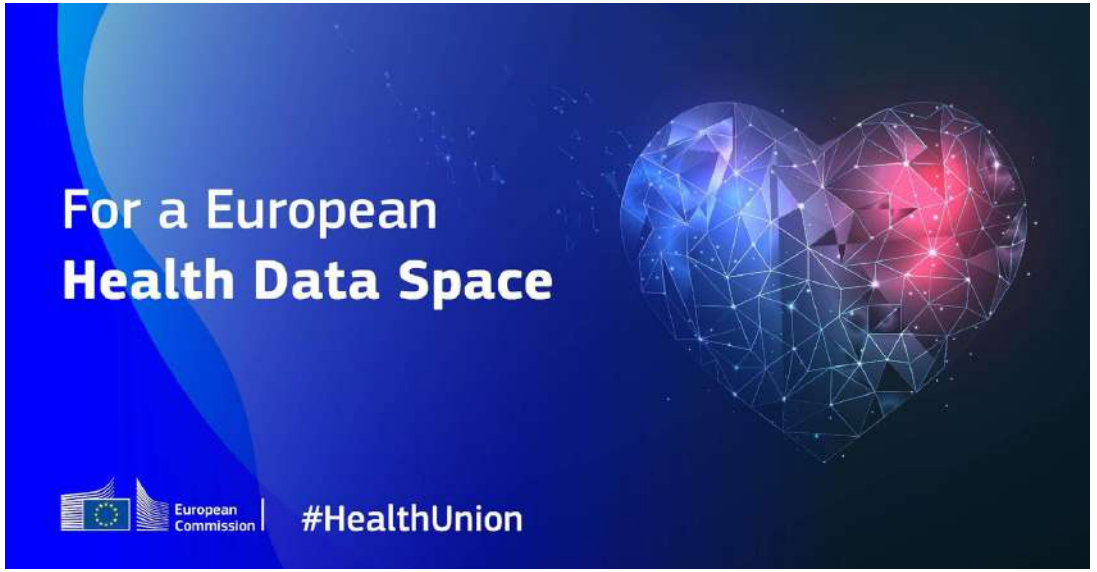
IHE® EUROPE EXPERIENCE DAYS

VIENNA 2025

24-25 JUNE

# EU-projects to support the EHDS



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Xt EHR @dataspace

Funded by the European Union

Klara Jirakova, CZ, Session Moderator

Andreas Neocleous,

CY, Xt-EHR Project Manager

WP5 – general requirements

Vanja Pajic, CZ

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

WP7 – new use cases

Esther Peelen, Nictiz, co-TL Medical Imaging Studies & Reports (NL)

WP8 – Conformity Assessment

Haralampos Karanikas,

Medical Informatics and e-Health Systems Senior Expert (IDIKA GR)

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VIENNA 2025

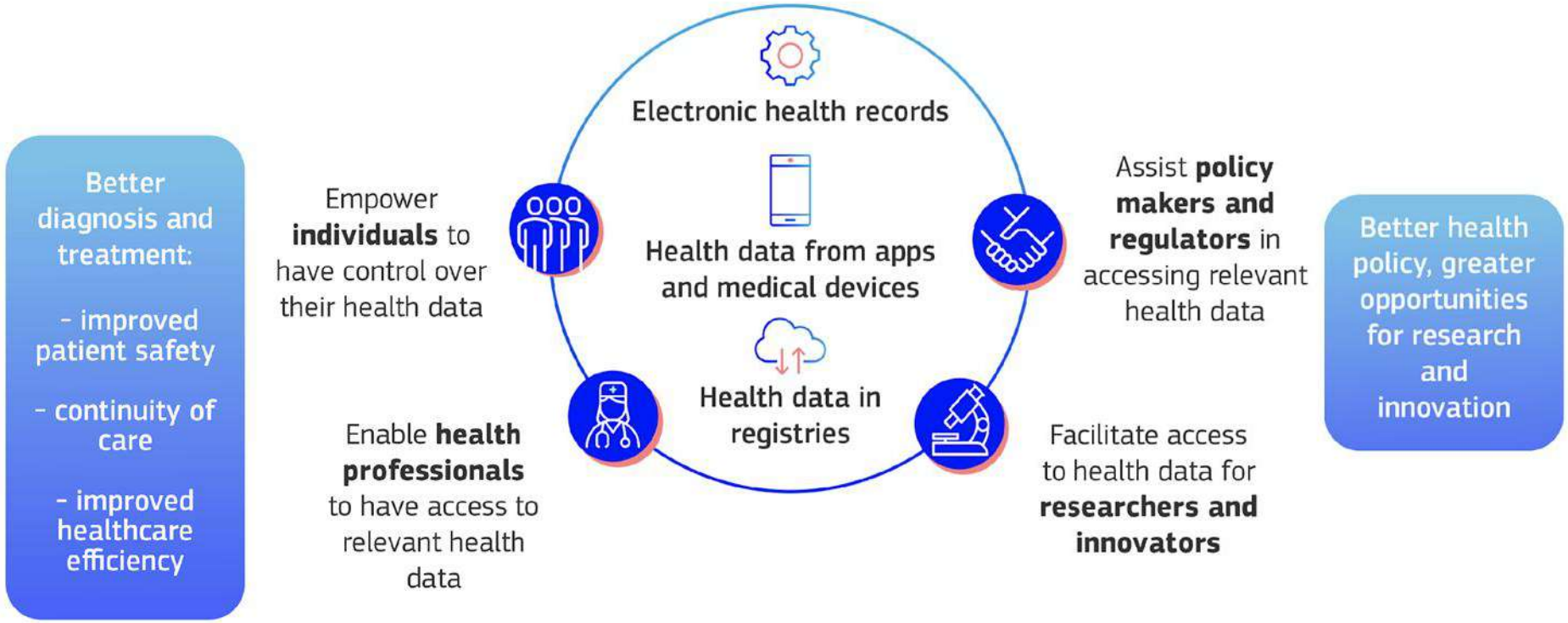
24-25 JUNE

EHR @dataspace

Funded by the European Union

Industry perspective, MedTech Europe, Verena Thaler

# EHDS - Creating a common European Health Data Space



# Extended EHR@EU Data Space for Primary Use (Xt-EHR)

Andreas Neocleous - Project Manager, *Xt-EHR Joint Action*

Xt-EHR website

Co-funded by the European Union

My health @ EU
eHealth Digital Service Infrastructure
A service provided by the European Union

*(Co-)Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.*

# Xt-EHR Objectives

01 Promote the **adoption of the EEHRxF in all EU EHR systems**

02 Provide adequate **technical specifications & implementation guides to allow the adoption of the EHDS regulation across MS**

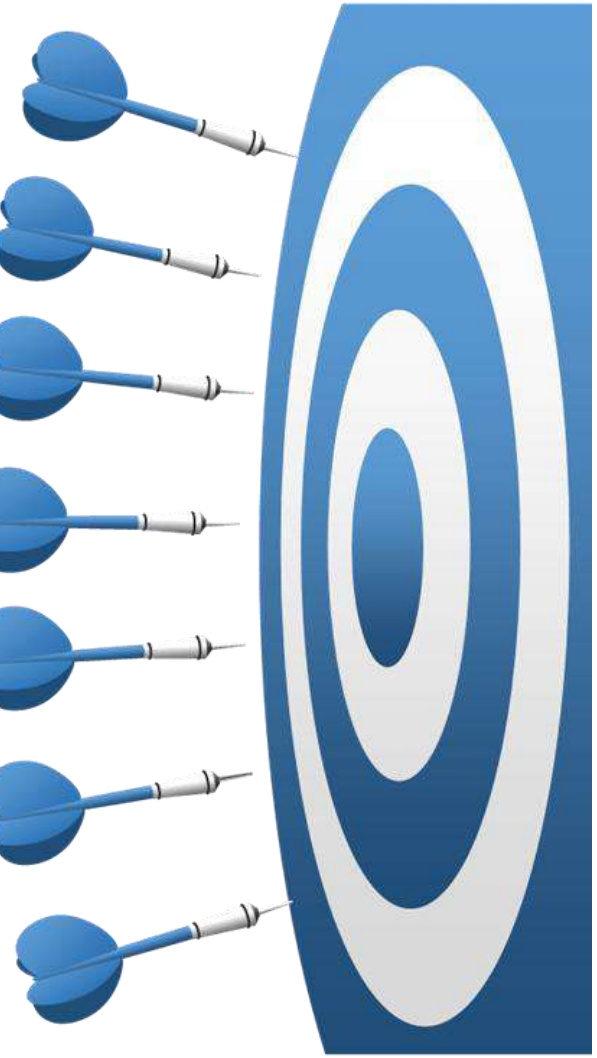
03 Promote the **EHR systems' & wellness apps' certification & labelling processes** in the European digital single market

04 Engage relevant **stakeholders and gather feedback**

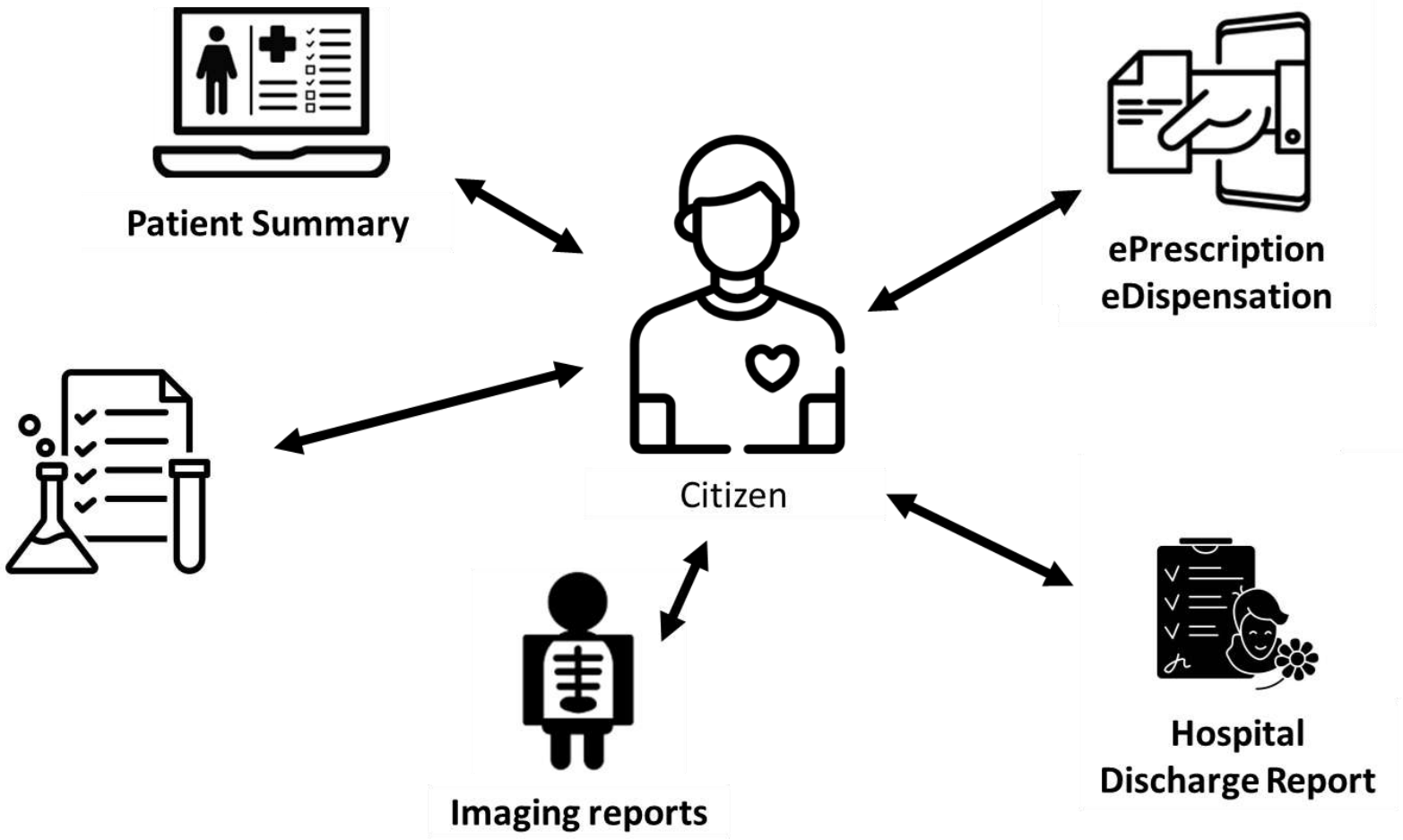
05 Promote **EHRs & cross border healthcare use cases beyond the MyHealth@EU**

06 Provide **proof of sustainability of the selected use cases**

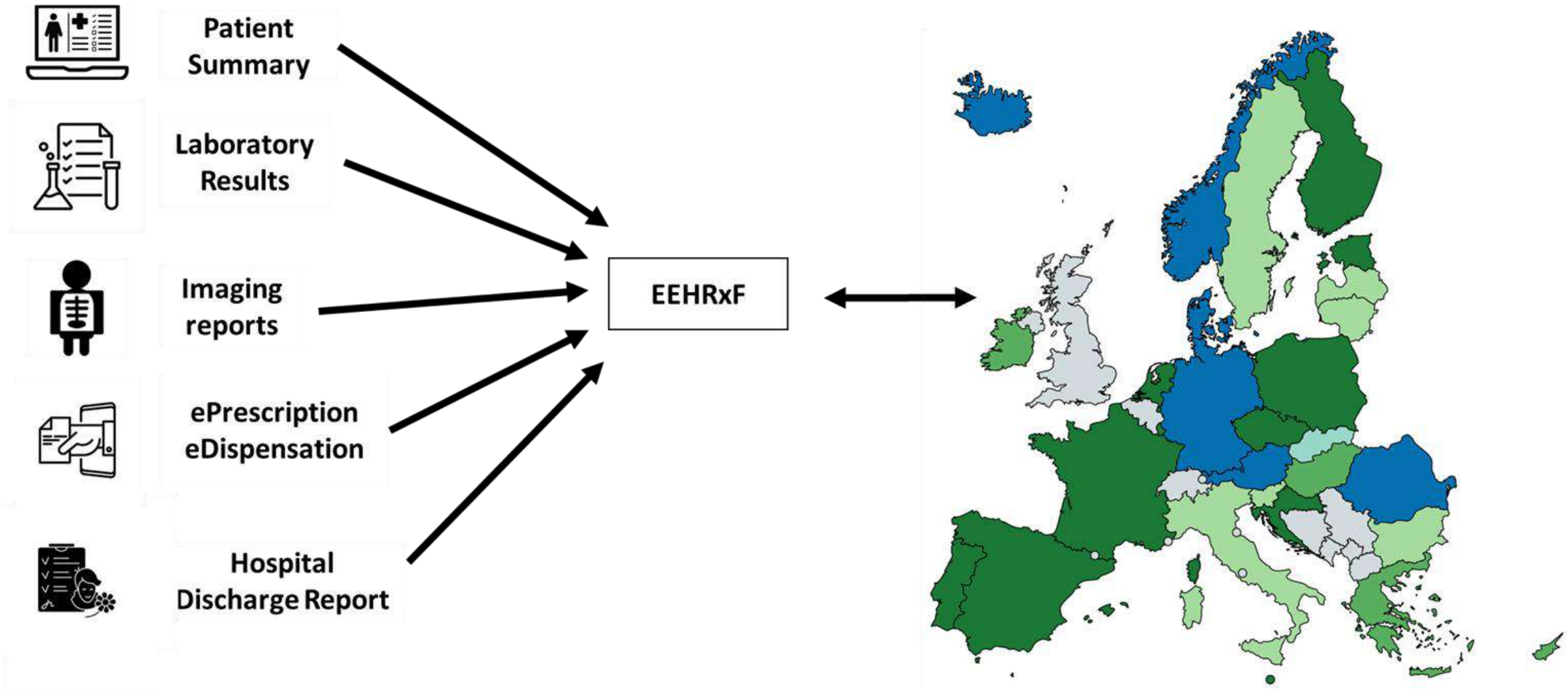
07 Expand on previous & cooperate with other **projects and initiatives in the domain of digital healthcare/interoperability** in EU



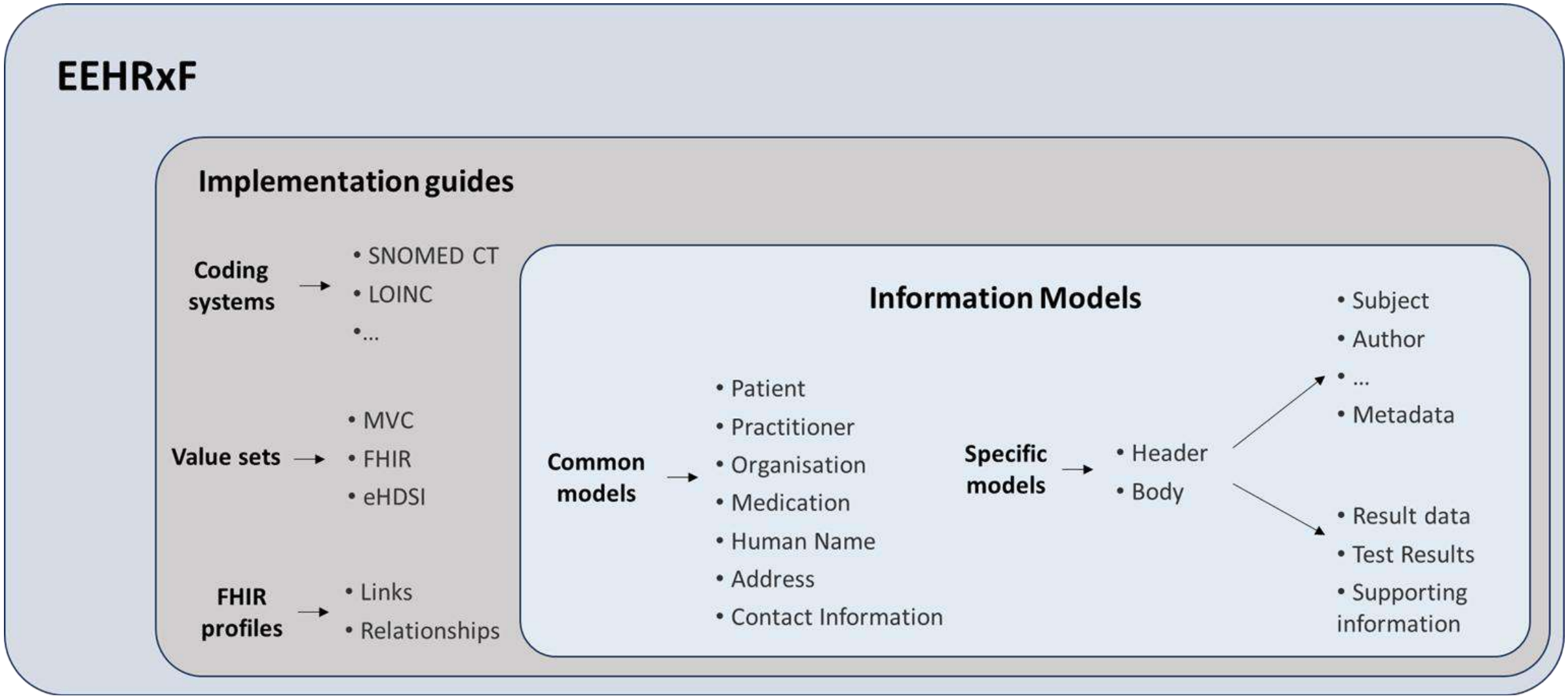
# The European Electronic Health Record Exchange Format (EEHRxF)



# The European Electronic Health Record Exchange Format (EEHRxF)



# Implementation Guides for EEHRxF



# Mapping Xt-EHR Logical Models to FHIR IGs

**Group 1** Mapping from Address model to Address (EU)

| **Source Concept Details** | **Relationship** | **Target Concept Details** | |
|---|---|---|---|
| **Codes** from https://www.xt-ehr.eu/specifications/fhir/StructureDefinition/EHDSAddress | | **Codes** from http://hl7.eu/fhir/base-r5/StructureDefinition/Address-eu | |
| use | is equivalent to | use | C.5.1 - Use |
| type | is equivalent to | type | C.5.2 - Type |
| text | is equivalent to | text | C.5.3 - Text |
| street | is narrower than | line | C.5.4 - Street |
| | is equivalent to | line.extension[streetName] | C.5.4 - Street |
| houseNumber | is narrower than | line | C.5.5 - House number |
| | is equivalent to | line.extension[houseNumber] | C.5.5 - House number |
| pOBox | is narrower than | line | C.5.6 - P.O. Box |
| | is equivalent to | line.extension[postBox] | C.5.6 - P.O. Box |
| city | is equivalent to | city | C.5.7 - City |
| postalCode | is equivalent to | postalCode | C.5.8 - Postal code |
| country | is equivalent to | country | C.5.9 - Country |
| | is equivalent to | country.extension[countryCode] | C.5.9 - Country |

# General requirements for EHRs and system interfaces

**Provide an interface**

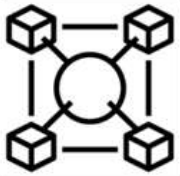
Patient safety

Can be supplied and installed


**Structural metadata**
Describes relationships among various parts of a resource.

## General requirements

Reliable and secure

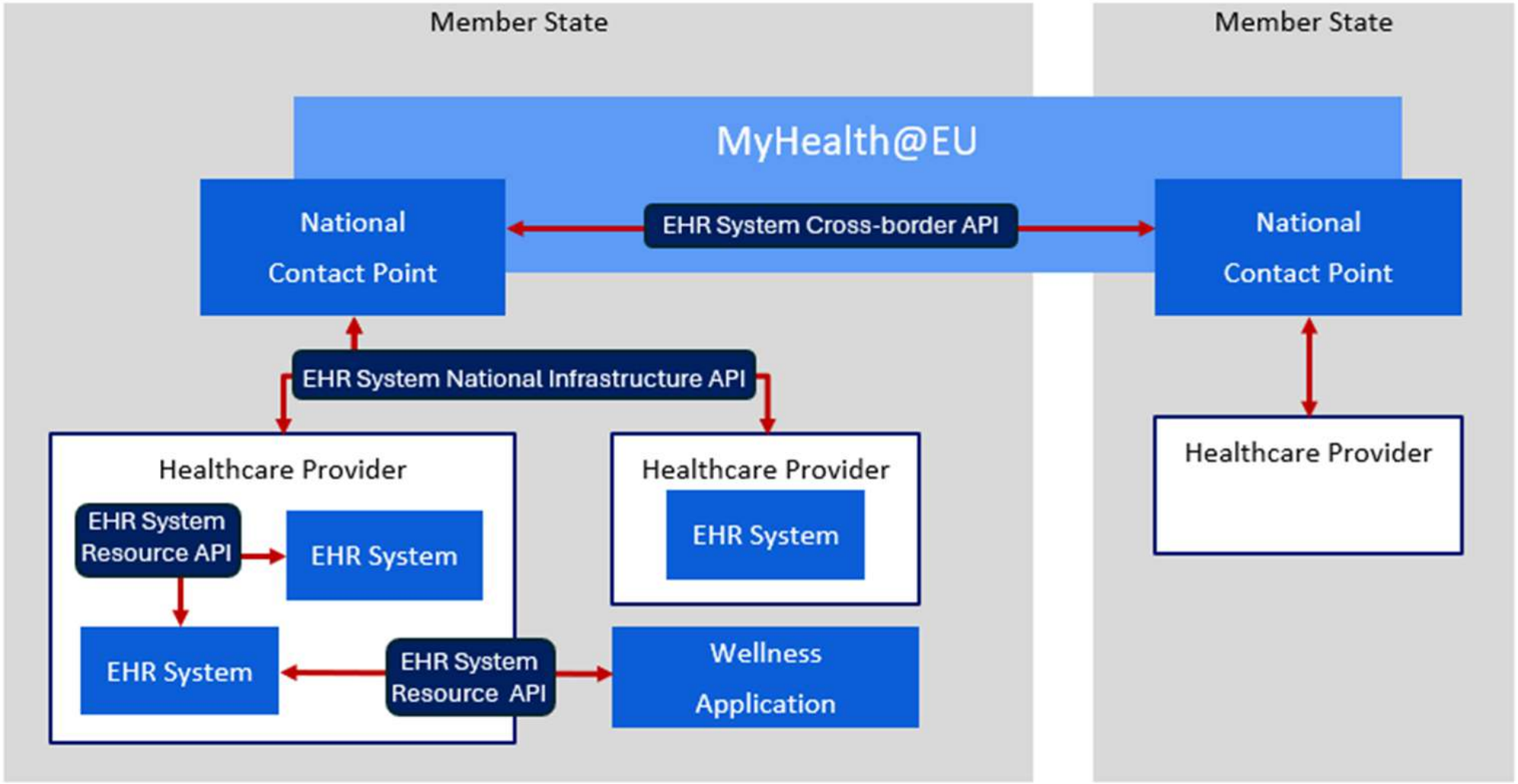


Interoperability and compatibility

Uphold the rights of natural persons

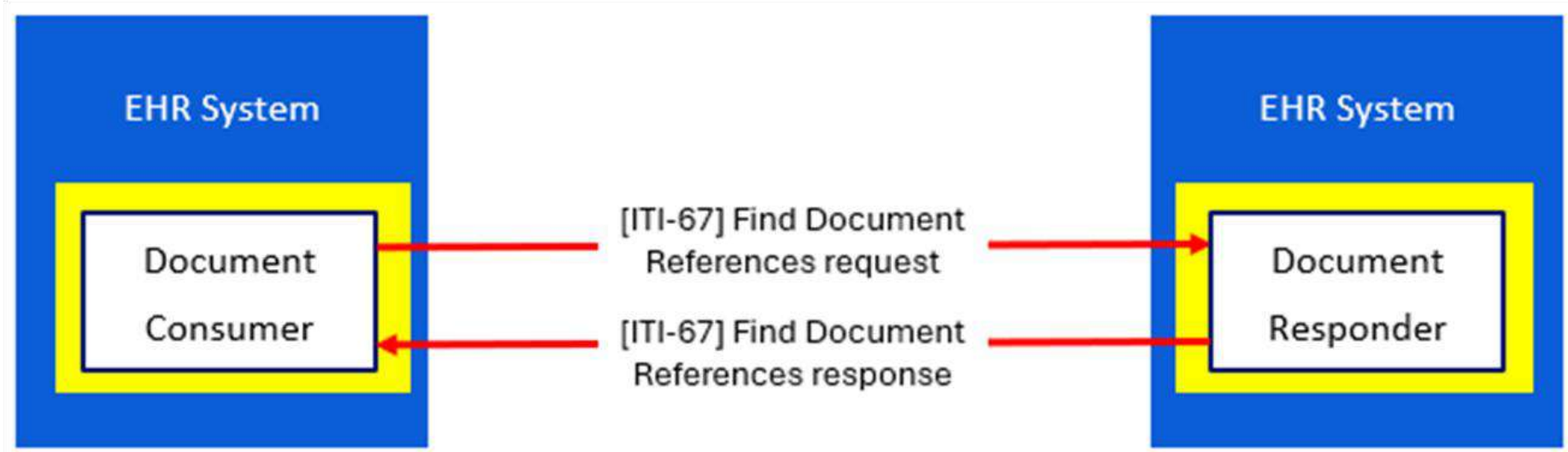
**Administrative metadata**
Facilitate the management of resources.

# Interoperability component



# Interoperability component

## Query for available personal electronic health data document(s)




The **Find Document References** transaction of the IHE MHD Profile is used to find DocumentReference Resources that satisfy a set of parameters. The result of the query is a FHIR Bundle containing DocumentReference Resources that match the query parameters.

# Maturity Model / Conformance Framework

**Entry/production of data**

**Level 1:** Unstructured and generic metadata only

(e.g. date, author organisation, etc)

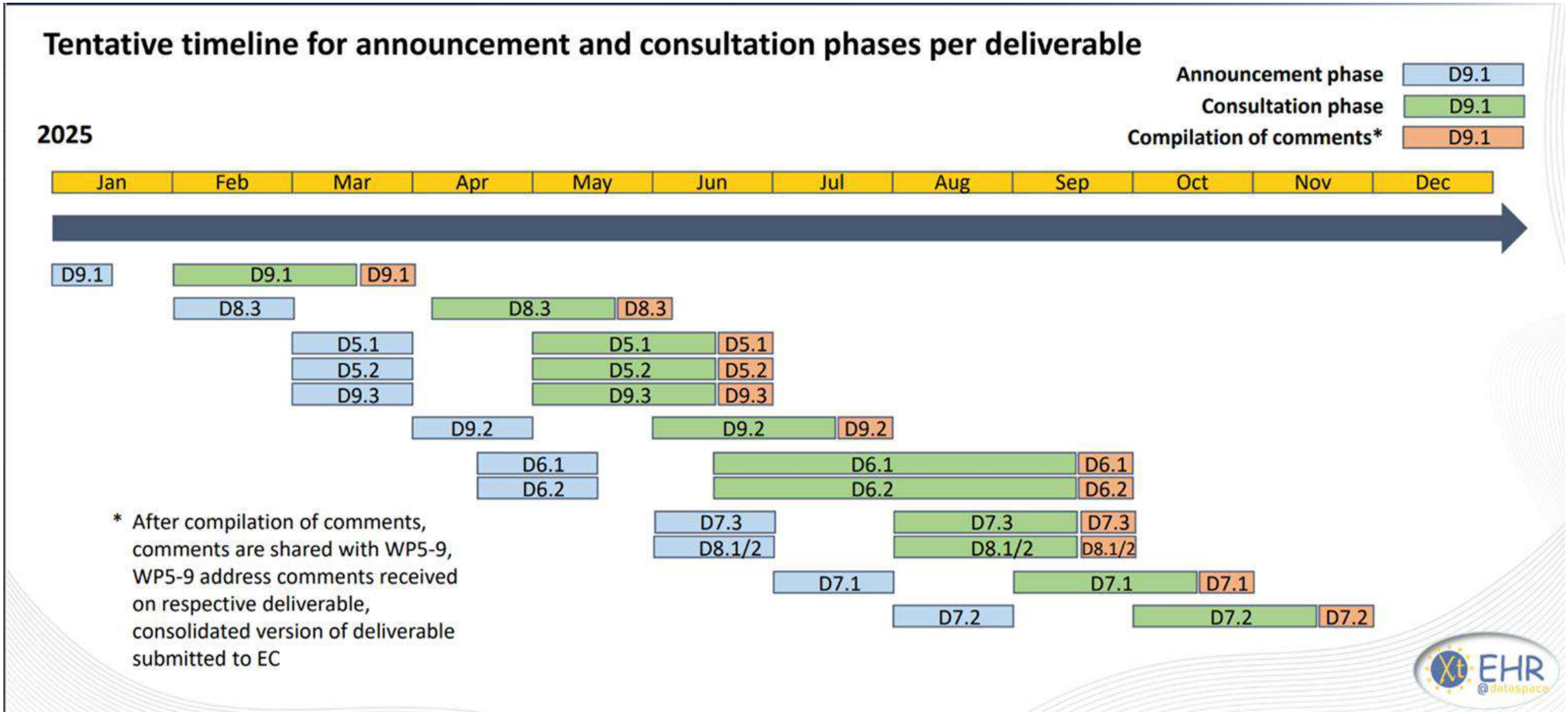
**Level 2:** Structured data and metadata without coding

**Level 3:** fully structured data

# Stakeholder engagement plan

| Timeline for Stkaeholer Consultation Procedure | | | |
|---|---|---|---|
| **Deliverable** | **Briefing Workshop** | **Consultation phase (6 weeks)** | |
| | | Start date | End date |
| **D5.1** Technical Requirements for EHRs and key system interfaces | 2025-05-12 | 2025-05-12 | 2025-06-20 |
| **D5.2** Technical Requirements for EEHRxF metadata | 2025-05-12 | 2025-05-12 | 2025-06-20 |
| **D6.1** Patient Summary: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems | 2025-06-03 | 2025-06-15 | 2025-09-15 |
| **D6.2** Electronic prescription and electronic dispensation: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems | 2025-05-28 | 2025-06-15 | 2025-09-15 |
| **D7.1** Laboratory results and reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems | 2025-09-02 | 2025-09-01 | 2025-10-13 |
| **D7.2** Medical images and reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems | 2025-09-23 | 2025-09-30 | 2025-11-11 |
| **D7.3** Discharge reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems | 2025-07-16 | 2025-07-31 | 2025-09-11 |
| **D8.1** Classification and functional profiles of EHR systems guidelines | 2025-06-16 | 2025-07-01 | 2025-09-14 |
| **D8.2** EHR Conformity Assessment Scheme assertion document and checklists | 2025-07-22 | 2025-08-04 | 2025-09-14 |
| **D8.3** Wellness application labelling guidelines | 2025-03-31 | 2025-03-31 | 2025-05-12 |
| **D9.1** Requirements and use cases on the availability of health data in cross-border telemedicine services | 2025-01-21 | 2025-02-03 | 2025-03-17 |
| **D9.2** Technical specifications on the availability of health data in cross-border telemedicine services | 2025-05-21 | 2025-05-29 | 2025-07-11 |
| **D9.3** Requirements for Large-Scale Uptake of Telemedicine Service | 2025-05-07 | 2025-05-14 | 2025-06-25 |

# Stakeholder engagement plan



# Contact

## Extended EHR@EU Data Space for Primary Use

**THANK YOU**

**Project Manager: Andreas Neocleous**

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https://www.xt-ehr.eu/

(+357) 22436000

67A Limassol Avenue, 2121,
Aglantzia, Cyprus

# Work Package 5

# 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

# 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

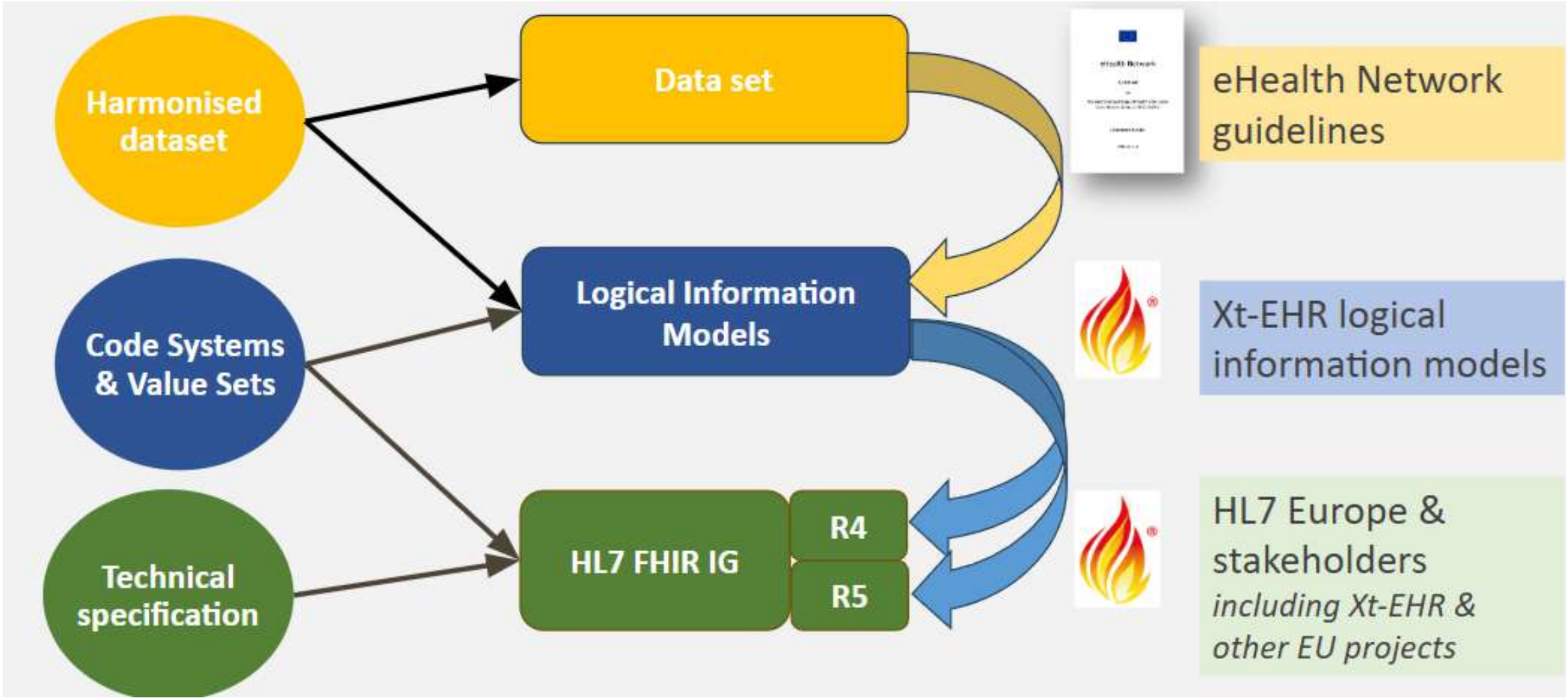
**Stakeholder consultations:**
14.07.2025-15.09.2025

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

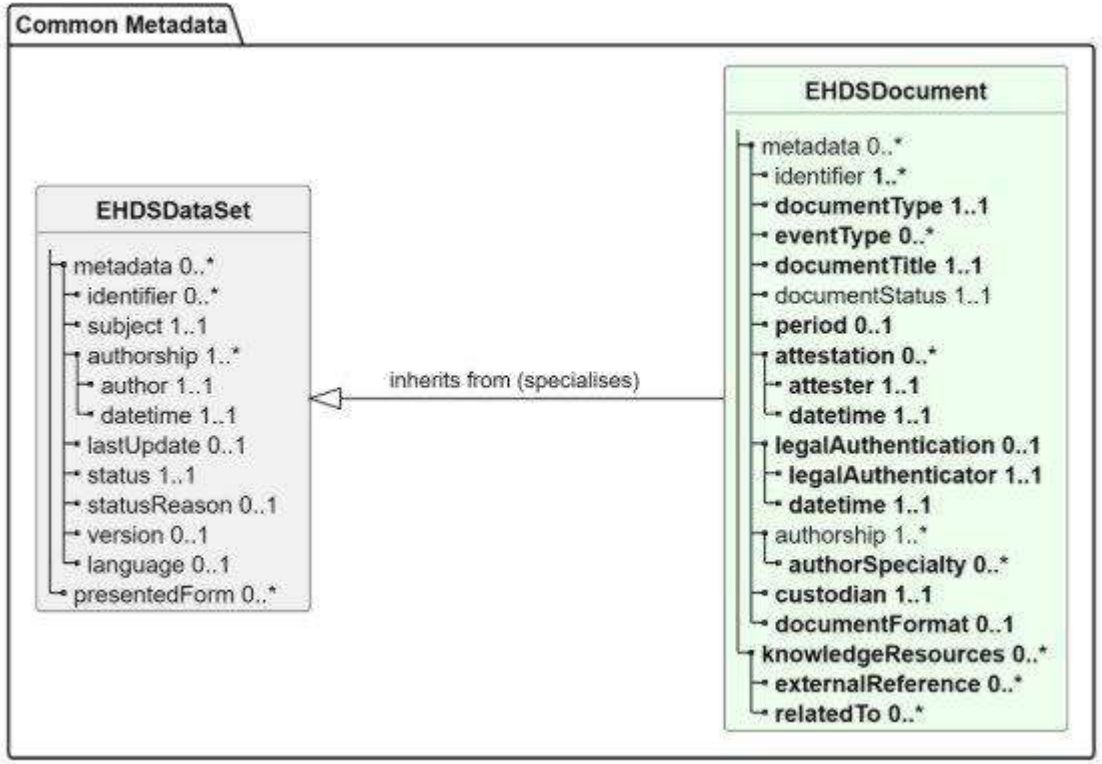
**EHDS Recital 25:** *Where such priority categories of data represent groups of electronic health data, this Regulation should apply to both the groups as a whole and to the individual data entries included in those groups.*

# Common metadata, but not everything is a document

**ePrescription**

**eDispensation**

**Patient Summary parts:**
EHDSCondition,
EHDSProcedure,
EHDSDeviceUse,
etc



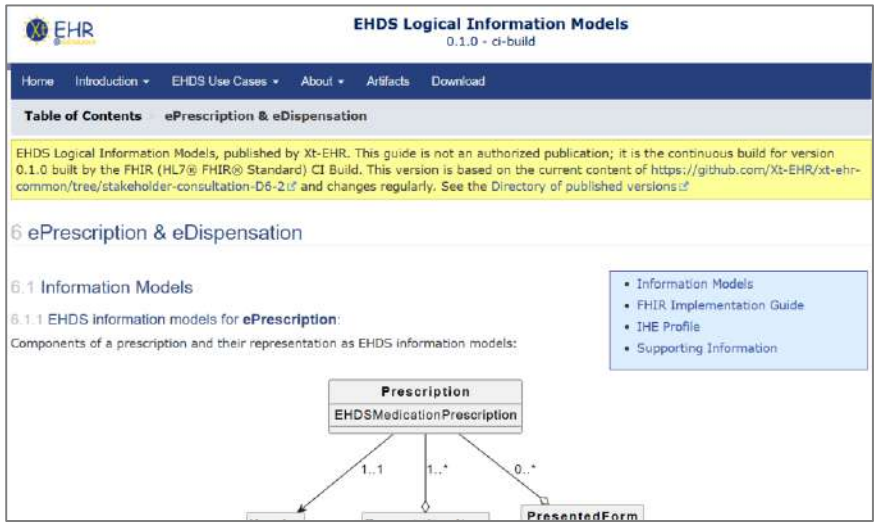

**Patient Summary**

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

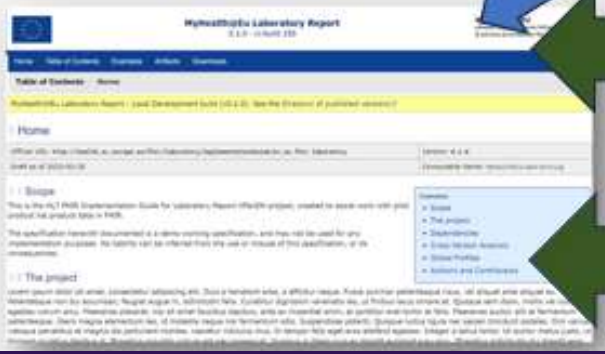
R5

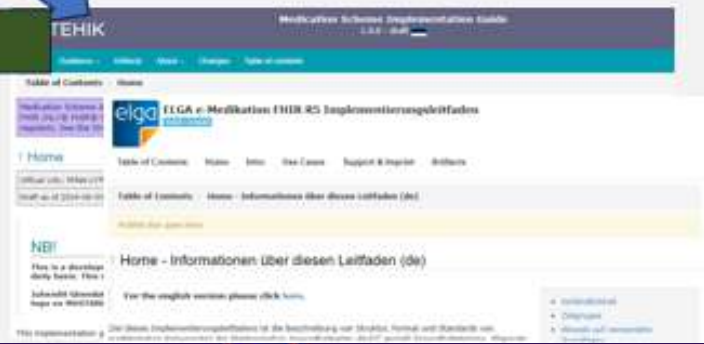
## MyHealth@EU crossborder specification

## 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

Esther Peelen

# Work Package 7

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

Lead: CZ

Lead: NL/CY

Lead: CZ

# Based on eHealth Network Guidelines

## Content

- Purpose and scope,
  determined by MS/HCP needs
- Address the 2011 Directive on patient rights in crossborder healthcare
- Use case descriptions
- Consider semantic and technical specifications
- Provide Dataset

# Goals Xt-EHR WP7

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

# Content of Xt-EHR Implementation Guides for EHR-systems

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

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


HL7 Europe

IHE EUROPE


ATHON A 2025

| 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

## Conformity Assessment

## D8.2

# Conformity Assessment framework for EHR

- To be placed on the market or put into use within the EU, EHR systems must contain the two harmonised software-components, namely:
  - The interoperability component,
  - and the logging component.
- These ‘components’ describe capabilities of EHR systems.
  - The interoperability component provides the capability to import/export data that falls under the priority categories in the EEHRxF.
  - The logging component provides the capability to generate logs that can be used in the health data access service to provide transparency on data access.

- A significant aspect of the EHDS is the establishment of common standards and compliance rules to ensure interoperability of data and digital solutions for healthcare across EU member states.
- This includes mandating that all electronic health record systems (EHR systems) align with the European electronic health record exchange format (EEHRxF), thereby facilitating seamless data exchange.
- WP8 is aiming to support the conformity schemes that are to be developed for the implementation of EHDS provisions.

**The EHR systems built according to the specifications need to be tested**

- WP8/D8.2, provide the basis for a Conformity Assessment Framework for EHRs.
  - A set of **testable assertions** that can be added to the test tools required to support interoperability certification.
  - **Means of verification** such as checklists for other types of requirements.

- This set of evaluation and testing criteria is intended to enable conformity assessment of EHR systems across Europe, using a **pragmatic readiness-based approach and according to the purpose of use of the EHR system.**

- CAS has two distinct parts
  - one focusing on the **governance** of the conformity assessment scheme (how to apply conformity assessment in the context of the EHDS regulation) and
  - the CAS **content** (testable assertions, test tools and means of verifications).

# CAS governance concepts (1)

- **Progressive adoption** to allow EHR vendors to adopt, test and incorporate EEHRxF into their products.
- Comply with EHDS regulation articles on **self-assessment procedures.**
- **Ensure equitability** of member states to incorporate the governance model.

- Propose CAS Owner based on Article 94 (EHDS Board)
- Propose EU declaration of conformity (Alignment with Article 39)

- Need for coordination at the European level:
  - The development of a consistent set of test tools that are actively maintained
  - The documentation and maintenance of test assertions integrated with the test tools
  - A feedback and release process on the above tools and assertions
  - The publication process of the conformity assessment reports
  - An audit process that verifies the quality of self-assessment retrospectively (based on ISO17025)
  - A feedback and review process on the conformity assessment efficiency

# CAS content (1)

- Content in the form of testable assertions and means of verification **is driven by multiple sources** such as previously established CAS models (EUROCAS, IHE CAS, SiAS, Label2Enable CAS, etc), WP5, WP6 and WP7 set of specifications, EN ISO/HL7 EHR-S FM model requirements.

- All of these assertions are described in such a way that they can be tested and verified to enable an **unbiased CAS self-assessment**.

- Testable assertions cover both **interoperability** and **logging** specifications.

# CAS content (2): From data level obligations to testable assertions

- The requirements for content testing are set out in the specifications (the underlying standards, XML/JSON schemas, tables, and, for FHIR content, StructureDefinition and the associated conformance resources).
  - As a consequence, we recommend not writing testable assertions that are too fine-grained, since these would simply be paraphrases of the Structure Definitions that software developers will use to specify their software.
- On the contrary, it is useful for developers of both EHR and testing tools to compile a list of high-level testable assertions that refer to the detailed technical specifications.
- This allows them to find everything they need to specify a product that will conform to the EHDS in one place.

- The **template for the testable assertions**, will have the same level of details and use the same wording.
- A template could be something like:
  - A product claiming conformance to the *[EHDS priority category]* as a *[Content Producer]* shall produce a FHIR [Resource type] that ...
  - Example: "A product claiming conformance to the Laboratory Result Report as a Content Producer shall produce a FHIR Bundle resource of type "document" that with all the required elements defined is the EU Laboratory Result Report StructureDefinition (http://hl7.eu/fhir/laboratory/StructureDefinition/Bundle-eu-lab) populated."

CAS content (4)

- How to test (needed testing tools capabilities) taking into account
  - Current testing tools used for myHealth@EU services
  - MS capabilities and deployed testing environments
  - Reduce overhead for EHR vendors

- Various questions from the vendor's side need to be addressed in the deliverables. Without their involvement, the implementation is at risk.
- For example:
  - Is my product within the scope of EHR system requirements of EHDS?
  - Which EHDS requirements must I design and implement in my product?
  - What do I have to do to demonstrate compliance to EHDS essential requirements?