EEHRxF Specification Overview

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Technical Lead - HL7 Europe

IHE Japan -
EHDS & EEHRxF Workshop

Virtual, 19 October 2025

HL7® Europe



Who am I

Giorgio Cangioli, PhD FHL7

- *Senior Consultant*
- *Technical Lead and Board member, HL7 Europe*
- *TSC and Board member, HL7 International*
- *Chair of the eHMSEG STF Architecture WG*
- *Author of several UV and EU HL7 CDA and FHIR IGs*

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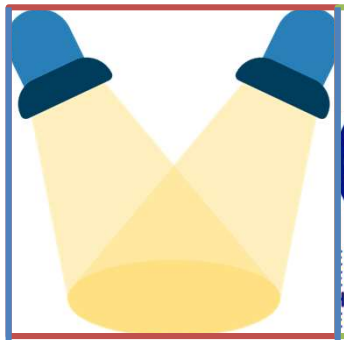


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Agenda



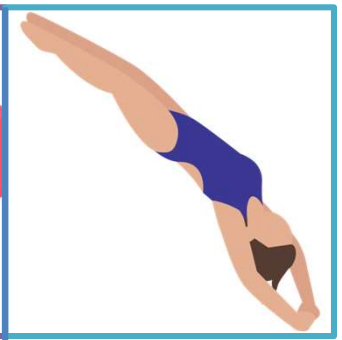
Setting the scenes



The “Format”



The EU IGs ecosystem



Dive-in

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SETTING THE SCENES



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EHDS : what is it about?

1. **Primary use** = use of data for the delivery of healthcare
   - Improving patients' access to their health data;
   - Ensuring seamless exchanges for continuity of healthcare.

2. **Secondary use** = use of data for research and public interest purposes
   - Making data available for research, policy-making etc. in a safe and secure way.

3. **Requirements for electronic health record** (EHR) systems
   - Creating a single market for electronic health records systems

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EHDS : Primary use

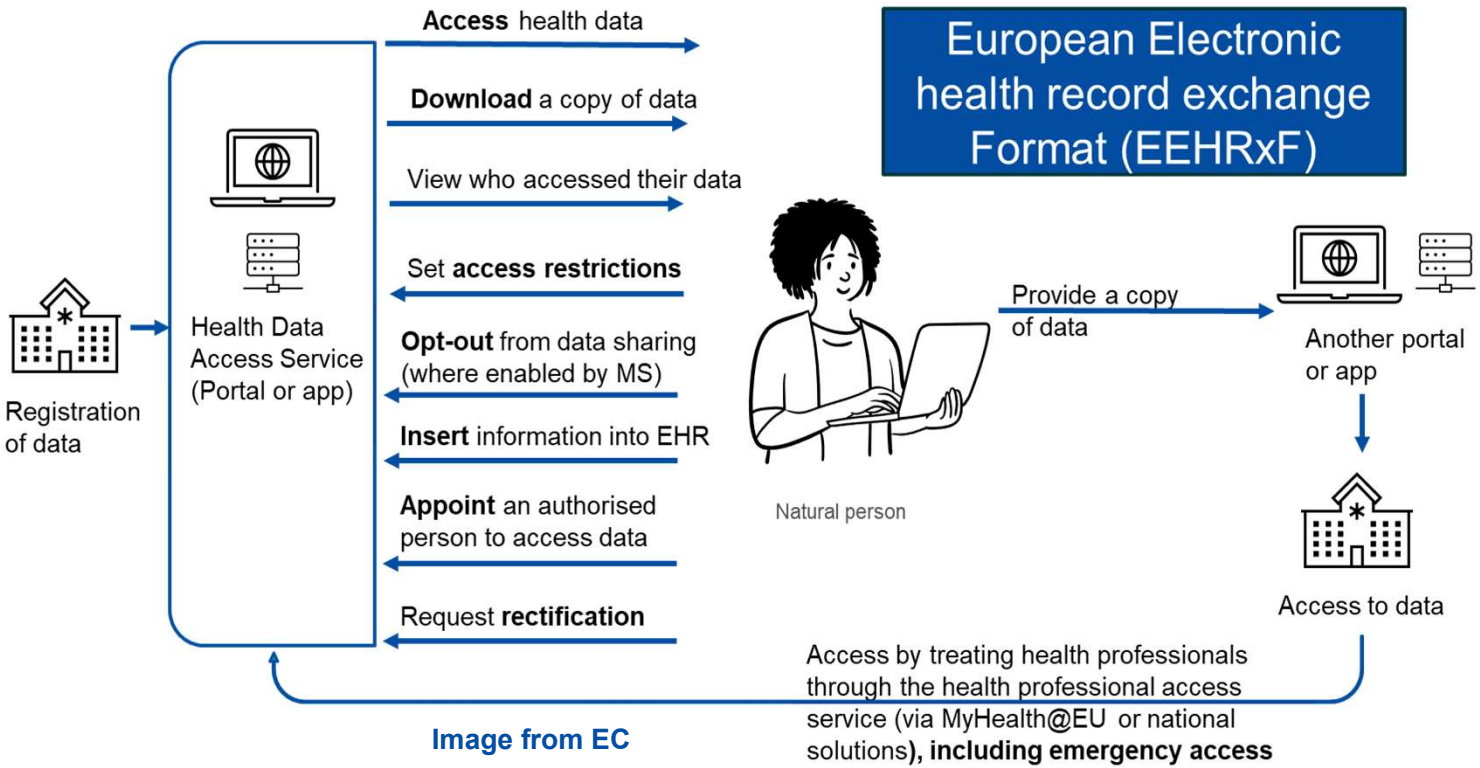


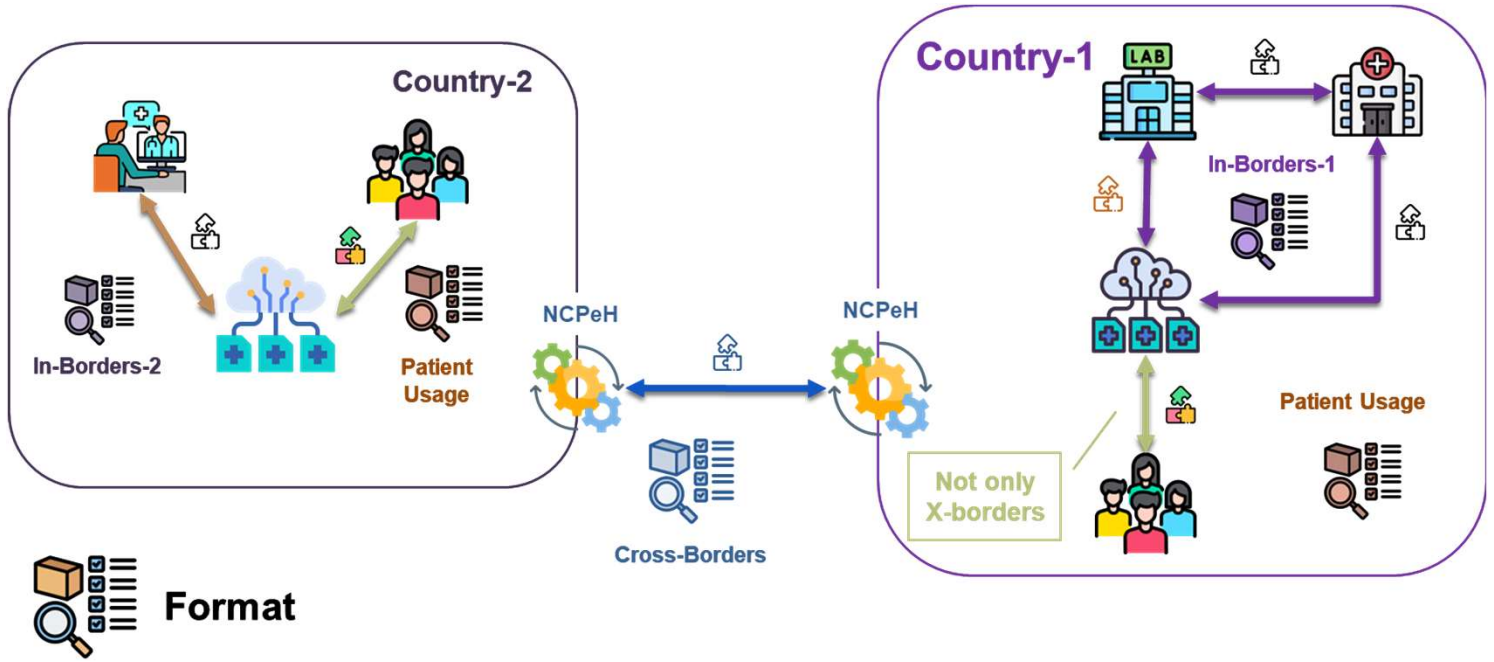
Image from EC

EUROPEAN ELECTRONIC HEALTH RECORD EXCHANGE FORMAT

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Not only cross-border !



EUROPEAN ELECTRONIC HEALTH RECORD EXCHANGE FORMAT

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Several actors engaged in the process

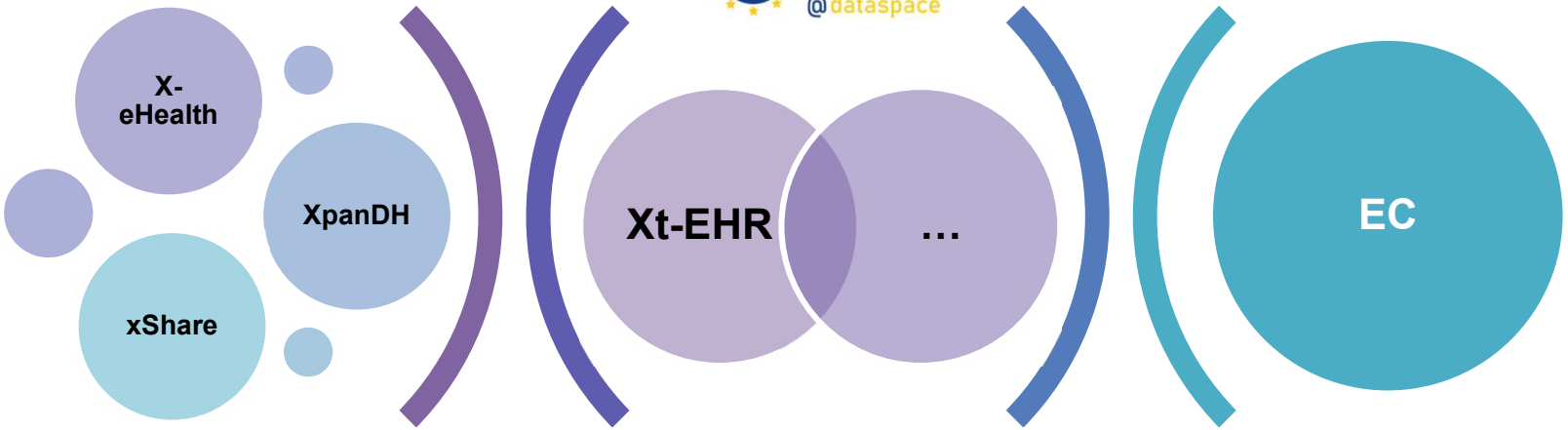
My health @ EU
eHealth Digital Service Infrastructure
A service provided by the European Union

By March 2027

XpanDH
Expanding Digital Health through a pan-European EHRxF-based Ecosystem

Xt EHR @dataspace

Share
EHR Xchange Format



Innovation & Experimentation

Formalization (proposal)

Implementing Acts

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The “format”



The “format” will be formally defined by European Commission in the Implementing Act !

By March 2027

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THE “FORMAT”



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EHDS : Primary use

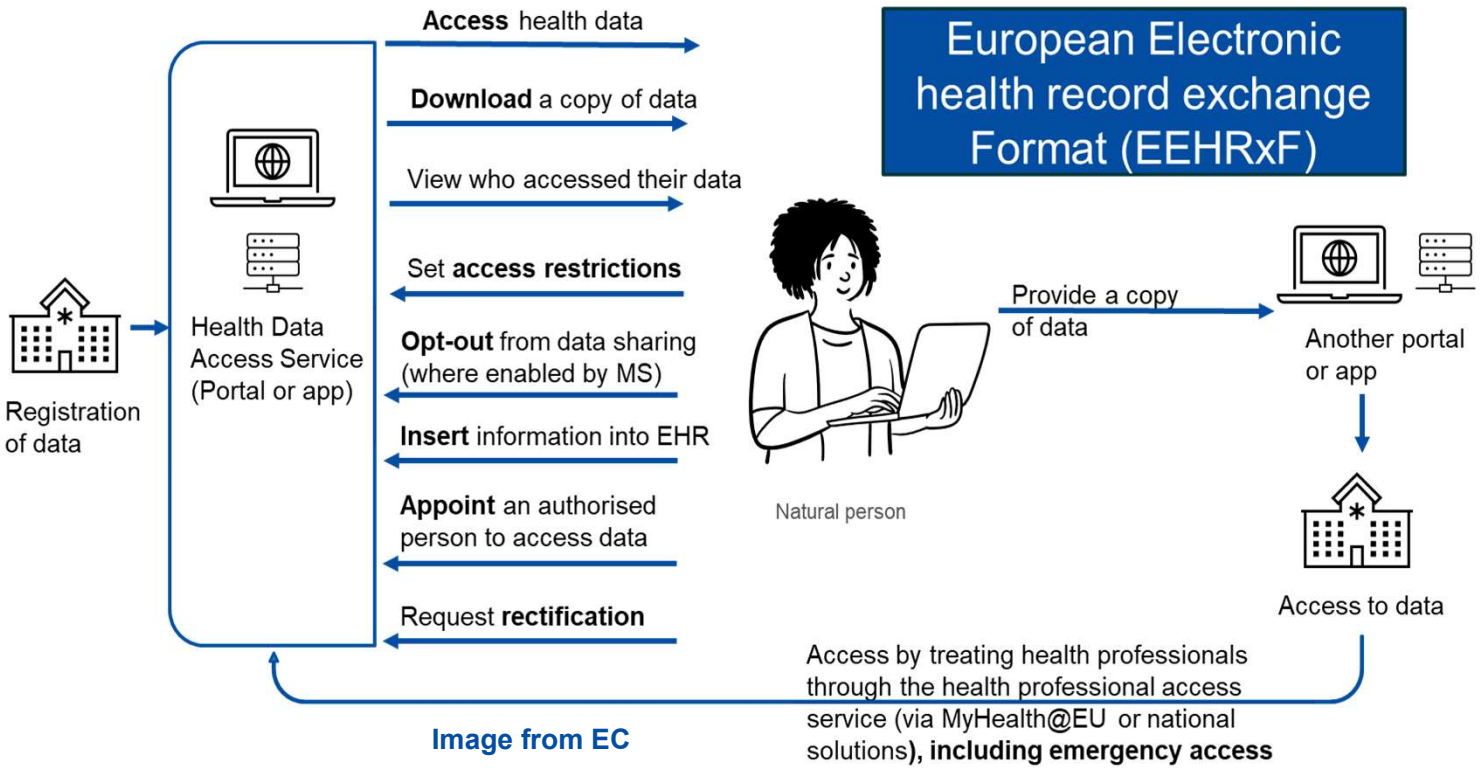


Image from EC

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Priority categories for primary use

EUROPEAN ELECTRONIC HEALTH RECORD EXCHANGE FORMAT

Member States may provide by virtue of national law that additional categories of personal health data are to be accessed and exchanged for primary use

The Commission is empowered to adopt delegated acts […] by adding, modifying or removing the main characteristics of the priority categories


Medical test results, including laboratory and other diagnostic results and related reports


Discharge report


Patient summary


Medical imaging studies and related imaging reports;


ePrescription/ eDispensation

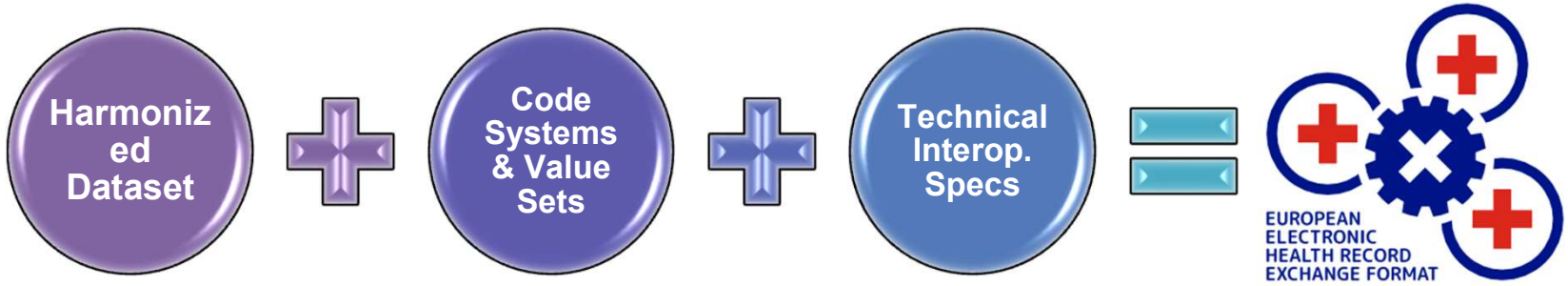
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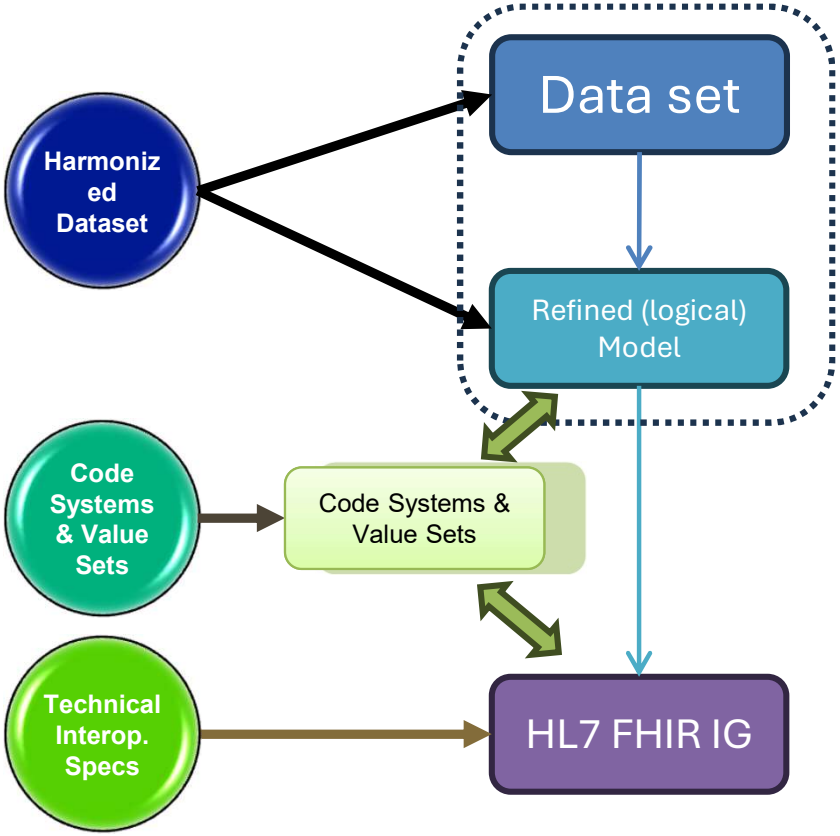
The European EHR eXchange Format

*"Such format shall be **commonly used**, **machine-readable** and allow **transmission** of personal electronic **health data** between different software applications, devices and healthcare providers.*

*Such format shall support transmission of **structured** and **unstructured** health data…" (EHDS art. 15)*



The EEHRxF content



eHN Guidelines – data sets

https://health.ec.europa.eu/publications_en

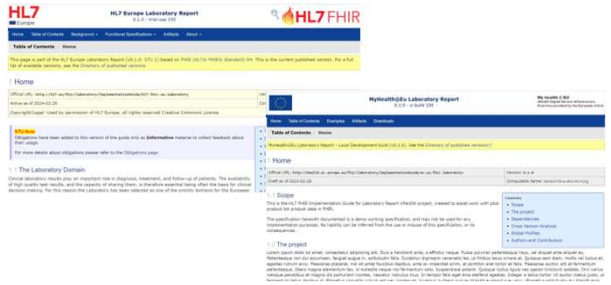


https://www.xt-ehr.eu/fhir/models

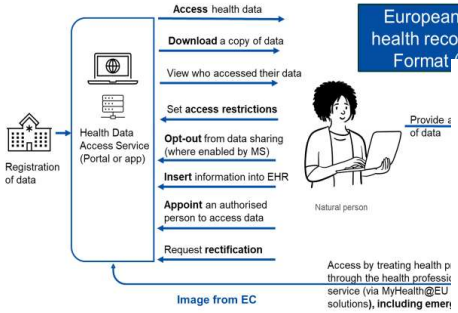


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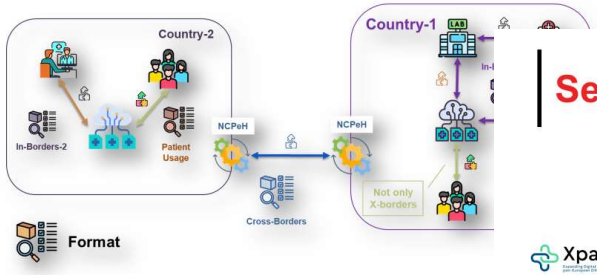
Key elements



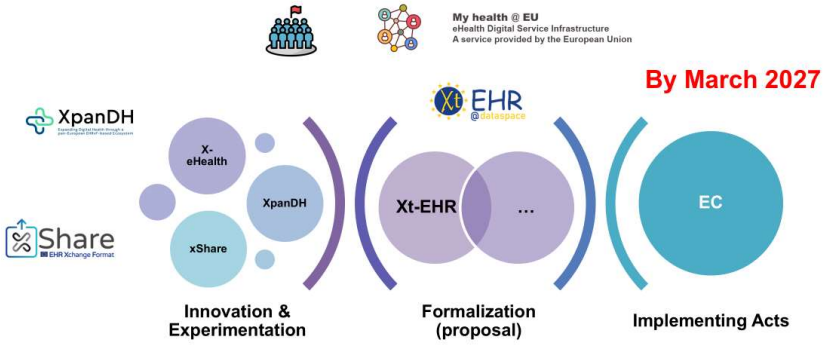
EHDS : Primary use



Not only cross-border !

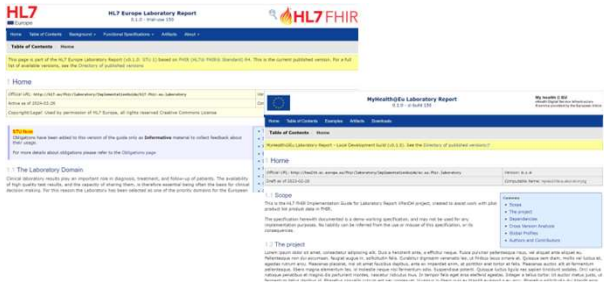


Several actors engaged in the process

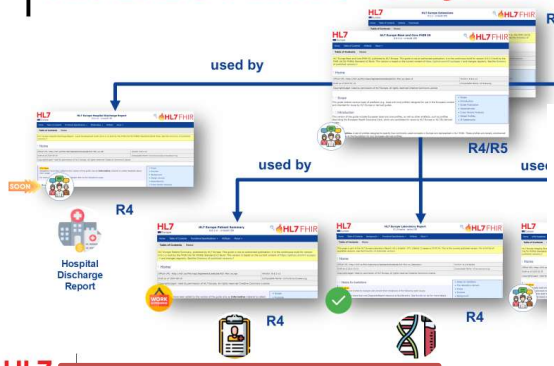


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The proposed solution

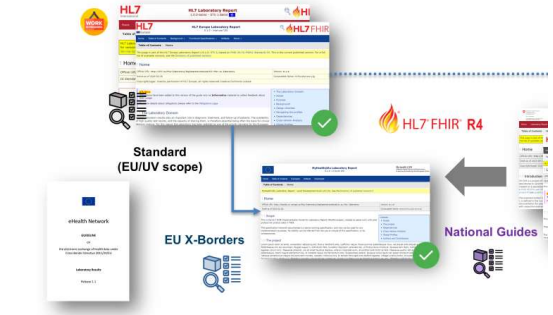


The EHDS FHIR IG ecosystem



Standard-based

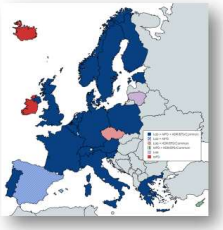
Laboratory Report



Flexibile

Collaborative Development in Motion

- **The result of a highly participatory, multi-stakeholder process spanning the European health ecosystem.**
  - **Laboratory Report**: **113 distinct participants** from **22 countries** (including USA) and EC Solution Providers [average ~30 attendees]
  - **MPD**: **114 distinct participants** from **26 countries** (including USA) and EC Solution Providers [average ~30 attendees]
  - **HDR/EPS/Common**: **160 distinct participants** from **24 countries** (including Sri Lanka, United Arab Emirates, Saudi Arabia and USA) and EC Solution Providers [average ~35 attendees]



Participated

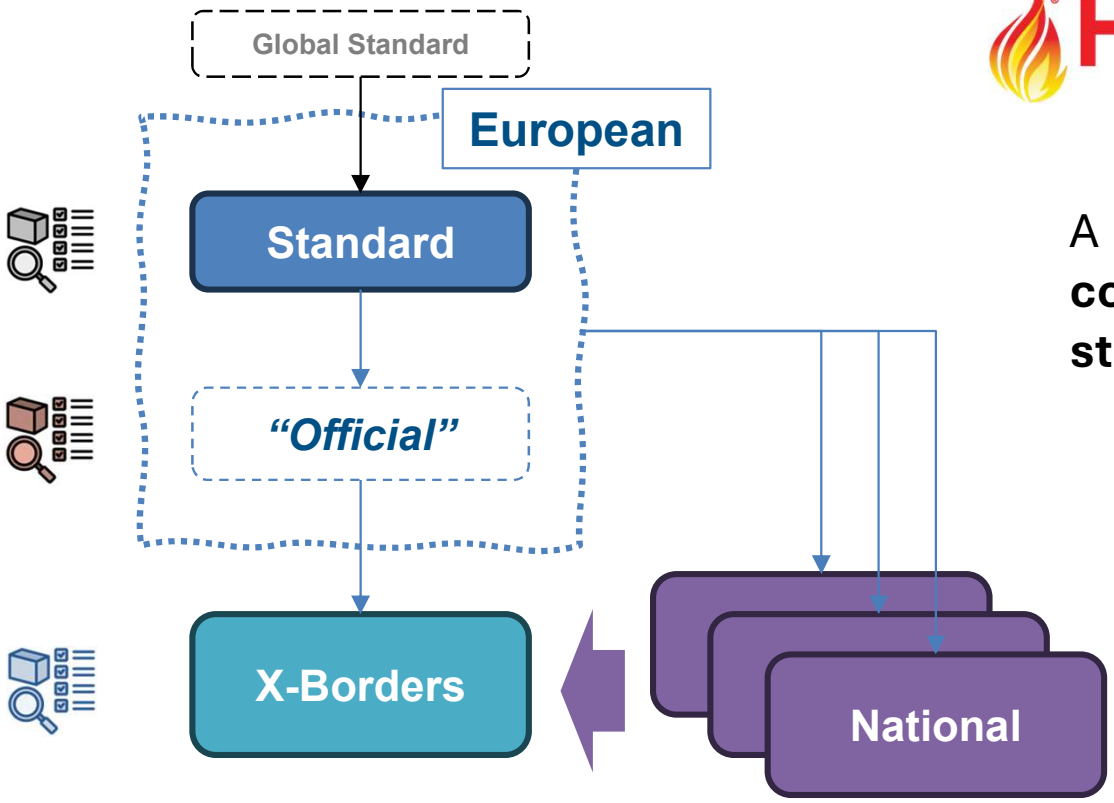
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THE FHIR IGS ECOSYSTEM



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The EU HL7 FHIR IGs design strategy



A consistent **system (i.e. a federation) of cooperating, coherent and possibly standard-based specifications**

*"The European electronic health record exchange format **could allow for different profiles** for its use at the **level of EHR systems** and at the level of the national contact points for digital health in **MyHealth@EU for cross-border data exchange**".*

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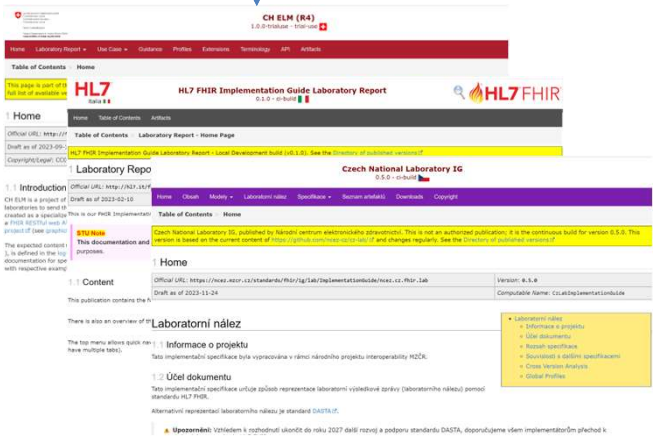
An example: the Laboratory Report



Standard (EU/UV scope)



HL7 FHIR R4



Laboratory Results

eHealth Network

GUIDELINE

on

the electronic exchange of health data under Cross-Border Directive 2011/24/EU

Laboratory Results

Release 1.1

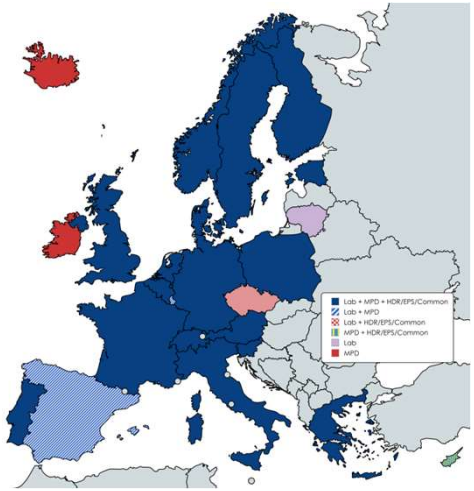
EU X-Borders

National Guides

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Collaborative Development in Motion

- The result of a highly **participatory, multi-stakeholder process spanning the European health ecosystem.**



- **Laboratory Report: 113 distinct participants** from 22 countries (including USA) and EC Solution Providers [average ~30 attendees]
- **MPD: 114 distinct participants** from 26 countries (including USA) and EC Solution Providers [average ~30 attendees]
- **HDR/EPS/Core: 180 distinct participants** from 24 countries (including Sri Lanka, United Arab Emirates, Saudi Arabia and USA) and EC Solution Providers [average ~35 attendees]

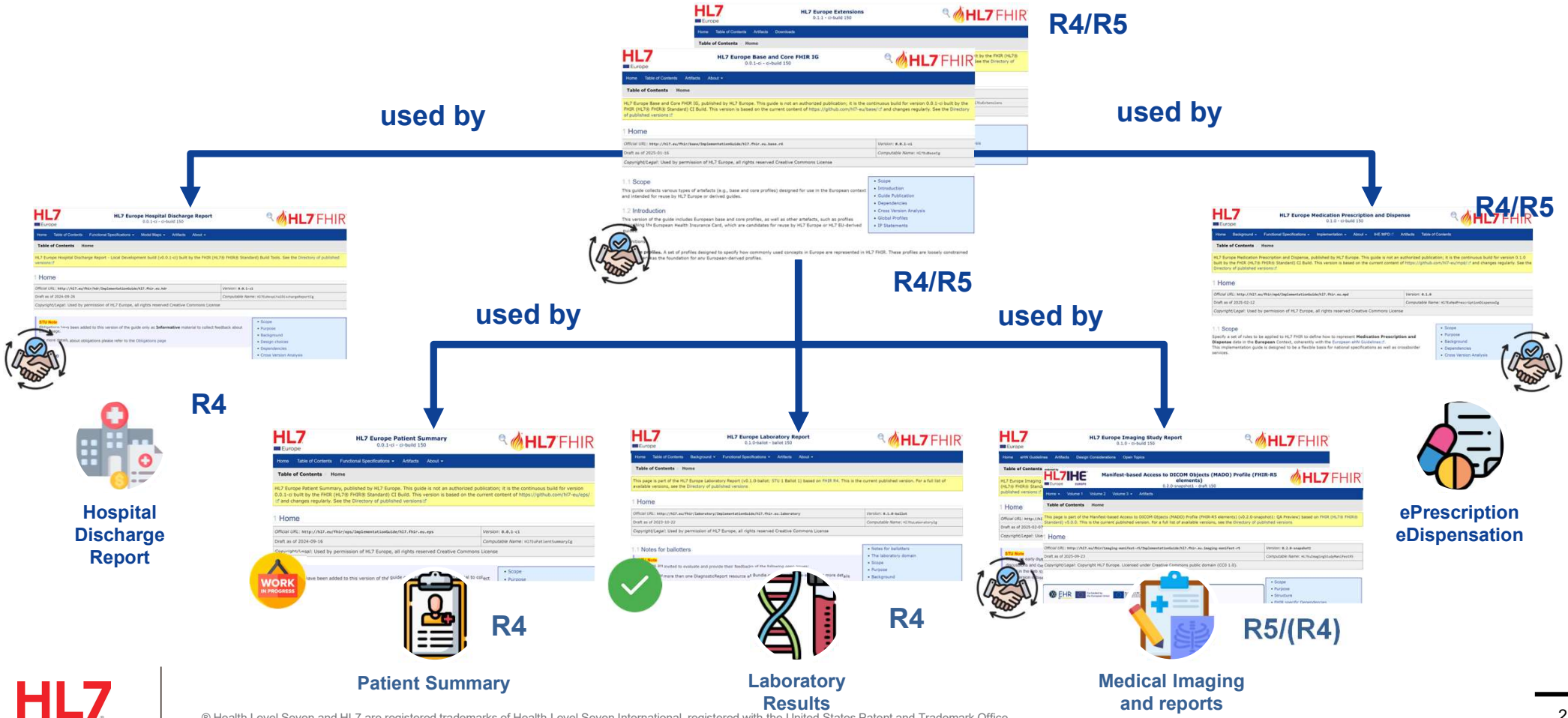




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The HL7 FHIR IG ecosystem for EHDS



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What about cross border specifications ?



TODAY

IHE XC* / HL7 CDA Based

HL7 CDA

- Patient Summary
- ePrescription/eDispensation
- Original Clinical Document (OrCD)

HL7 FHIR / IHE / DICOM

HL7 FHIR

- Laboratory Result Reports
- Hospital Discharge Reports — NEXT WAVE
- Medical Imaging Studies — NEXT WAVE

DICOM
Digital Imaging and Communications in Medicine

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What about cross border specifications ?



HL7 FHIR / IHE / DICOM

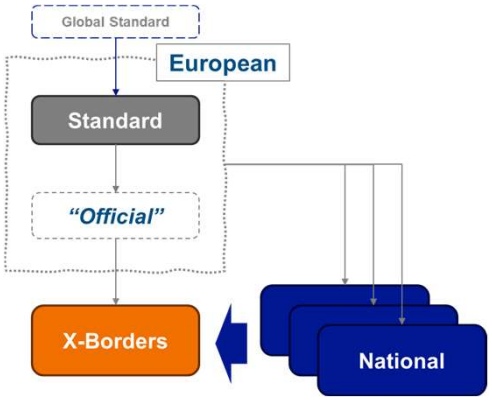
HL7® FHIR®

- Patient Summary
- ePrescription/eDispensation
- Original Clinical Document (OrCD)
- Laboratory Result Reports
- Hospital Discharge Reports
- Medical Imaging Studies

DICOM®
Digital Imaging and Communications in Medicine

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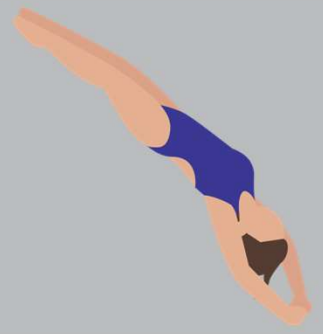
HL7 FHIR IGs overview



	Patient Summary	Laboratory Results	Hospital Discharge Report	ePrescription eDispensation	Medical Imaging and reports	BASE
Global Standard	✓	🤝	🤝	🤝	🤝	🔥
European Standard	WORK IN PROGRESS	✓ WORK IN PROGRESS	🤝	🤝	🤝	🤝
European *"Official"*	IF...	IF...	IF...	IF...	IF...	IF...
European X-border	👢	✓	🖥	WORK IN PROGRESS	🖥	👢

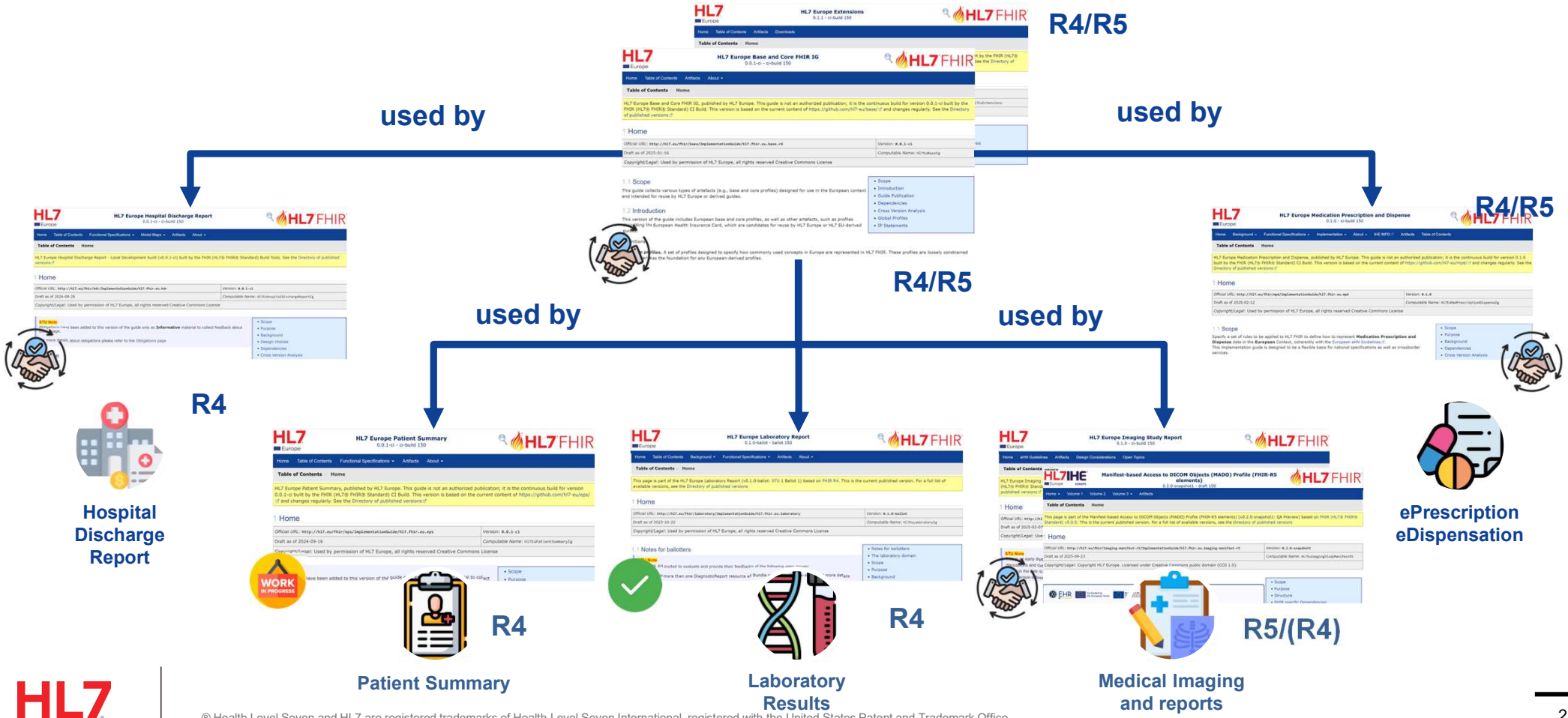
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DIVE-IN



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The HL7 FHIR IG ecosystem for EHDS



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EU Extensions

Ballot Reconciliation

On Going


HL7 Europe

HL7 Europe Extensions
0.1.1-ballot - ballot 150

HL7 FHIR

Home | Introduction | About | Artifacts

Table of Contents » Home

HL7 Europe Extensions, published by HL7 Europe. This guide is not an authorized publication; it is the continuous build for version 0.1.1-ballot built by the FHIR (HL7® FHIR® Standard) CI Build. This version is based on the current content of https://github.com/hl7-eu/extensions/ and changes regularly. See the Directory of published versions

1 Home

Official URL: http://hl7.eu/fhir/extensions/ImplementationGuide/hl7.fhir.eu.extensions	Version: 0.1.1-ballot
Draft as of 2025-04-23	Computable Name: Hl7EuExtensions

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1.1 Scope

This guide sets out a collection of HL7 Europe extensions designed for applicability within the EU realm.

This includes extensions defined for HL7 Europe implementation guides, such as:

- HL7 Europe Laboratory Report
- HL7 Europe Medication Prescription and Dispense
- HL7 Europe Hospital Discharge Report
- HL7 Europe Imaging Study Report
- HL7 Europe European Patient Summary
- HL7 Europe Base

HL7 FHIR R5

https://hl7.eu/fhir/extensions

5.2.1 Release-specific NPM Package and Definitions

- R4 NPM Package
- R5 NPM Package

5.3 Examples



HL7 FHIR R5

HL7 FHIR R4

Publication (Version) History

This guide lists the extensions specified for the European REALM.

The following versions have been published:

Date	IG Version	FHIR Version	Description	Links
Current Versions				
2025-04-30	B 0.1.1-ballot	5.0.0	Version used for the HL7 EU MPD ballot. First version covering both HL7 FHIR R4 and R5.	
(current)	(last commit - if in the last 3 months)	n/a	undefined	
Release Sequence				
2025-09-21	P 0.1.1-snapshot	5.0.0	This is a snapshot of the STU 1 version created for supporting the Xt-EHR stakeholder consultation. It is provided for review use only, and is not intended for production use. The official version will be published as part of the STU release.	
2025-04-30	B 0.1.1-ballot	5.0.0	Version used for the HL7 EU MPD ballot. First version covering both HL7 FHIR R4 and R5. *(Permanent Home)*	
2024-02-20	T 0.1.0	4.0.1	This is the first STU version released	

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EU Base and Core

Ballot Reconciliation

On Going



HL7 FHIR R4 **https://hl7.eu/fhir/base**

HL7 FHIR R5 **https://hl7.eu/fhir/base-r5**

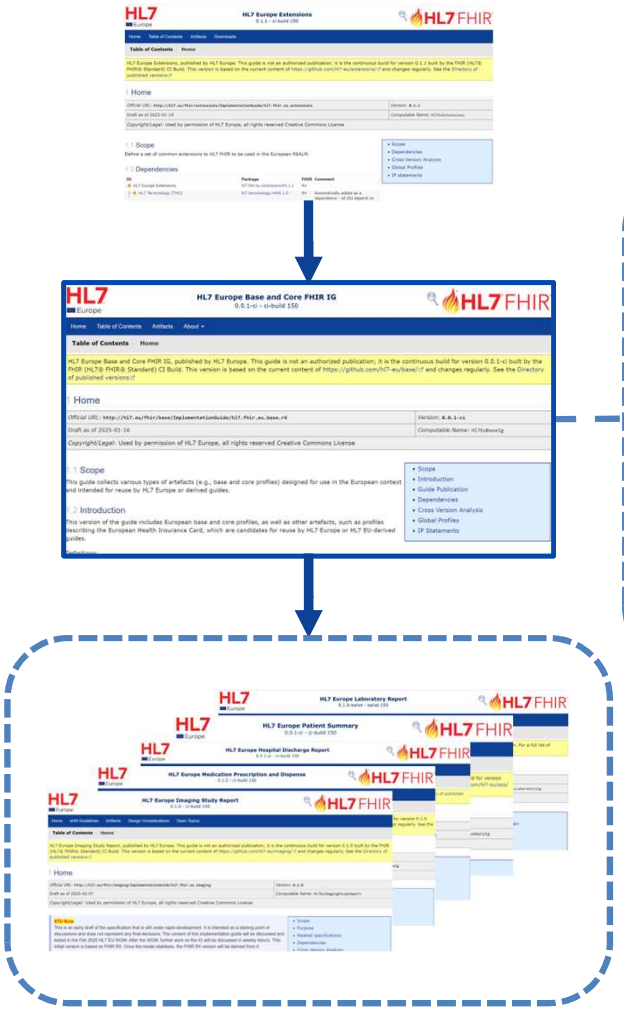
BASE

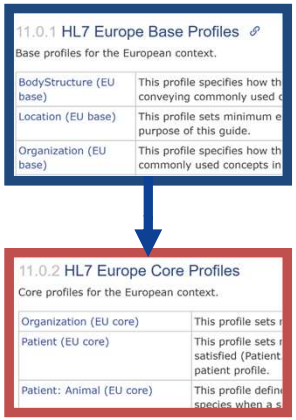
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Extensions (R4/R5)

Base and Core (R4/R5)

Scoped HL7 EU IGs (R4/R5)





Base

- **Baseline** for all HL7 Europe profiles.
- **Loosely constrained**, providing a flexible foundation.
- **Rarely used "as is"**, but always extended or specialized.

Core

- Defines **essential constraints** that cut across many use cases.
- Serves as the **first reference point** for the large majority of HL7 Europe FHIR IGs.
- Can often be used **"as is"**, without further refinement.
- Realizes the **common EHDS logical models** in practice.

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Core Profiles



EHDS Models

Realise

Base Profiles

11.0.1 HL7 Europe Base Profiles

Base profiles for the European context.

BodyStructure (EU base)	This profile specifies how th conveying commonly used c
Location (EU base)	This profile sets minimum e purpose of this guide.
Organization (EU base)	This profile specifies how th commonly used concepts in

Derived from

11.0.2 HL7 Europe Core Profiles

Core profiles for the European context.

Organization (EU core)	This profile sets r
Patient (EU core)	This profile sets r satisfied (Patient. patient profile.
Patient: Animal (EU core)	This profile define species when a si

Pursue Alignment with

HL7 FHIR IPS

The "IPS"



Composed from the "IPS Library"



Used by



HL7 Europe IGs

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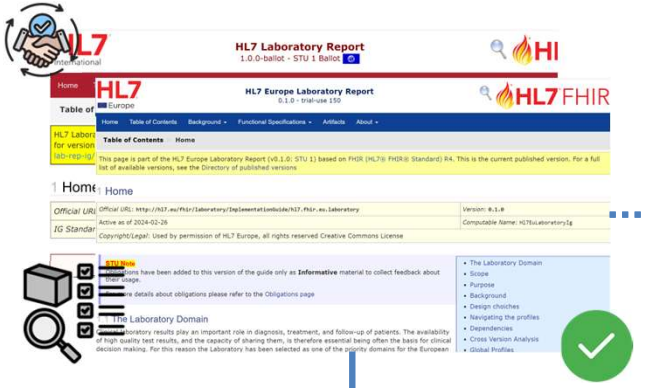
EU Base and Core

- Patient, Practitioner, Organization, Location Resources

Body structure (EU base)	This profile specifies how the HL7 FHIR BodyStructure resource should be used for conveying commonly used concepts in the European context.
Coverage: EHIC	Coverage profile for the European Health Insurance Card
Location (EU base)	This profile sets minimum expectations for the Location resource to be used for the purpose of this guide.
Organization (EU base)	This profile specifies how the HL7 FHIR Organization resource should be used for conveying commonly used concepts in the European context.
Organization (EU core)	This profile sets minimum expectations for the Organization resource common to most of the use cases.
Patient (EHIC)	This profile represents the constraints applied to the Patient resource when sed with the EHIC coverage profile.
Patient (EU base)	This profile specifies how the HL7 FHIR Patient resource should be used for conveying commonly used concepts in the European context.
Patient (EU core)	This profile sets minimum expectations for the Patient resource common to most of the use cases. When the ips-pat-1 invariant is satisfied (Patient.name.given, Patient.name.family or Patient.name.text SHALL be present) then this profile complies with the IPS patient profile.
Patient: Animal	This profile defines how to represent an Animal as subject of care in FHIR for the purpose of this guide. This is used to identify the species when a specimen is collected from an animal
Practitioner (EU base)	This profile specifies how the HL7 FHIR Practitioner resource should be used for conveying commonly used concepts in the European context.
Practitioner (EU core)	This profile sets minimum expectations for the Practitioner resource common to most of the use cases.
PractitionerRole (EU base)	This profile specifies how the HL7 FHIR PractitionerRole resource should be used for conveying commonly used concepts in the European context.
PractitionerRole (EU core)	This profile sets minimum expectations for the PractitionerRole resource common to most of the use cases.

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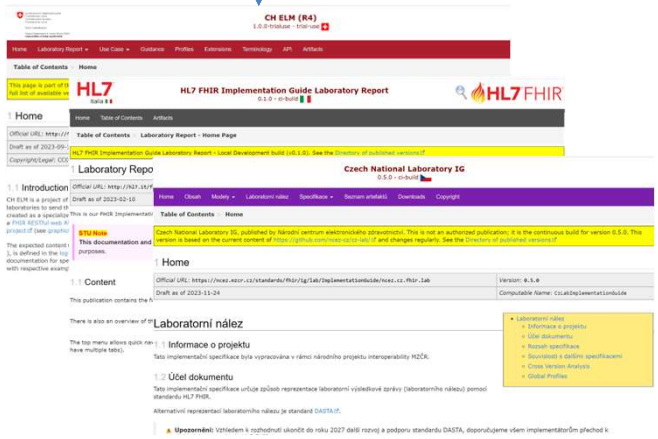
Laboratory Report



Standard (EU/UV scope)



HL7 FHIR R4



Laboratory Results

eHealth Network

GUIDELINE

on

the electronic exchange of health data under Cross-Border Directive 2011/24/EU

Laboratory Results

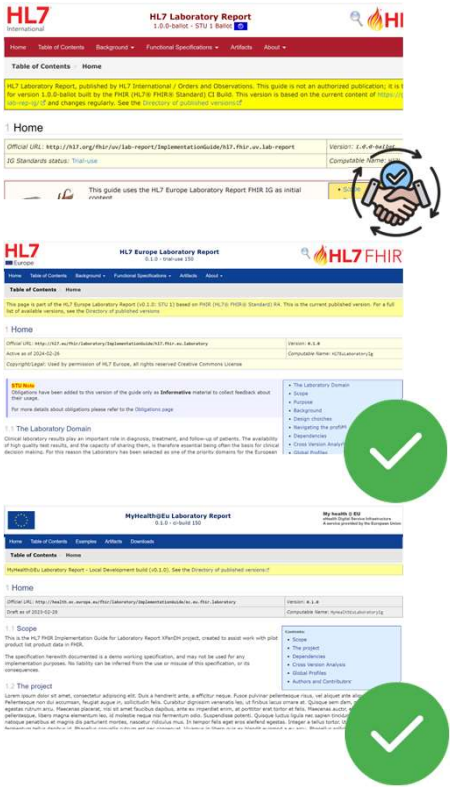
Release 1.1

EU X-Borders

National Guides

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Laboratory Report



https://build.fhir.org/ig/HL7/uv-lab-rep-ig/

https://hl7.eu/fhir/laboratory/

https://build.fhir.org/ig/hl7-eu/laboratory/

https://fhir.ehdsi.eu/laboratory/

https://build-fhir.ehdsi.eu/laboratory/

Laboratory Results

HL7 FHIR R4

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Balancing different requirements

Legally signed documents

Often structured and including different kinds of test results

Still HL7 CDA and document exchange infrastructures in use

HL7 FHIR REST consumers expect to get Laboratory Reports by **searching per DiagnosticReport**

In R5 the DiagnosticReport refers the Composition

Document Bundle

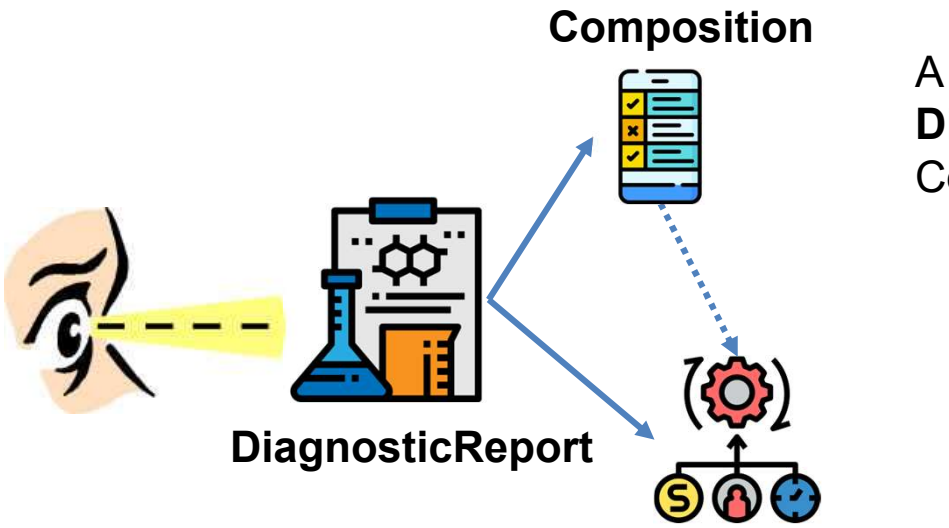
Diagnostic Report

Document Bundle always including a DiagnosticReport



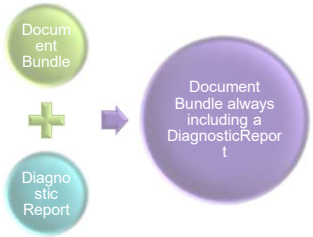
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The Laboratory Report



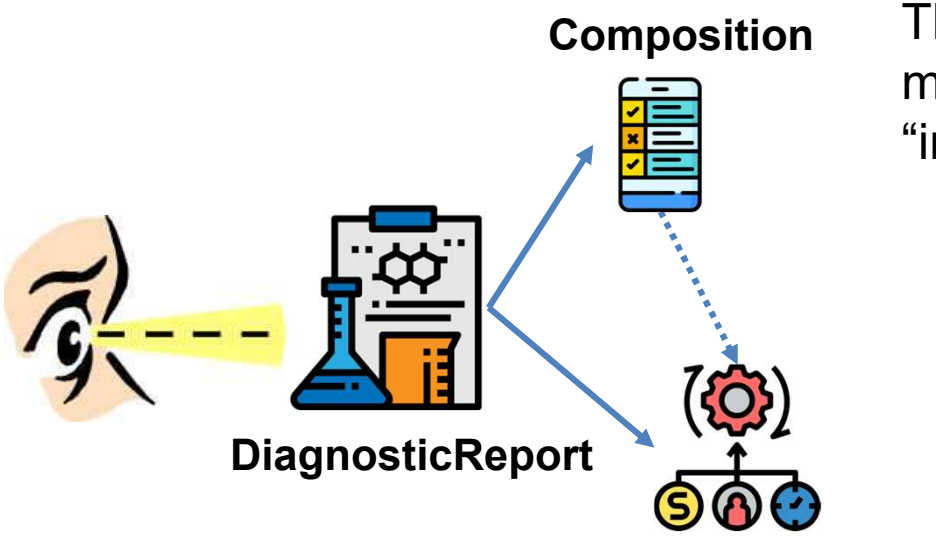
A Lab **report** is always **represented by** a **DiagnosticReport.** This resource always refers a Composition

The **Composition defines** the report **structure** (it might be just a single section) and it acts as an “index” for all the used resources

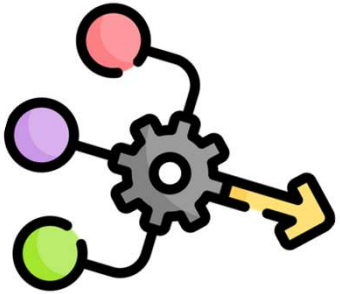


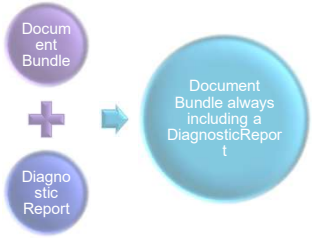
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The Laboratory Report



The **Composition defines** the report **structure** (it might be just a single section) and it acts as an "index" for all the used resources

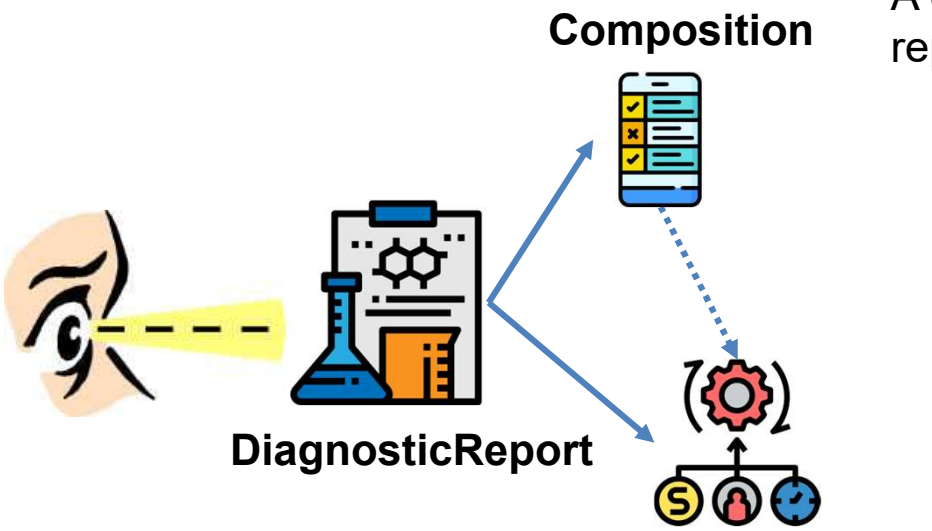




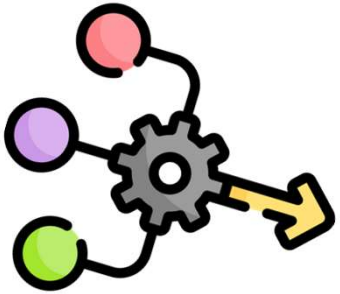
It is the mean for assembling the report as a document (**document Bundle**)

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The Laboratory Report

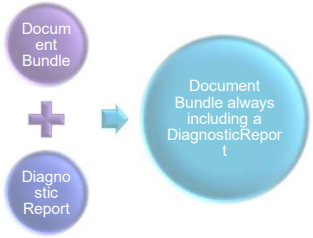


A **document Bundle** represents the legally signable report, and it includes all the data defining the report.



Bundle
[type = document]





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Medication Prescription & Dispense



ePrescription
eDispensation

IHE INTERNATIONAL Integrating the Healthcare Enterprise

HL7

GEMINI

HL7 Europe



aligned



derived







Name	Flags	Card.	Type	De
EHDSMedicationPrescription		0..*	EHDSDataSet	
header		1..1	Base	Pr
subject		1..1	EHDSPatient	Th
identifier		0..*	Identifier	Bu
authorship		1..*	Base	Re
author[x]		1..1		Th
authorEHDSHealthProfessional			EHDSHealthProfessional	
authorEHDSOrganisation			EHDS	

HL7 FHIR R5

HL7 FHIR R4

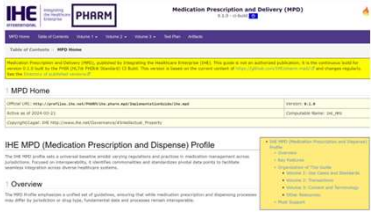
Xt EHR @dataspace

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Medication Prescription & Dispense



ePrescription
eDispensation



HL7 FHIR R5 https://profiles.ihe.net/PHARM/MPD/



HL7 FHIR R5 https://hl7.eu/fhir/mpd



HL7 FHIR R4 https://hl7.eu/fhir/mpd-r5



Ballot Reconciliation

On Going

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Medication Prescription & Dispense

In Scope

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

Out of Scope

- Hospital use (in scope for IHE MPD)
- Workflow (in scope for IHE MPD)
- Reimbursement
- Prescription list
- Non-medication
- Requests to administrating devices

Courtesy of Rutt Lindström

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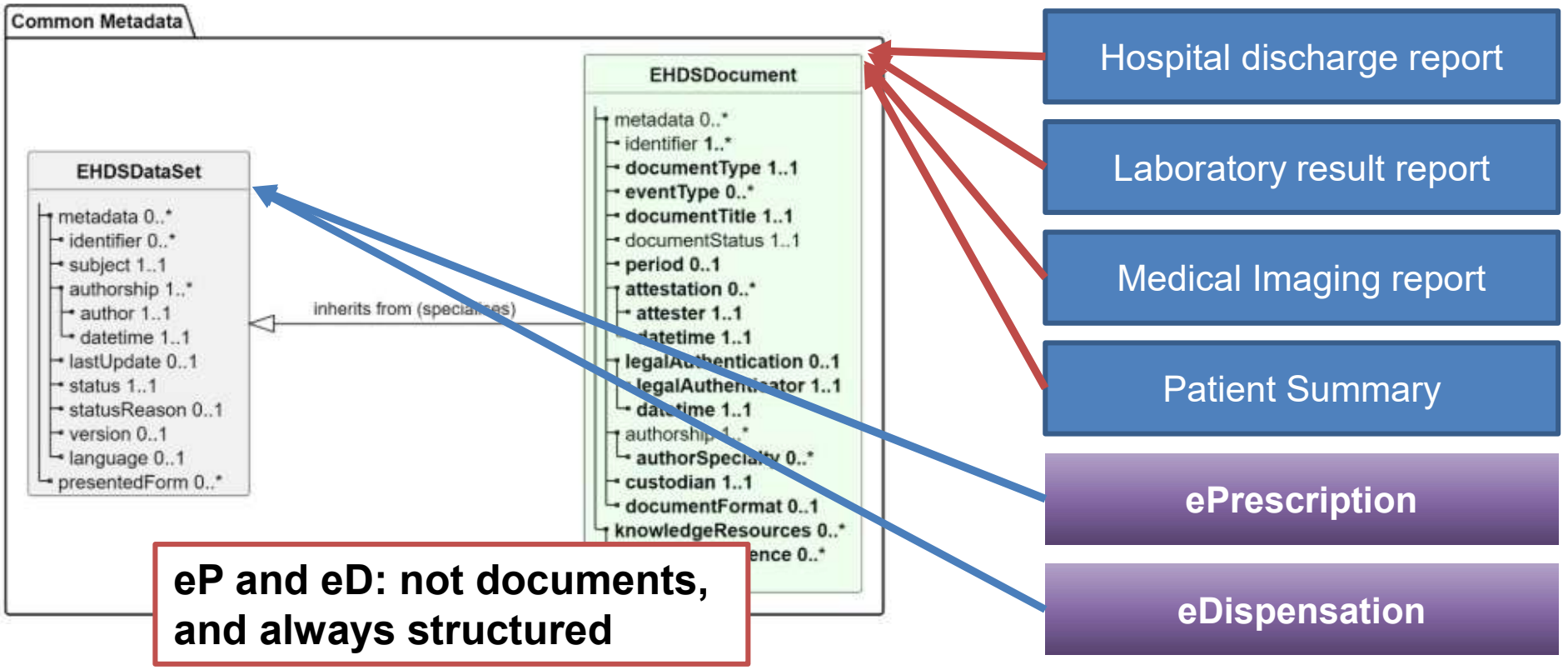
Medication Prescription & Dispense

Situations addressed

- Multi-item prescriptions, single-item dispenses
- Indication (Optional)
- Additional health information not on prescription
- Extensions on Medication to allow detailed description of the product
- Flirting with ISO IDMP to facilitate data flow from medicines agencies
- Flexible dosing information
- Flexible use of code systems

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Medication Prescription & Dispense



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Courtesy of Rutt Lindström

Hospital Discharge Report



Hospital Discharge Report











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Hospital Discharge Report

Ballot Reconciliation

On Going





https://hl7.eu/fhir/hdr

HL7® FHIR® R4

https://fhir.ehdsi.eu/hdr/

https://build-fhir.ehdsi.eu/hdr/

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Hospital Discharge Report

Flexible Section Structure

- **“Flat structure"** as a reusable **section library**.
- Sections can be organized **flat or nested**, based on institutional requirements.
- **Key principles:**
  - ✅ A few **required sections**.
  - ✅ **Open slicing**: implementers can add more top-level sections.
  - ✅ **Sub-sections allowed**, with few exceptions.
- 📌 This flexibility ensures:
  - Local adaptability
  - Standardized content model
  - Consistency across implementations

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Hospital Discharge Report

Section Entry Optionality

- Supports varied document maturity levels:
  - Structured
  - Text-only
  - Unstructured
- ❗ Entries in sections *are not mandatory,* but strongly recommended to promote:
  - Structured data
  - Better interoperability
  - Higher data quality
- 📘 Obligations in the guide help implementers align with interoperability goals

HL7 Europe

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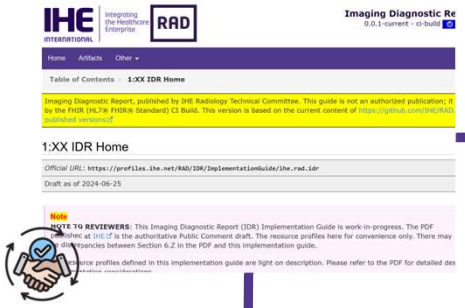
Imaging Study Report

HL7 FHIR R5

IHE INTERNATIONAL Integrating the Healthcare Enterprise



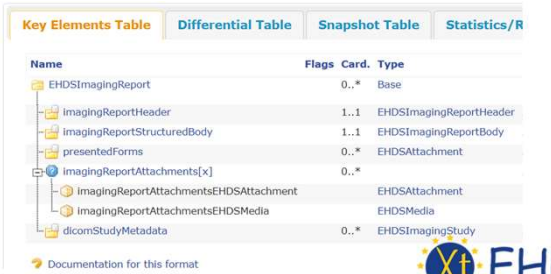
Medical Imaging and reports



aligned

aligned





Xt EHR @dataspace



HL7 FHIR R5



HL7 FHIR R4



HL7 Europe IHE EUROPE

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Imaging Study Report

Ballot Reconciliation

On Going

HL7 FHIR R5



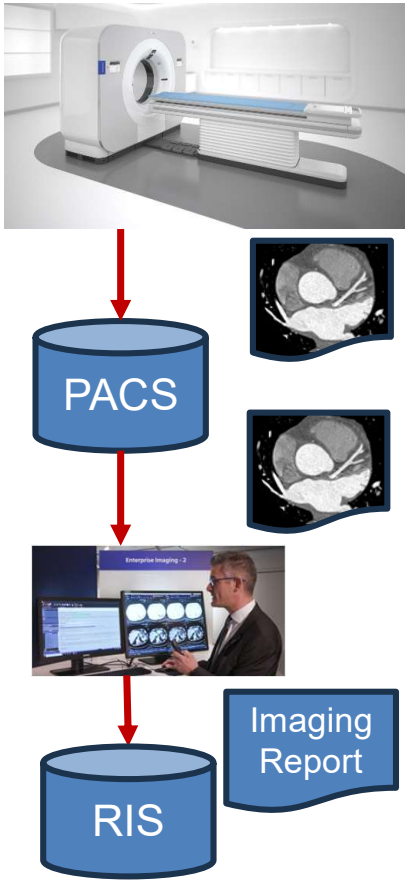
- https://hl7.eu/fhir/imaging-r5 (ballot)
- https://hl7.eu/fhir/imaging-r5/0.1.0-snapshot1 (post-ballot snapshot)

Medical Imaging and reports

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Imaging workflow

- Imaging is generated by imaging modalities
- The result is a DICOM **Imaging Study**
- The Imaging Study is stored in a PACS
- The Radiologist reads the Imaging Study from the PACS and writes an **Imaging Report**.
- This is typically stored in the RIS/EHR.



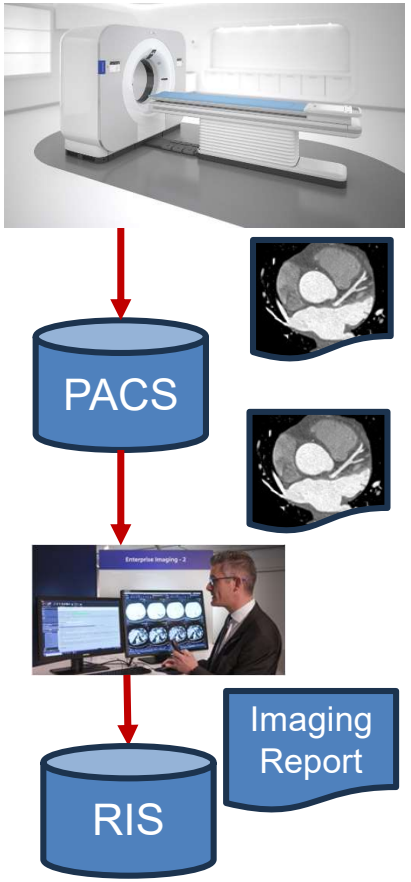
Courtesy of Bas van den Heuvel

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EHDS and Imaging Documents

- **HL7 FHIR Imaging Manifest** that holds the information required to access the imaging data (data from the PACS).
  - ➔ **Moved to the new on-develop IHE MADO profile**
- **HL7 FHIR Imaging Report** that holds the Imaging Report (data from RIS).

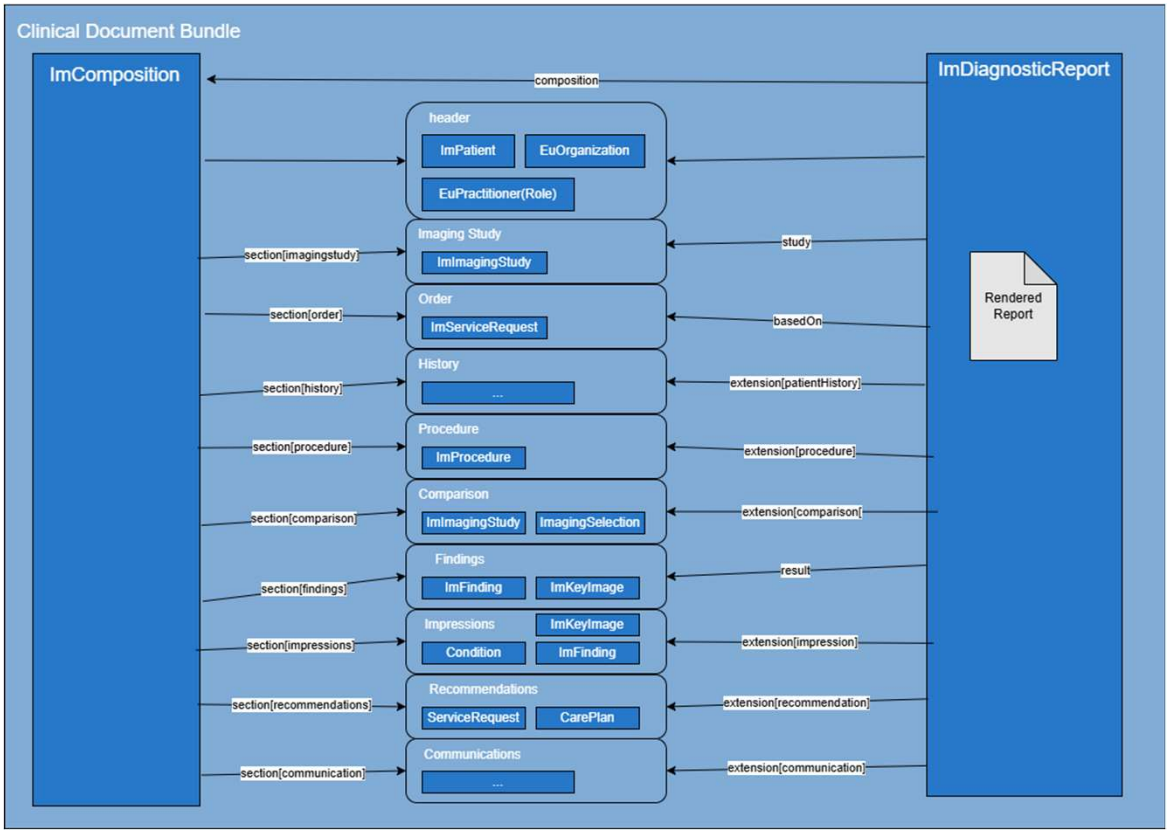




Courtesy of Bas van den Heuvel

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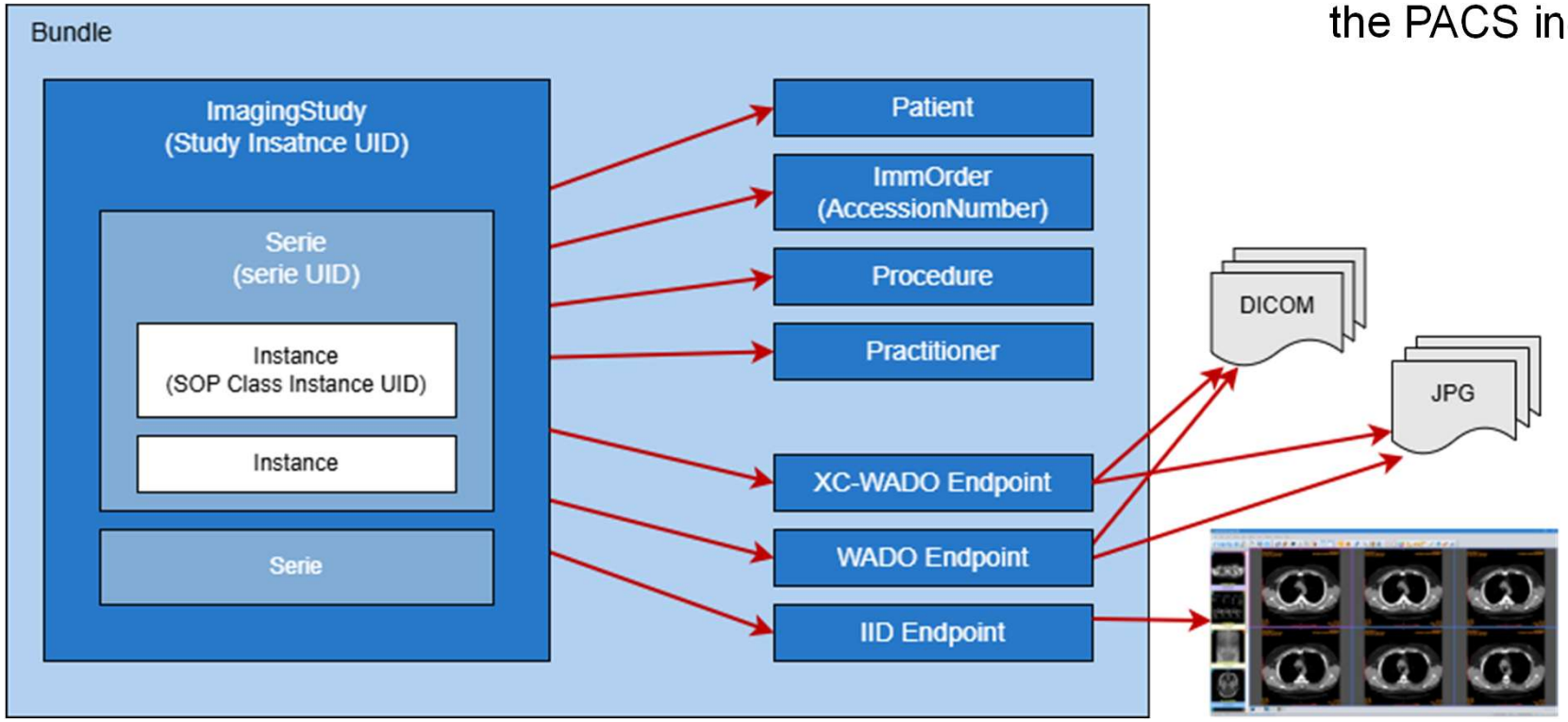
Imaging Report



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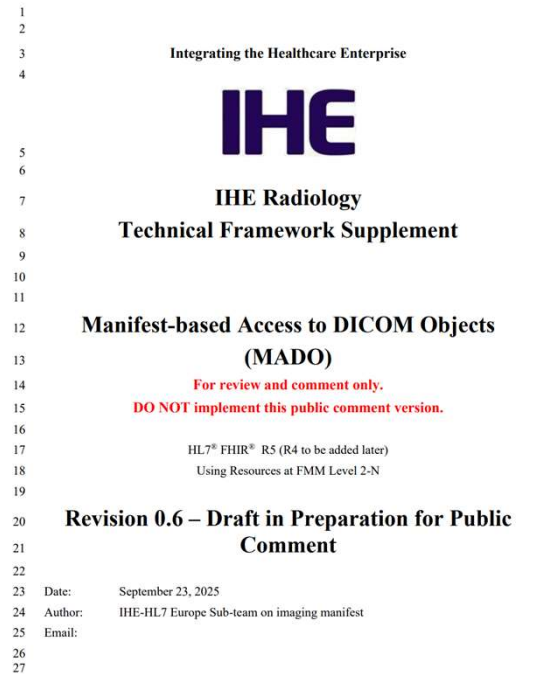
Imaging Manifest

Manifest holds data as stored in the PACS including endpoints.



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Imaging Manifest



Integrating the Healthcare Enterprise

IHE

IHE Radiology
Technical Framework Supplement

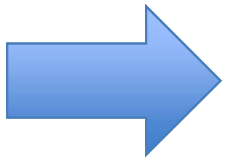
Manifest-based Access to DICOM Objects
(MADO)

For review and comment only.
DO NOT implement this public comment version.

HL7® FHIR® R5 (R4 to be added later)
Using Resources at FMM Level 2-N

Revision 0.6 – Draft in Preparation for Public Comment

Date: September 23, 2025
Author: IHE-HL7 Europe Sub-team on imaging manifest
Email:





Manifest-based Access to DICOM Objects (MADO) Profile (FHIR-R5 elements)
0.2.0-snapshot1 - draft 150

Home | Volume 1 | Volume 2 | Volume 3 | Artifacts

Table of Contents | Home

This page is part of the Manifest-based Access to DICOM Objects (MADO) Profile (FHIR-R5 elements) (v0.2.0-snapshot1: QA Preview) based on FHIR (HL7® FHIR® Standard) v5.0.0. This is the current published version. For a full list of available versions, see the Directory of published versions

1 Home

Official URL: http://hl7.eu/fhir/imaging-manifest-r5/ImplementationGuide/hl7.fhir.eu.imaging-manifest-r5	Version: 0.2.0-snapshot1
Draft as of 2025-09-23	Computable Name: Hl7EuImagingStudyManifestR5
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Acknowledgment
The development of this Implementation Guide version has been supported by the Xt-EHR Joint Action. Xt-EHR provided expertise, alignment with European health policy priorities, and validation of specifications to enable consistency with EHDS requirements.

- Scope
- Purpose
- Structure
- FHIR specific Dependencies
- Cross Version Analysis
- Global Profiles
- IP statements
- Authors and Contributors

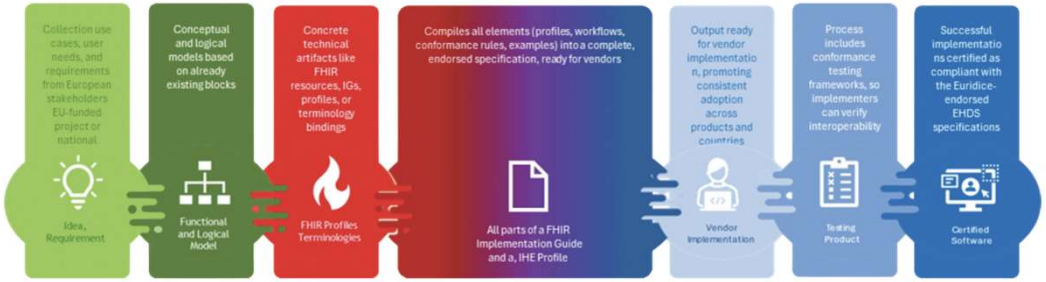
https://hl7.eu/fhir/imaging-manifest-r5

https://euridice.org/index.php/mado/

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Euridice = HL7 Europe + IHE Europe

- *EURIDICE stands for **Eu**ropean **I**nteroperability Specifications for **Di**gital Solutions in Health**care**.*
- EURIDICE is a **joint HL7 Europe and IHE-Europe initiative**, focused on creating well-architected and implementable specifications for EHDS.



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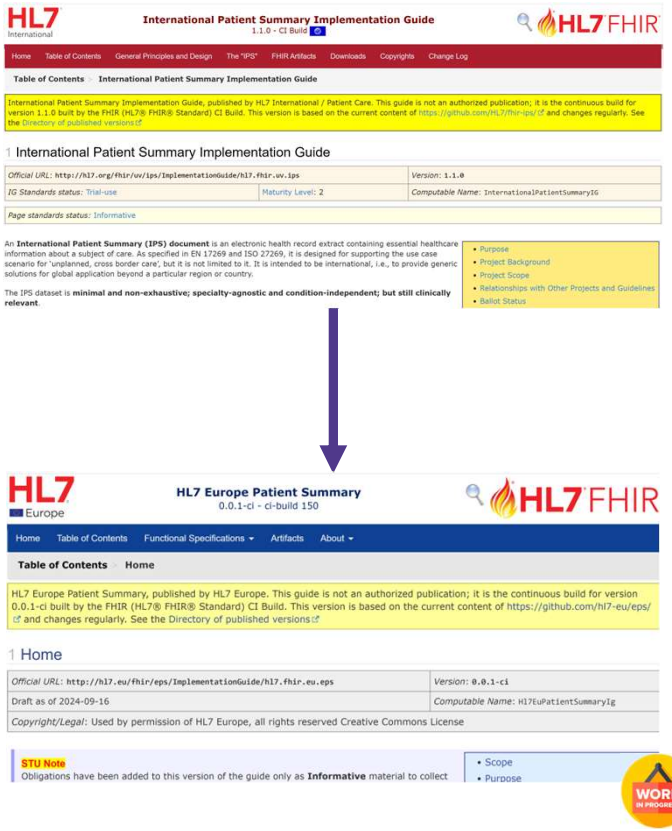
Patient Summary















Patient Summary

HL7 Europe





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Patient Summary



https://hl7.org/fhir/uv/ips/
https://build.fhir.org/ig/HL7/fhir-ips



https://build.fhir.org/ig/hl7-eu/eps

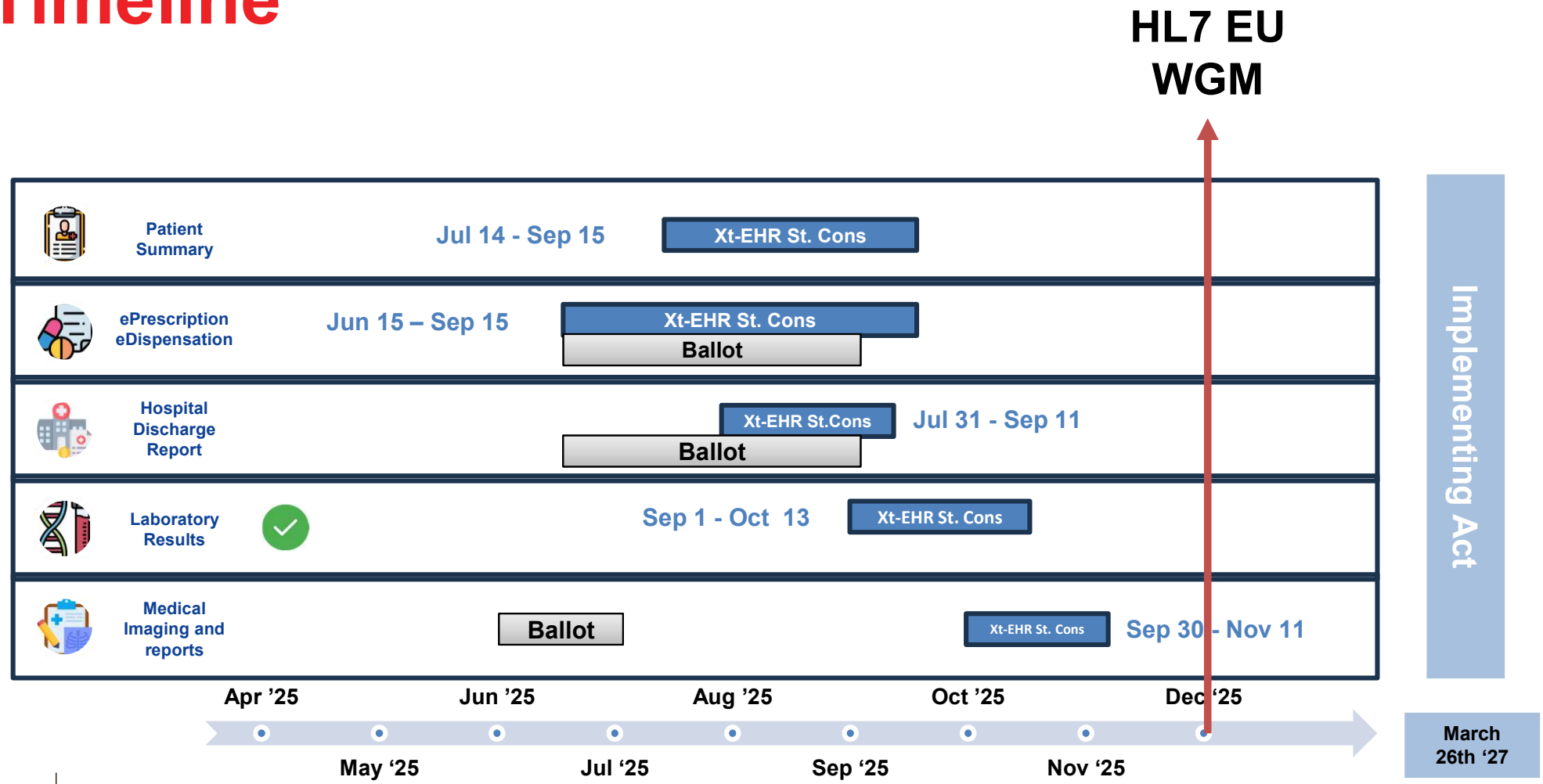


Patient Summary

HL7 FHIR R4

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Timeline



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Shaping the Future of FHIR in Europe

HL7 Europe Working Group Meeting Cologne, Germany 1-5 December 2025



HL7 Europe

hl7europe.org

for more information

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Highlights



- HL7® FHIR® Specifications for the EHDS
- Hands-on and Tutorials
- Testing and Refinement
- Networking with Experts
- HL7 Europe Initiatives and Projects

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HL7 Europe

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