplemented with other specific areas of laboratory medicine (e.g. for microbiology) based on the consensus of experts from clinical disciplines and feedback from ongoing pilot implementations in European countries. The basic building blocks of the model are applicable not only to laboratory reports, but also to other types of reports containing medical test results, such as discharge summaries, patient summaries, etc., and in all types of EHR systems processing medical test results.

5 Stakeholder feedback requested for D7.1

To ensure D7.1 is complete and aligned with the stakeholder needs, WP7 seeks **specific feedback**. Therefore, the following areas are the main focus for the stakeholder consultation process:

1. Scope, Terms and Definitions

The document presents different definitions that were summarised for the use of this document. The main sources used for the definitions were the proposed EHDS regulation, eHN guidelines and MyHealth@EU. Other sources were used when available to complement missing definitions.

1	Feedback Requested
	• Are the definitions clearly and appropriately described for the context of this document? • Are there terms that require additional clarification or alignment with national interpretations? • Does the stated scope match real-world clinical and administrative expectations?

2. Methodology and Alignment with existing Framework

- 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? • 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*
- Chapter 4.1.1: *Business Requirements for EHR systems*
- Chapter 4.1.2: *Common actors*
- Chapters 4.1.5 – 4.1.9 (Use case generation, transmission, storage, retrieval, and viewing)

3	Feedback Requested
	• Are the described use cases (generation, transmission, retrieval, viewing, etc.) comprehensive and aligned with national and cross-border workflows? • Are the functional workflows and statuses realistic and practical? • Are any use cases relevant for European interoperability missing? • Are the actors and roles listed in Chapter 4.1.2 appropriate and sufficient for the full end-to-end process? • Are functional and conformity requirements correct and clearly stated?

4. Semantic Specifications and Code Systems

Relevant Sections:

- Chapter 4.2: “Semantic Specifications (Code Systems and Values)”
  (esp. subchapters 4.2.3 and 4.2.4)

4	Feedback Requested
	• Is the differentiation of laboratory test results and medical test results described in chapter 4.2.1 clear and sufficiently covered?

- Are the proposed code systems (SNOMED CT, LOINC, NPU, etc.) suitable for your national context?
- Use of different code systems in Europe for laboratory test coding represents an interoperability challenge. Which of the solutions below would you prefer? Please provide a reason for your choice.
  1. Use of just one code system:
     - LOINC
     - NPU
     - SNOMED CT
  2. Use multiple code systems and accept English designations
  3. Use multiple code systems and accept the need for full language localisation
  4. Do something else, please describe.
- Are there any critical semantic resources or aspects missing?
- Are the value sets and binding guidance included in the Xt-EHR logical model and FHIR IG practical and sufficiently detailed?
- What measures should be taken on the EU level to maintain EEHRxF, value sets and other semantic assets necessary to ensure EU-wide interoperability of medical result reports?

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?
- Would it be a challenge to meet the stated technical requirements in your national infrastructure?
- Are there any concerns with the proposed transport protocols (e.g. VPN, TLS)?

6. Data Models and Dataset Specifications

Deliverable D7.1 provides a comprehensive logical data model to standardise the content and structure of medical result reports. It outlines data elements, including patient demographics, specimen information, supporting clinical details (diagnoses, procedures, medications), medical test results including interpretations and standard ranges, overall interpretation of the findings, recommendations and technical notes, presented

form of the report, optional attachments, and administrative data (document id, author identification, dates, report status, etc.).

Data model features:

1. Definitions of mandatory and optional data elements.
2. Cardinality (the allowed number of occurrences of data elements).
3. Specification of data types (e.g., coded elements, numeric values, date-time).
4. Preferred code systems (SNOMED CT, LOINC, NPU, UCUM, HL7 codes).

Relevant Sections:

- Chapter 4.4: “Data Models”

6 Feedback Requested

- Are the logical data models well-structured and comprehensive?
- Does the dataset cover all necessary data elements?
- Would you appreciate a specific model for exchange of the microbiology observation?

7. Functional and Data Level Conformity Requirements

Deliverable D7.1 formulates functional requirements and conformity requirements per use case as well as data level conformity requirements for different level of EHR system maturity. Functional requirements can be seen as recommendations for best practice while conformity requirements represent obligations that SHALL/SHOULD/MAY be implemented by conformant EHR systems.

Relevant Sections:

- Subchapters 4.1.5.6, 4.1.5.7, 4.1.6.2, 4.1.6.3, 4.1.7.2, 4.1.8.2, 4.1.8.3
- Subchapters 4.4.3.1 (“Document-level Conformity Requirements”) and 4.4.3.2 (“Data element-level conformity requirements”)

7 Feedback Requested

- Are the interoperability requirements clear and aligned with EHDS expectations?
- Are maturity levels, obligations and other components of the conformance model clear?

8. FHIR Implementation Guide

Relevant Reference:

- External link to the FHIR IG (https://build.fhir.org/ig/hl7-eu/laboratory/)

8	Feedback Requested

- Are these implementation guides sufficiently detailed, clear, and practical to support real-world deployment?
  - Is the mapping from D7.1 to the FHIR Implementation Guide complete and accurate?
  - Are the included profiles, code bindings, cardinalities, and structure correct?
- 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 (we know that they are not yet fully implemented in the IG)?
- 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?

9. Overall impression

Intention of the T7.1 was to prepare conscious document that would have logical structure, be easy to read and include key information that would serve as a basis for development of the EHDS Implementation act. We'd like to ask consulting parties to express their overall impression on it.

9	Feedback Requested

- Is information in the document structured meaningfully and logically?
- Do you miss any important information?
- Are there redundant parts that can be omitted?
- What are your key recommendations to improve content quality and readability?

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 D7.1 content**: please reach out to the following Xt-EHR WP7 representatives:
  - WP7 T7.1 Leaders (Kraj vysočina): Hynek Kružík (hynek.kruzik@mzd.gov.cz), Klára Jiráková (Jirakova.K@kr-vysocina.cz)