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

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D7.2 - Medical imaging studies and reports: implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems

Stakeholder Consultation
Briefing Supporting Document

2025, September 4th

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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 7.2 (D7.2) contributes to this objective by providing a comprehensive implementation guide for medical imaging studies and imaging reports. It sets out the functional and technical requirements for EHR systems to ensure the availability, exchange, and use of this information within the EHDS framework. It includes a logical data model, references to appropriate international terminologies and standards, and provides alignment with both Article 6, 23 and 36 of the EHDS Regulation.

2 Purpose of the Stakeholder Consultation Target Groups

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 D7.2. 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 intends to engage stakeholders with knowledge on the following topics:

- EHRs interoperability standards and frameworks;
- Clinical and administrative procedures related to medical imaging studies and related imaging 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 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
- HL7 FHIR experts
- IHE profiles 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 imaging studies and imaging reports in compliance with the EEHRxF;
- Evaluate the **logical data model** developed, including cardinality, data elements, and reuse of models;
- Assess general alignment of D7.2 with the **eHN Guidelines** and existing standards such as DICOM, HL7 FHIR, IHE profiles;
- 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 D7.2 focuses specifically on defining the requirements for the interoperable and secure exchange of medical imaging studies and medical imaging reports. Building upon the foundations laid down by the X-eHealth project and the eHealth Network (eHN) guidelines and in collaboration with the eHN and eHDSI communities and SDOs, Deliverable D7.2 follows a principle of reusing existing building blocks to build a comprehensive set of technical requirements to support key articles such as 3-15, 36, and Annex II of the EHDS regulation, with the aim of facilitating the exchange of medical imaging studies and imaging reports through the EEHRxF.
Bringing together experts from various Member States and working in close collaboration with Standards Development Organisations (SDOs), Deliverable D7.2 presents a sustainable framework designed to meet the functional requirements of the EHDS.

D7.2 provides guidance on which relevant widely adopted international standards to use, such as HL7 FHIR, DICOM, IHE Integration profiles, LOINC, SNOMED CT and other international code systems to facilitate interoperability.

4 Overview of Deliverable 7.2 – Medical imaging studies and reports: implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems

D7.2 – *Medical imaging studies and reports: implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems* aims to outline the necessary requirements, standards, and specifications to enable EHR systems to effectively support the making available and exchange of medical imaging studies and reports within the framework of the EEHRxF. By applying commonly agreed on specifications including recommended standards and terminologies the interoperability component will be supported.

D7.2 supports the implementation of the EHDS Regulation by providing detailed technical and functional elements that facilitate both national and cross-border scenarios.

Key aspects include:

- **Purpose and Scope**: The deliverable defines clear, interoperable, and practical requirements for sharing medical imaging studies and 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 medical imaging studies and medical imaging reports accessibility and governance.

- **Analysis of existing guidelines for sharing imaging studies and reports, including Gap Analysis**: A systematic analysis of current guidelines such as the eHealth Network Guidelines and MyHealth@EU specifications. The gap analysis identifies shortcomings related to semantic alignment, technical standards, metadata harmonisation, regulatory compliance. This includes identifying barriers to standardisation and implementation at scale.
- **Use Cases**: The document presents basic scenarios covering the sharing of imaging studies and their related reports, including:
    - Description of functional (business) and technical system actors
    - Sharing a medical imaging study and/or related imaging report in a non-critical situation
    - Sharing a medical imaging study and/or related imaging report in a critical situation
    - Patient Access – Viewing and Downloading medical imaging study and/or related imaging report
    - Patient Access – Sharing and Uploading a medical imaging study and/or report
- **Semantic Specifications**: The deliverable promotes the adoption of controlled vocabularies such as **SNOMED CT**, **ICD-10**, **NPU and LOINC**. 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 international HL7 FHIR standard and IHE Integration Profiles.
- **Technical Specifications**: The report includes concrete technical recommendations, notably:
    - Use of generic transactions for querying and retrieving of imaging studies, related reports and imaging study manifests, supporting interoperability between different EHR- systems and the NCPeH.
    - Recommended IHE-Profiles for the transactions
    - Initiation of new IHE Profile ‘Manifest-Based Access to DICOM’ or ‘MADO’. Purpose: to allow document consumer systems to use the imaging study manifest information to retrieve DICOM images, supporting DICOM KOS and FGIR Imaging Study. This draft profile is open for public comments. (link will be shared around 24th of September 2025)
    - Use of HL7 FHIR for data exchange
    - API-level interoperability guidance and profiles
- **Logical Models**: A comprehensive model is proposed to define the structure of imaging 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: Imaging report model - EHDS Logical Information Models v0.1.0
- **Imaging Study Report FHIR Implementation Guide**: Home - HL7 Europe Imaging Study Report v0.1.0-build.

  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 imaging such as Manifest data, 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 imaging reports, but also to other types of reports containing medical imaging information, such as discharge summaries, patient summaries, etc., and in all types of EHR systems processing medical imaging studies and/or reports.

5 Stakeholder feedback requested for D7.2

To ensure D7.2 is complete and aligned with the stakeholder needs, WP7 seeks **specific feedback**. Therefore, for each section the following questions are the main focus for the stakeholder consultation process:

01 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? • What improvements would you like to propose? • Does the stated scope match real-world clinical expectations?

02 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?

03 Functional requirements and use cases

In section 4.1 the functional requirements are described, including:

- 4.1.2 *Role of IHE profiles and HL7 standards*
- 4.1.3 *Common actors*
- 4.1.4 *Use case descriptions and real life examples*
- 4.1.5 *Search and filtering parameters*

- 4.1.6 *Imaging study manifest*

The current structure of eHealth Network guidelines, HL7 standards and IHE profiles provide a baseline for the functional and technical requirements. The section contains a brief explanation of the purpose, relevance, situation, context, main participants, information flow, and functional process steps.

3	Feedback Requested
	• Are these use cases feasible and suitable for implementation? • How can the use cases be refined/improved? • Functional Process steps: ○ Are the functional process steps for each use case clear and logically sequenced? • Should additional scenarios or improvements be considered? If so, please provide examples and a corresponding justification. • Do you see a need to add other examples of patient journeys, and if yes, please provide.

04 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
	• Are the value sets and binding guidance included in the Xt-EHR logical model and FHIR IG practical and sufficiently detailed? • Is the binding guidance on value sets and other semantic assets sufficient to ensure EU-wide interoperability of medical imaging studies and reports?

05 Technical Requirements and exchange protocols

Chapter 4.3: "Technical Specifications" includes descriptions of the recommended transactions for query and retrieve of available imaging studies and reports via IHE profiles, manifest data exchange, search parameters, APIs, identity management.

5	Feedback Requested
	• Are there any concerns with the proposed actors and transactions to cover the various architectural deployments (cross-border, national, regional, intra-provider) • Are the technical requirements (e.g. IHE MHD profile for querying and retrieving, search parameters, role of Imaging Study Manifest) clear? • Would it be a challenge to meet the stated technical requirements in your national infrastructure?

- Would it be a challenge to meet the stated technical requirements in the various EHR systems involved in imaging (Medical Record, PACS, RIS, VNA)?

06 Data Models and Dataset Specifications

Deliverable D7.2 provides a comprehensive logical data model to standardise the content and structure of medical imaging reports. It outlines data elements, including patient demographics, metadata information (documentID, document format, Study Instance UID, Accession number and more), supporting clinical details (diagnoses, procedures, medications), overall interpretation of the findings, recommendations.

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?

07 FHIR Implementation Guide

Relevant Reference:
External link to the FHIR IG (Home - HL7 Europe Imaging Study Report v0.1.0-build)

7 Feedback Requested

- Are these implementation guides sufficiently detailed, clear, and practical to support real-world deployment?
  - Is the mapping from D7.2 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?

08 Overall impression

Intention of the T7.2 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.

8	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 D7.2 content**: please reach out to the following Xt-EHR WP7 representatives:

  WP7 T7.2 Leaders (Nictiz and University of Cyprus) Esther Peelen (esther.peelen@nictiz.nl) and Costas Pattichis (pattichis.costas@ucy.ac.cy)