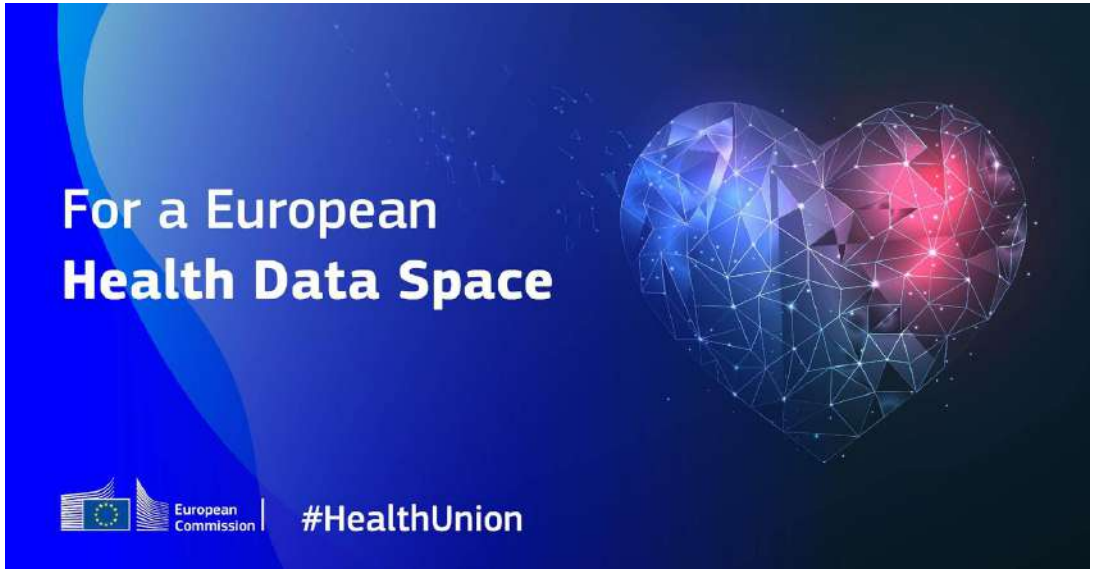
IHE® EUROPE EXPERIENCE DAYS

VIENNA 2025

24-25 JUNE

EU-projects to support the EHDS



Xt EHR @dataspace

Funded by the European Union

Klara, Session Moderator

Andreas, Xt-EHR Project Coordinator

WP5 – general requirements

Vanja

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EHR @dataspace

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WP6 – electronic prescriptions & PS
Rutt Lindström, TEHIK (Estonia)

WP7 – new use cases

Esther Peelen, Nictiz, TL Medical

Imaging Studies & Reports

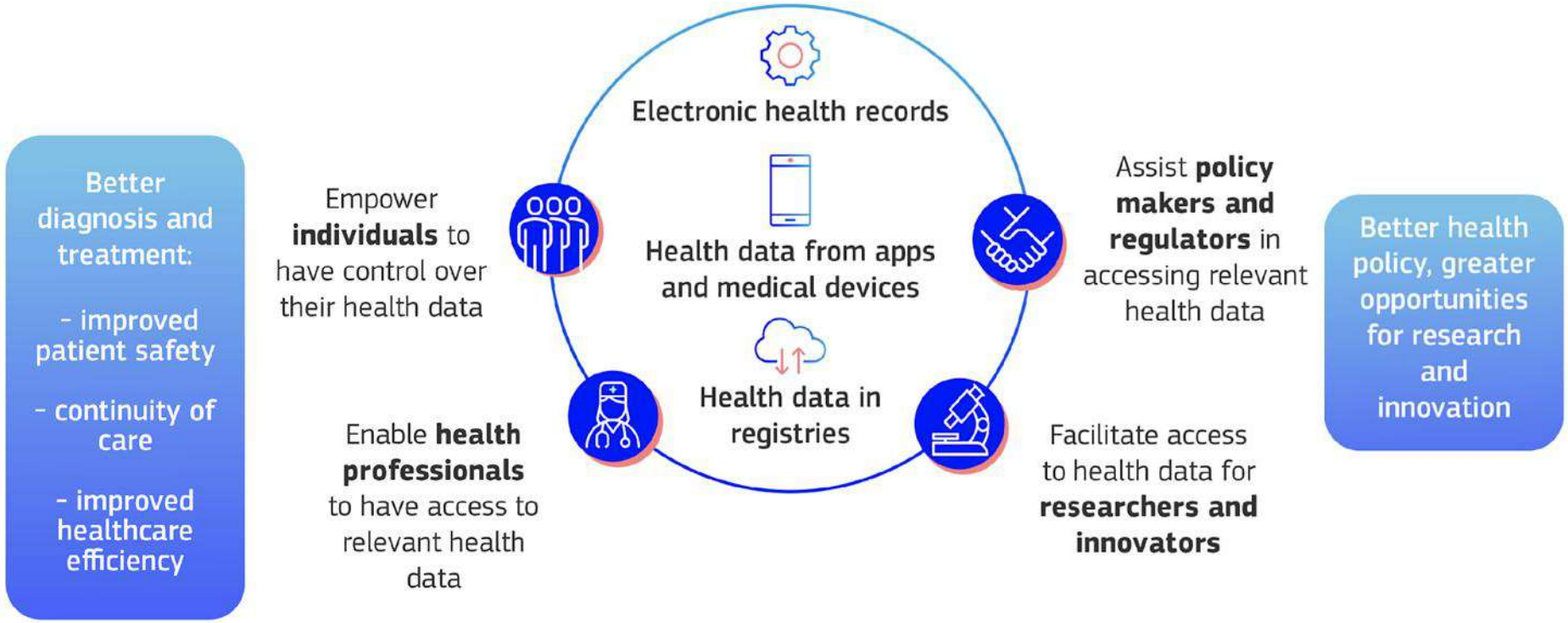
WP8 – Certification & Labeling

Framework
Harry

Funded by the European Union

Industry perspective, Verena

EHDS - Creating a common European Health Data Space



Work Package 5 - General requirements for EHRs and system interfaces

T5.1 General, interoperability, security and logging requirements for EHR systems

Develop requirements for implementing standardised EHR systems in the EU

T5.2 EHR data input and output requirements for algorithm-based clinical decision support (primary use of data)

Identify challenges regarding the data and metadata structures and requirements for communication interfaces between EHR systems and algorithm-based tools.

T5.3 Requirements for identification and authentication processes across Europe

Addresses patient identification and define patient identifiers in cross-border exchange

T5.4 Metadata standards for the EEHRxF

Define metadata to classify and identify information across domains

Define implementation guide with metadata standards for clinical documentation

D5.1 Technical Requirements for EHR systems and key system interfaces

Aim of D5.1: *Ensure the secure, interoperable, and efficient exchange of personal electronic health data in the European Electornic Health Record Exchange Format (EEHRxF)*

by outlining: 1) General, 2) Interoperability, 3) Security and Logging Requirements for Electronic Health Record (EHR) Systems

Scope (of the requirements)

- Requirements cover only two harmonized components of EHR systems
  - **European Interoperability Software Component**
  - **European Logging Software Component**

- Each EHR system that process priority categories of personal electronic health data (Art. 14 EHDS) FALLS in the scope and WILL HAVE TO implement requirements to be in line with EHDS
  - E. g.: *systems intended to be placed on market, SaaS licensing systems, in-house systems*
- Relevance of requirements depend on the intended purpose of the EHR system

Purpose of the deliverable

1) Provide Guidance for Implementation, 2) Ensure Compliance, 3) Facilitate Interoperability

Main Target Group: EHR systems manufacturers and experts

EHDS Regulation

- Provides list of essential requirements for EHR systems = ANNEX II of the EHDS

Deliverable 5.1 lays down detailed technical (normative as well as non-normative) requirments

EHDS Annex II – structure

- General Requirements - *system performance, patient rights, safety, security and integrity, instructions for supply, installation, and operational procedures*
- Interoperability Requirements - *design and technical capabilities needed for the secure exchange and receipt of personal electronic health data*
- Security and Logging Requirements - *mechanisms for identification and authentication of health professionals, logging of access events, and the tools for log review and analysis*

D5.1 – General Requirements

General requirements lays down the foundation for every harmonised EHR component:

1. Performance and Patient Safety
   - *States the performance and patient-safety threshold the software must meet in clinical use*
2. Design and Instructions for Supply, Installation, and Operational Integrity
   - *Describes, how it must be packaged, installed and updated without degrading that threshold*
3. Interoperability, Safety and Security Features Upholding Rights of Natural Persons
   - *Turns the duty to respect rights of natural persons into concrete interoperability, safety and security controls*
4. Interoperability and Compatibility with other Products
   - *Ensure that same guarantees apply when the component exchanges data with external devices or apps*

D5.1 - Interoperability Requirements

Interoperability requirements section translate the interoperability duties into concrete software behaviour and is composed of following chapters:

1. Interface for Access in EEHRxF
   - *Details the outward API through which data are exposed in EEHRxF*
2. Capability to Receive Data in EEHRxF
   - *Details inbound channel for receiving that same format*
3. Provision of Access to Data in EEHRxF
   - *Specifies two-way access node that must both ingest and re-serve data*
4. Granularity and Structured Data Entry
   - *Outlines rules for entering structured information at a granularity that can be exported loss-free*
5. Prohibition of Access or Sharing Restrictions
   - *Details obligations preventing placing barriers or restriction on data use and sharing*
6. Prohibition of Export Restrictions for System Replacement
   - *Specifies rules preventing restrictions or undue burden on data export*

D5.1 - Security and Logging Requirements

Security and Logging requirements define mechanisms for identification and authentication, logging of access events, tools for log review and analysis:

1. Identification, Authentication and Authorization
   - *Outlines rules for secure electronic identification for both health professionals and other users*
2. Comprehensive Logging of Access Events
   - *Details rules ensuring that every instance of access to patient data is logged, traceable, and auditable*
3. Tools for Log Review and Analysis
   - *Specifies rules ensuring that log data is not merely stored but actively utilized for auditing, anomaly detection, compliance verification, and regulatory reporting*
4. Support for Retention Periods and Access Rights
   - *Defines retention and access policies*

D5.1 – Annex 1: European Interoperability Software Component

Annex 1 provides illustrative technical guidance for implementing the European interoperability software component of EHR systems:

Relevant areas / component functionalities covered:

- Searching and retrieving priority data categories
- API-based data exchange within and across healthcare provider domains, at national and cross-border levels
- Application of standards like HL7 FHIR or IHE XDS/MHD
- Mapping actors and transactions for interoperability scenarios, using diagrams and example use cases

D5.1 – Annex 2: Scrutiny Testing Requirements for Harmonised Components

Annex 2 outlines testing and validation approaches that can be used to demonstrate compliance with the technical requirements of harmonised components :

Key elements include:

- Test scenarios for accessing and retrieving personal electronic health data
- Functional overviews of FHIR-based transactions as defined in the IHE MHD profile
- Detailed mappings of:
  - Roles (e.g. Document Consumer/Responder)
  - Required parameters (e.g. Patient ID, Document Category)
  - Technical constraints

Work Package 6 - Electronic prescriptions and patient summary towards EHDS

Lead: Italy
Co-lead: Sweden

D6.1 – Patient Summary:
Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems

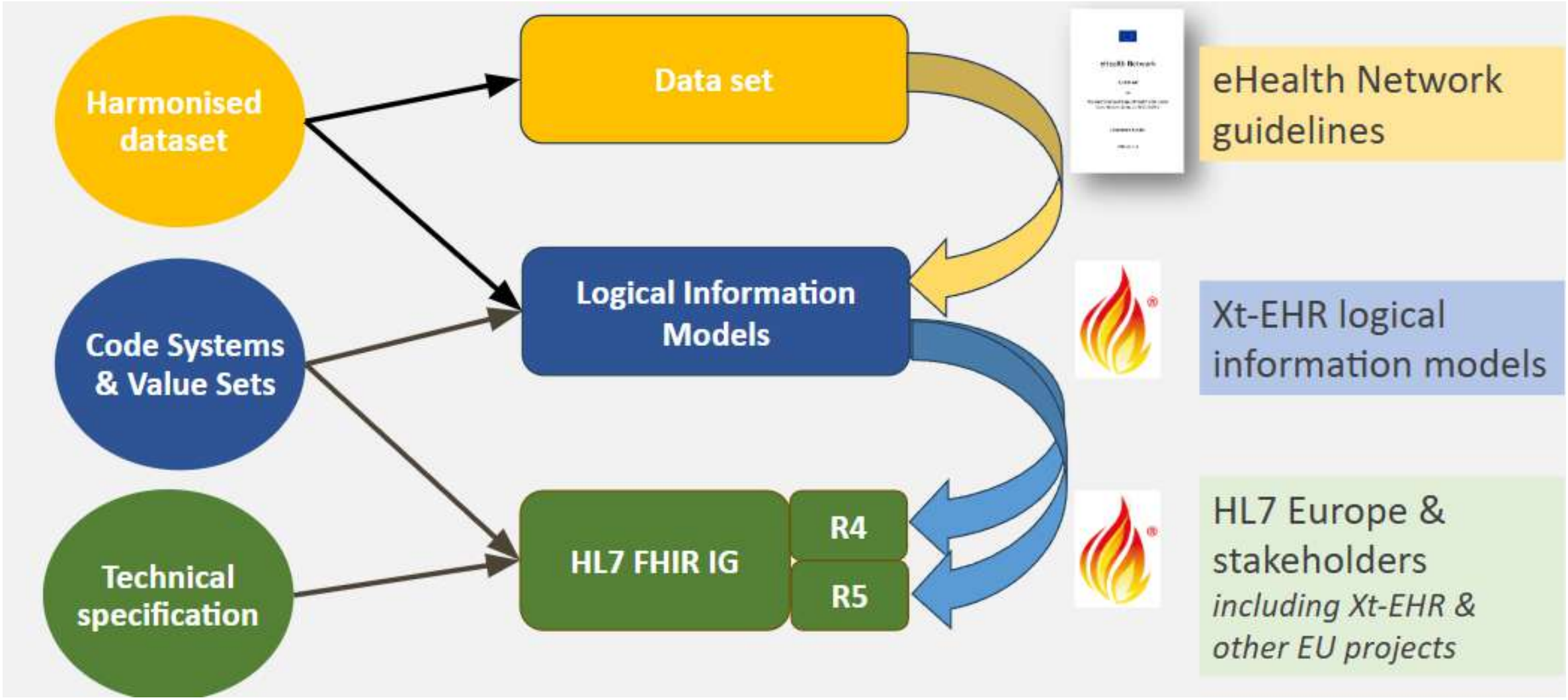
Stakeholder consultations:
14.07.2025-15.09.2025

Lead: Sweden
Co-lead: Italy

D6.2 – Electronic prescription and electronic dispensation:
Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems

Stakeholder consultations:
15.06.2025-15.09.2025

A new leg of a long journey!


Harmonised dataset
Code Systems & Value Sets
Technical specification
Data set
Logical Information Models
HL7 FHIR IG
R4
R5
eHealth Network guidelines
Xt-EHR logical information models
HL7 Europe & stakeholders
including Xt-EHR & other EU projects

Scope of D6.2 ePrescription and eDispensation

- **Prescription** for
- a medicinal product
- issued by a health professional
- for a patient
- to be dispensed by a pharmacy.

Dispense of

- a medicinal product
- by a pharmacy,
- including online pharmacy,
- to a natural person
- based on a prescription.

Declining a dispense

Scope of D6.1 Patient Summary

- Alignment with ISO/HL7 FHIR International Patient Summary
- Survey on the implementation of PS by EU member states
- Large overlap with reports: common models
- Patient Summary as a document but also as individual sections

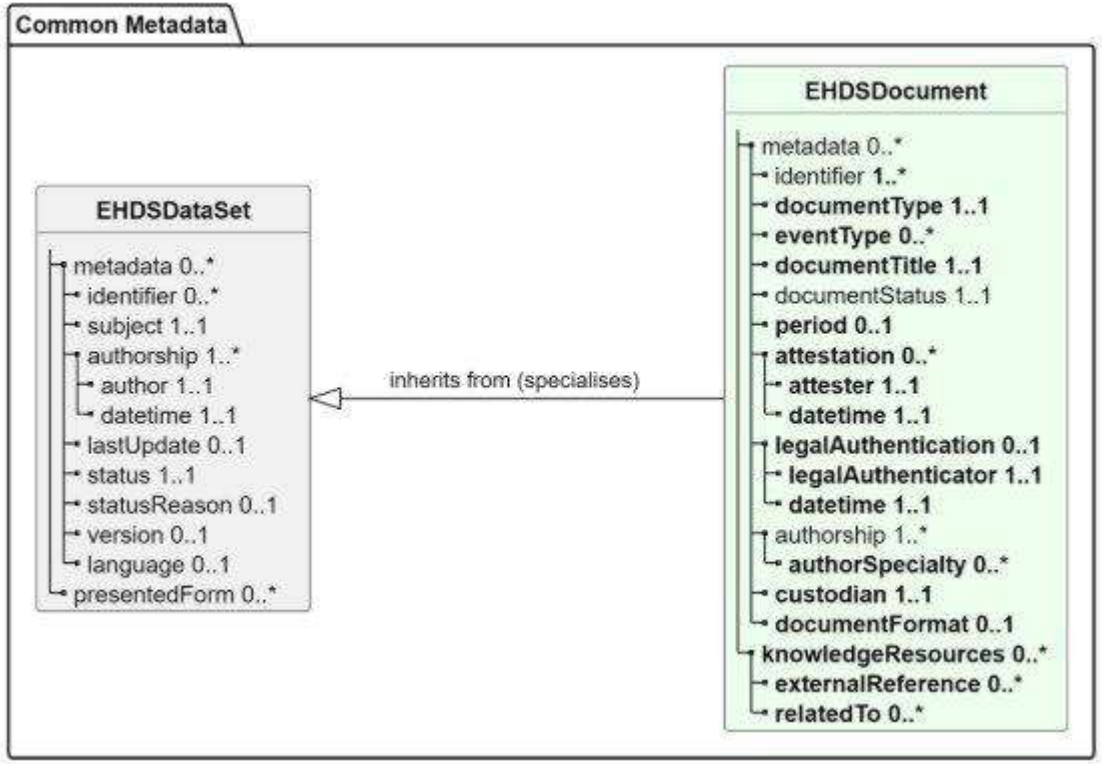
EHDS Recital 25: *Where such priority categories of data represent groups of electronic health data, this Regulation should apply to both the groups as a whole and to the individual data entries included in those groups.*

Common metadata, but not everything is a document

ePrescription

eDispensation

Patient Summary parts:
EHDSCondition,
EHDSProcedure,
EHDSDeviceUse,
etc



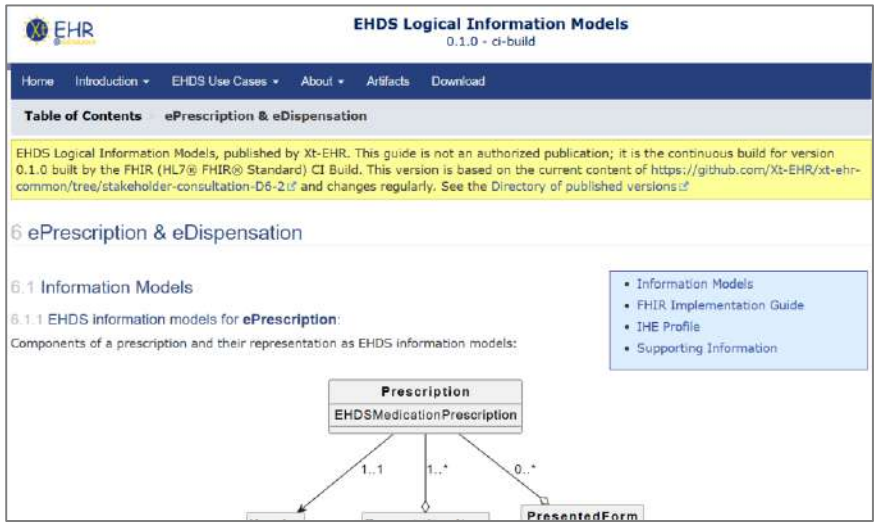
Patient Summary

Discharge Report

Medical Test Result Report

Medical Imaging Report

The Deliverable:



Use cases,
background information,
terminology considerations,
data sets,
description of IGs

Computable logical models,
aiming to keep consistency
across different data categories

FHIR profiles,
implementation recommendations,
mappings from models to FHIR,
R4 and R5 versions when available

EHDS Logical models (Xt-EHR)

HL7 Europe FHIR IG

Global IGs:
IHE MPD for eP/eD
HL7/ISO Patient Summary

EU requirements

Global requirements

R4

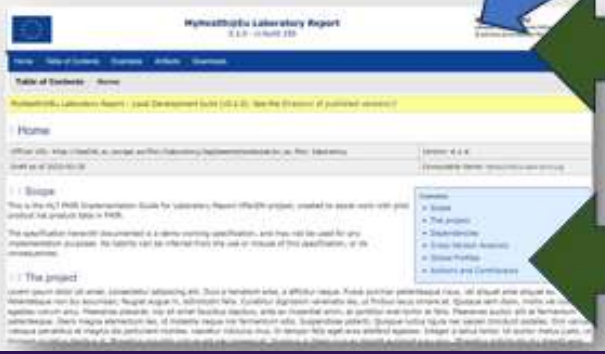
R5

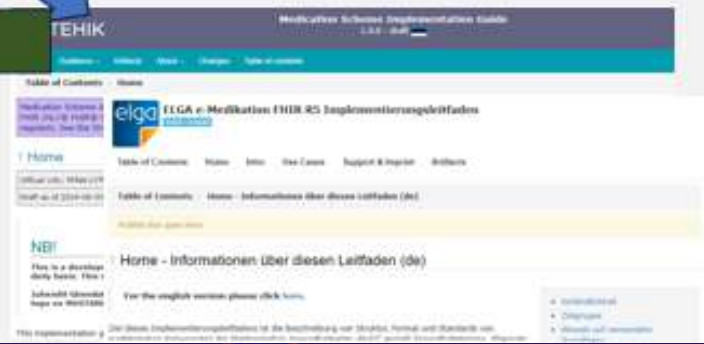
MyHealth@EU crossborder specification

National Specifications

Transform

Transform





Xt-EHR Stakeholders consultation D6.2

June 15 – September 15

- Deliverable D6.2 (Document)
- EHDS logical models
- HL7 Europe FHIR IG

HL7 Europe ballot June 15 - August 31

Xt-EHR Stakeholders consultation D6.1

July 14 – September 15

- Deliverable D6.1 (Document)
- EHDS logical models
- HL7 Europe FHIR IG - probably early draft

Work Package 7 - New services for EHR systems towards EHDS – Lead: PT

Lead: CZ

Lead: NL/CY

Lead: CZ

Content

- Purpose and scope,
  determined by MS/HCP needs
- Addresses the 2011 Directive on patient rights in crossborder healthcare
- Use case description
- Considers semantic and technical specifications
- Dataset

- To deliver the Implementation Guides for EHR-systems
- Building the EEHRxF
- Interoperability

Content of Implementation Guides for EHR-systems

- Introduction
- Use cases
- References to EHDS articles, Annex II
- Logical Information Model
- EU FHIR Implementation Guide
- Technical specifications when applicable

Cooperation with SDO's to support the Implementation Guides for EHR-systems

HL7 Europe

IHE EUROPE

Stakeholder consultation

WP/ Number of Deliverable	Deliverable Name	**Stakeholder consultation phase -> tentative date** for when deliverable is shared for comments - deadline to provide comments
WP7/ D7.1	Medical test results, including laboratory and other diagnostic results and related reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	01.09.2025 - 13.10.2025
WP7/ D7.2	Medical imaging studies and related imaging reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	30.09.2025 - 11.11.2025
WP7/ D7.3	Discharge reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	31.07.2025 - 11.09.2025

Work Package 8 - Certification and labelling framework

Background information

MedTech Europe
from diagnosis to cure

MedTech Europe is the European trade association for the **medical technology industry including diagnostics, medical devices and digital health**. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

XpanDH industry x-net recommendations available online

Industry x-Net recommendations

Use-Case-Driven Guidance

Interpreting requirements across diverse digital health product categories.

Scaling Testing Frameworks

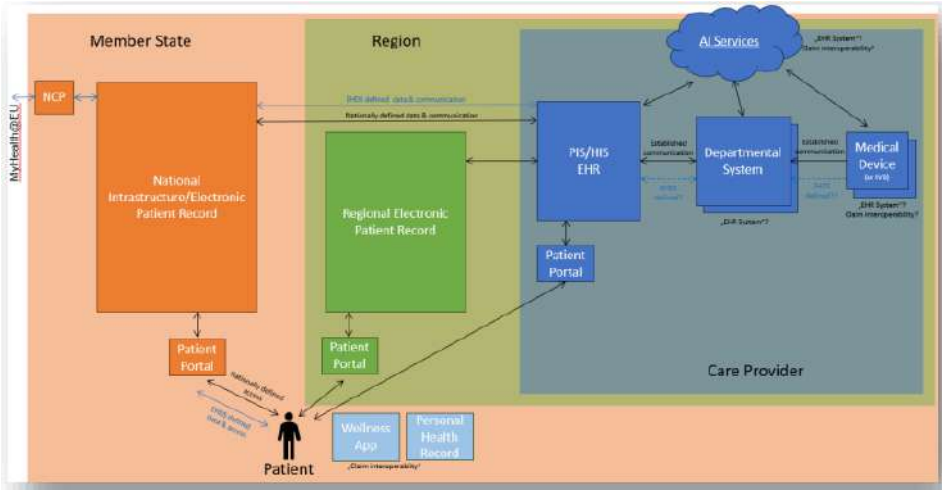
Ensuring EHDS interoperability for large-scale implementation.

Simplified Interoperability Architecture

Emphasizing the separation of exchanged content and transport transactions.

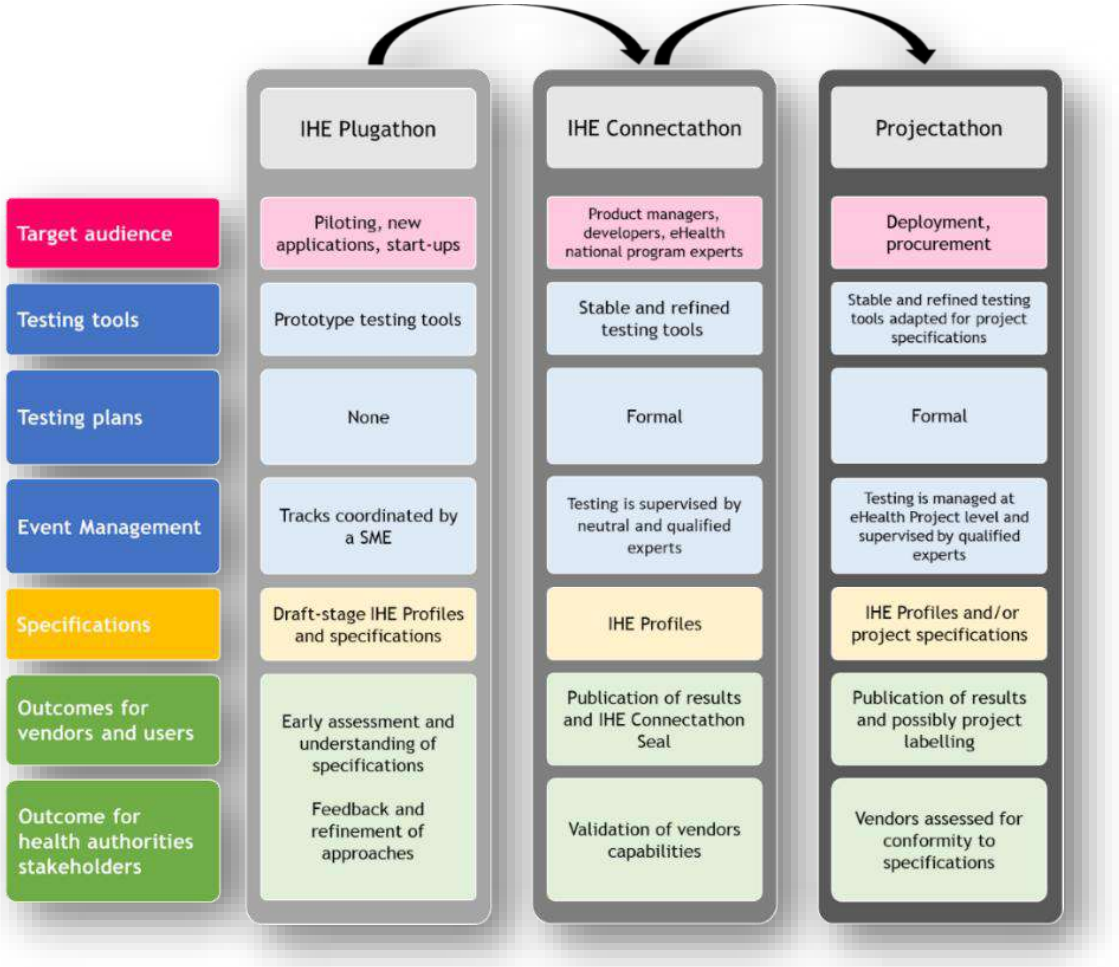
Use-Case-Driven Guidance

- Many digital health software and device products provide functionalities which are often very different from “classical EHR systems”
- Digital infrastructure supporting care providers comprises numerous (inter-) connected systems.
- Reasonable interpretation for the various (potentially highly complex) information systems that might be in scope.
- Timelines are essential for predictability for manufacturers.
- Collaborative Approach: Policymakers, industry leaders, and healthcare stakeholders working together.
- Clear and actionable guidance for applying EHDS requirements across diverse digital health solutions.



Scaling Testing Frameworks

- Effective testing = cornerstone of achieving interoperability
- Rely on existing frameworks and mechanisms (phased approach)
- continued evolution of testing tools and plans will further strengthen EHDS implementation



Collaboration will be key for a successful EHDS implementation

Industry welcomes opportunity to share feedback via

- Targeted consultations,
- Stakeholder forum and other events (e.g. Athens Digital Health Week, MedTech Forum and the IHE connectathon)
- Exchanges with SDO's and associations.

Reflections

- Industry is committed to providing meaningful input, also in constrained timelines → ongoing exchange remains essential
- Harmonised implementation needs to stay key priority.
- Regulatory clarity, avoid duplicative/conflicting/overlapping requirements
- References to EHDS requirements → highlight requirements vs. best practices.
- Clear responsibilities for manufacturers and other stakeholders → align on specification efforts
- High level functional goals in recommendation → implementation: details on technical specs need to build on SDO and industry expertise

THANK YOU