The HL7 Europe Imaging Study FHIR IG and how to contribute

Webinar, 13 June 2025

14.00-15.00 CEST

Online on Teams

The EHDS FHIR IG ecosystem

An HL7 Europe webinar series 2025

The HL7 Europe Imaging Study FHIR IG and how to contribute

Introductions

- Presenters:
  - Line Andreassen Sæle, HL7 Norway
  - Giorgio Cangioli, HL7 Europe
  - Bas van den Heuvel, Philips
- Facilitator: Michael Strübin, HL7 Europe

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Housekeeping

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  - Use the chat (for comments, questions…)
  - Use reactions/emojis during the presentations
  - Raise your hand if you'd like to speak
  - If you are invited to speak, please turn on your video and say who you are

- The webinar will be recorded.
- Link to recording and slides (in pdf) on www.hl7.tv will be emailed to all registered participants.

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The HL7 Europe Imaging Study FHIR IG and how to contribute

Agenda

- Welcome, introductions, housekeeping
- The EHDS policy context
  Line Andreassen Sæle, HL7 Norway
- The EHDS FHIR IG ecosystem
  Giorgio Cangioli, HL7 Europe
- HL7 Europe Imaging Study Report FHIR IG
  Bas van den Heuvel, Philips
- Our collaborative platforms and how to contribute
  Giorgio Cangioli, HL7 Europe
- Discussion and Q&A
- Next steps

End

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The EHDS policy context

The role of HL7 Europe and HL7 FHIR in the EHDS

Line A. Saele, HL7 Norway

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About me

- Enterprise Architect at the Norwegian Institute of Public Health
- Background – Master of Cybernetics from NTNU
- Representative from Norway at the eHN Technical subgroup
- Chair HL7 Norway
- Affiliate Director HL7 International

HL7 International

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HL7 EUROPE

- Not just EU
- Collaboration of all the Europe Affiliates
- Together we bring HL7 FHIR into the EHDS

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The Electronic Health Data Space regulation

- EHDS regulation went into effect on 25 March 2025
- Formal processing in the EEA can start now after decision in the EU

11 Feb 2025: Signing ceremony for EHDS regulation in Brussels

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EHDS in a nutshell – 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 – Overall timeline for application

Article 13 Registration of electronic health data

1. Member States shall ensure that, where electronic health data are processed for the provision of healthcare, healthcare providers **register** the relevant personal electronic health data falling fully or partially under at least the priority categories of personal electronic health data referred to in Article 14 **in an electronic format in an EHR system**.
2. When processing data in an electronic format, healthcare providers shall ensure that the personal electronic health data of the natural persons under their treatment are **updated** with information related to the healthcare.
3. Where personal electronic health data are registered in a Member State of treatment that differs from the Member State of affiliation of the natural person concerned, the Member State of treatment shall ensure that the **registration is performed under the identification data of the natural person in the Member State of affiliation**.
4. By 26 March 2027, the Commission shall, by means of implementing acts, **determine data quality requirements, including in relation to semantics, uniformity, consistency, accuracy and completeness, for the registration of personal electronic health data in an EHR system as relevant**. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).

When personal electronic health data are registered or updated, the electronic health records shall identify the health professional and healthcare provider that carried out such registration or update, and the time at which such registration or update was carried out. Member States may require other aspects of data registration to be recorded.

Minimum: uphold the rights of natural persons.
Any suggestion would need the support of a majority of Member States

Comparison to eHealth Network, subgroups, current MyHealth@EU governance

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Comparison to eHealth Network, subgroups, current MyHealth@EU governance

Comitology Committee

EHDS Board
NB: covering primary *and* secondary uses

eHealth Network
(adopts guidelines)

eHN Semantic SG

eHN Technical IOP SG

eHN Coordinated

EHDS Board Subgroups (to be established by Board, likely mirroring current subgroups + additional ones for secondary)

eHealth Stakeholders Group (an expert group)

Stakeholder Forum

Steering Groups for MyHealth@EU and HealthData@EU

eHOMB
(adopts Change Proposals)

eHMSEG – eHealth Member State Expert Group
(adopts technical specifications and other MyHealth@EU artefacts)

Subgroups of Steering Groups

Same - COM

Semantic WG

Requirements WG

Cluster

New use cases WG

KPI and Monitoring Framework TF

Communication TF

MyHealth@EU governance structures
(including for the Change Proposal process)

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Actions related to the European electronic health record exchange format (EEHRxF)

Innovation, experimentation

epSOS, EXPAND, JAseHN, eHAction

- Development of the MyHealth@EU infrastructure

X-eHealth

- Work on lab results, hospital discharge reports, medical imaging
- Defined use cases, data sets, data models
- Implementation guides for CDA and FHIR

XpanDH

- Further elaboration of the format
- Pilots, verification of implementability
- Set-up of the ecosystem

xShare

- Practical implementation of patient-mediated workflow for data portability
- Further development of the exchange format (e.g. care plans, telemonitoring)

Further actions

- In-service deployment of the EEHRxF
- Patient access to health data using MyHealth@EU
- EEHRxF support centre
- EUVAC

Formalisation

Work on the eHealth Network guidelines

- Use cases, data sets, principles
- Adopted by Member States in the eHN

Work by MyHealth@EU Solution Provider

- Implementable specifications, other artefacts
- Implementation in OpenNCP fo MyHealth@EU
- Adopted by Member States in th eHMSEG

Joint action Xt-EHR

- Work on the formalisation of the format
- Requirements for the certification of EHR systems

(recommendations for possible future implementing acts under HDS)

Implementing Decisions under the upcoming EHDS

Legally binding requirements and specifications for the European health record exchange format

Legally binding requirements for the certification of EHR systems

Infrastructure, deployment

MyHealth@EU current and future

- Patient Summary and ePrescriptions/ eDispensations
- Original Clinical Documents
- Lab results, hospital discharge reports, medical imaging
- Further data categories

HL7 International

Xt-EHR already referencing HL7 FHIR “all over”

Xt-EHR: collaborative authoring of HL7 FHIR IG

HL7 Europe

HL7 Europe Medication Prescription and Dispense
0.1.0 - ci-build 150

HL7 FHIR

Home | Introduction | Functional | Implementation | About | Artifacts | R5 IG

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1 Home

Official URL: http://hl7.eu/fhir/mpd/Implementation	on: 0.1.0
Draft as of 2025-05-19	*Computable Name*: HL7EuMedPrescriptionDispenseIg
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HL7 FHIR R4 & R5

1.1 Scope

The scope of this implementation guide is **Medication Prescription and Dispense** in the **European** Context. It is coherent with the European eHN Guidelines and preparatory EHDS work.

This implementation guide is designed to be a flexible basis for national specifications as well as crossborder services.

Additional information can be found in the Scope and Content section.

- Scope
- Purpose
- Background

1.2 Purpose

The goal of this Implementation Guide is to define the European standard for Medication Prescriptions and Dispense data to facilitate the

- HL7 Europe
- IHE Pharmacy
- **Xt-EHR**
- XpanDH
- xShare
- EUVAC
- HL7 Pharmacy
- EHR vendors and community

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Xt EHR

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QUESTIONS?

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End

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The focus: priority categories for primary use (art. 14)

EUROPEAN ELECTRONIC HEALTH RECORD EXCHANGE FORMAT

Member States may provide by virtue of national law that additional categories of personal

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

Several actors engaged

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

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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Not only cross-border !

HL7 (Europe): Consume with Confidence

- **Open, transparent, and consensus-driven processes**
- Continuously maintained and evolved by a global and European **community** of experts
- A **neutral platform** supporting national and **regional** health programs
- Broad and active **stakeholder engagement** across sectors
- Fueled by multi-stakeholder communities **turning standards into practice**

The proposed solution

Standard

Flexibility

Participation

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The EHDS FHIR IG ecosystem

EUROPEAN ELECTRONIC HEALTH RECORD EXCHANGE FORMAT

HL7 Europe

EU extensions

Ballot

June 1st – June 30th 2025

https://hl7.eu/fhir/extensions

HL7® FHIR® R5

HL7® FHIR® R4

HL7® FHIR® R5

EU Base and Core

Ballot

June 1st – June 30th 2025

BASE

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

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

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

Medication Prescription & Dispense

Ballot

June 15th – August 31st 2025

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**

ePrescription
eDispensation

Hospital Discharge Report

Ballot

June 15th – August 31st 2025

HL7 Europe

HL7 Europe Hospital Discharge Report
0.0.1-ci - ci-build 150

HL7 FHIR

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HL7 Europe Hospital Discharge Report - Local Development build (v0.0.1-ci) built by the FHIR (HL7® FHIR® Standard) Build Tools. See the Directory of published versions

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Official URL: `http://hl7.eu/fhir/hdr/ImplementationGuide/hl7.fhir.eu.hdr`	*Version:* `0.0.1-ci`
Draft as of 2024-09-26	*Computable Name:* `Hl7EuHospitalDischargeReportIg`
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STU Note
Obligations have been added to this version of the guide only as **Informative** material to collect feedback about their usage.

For more details about obligations please refer to the Obligations page

- Scope
- Purpose
- Background
- Design choices
- Dependencies
- Cross Version Analysis

1.1 Scope

Hospital Discharge Report

https://hl7.eu/fhir/build/hdr

HL7 FHIR R4

Patient Summary

Patient Summary

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

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

HL7 FHIR R4

Timeline

Patient Summary
Jul 14 - Sep 15
Xt-EHR St. Cons
Ballot
ePrescription eDispensation
Jun 15 – Sep 15
Xt-EHR St. Cons
Ballot
Hospital Discharge Report
Xt-EHR St.Cons
Jul 31 - Sep 11
Ballot
Laboratory Results
Sep 1 - Oct 13
Xt-EHR St. Cons
Medical Imaging and reports
Ballot
Xt-EHR St. Cons
Sep 30 - Nov 11
Implementing Act
Apr '25
May '25
Jun '25
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Aug '25
Sep '25
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Nov '25
Dec '25
March 26th '27

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HL7-EU
Imaging Study Report

Bas van den Heuvel (Philips)
13 June 2025

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Who am I?

- Bas van den Heuvel
- Standardization Architect @ Philips
- Background:
  - Active in HL7 since 2017
  - Co-chair of HL7-EU imaging

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HL7 Europe

HL7 Europe Imaging Study Report
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HL7 FHIR

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Draft as of 2025-05-19	*Computable Name*: `HL7EuImagingStudyReport`
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STU Note
This is the 0.1.0-ballot version of the specification.

The source of this IG is stored on github (https://github.com/hl7-eu/imaging).

The content of this implementation guide is discussed HL7 EU calls (HL7-eu imaging on Confluence).

This version is based on FHIR R5. A FHIR R4 version will be derived from this ballot version and is expected to be published in the near future.

- Scope
- Purpose
- References
- Dependencies
- Cross Version Analysis
- Global Profiles
- IP statements
- Authors and Contributors

1.1 Scope

This implementation guide specifies imaging study data in the **European** context, as defined in eHN Imaging Studies and Reports and refined by XtEHR Imaging Logical Model , as a FHIR model. It defines:

- The structure and contents of a FHIR imaging studies and reports.
- Different options for publishing and searching for such studies and reports.
- Discovery of available mechanisms to access the imaging data.

The specification is to be used in a variety of deployment models, which includes the EHDS use cases: exchange data within healthcare organizations, across nations/regions and cross border information exchange. In all of these use cases it is important that it is compatible with the existing ecosystem.

Current approaches within Europe use different approaches to information exchange:

- **Document based exchange**, the document is represented as a FHIR Document Bundle.
- **REST API based access to documents**, a `Composition` and `DiagnosticReport` for each document including instances of the referred resources
- **REST API based access to resources**, as the previous but the (important) resources are *harmonized*, meaning that all documents point to the same `Patient` , `Organization` and other resources.

Joint activity between
IHE-eu and HL7-eu

Timeline:

Jan – initial version
based on eHN guidelines
and IHE-IDR
Feb kick-off @ HL7-eu WGM
Feb-May refine during weekly telco'
May tested @ HL7 Connecthaton

May 26 – June 26 –0.1.0-ballot

June 23-25 – IHE Plugathon tests
July & August
Process ballot comments

August – first publication

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HL7 Europe

HL7 Europe Imaging Study Report

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1.1 Scope

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HL7 Europe

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Draft as of 2025-05-19	*Computable Name*: `HL7EuImagingStudyReport`
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HL7 Europe

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HL7 FHIR

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  - 1.2 Adapting Guidelines for Country use
  - 1.3 Contributors
- 2 Actors and Transactions
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  - 3.2 Mapping to XtEHR Logical Model
- 4 Deployment profiles
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- 5 Design Considerations
- 6 Artifacts
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  - 7.2 Imaging Study Report Provider/Creator
  - 7.3 Address model
  - 7.4 Alert flag model
  - 7.5 Allergy intolerance model

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XtEHR logical model -> FHIR

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3.2 Mapping to XtEHR Logical Model

3.2.1 Logical model mapping onto HL7 FHIR

The following FHIR describe the way the logical model has been mapped onto the FHIR profiles defined in this specification.

Name	Title	Description
EHDSAddressMap	EHDSAddress Mapping	Map for EHDSAddress
EHDSAllergyIntoleranceMap	EHDSAllergyIntolerance Mapping	Map for EHDSAllergyIntolerance
EHDSAttachmentMap	EHDSAttachment Mapping	Map for EHDSAttachment
EHDSCarePlanMap	EHDSCarePlan Mapping	Map for EHDSCarePlan
EHDSConditionMap	EHDSCondition Mapping	Map for EHDSCondition
EHDSCoverageMap	EHDSCoverage Mapping	Map for EHDSCoverage

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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.

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EHDS and Imaging Documents

- **FHIR Imaging Manifest** that holds the information required to access the imaging data (data from the PACS).
- **FHIR Imaging Report** that holds the Imaging Report (data from RIS).

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Imaging Manifest

Manifest holds data as stored in the PACS including endpoints.

WADO access to DICOM and rendered images

IID launch viewer on images

Imaging Manifest - HL7 Europe Imaging Study Report v0.1.0-ballot

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Imaging Report

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Modelling

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HL7 FHIR

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4.2 Imaging Report

4.2.2 Report Profiles

These define obligations on FHIR resources for systems conforming to this implementation guide.

The imaging specific obligations are specified in:

Name	Title	Description
Report_ImReport	Report obligations for ImReport	Report obligations for ImReport
Report_ImAdverseEvent	Report obligations for ImAdverseEvent	Report obligations for ImAdverseEvent
Report_ImComposition	Report obligations for ImComposition	Report obligations for ImComposition
Report_ImDiagnosticReport	Report obligations for ImDiagnosticReport	Report obligations for ImDiagnosticReport
Report_ImFinding	Report obligations for ImFinding	Report obligations for ImFinding
Report_ImGestationalAgeObservation	Report obligations for ImGestationalAgeObservation	Report obligations for ImGestationalAgeObservation
Report_ImImagingStudy	Report obligations for ImImagingStudy	Report obligations for ImImagingStudy
Report_ImOrder	Report obligations for ImOrder	Report obligations for ImOrder
Report_ImPatient	Report obligations for ImPatient	Report obligations for ImPatient
Report_ImProcedure	Report obligations for ImProcedure	Report obligations for ImProcedure
Report_ImRadiationDoseObservation	Report obligations for ImRadiationDoseObservation	Report obligations for ImRadiationDoseObservation
Report_ImReportDocumentReference	Report Obligations for ImReportIheMhdDocumentReference	Report Obligations for ImReportIheMhdDocumentReference

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Content | Detailed Descriptions | Mappings | XML | JSON | TTL

7.144.1 Resource Profile: Report obligations for ImComposition

Official URL: `http://hl7.eu/fhir/imaging-r5/StructureDefinition/Report-ImComposition`	*Version*: `0.1.0-ballot`
Draft as of 2025-05-19	*Computable Name*: `Report_ImComposition`
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Report obligations for ImComposition

For report creators, this page provides guidance on how to populate the narrative of each section, which is encoded in the `Composition.section.text` element of each section slice of this profile.

The table below suggests the data points that SHOULD be included, and the source of those data. Those data points can be in a first order resource, referenced directly from the Composition (e.g. ImOrder), or they can live in a second,third order resource (e.g. Medication). For the later, a second query or a FHIR path (resolve) expression is required to fetch them.

NOTE: Structural concerns and rationale on the ImComposition profile can be found in the ImComposition, which is the parent type of this Report-ImComposition profile.

7.144.2 Elements to include in sections narratives

7.144.2.1 Imaging Study

The following table lists the elements that should be included in the narrative of the Imaging Study section.

First order resource	Element	Referenced resource	Logical model resource.field
EuDevice	type		EHDSDevice.type
ImImagingStudy	series.specimen	EuSpecimen	EHDSImagingReportBody.specimen
ImImagingStudy	series.modality		EHDSImagingReportBody.examinationReport.modality
ImImagingStudy	series.bodySite	EuBodyStructure	EHDSImagingReportBody.examinationReport.bodyPart.bodyLocation
ImImagingStudy	series.bodySite	EuBodyStructure	EHDSImagingReportBody.examinationReport.bodyPart.laterality
EuBodyStructure	includedStructure.laterality		EHDSImagingReportBody.examinationReport.bodyPart.laterality

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The HL7 Europe Imaging Study FHIR IG and how to contribute

Agenda

- Welcome, introductions, housekeeping
- The EHDS policy context
  Line Andreassen Sæle, HL7 Norway
- The EHDS FHIR IG ecosystem
  Giorgio Cangioli, HL7 Europe
- HL7 Europe Imaging Study Report FHIR IG
  Bas van den Heuvel, Philips
- Our collaborative platforms and how to contribute
  Giorgio Cangioli, HL7 Europe
- Discussion and Q&A
- Next steps

End

HL7 Europe

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How to be engaged …

STAYING TUNED (WEBINARS, TUTORIALS)

PROVIDING YOUR FEEDBACK (BALLOT, JIRA)

ATTENDING THE HANDS-ON EVENTS (HL7 FHIR CONNECTATHON)

JOINING THE MEETINGS

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Two distinct formal processes

Balloting

the formal process that HL7 uses to review and **vote** on specifications prior to publication

Limited in Time

Only HL7 voting members

Any Time

Anyone

Specification Feedback

the official mechanism for providing feedback about any HL7 specification

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Ballot (formal vote)

Balloting
the formal process that HL7 uses to review and **vote** on specifications prior to publication

Limited in Time

Only HL7 voting members

One vote per European Affiliate !

Contact your HL7 Affiliate if you want to impact on your national vote !

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Ballot (comments)

Specification Feedback

the official mechanism for providing feedback about any HL7 specification

Any Time

… during ballot is better !

Your review and feedback matter most during the ballot !

Anyone

Provide input **during the ballot period** to:
…influence the content before first publication
…support your affiliate in shaping their vote

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Specification Feedback

Any Time

Anyone (registered user)

https://jira.hl7.org/

https://confluence.hl7.org/display/HL7/Specification+Feedback#SpecificationFeedback-submitting

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Specification Feedback

Jira Software | Dashboards | Projects | Issues | Boards | Plans | Create

Create Issue | Configure Fields

All fields marked with an asterisk (*) are required

Project* FHIR Specification Feedback (...

Issue Type* Change Request

Default* Advanced

Submitting a Change Request
A request for a change that is more than a simple Technical Correction to one of HL7's specifications.

Specification* EU Laboratory Report (FHIR)

List of all specifications that might be reviewed during ballot or otherwise have feedback provided on them. (Filters to those relevant for the Issue project)

Raised in Version Type to search

The specification release that wasofficial at the time the specification comment was raised

Summary*

Related URL

The URL of the page (or better yet the specific anchor of the section) the comment relates to

Create another | Create | Cancel

Required fields are marked with an asterisk *

Project* FHIR Specification Feedback (...

Issue Type* Change Request

- Technical Correction
- Question
- Comment

Default* Advanced

Submitting a Change Request

Specification* EU

- US Pharmaceutical Quality/Chemistry, Manufacturing and Controls (PQ-CMC) (FHIR)
- **EU** Laboratory Report (FHIR)
- **EU** Extensions (FHIR)
- **EU** Base and Core (R4) (FHIR)
- **EU** Base and Core (R5) (FHIR)
- **EU** Extensions (R5) [deprecated] (FHIR)
- **EU** Imaging Study Report (FHIR)
- **EU** Hospital Discharge Report (FHIR)
- **EU** Medication Prescription and Dispense (R4) (FHIR)
- **EU** Medication Prescription and Dispense (R5) (FHIR)

Raised in Version

Summary*

Related URL

Related Artifact(s)

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HL7 FHIR IGs overview

Base and Core + extensions	**Ballot**	Ballot (Votes and Comments)	June 1st – June 30th 2025
Laboratory Results	**STU**	Specification Feedback	Any Time
Medical Imaging and reports	**Ballot**	Ballot (Votes and Comments)	June 1st – June 30th 2025
Hospital Discharge Report	SOON **Ballot**	Ballot (Votes and Comments)	June 15th – August 31st 2025
ePrescription eDispensation	SOON **Ballot**	Ballot (Votes and Comments)	June 15th – August 31st 2025
Patient Summary	***WIP***		

Xt-EHR Targeted Stakeholders' consultation

- **Xt-EHR deliverable (D) 6.2** "***Electronic prescription and electronic dispensation***: *Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems*"

Xt-EHR Logical Models | HL7 EU FHIR IG | D6.2 as PDF

- **When**: June 15th – Sept 15
- **How to be engaged ?**
  - https://www.xt-ehr.eu/stakeholders-engagement/
- **Not selected ?** Submit your comments via HL7 Europe.

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Next steps

- Webinar recording and slides to be posted on www.hl7.tv
- Find us at **Plugathon Vienna**, 23 to 27 June 2025: link
- **Get involved**:
  - HL7 Europe: Go to https://hl7europe.eu/get-engaged/
  - XT-EHR: Go to https://www.xt-ehr.eu/stakeholders-engagement/
- And last not least:
  - Follow HL7 Europe on LinkedIn
  - Subscribe to HL7 Europe news and updates

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HL7 Europe

Thank you !

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