

**The HL7 EU FHIR
Implementation Guide for
laboratory report: what it is,
why it matters, and how to
become involved**

**Webinar, 24 November 2023
16.00-17.00 CET**

Online on Zoom



The HL7 FHIR Implementation Guide for laboratory results Agenda

16.00 Welcome (Michael Strübin, *HL7 Europe*)

16.05 The policy context (Henrique Martins, *former chair of the eHealth Network*)

16.15 The HL7 EU Lab Report FHIR IG (Giorgio Cangioli, *HL7 Europe*)

16.30 Q&A with stakeholders and the audience

- Hynek Kružík, *National eHealth Center, Czech Republic*
- Patrizio Fonzi, *Sogei (Ministry of Economy and Finance), Italy*
- Manel Domingo Falcón, *Ministry of Health, Spain*
- George Karapetakos, *Computer Control Systems, Greece*

16.50 Next steps on the Lab Report FHIR IG (Catherine Chronaki, *HL7 Europe*)

17.00 End

Welcome and ground rules

- Thank you for joining the webinar
- The webinar will be recorded
- To help ensure a successful webinar please
 - Mute yourself
 - Feel free to use emojis during the presentations
 - Use the chat to make comments or raise your questions
 - 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 HL7 FHIR Implementation Guide for laboratory results Agenda

16.00 Welcome (Michael Strübin, *HL7 Europe*)

16.05 The policy context (Henrique Martins, *former chair of the eHealth Network*)

16.15 The HL7 EU Lab Report FHIR IG (Giorgio Cangiali, *HL7 Europe*)

16.30 Q&A with stakeholders and the audience

- Hynek Kružík, *National eHealth Center, Czech Republic*
- Patrizio Fonzi, *Sogei (Ministry of Economy and Finance), Italy*
- Manel Domingo Falcón, *Ministry of Health, Spain*
- George Karapetakos, *Computer Control Systems, Greece*

16.50 Next steps on the Lab Report FHIR IG (Catherine Chronaki, *HL7 Europe*)

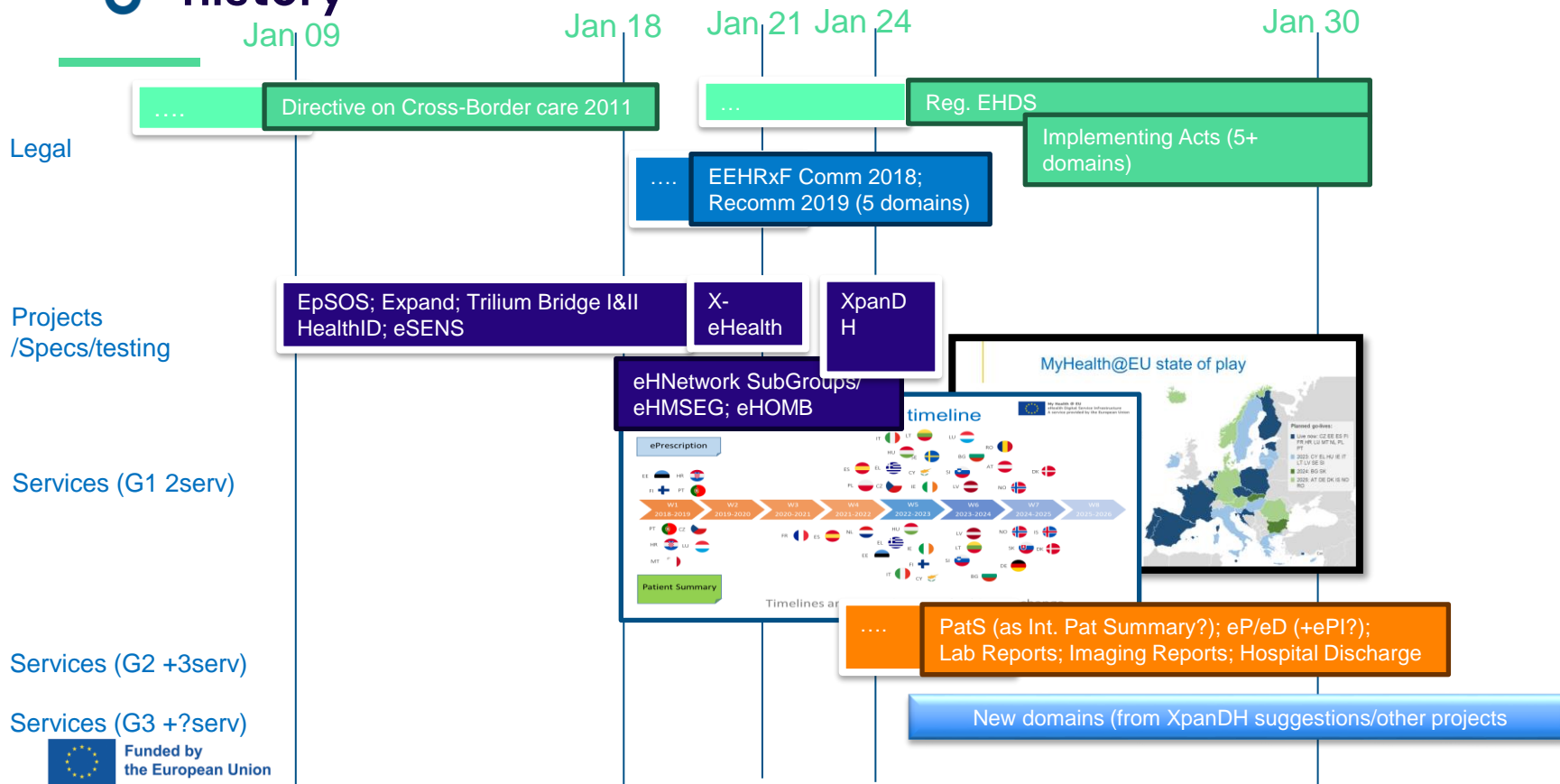
17.00 End



European electronic health record exchange format (EEHRxF) in context of the European Health Data Space (EHDS) Regulation

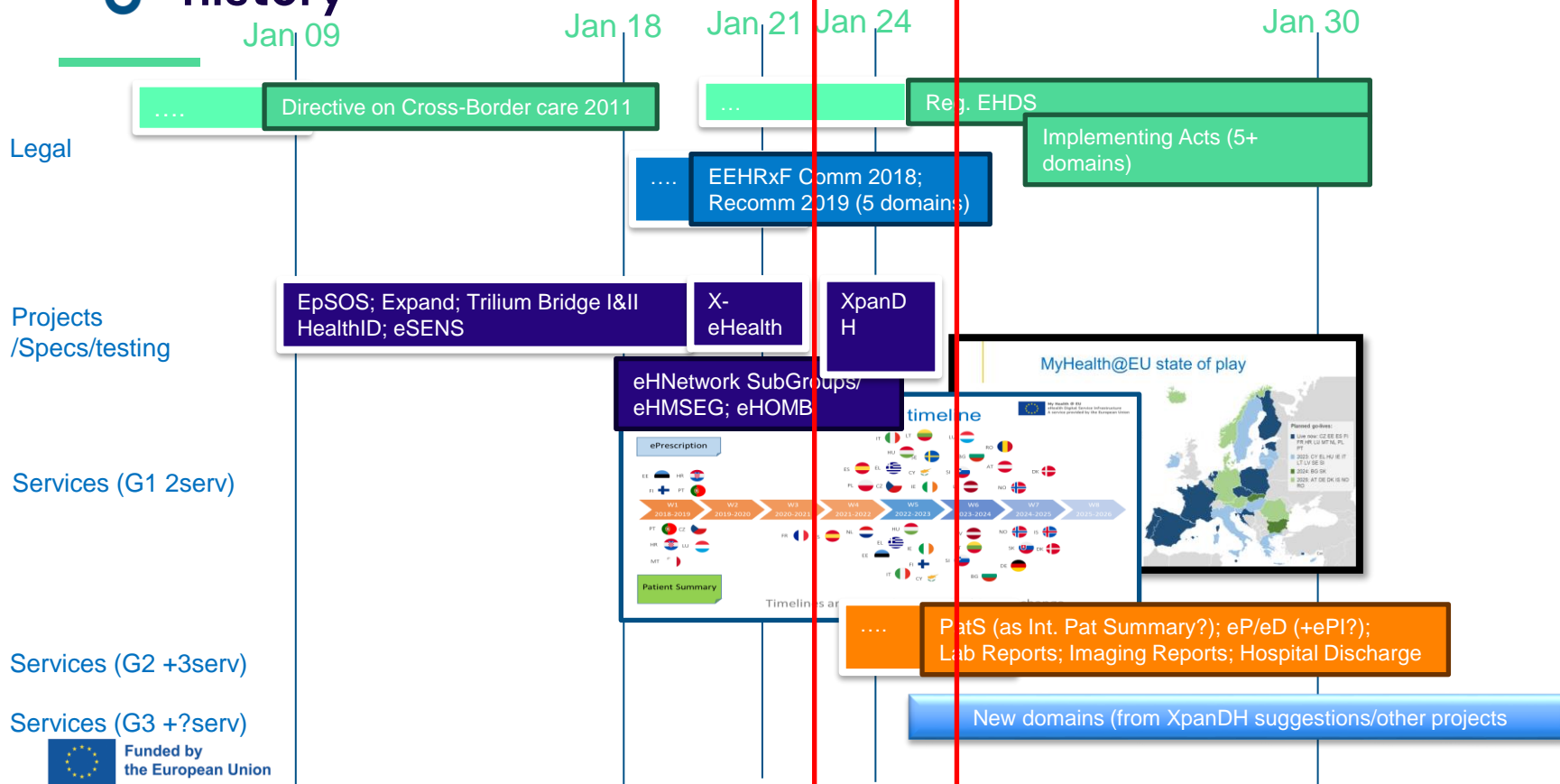


X-border interoperability “legal, project and service” brief history



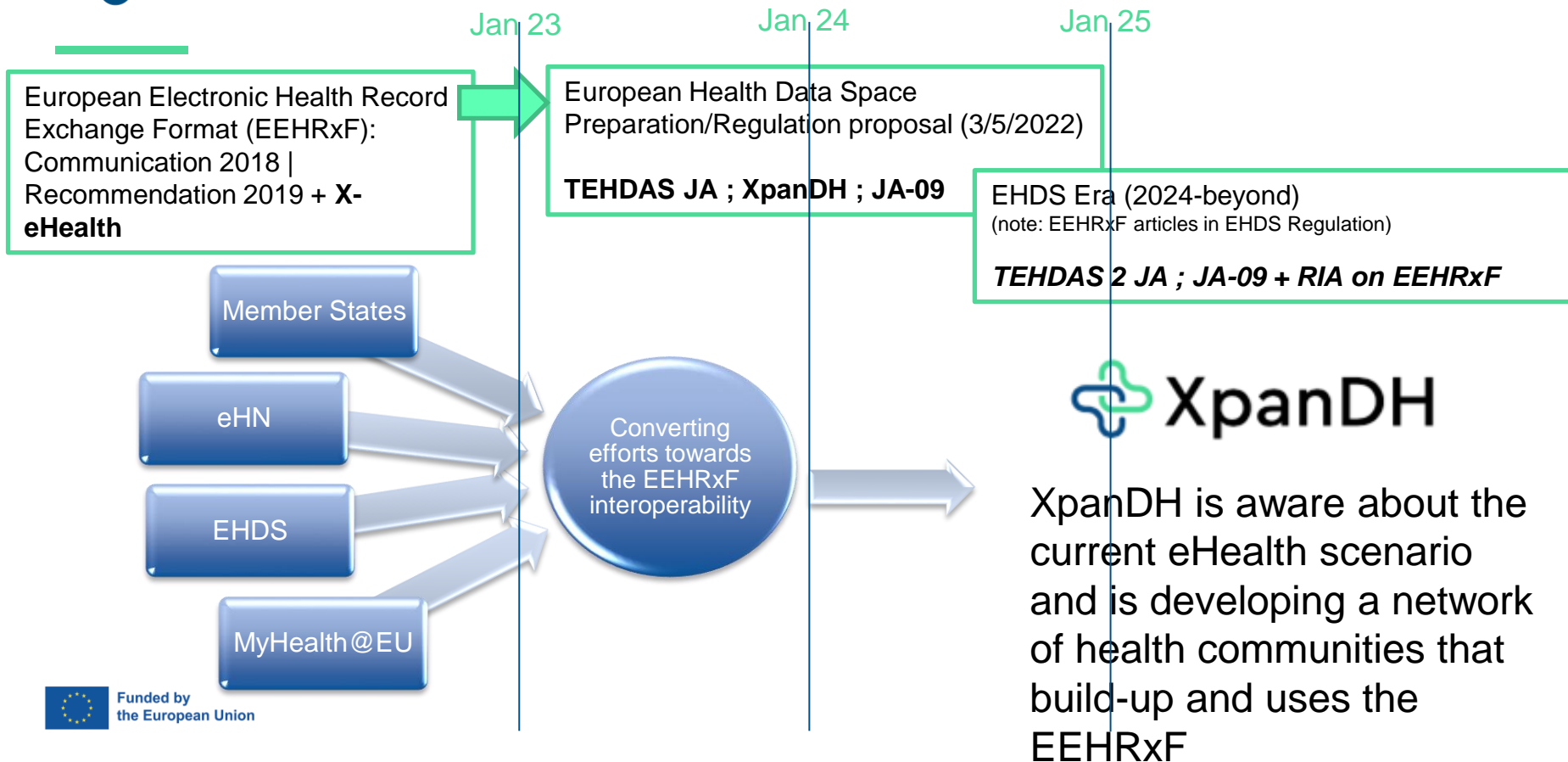


X-border interoperability “legal, project and service” brief history





XpanDH introduction & Context



XpanDH XpanDH landscape and project vision

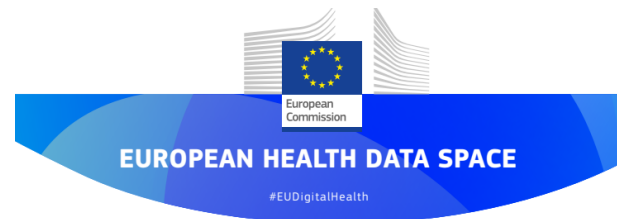
In that context the **EC is building up a regulation proposal** about the *European Health Data Space* - EHDS with some key statements:

- “requirements that have been imposed on **software** through the **Medical Devices Regulation**”
- “regulatory gap has been identified when it comes to **information systems used in the health domain**, also called electronic health record systems (**EHR systems**)”
- “the EDHS sets **essential requirements specifically for EHR systems** in order to **promote interoperability and data portability**”

Specifically, to **EEHRxF**:

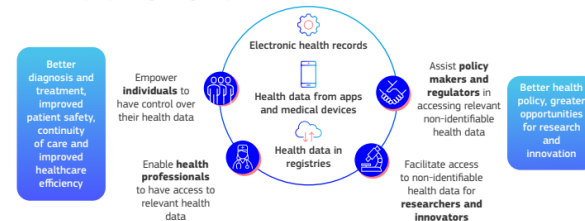
- **datasets defining structures**, such as data fields and data groups for the content representation
- **coding systems** and values sets
- **technical specifications** for the exchange of electronic health data

EC is empowered to **adopt delegated acts** to amend the list of **priority categories by adding, modifying or removing** the main characteristics of the **priority categories of electronic health data** deferred application date.



OBJECTIVES

- ✓ Empower individuals through better digital access to their personal health data; support free movement by ensuring that health data follow people;
- ✓ Unleash the data economy by fostering a genuine single market for digital health services and products;
- ✓ Set up strict rules for the use of individual's non-identifiable health data for research, innovation, policy-making and regulatory activities.



GROWTH POTENTIAL OF THE HEALTH DATA ECONOMY



EHDS proposal Article 6

Article 6

European electronic health record exchange format

1. The Commission shall, by means of **implementing acts**, lay down the **technical specifications** for the **priority categories** of personal electronic health data referred to in Article 5, setting out the European electronic health record exchange format. The format shall include the following elements:

(a) **datasets** containing electronic health data and defining structures, such as data fields and data groups for the content representation of clinical content and other parts of the electronic health data;

(b) **coding systems** and **values** to be used in datasets containing electronic health data;

(c) **technical specifications** for the **exchange** of electronic health data, including its **content representation, standards** and **profiles**.

2. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). Member States shall ensure that where the priority categories of personal electronic health data referred to in Article 5 are **provided by a natural person directly** or **transmitted to a healthcare provider** by automatic means in the format referred to in paragraph 1, such data shall be **read** and **accepted** by the data recipient.

3. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are **issued** in the format referred to in paragraph 1 and such data shall be read and accepted by the data recipient.



EHDS proposal Article 12 and 23

Article 12

MyHealth@EU

...

3. Each national contact point for digital health shall enable the exchange of the personal electronic health data referred to in Article 5 with all other national contact points. **The exchange shall be based on the European electronic health record exchange format.**

Article 23

Common specifications

1. The Commission shall, by means of implementing acts, adopt common specifications in respect of the essential requirements set out in Annex II, including a time limit for implementing those common specifications. Where relevant, the common specifications shall take into account the specificities of medical devices and high risk AI systems referred to in paragraphs 3 and 4 of Article 14.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).

Article 23

Common specifications (cont.)

2. The common specifications referred to in paragraph 1 shall include the following elements:

- (a) scope;
- (b) applicability to different categories of EHR systems or functions included in them;
- (c) version;
- (d) validity period;
- (e) normative part;
- (f) explanatory part, including any relevant implementation guidelines.

3. The common specifications may include elements related to the following:

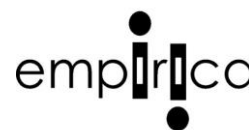
- (a) datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;
- (b) coding systems and values to be used in datasets containing electronic health data;
- (c) other requirements related to data quality, such as the completeness and accuracy of electronic health data;
- (d) technical specifications, standards and profiles for the exchange of electronic health data;
- (e) requirements and principles related to security, confidentiality, integrity, patient safety and protection of electronic health data;
- (f) specifications and requirements related to identification management and the use of electronic identification.



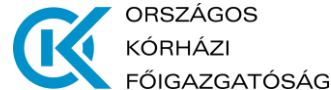
Thank you from our XpanDH expanding consortium AND PLEASE JOIN OUR INDUSTRY X-NET Summit



— Conhecimento e Inovação
Portugal



Κέντρο Τεκμηρίωσης & Κοστολόγησης
Νοσοκομειακών Υπηρεσιών
Ελληνικό Ινστιτούτο DRG



[edha - european digital health academy gGmbH](#)



XpanDH Project

Coordinator:
Henrique Martins
Project manager:
Anderson Carmo
2023-2024

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

XpanDH project supports an expanding ecosystem of individuals and organizations that are developing, experimenting and adopting the European Electronic Health Record Exchange Format (EHRxF) providing a crucial contribution to the European Health Data Space. It is a 2-year Coordination and Support Action financed by the Horizon Europe Framework Programme.

XpanDH's vision comes to live through 4 main scopes



Establishing a scalable public infrastructure for digital health innovation



Demonstrating real-life interoperable digital solutions for individuals, researchers, health services, and the workforce across borders



Establishing a Pan-European ecosystem of digital health



Creating and validating a framework for further exploitation of the public infrastructure for digital health innovation.

<https://xpanDH-project.iscte-iul.pt/>



Funded by
the European Union

The HL7 FHIR Implementation Guide for laboratory results Agenda

16.00 Welcome (Michael Strübin, *HL7 Europe*)

16.05 The policy context (Henrique Martins, *former chair of the eHealth Network*)

16.15 The HL7 EU Lab Report FHIR IG (Giorgio Cangiali, *HL7 Europe*)

16.30 Q&A with stakeholders and the audience

- Hynek Kružík, *National eHealth Center, Czech Republic*
- Patrizio Fonzi, *Sogei (Ministry of Economy and Finance), Italy*
- Manel Domingo Falcón, *Ministry of Health, Spain*
- George Karapetakos, *Computer Control Systems, Greece*

16.50 Next steps on the Lab Report FHIR IG (Catherine Chronaki, *HL7 Europe*)

17.00 End

The HL7 EU Lab Report FHIR IG: an introduction

Webinar, November 24th, 2023

Giorgio Cangiali, HL7 Europe, Technical Lead

HL7 Europe Laboratory Report FHIR IG, facilitator

eHMSEG STF, Architecture WG co-chair



The HL7 EU Laboratory Report FHIR IG



THE FIVE Ws

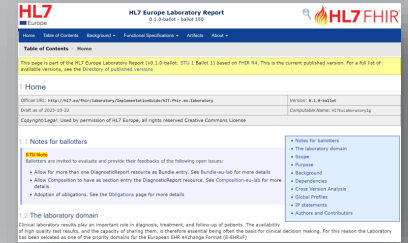


**GUIDE
OVERVIEW**



**GETTING
INVOLVED**

THE FIVE Ws



THE FIVE
Ws



GUIDE
OVERVIEW



GETTING
INVOLVED

The HL7 EU Laboratory Report FHIR IG



**THE FIVE
Ws**



GUIDE
OVERVIEW



GETTING
INVOLVED



**WHAT.. IT
IS**



**WHY ..AND
WHY NOW**



**WHEN ..
TIMELINE**



**WHO ..IS
INVOLVED**



**WHERE
..TO START**

The HL7 EU Laboratory Report FHIR IG

HL7 Europe
HL7 Europe Laboratory Report
0.1.0-ballot - ballot 150

Home Table of Contents Background Functional Specifications Artifacts About

Table of Contents Home

This page is part of the HL7 Europe Laboratory Report (v0.1.0-ballot: STU 1 Ballot 1) based on FHIR R4. 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/Laboratory/ImplementationGuide/hl7.fhir.eu.Laboratory	Version: 0.1.0-ballot
Draft as of 2023-10-22	Computable Name: HL7EULaboratoryIg
Copyright/Legal: Used by permission of HL7 Europe, all rights reserved Creative Commons License	

1.1 Notes for balloters

STU Note
Balloters are invited to evaluate and provide their feedbacks of the following open issues:

- Allow for more than one DiagnosticReport resource as Bundle.entry. See Bundle-eu-lab for more details
- Allow Composition to have as section entry the DiagnosticReport resource. See Composition-eu-lab for more details
- Adoption of obligations. See the Obligations page for more details

- Notes for balloters
- The laboratory domain
- Scope
- Purpose
- Background
- Dependencies
- Cross Version Analysis
- Global Profiles
- IP statements
- Authors and Contributors

1.2 The laboratory domain

Clinical laboratory results play an important role in diagnosis, treatment, and follow-up of patients. The availability of high quality test results, and the capacity of sharing them, is therefore essential being often the basis for clinical decision making. For this reason the Laboratory has been selected as one of the priority domains for the European EHR eXchange Format (E-EHRxF)



WHAT.. IT IS



WHY ..AND
WHY NOW



WHEN ..
TIME PLAN



WHO ..IS
INVOLVED



WHERE
..TO START

What is a FHIR Implementation Guide (IG)

HL7 FHIR IG

Human Readable
(Web Browsable)

Formal
Computable
(FHIR Resources)

Set of rules about how FHIR resources are used (or should be used) to solve a particular problem, with associated documentation to support and clarify the usage.

HL7 Europe Laboratory Report
0.1.0-ballot - ballot 150

Home Table of Contents Background Functional Specifications Artifacts About

Table of Contents Home

This page is part of the HL7 Europe Laboratory Report (v0.1.0-ballot: STU 1 Ballot 1) based on FHIR R4. 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/laboratory/ImplementationGuide/hl7.eu.Laboratory	Version: 0.1.0-ballot
Draft as of: 2023-10-22	Computable Name: hl7.eu.LaboratoryIg
Copyright/Legal: Used by permission of HL7 Europe, all rights reserved Creative Commons License	

1.1 Notes for ballots

- Notes for ballots
- The laboratory domain
- Scope
- Purpose
- Background
- Dependencies

1.2 The laboratory domain

Clinical laboratory results play an important role in diagnosis, treatment, and follow-up of patients. The availability of high quality test results, and the capacity of sharing them, is therefore essential being often the basis for clinical decision making. For this reason the Laboratory has been selected as one of the priority domains for the European eHX exchange Format (E-BoxH).

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



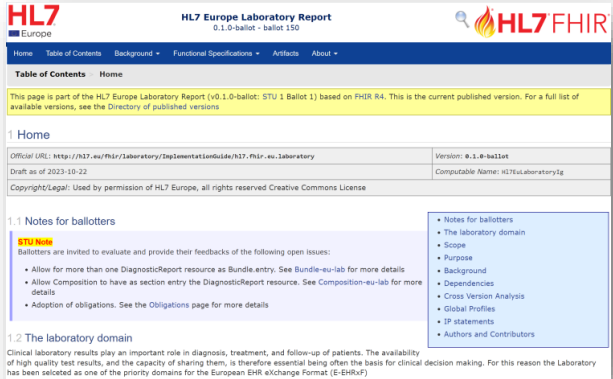
Laboratory Results

- hl7.fhir.eu.laboratory#dev
- hl7.fhir.pubpack#0.1.4
- hl7.fhir.pubpack#0.1.5

What this guide is about..



Laboratory Results



Laboratory Report

- No Pathology or Genetic Laboratory Report
- Lab results as by product

Only the content !

- Not how reports/results are searched and exchanged

European context

- Not only cross-border
- Reusable nationally for different use cases

Not only human beings

- Human Subjects can be “recognized” persons or not

Why and Why now

European
EHRxF



Medical Imaging
and reports



Laboratory Results



Hospital Discharge
report



Patient Summary



ePrescription

Common rules for representing a Laboratory Report in the European context

The screenshot shows the 'HL7 Europe Laboratory Report' website. The page title is 'HL7 Europe Laboratory Report' with the version '0.1.0-ballot - ballot 150'. The navigation menu includes 'Home', 'Table of Contents', 'Background', 'Functional Specifications', 'Artifacts', and 'About'. The 'Table of Contents' is expanded to show 'Home'. A yellow banner states: 'This page is part of the HL7 Europe Laboratory Report (v0.1.0-ballot: STU 1 Ballot 1) based on FHIR R4. This is the current published version. For a full list of available versions, see the Directory of published versions'. The main content area is titled '1 Home' and includes metadata such as 'Official URL: http://hl7.eu/fhir/LaboratoryImplementationGuide/hl7-fhir.eu/Laboratory', 'Version: 0.1.0-ballot', 'Draft: as of 2023-10-22', and 'Copyright/Legal: Used by permission of HL7 Europe, all rights reserved Creative Commons License'. Below this is section '1.1 Notes for ballots' with a 'STU Note' stating: 'Balloters are invited to evaluate and provide their feedbacks of the following open issues:'. A list of issues includes: 'Allow for more than one DiagnosticReport resource as Bundle.entry. See Bundle-eu-lab for more details', 'Allow Composition to have as section entry the DiagnosticReport resource. See Composition-eu-lab for more details', and 'Adoption of obligations. See the Obligations page for more details'. A sidebar on the right lists: 'Notes for ballots', 'The laboratory domain', 'Scope', 'Purpose', 'Background', 'Dependencies', 'Cross Version Analysis', 'Global Profiles', 'JP statements', and 'Authors and Contributors'. Section '1.2 The laboratory domain' begins with the text: 'Clinical laboratory results play an important role in diagnosis, treatment, and follow-up of patients. The availability of high quality test results, and the capacity of sharing them, is therefore essential being often the basis for clinical decision making. For this reason the Laboratory has been selected as one of the priority domains for the European EHR eXchange Format (E-EHRxF)'.

EHDS - Art 5 Priorities

Facilitate the harmonization among the national initiatives

Support the development of the European-EHRxF

2022

2023

2024

2025

Laboratory results and reports



Laboratory Results

Proof of Concept

Implementation in MyHealth@EU (Wave 8)

European EHRxF

(Hospital) discharge reports and Medical images and image reports



Hospital Discharge report



Medical Imaging and reports

Implementation in MyHealth@EU (Wave 9)

X-eHealth

XShare

XpanDH

Xt-EHR (JA-09)

National Initiatives

Standardization Activities

March 2023

November 2023

Who is involved

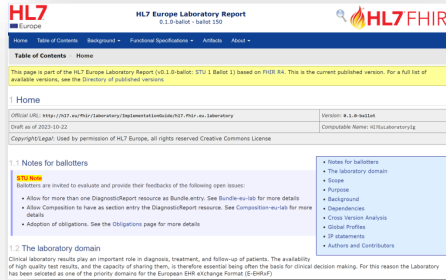


Laboratory Results

The result of a participatory multi-stakeholders effort

Experts from several countries

European projects and initiatives engaged (e.g. XpanDH, MyHealth@EU)



Two collaborating focused sub-groups:


- functional requirements /semantic
- HL7 FHIR specifications

Where to start with

The screenshot shows the HL7 Europe Laboratory Report website. The main content area is titled "Publication (Version) History" and contains the following text:

This guide defines a set of common rules to be applied to HL7 FHIR to define how to represent a Laboratory Report in the European Context. It covers laboratory reports within the core fields of in-vitro diagnostics, for example clinical biochemistry, haematology, immunohematology, microbiology, immunology, while leaving out some specialised laboratory domains requiring specialised reporting structure like histopathology or medical genetics.

The following versions have been published:

Date	IG Version	FHIR Version	Description	Links
Current Versions				
2023-10-22	0.1.0-ballot	4.0.1	This is the version released for the STU 1 ballot	  
(current)	(last commit)	n/a	undefined	  
STU 1 Sequence				
2023-10-22	0.1.0-ballot	4.0.1	This is the version released for the STU 1 ballot (Permanent Home)	  

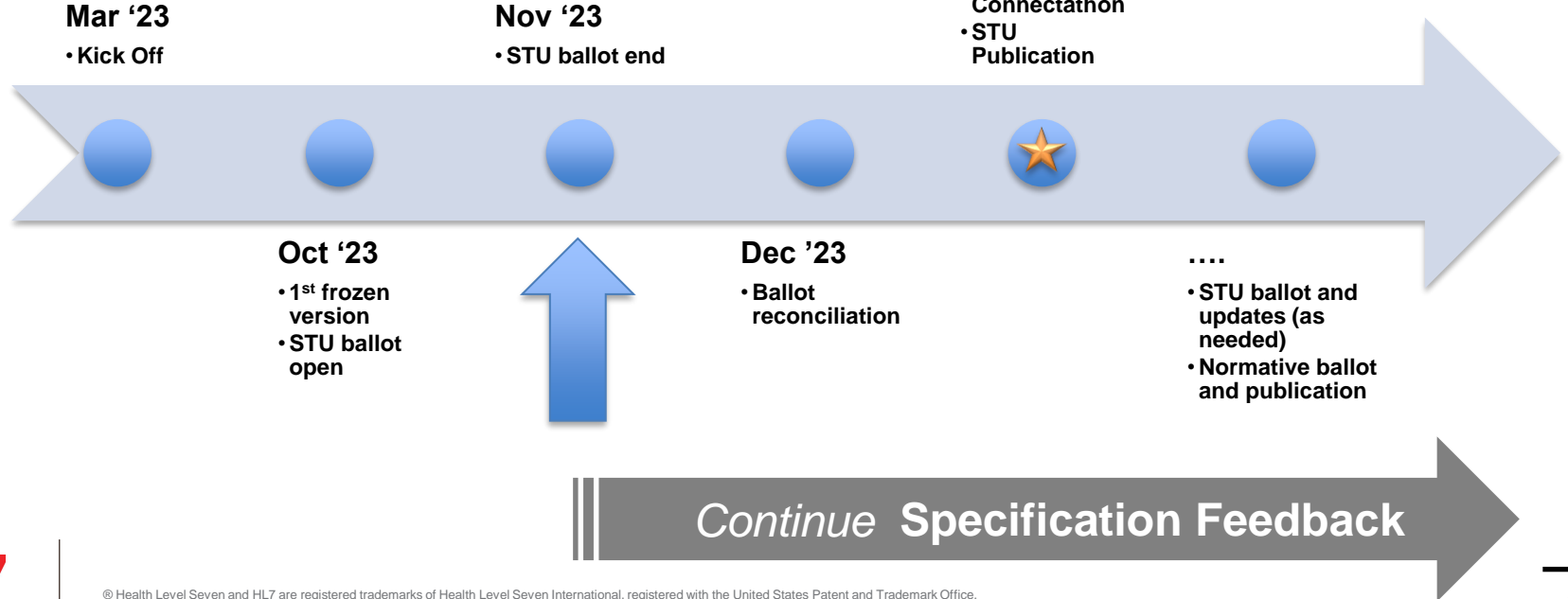
<https://hl7.eu/fhir/laboratory/history.html>

The screenshot shows a GitHub repository page for "HL7 Europe Laboratory Report HL7 FHIR IG". The repository is in the "master" branch and has 0 tags. The commit history shows several recent commits by user "gcanjoli", including updates to references, templates, and configuration files. The README file is visible, containing the title "HL7 Europe Laboratory Report HL7 FHIR IG" and the code repository path "HL7 Europe Laboratory Report HL7 FHIR IG code: laboratory".

<https://github.com/hl7-eu/laboratory>

When .. the timeline

Balloting



Two distinct processes

Balloting

the formal process that HL7 uses to get feedback and comments 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

Specification Feedback



Any Time

Anyone
(registered user)



<https://jira.hl7.org/>

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

GUIDE OVERVIEW



THE FIVE
Ws



**GUIDE
OVERVIEW**



WHAT'S
NEXT

The HL7 EU Laboratory Report FHIR IG



THE FIVE
Ws



GUIDE
OVERVIEW



WHAT'S
NEXT



WHAT IS IN



DESIGN CHOICE



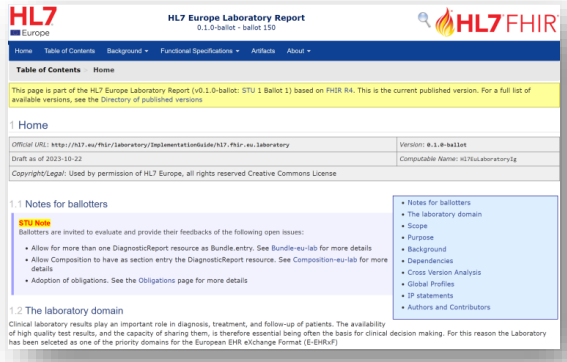
THE ENVISIONED
GUIDES
ECOSYSTEM

What is in..



HL7 FHIR
Logical
Models

The data set



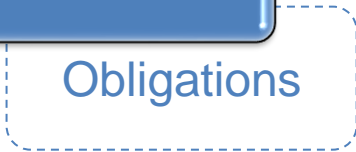
How data are
represented in HL7
FHIR

Models to
Profiles
Mapping



HL7 FHIR
Profiles

How to use HL7
FHIR



Guideline data set formalization




eHealth Network
 GUIDELINE
 on
 the electronic exchange of health data under
 Cross-Border Directive 2011/24/EU

Laboratory Results

 Release 1.1

4 LABORATORY RESULT DATASET

The datasets indicated in the following tables are considered relevant for patient safety and the provision of adequate level of care both at cross-border and national level.

It is up to each implementation project to decide on the conformity and cardinality (i.e. data elements required or optional and number of repetitions), unless specifically stated.

Implementation projects need to make a final decision on mandatory and/or required (null allowed) elements.

4.1 Report header

Field	Field description	Preferred Code System
A.1 Report header data elements		
A.1.1 Identification of the patient/subject		
A.1.1.1 Family name/surname	The family name/surname/last name of the patient. This field can contain more than one element or multiple fields could be present.	
A.1.1.2 Given name	The given name/first name of the patient (also known as forename or first name). This field can contain more than one element.	
A.1.1.3 Date of birth	The date of birth of the patient [ISO TS 22220]. As age of the patient might be important for correct interpretation of the test result values, complete date of birth should be provided.	Complete date, without time, following the ISO 8601
A.1.1.4 Personal identifier	An identifier of the patient that is unique within a defined scope. Example: National ID (birth number) for Czech patient. Multiple identifiers could be provided.	



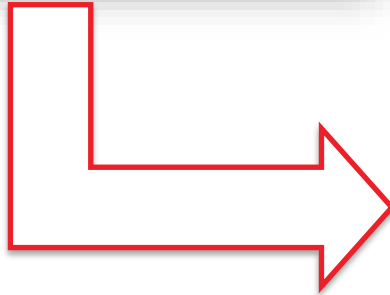
Logical Model

LabReport	0..*	Base	Laboratory Report
header	1..1	BackboneElement	A.1 Report header data elements
subject	1..1	Subject	A.1.1 - A1.2 Patient/subject
payer	0..1	Payer	A.1.3 Health insurance and payment information
informationRecipient	0..1	Recipient	A.1.4 Information recipient
author	0..*	Author	A.1.5 Author
legalAuthenticator	0..*	LegalAuthenticator	A.1.6 Legal authenticator
validator	0..*	Validator	A.1.7 Result validator
metadata	1..1	BackboneElement	A.1.8 Laboratory report metadata
type	1..1	CodeableConcept	A.1.8.1 Document type
status	1..1	CodeableConcept	A.1.8.2 Document status
dateTime	1..1	dateTime	A.1.8.3 Report date and time
title	0..1	string	A.1.8.4 Document title
custodian	0..1	BackboneElement	A.1.8.5 Report custodian
order	0..*	Order	A.2-A.3 Order
specimen	0..*	SpecimenLab	A.4 Specimen information
result	0..*	Result	A.5 Results data elements

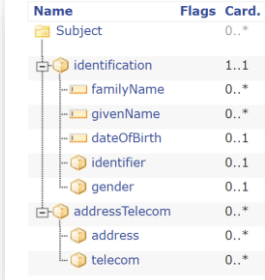
HL7 FHIR
Logical
Models

Models to
Profiles
Mapping

HL7 FHIR
Profiles



Guideline data set formalization



Group 1 Mapping from A1.1, A1.2 - Subject of care to Patient: Identified Person

Source Code	Relationship	Target Code
Subject.identification (A.1.1 Identification of the patient/subject)	is related to	Patient
Subject.identification.familyName (A.1.1.1 Familyname/surname)	is equivalent to	Patient.name.family
Subject.identification.givenName (A.1.1.2 Given name)	is equivalent to	Patient.name.given
Subject.identification.dateOfBirth (A.1.1.3 Date of birth)	is equivalent to	Patient.birthDate
Subject.identification.identifier (A.1.1.4 Personal identifier)		
Subject.identification.gender (A.1.1.5 Gender)		
Subject.addressTelecom (A.1.2 Patient/subject related contact information)		
Subject.addressTelecom.address (A.1.2.1 Address)		
Subject.addressTelecom.telecom (A.1.2.2 Telecom)		



Name	Flags	Card.	Type	Description & Constraints
Patient			PatientUVIps	
identification		0..*	Identifier	Patient identifiers
name	[C]	1..*	HumanNameEu	Name of a human - parts and usage eu-pat:1: Patient.name.given, Patient.name.family Text representation of the full name.
text		0..1	string	
family		0..1	string	
given		0..*	string	
telecom		0..*	ContactPoint	
gender		0..1	code	
address	[C]	0..*	AddressEu	

HumanName	HumanName	Description
family	0..1 string	Family name (often called 'Surname') Example spanish name: Valero Iglesias Extension
Slices for extension	0..* Extension	Extension
fathersFamily	0..* string	Slice: Unordered, Open by value:url Portion of family name derived from father URL: http://hl7.org/fhir/StructureDefinition/fathersFamily
mothersFamily	0..* string	Example spanish name: Valero Portion of family name derived from mother URL: http://hl7.org/fhir/StructureDefinition/mothersFamily
given	0..* string	Example spanish name: Iglesias Given names (not always 'first'). Includes 'middle' names Example spanish name: Borja

MAY be selected from ISO Country Alpha-3, IF the country is not specified in value set http://hl7.org/fhir/ValueSet/iso3166-1



Obligations

NEW

Name	Flags	Card.	Type
Patient			PatientUvIps
identifier		0..*	Identifier
name	C	1..*	HumanNameEu
text		0..1	string
family		0..1	string
given		0..*	string
telecom		0..*	ContactPoint
gender		0..1	code
address	C	0..*	AddressEu

Structural constraints

- e.g. Patient.birthdate 0..
- Observation.code derived from the Value Set XYZ (extensible)
-

Functional constraints

- e.g. The sender shall populate the Patient.birthdate if known
- Observation.code.text shall be displayed by the consumer if applicable
-

Name	Flags	Card.	Type	Description & Constraints
Patient		0..*	Patient	Information about an individual or animal receiving health care services
identifier	C	0..*	Identifier	An identifier for this patient
text	C	0..1	string	Text representation of the full name
family	C	0..1	string	Family name (often called 'Surname')

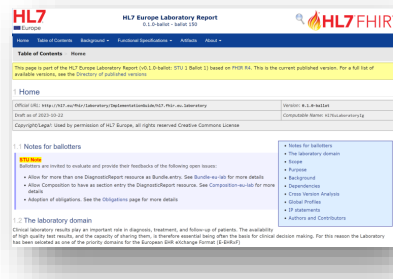
Obligations	Actor	Elements
handle	ActorLabRptConsumer	generalPractitioner
send	ActorLabRptCreator	address
send	ActorLabRptCreator	telecom
send	ActorLabRptCreator	generalPractitioner

Obligations	Actor
handle	ActorLabRptRepos
send	ActorLabRptRepos

Obligations	Actor
handle	ActorLabRptRepos
send	ActorLabRptRepos

It describes the capabilities that each Actor may, should, or shall support

The HL7 EU Laboratory Report FHIR IG



THE FIVE
Ws



GUIDE
OVERVIEW



WHAT'S
NEXT



WHAT IS IN



DESIGN CHOICE



THE ENVISIONED
GUIDES
ECOSYSTEM

Balancing different (EU) requirements



Legally signed documents

Often structured and including different kinds of test results

Still HL7 CDA and document exchange infrastructures in use

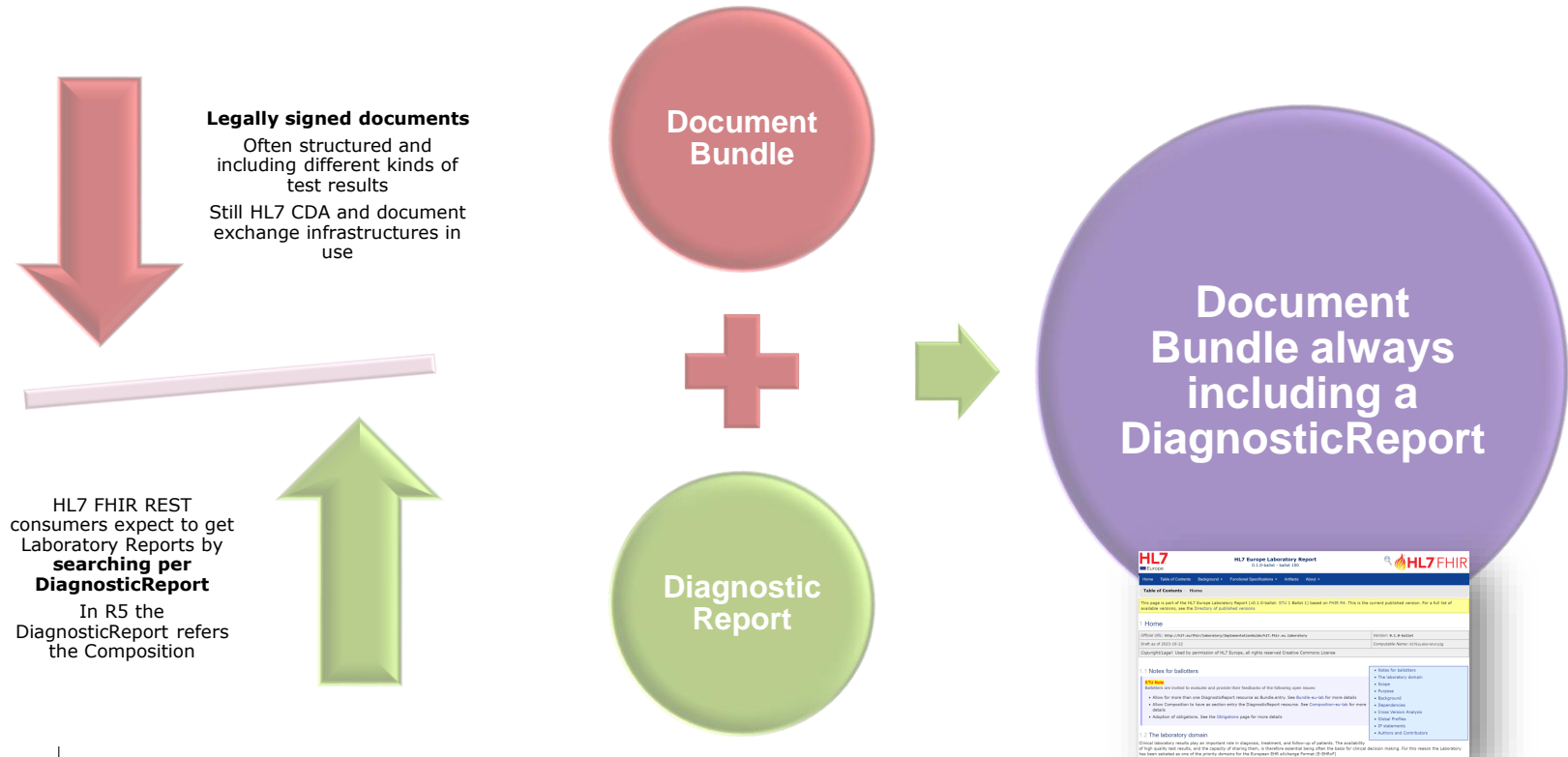


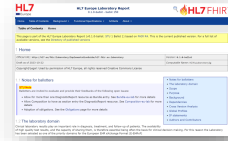
HL7 FHIR REST consumers expect to get Laboratory Reports by **searching per DiagnosticReport**

In R5 the DiagnosticReport refers the Composition

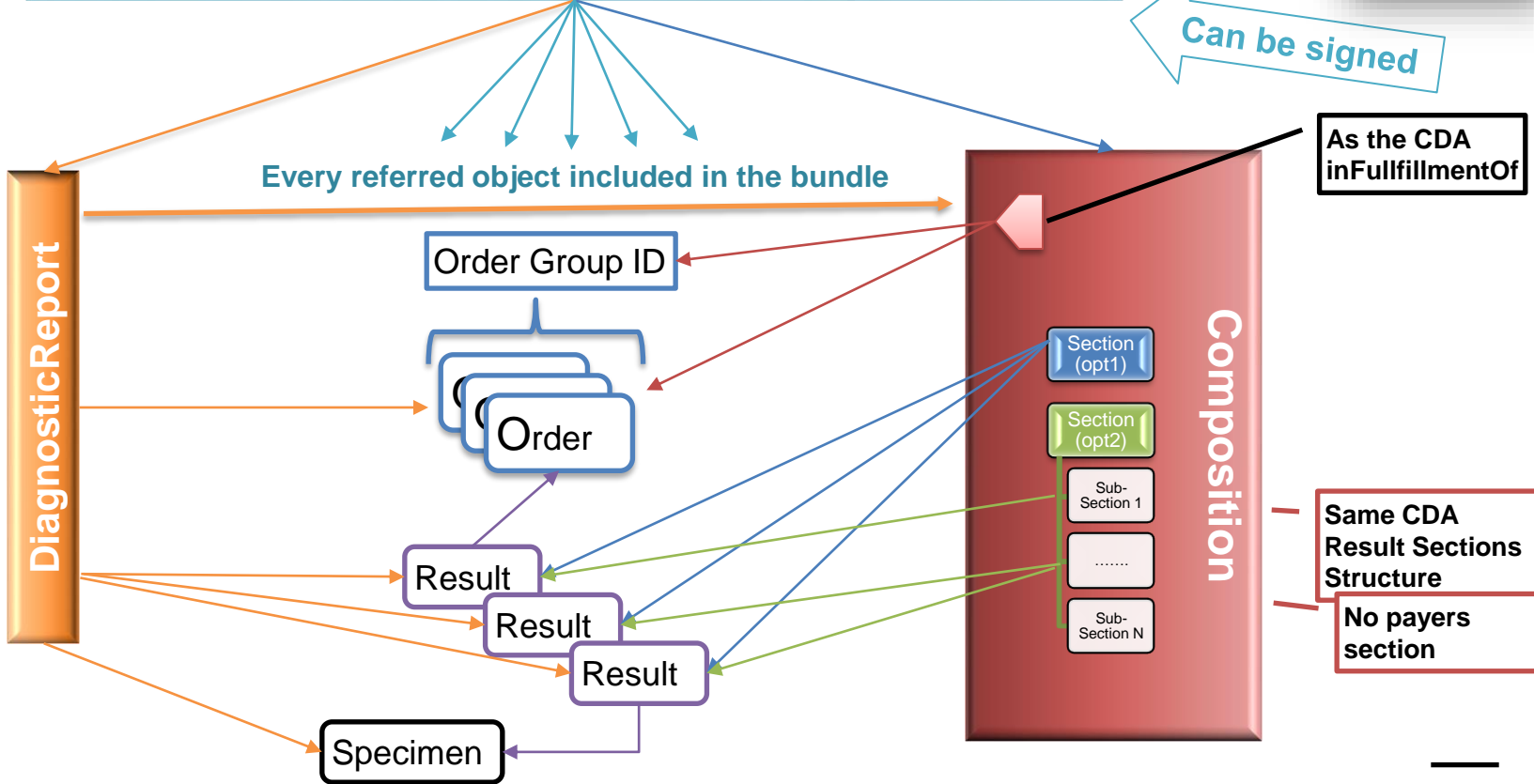


Balancing different (EU) requirements





Bundle (type=document)



The HL7 EU Laboratory Report FHIR IG



Laboratory Results



THE FIVE
Ws



GUIDE
OVERVIEW



WHAT'S
NEXT



WHAT IS IN

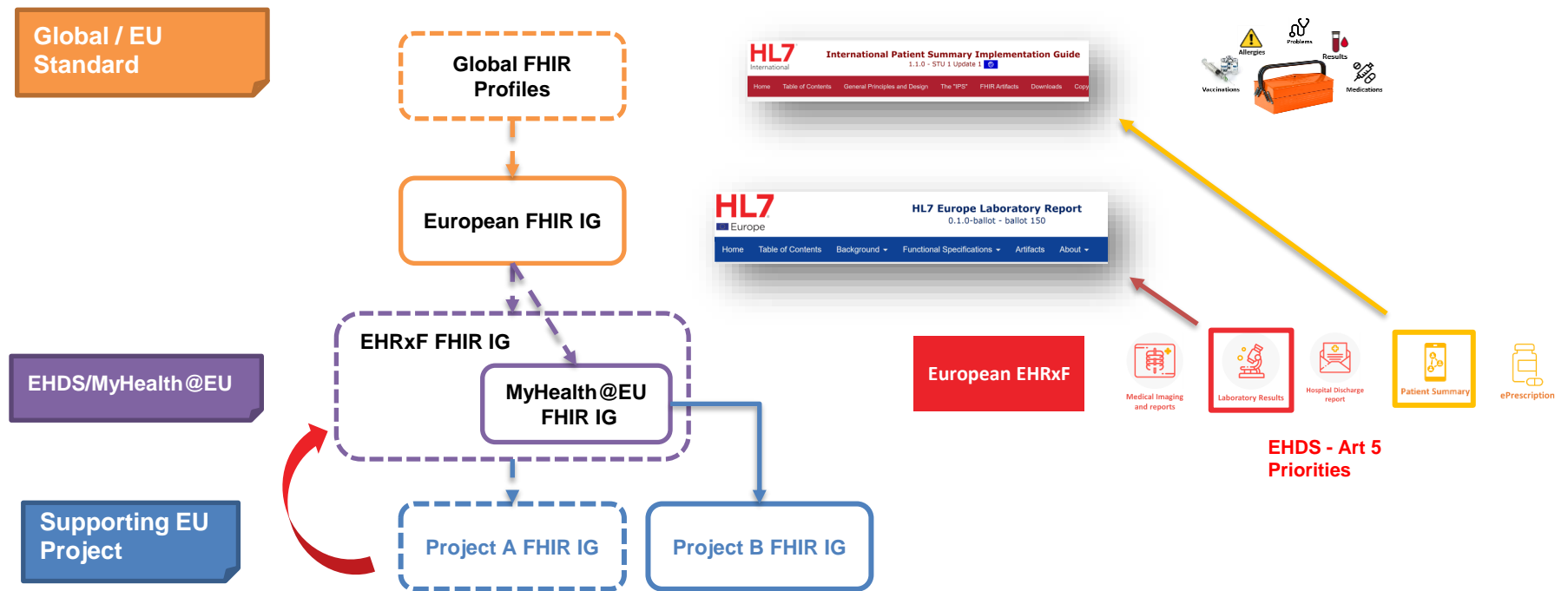


DESIGN
CHOICE



THE ENVISIONED
GUIDES
ECOSYSTEM

The envisioned ecosystem: the added value



Layered Specifications: advantages

European EHRxF



Medical Imaging and reports



Laboratory Results



Hospital Discharge report



Patient Summary



ePrescription

EHDS - Art 5 Priorities

HL7
Europe

HL7 Europe Laboratory Report
0.1.0-ballot - ballot 150

Home Table of Contents Background Functional Specifications Artifacts About

Name	Flags	Card.	Type
Observation	C	0..*	Observation
status		1..1	code
Slices for category		1..*	CodeableConceptIPS
category:laboratory		1..1	CodeableConcept

Observation Results: laboratory

It is not derived from

...but, when the subject is recognized and human

It is conformant with

HL7
International

International Patient Summary Implementation Guide
1.1.0 - STU 1 Update 1

Home Table of Contents General Principles and Design The "IPS" FHIR Artifacts Downloads Copy

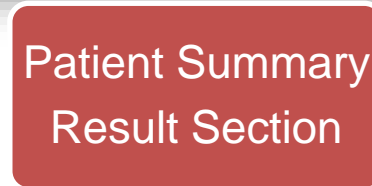
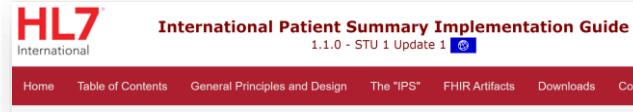
Name	Flags	Card.	Type
Observation	C	0..*	ObservationResultsUvIps
Slices for category		1..*	CodeableConceptIPS
category:laboratory	S	1..1	CodeableConceptIPS
coding		1..*	Coding
system		1..1	uri
code		1..1	code
code	S	1..1	CodeableConceptIPS

Observation Results: laboratory (IPS)

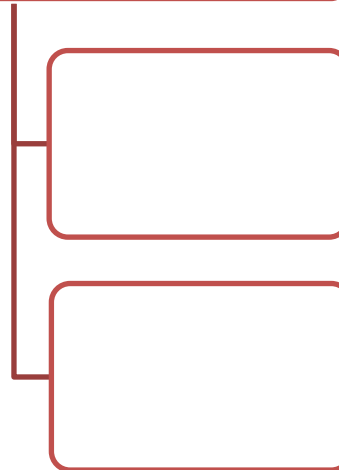
Layered Specifications: advantages



Laboratory Results



Patient Summary



GETTING INVOLVED





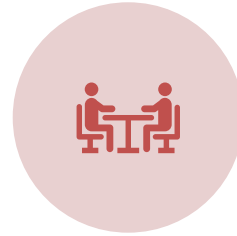
How to be engaged ...



STAYING TUNED
(WEBINARS,
TUTORIALS)



PROVIDING YOUR
FEEDBACK (JIRA)



ATTENDING THE
HANDS-ON EVENTS
(HL7 FHIR
CONNECTATHON)



JOINING THE
MEETINGS



Thank you!

The HL7 FHIR Implementation Guide for laboratory results Agenda

16.00 Welcome (Michael Strübin, *HL7 Europe*)

16.05 The policy context (Henrique Martins, *former chair of the eHealth Network*)

16.15 The HL7 EU Lab Report FHIR IG (Giorgio Cangioli, *HL7 Europe*)

16.30 Q&A with stakeholders and the audience

- Hynek Kružík, *National eHealth Center, Czech Republic*
- Patrizio Fonzi, *Sogei (Ministry of Economy and Finance), Italy*
- Manel Domingo Falcón, *Ministry of Health, Spain*
- George Karapetakos, *Computer Control Systems, Greece*

16.50 Next steps on the Lab Report FHIR IG (Catherine Chronaki, *HL7 Europe*)

17.00 End

Round of stakeholders

- Hynek Kružík
National eHealth Center, Czech Republic
- Patrizio Fonzi
Sogei (Ministry of Economy and Finance), Italy
- Manel Domingo Falcón
Ministry of Health, Spain
- George Karapetakos
Computer Control Systems, Greece
- Audience Q&A



MINISTERSTVO ZDRAVOTNICTVÍ
ČESKÉ REPUBLIKY

Czech National Interoperability Project

Hynek Kružík,
Interoperability Lead
Czech National eHealth Center (NCEZ)
Ministry of Health



About Czech National eHealth Center

- Section of the MoH, responsible for
 - Conceptual, strategic and program management of the digital health
 - Support of legislation in the digital health
 - Overall responsibility for digitization of the healthcare sector
 - Develop national digital health architecture
 - Preparation and management of implementation projects
 - Management of a national digital health infrastructure
 - Manage interoperability assets
 - Standards
 - Terminologies etc.



About Myself

- 25+ years of experience in digital health, 16+ years in lab field
- National Interoperability Program Manager
- Head of the interoperability standards department at NCEZ
- HL7 Czech Republic Technical Lead
- Member of the eHN SGS and TIO
- X-eHealth laboratory functional specification task leader
- HL7 Europe laboratory FHIR IG Project facilitator





Czech National Interoperability project

- New eHealth act (325/2021)
 - MoH can published preferred and mandatory eHealth standards
- EU Funded project (2022 - 2025)
- Strategic decision to implement all new services based on HL7 FHIR
- Development and implementation of EEHRxF based (derived) national standards in all priority areas
- Draft guidelines (for trial use) developed and published in spring 2023
 - Final standards to be gradually published 2024+
- National roll-out projects will start in 2024

https://build.fhir.org/ig/ncez-cz/cz-lab/

Laboratorní náález

1.1 Informace o projektu

Tato implementační specifikace byla vypracována v rámci národního projektu interoperability MZČR.

1.2 Účel dokumentu

Tato implementační specifikace určuje způsob reprezentace laboratorní výsledkové zprávy (laboratorního nálezu) pomocí standardu HL7 FHIR.

Alternativní reprezentací laboratorního nálezu je standard [DASTA](#).

⚠ Upozornění: Vzhledem k rozhodnutí ukončit do roku 2027 další rozvoj a podporu standardu DASTA, doporučujeme všem implementátorům přechod k mezinárodnímu standardu HL7 FHIR.

1.3 Rozsah specifikace

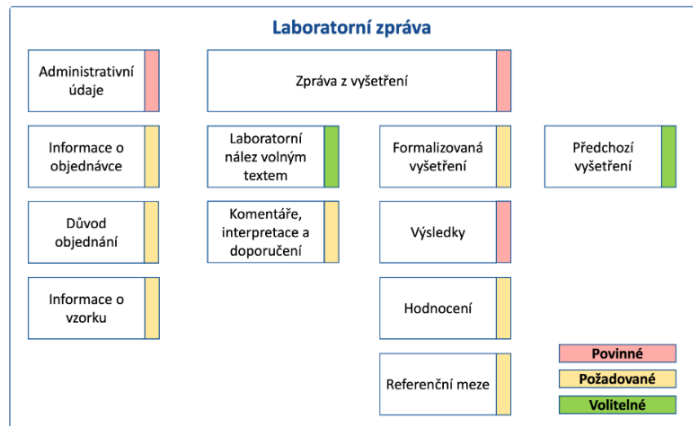
Tato implementační specifikace vychází z dokumentu **Funkční specifikace laboratorního nálezu**, který stanovuje základní požadavky, obsah a strukturu laboratorního nálezu.

ZAHRNUTÉ OBLASTI: Laboratorní výsledky v rámci stěžejních oborů in vitro diagnostiky jako jsou klinická biochemie, hematologie, transfúzní lékařství, mikrobiologie a imunologie.

NEZAHRNUTÉ OBLASTI: Specializované laboratorní oblasti vyžadující specifickou strukturu výsledkových zpráv jako jsou histopatologie nebo lékařská genetika.

Následující obrázek vyjadřuje základní informační bloky laboratorního nálezu.

Obrázek 1: Obsah laboratorního nálezu

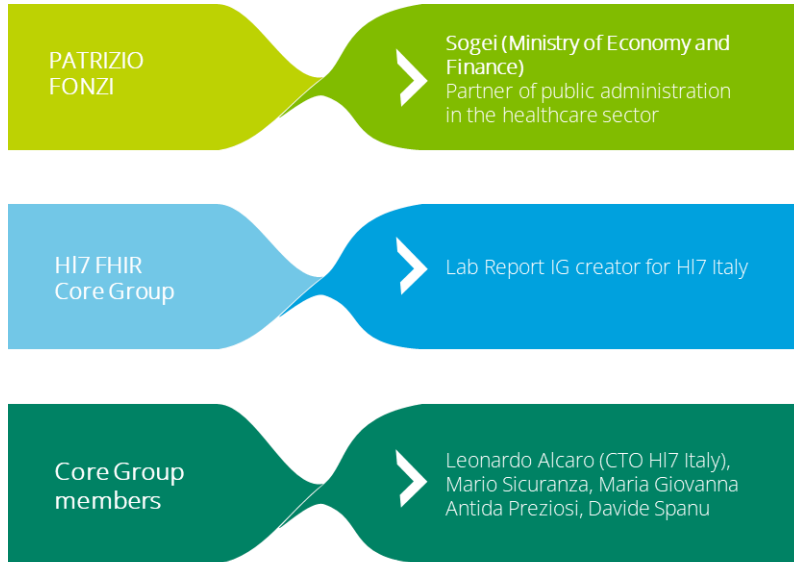


- Laboratorní náález
 - Informace o projektu
 - Účel dokumentu
 - Rozsah specifikace
 - Souvislosti s dalšími specifikacemi
 - Cross Version Analysis
 - Global Profiles

Round of stakeholders

- Hynek Kružík
National eHealth Center, Czech Republic
- Patrizio Fonzi,
Sogei (Ministry of Economy and Finance), Italy
- Manel Domingo Falcón
Ministry of Health, Spain
- George Karapetakos
Computer Control Systems, Greece
- Audience Q&A

Lab report FHIR IG, HI7 Italy - Organization



Development

GitHub: development environment for all the artifacts necessary to generate the IG HL7 FHIR.

Input files:

- File Word e XHTML for IG templates;
- JPEG o PNG for logos and images;
- File in **FHIR Shorthand** (FSH) for the artifacts
- All input files will be processed by the FHIR Implementation Guide Publisher (FSH+SUSHI)

<https://github.com/hl7-it/lab-report>

Publication

The publication of the artefacts produced for the IG HL7 FHIR involves three different environments:

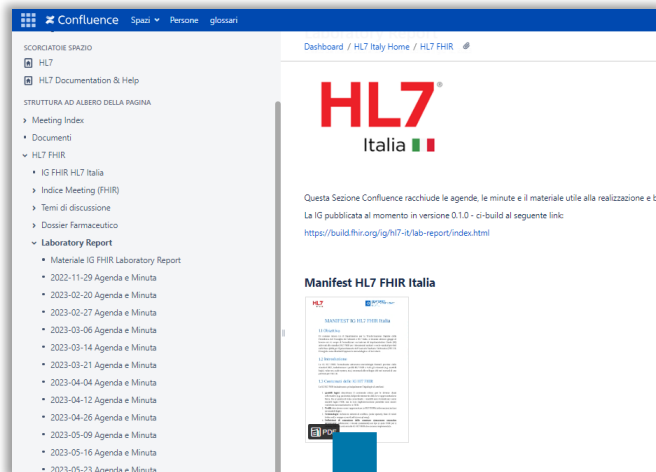
- a test environment (sandbox)
- a development environment (build)
- a release environment after ballot procedure (production)

<https://build.fhir.org/ig/hl7-it/lab-report>

Ballot

The ballot procedure, which began on 06/30/2023, follows the Jira Balloting standard of HL7 international FHIR, which involves the use of GitHub Issues.

Dependency HL7 Europe Laboratory Report FHIR IG



HL7
Italia

DIPARTIMENTO
PER LA TRASFORMAZIONE
DIGITALE

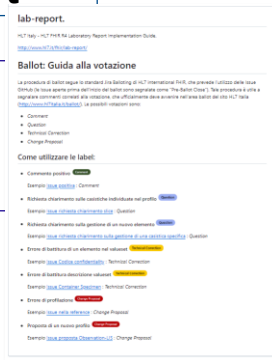
MANIFEST IG HL7 FHIR Italia

1.1 Obiettivo

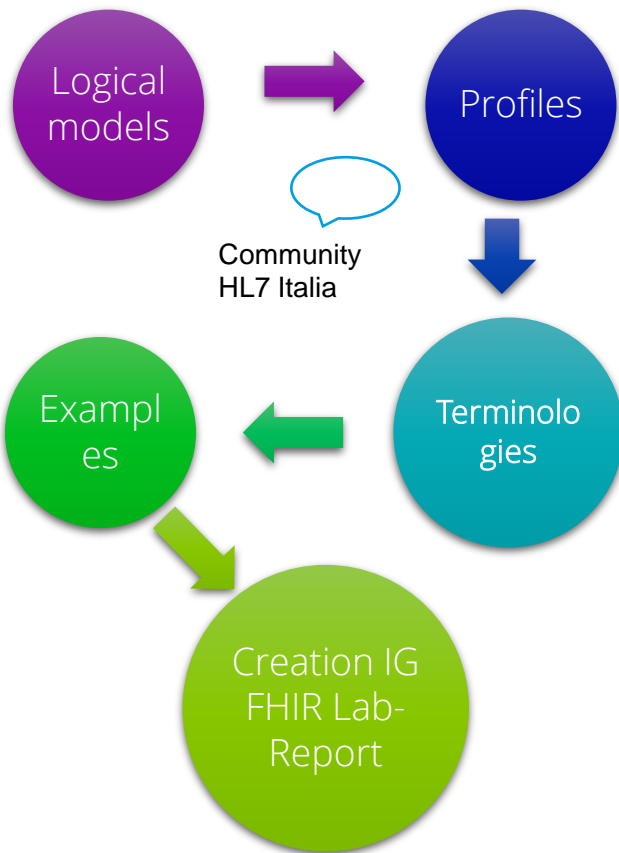
Di comune intesa tra il Dipartimento per la Trasformazione Digitale della Presidenza del Consiglio dei Ministri e HL7 Italia, si intende attivare gruppi di lavoro con lo scopo di formalizzare un insieme di Implementation Guide (IG) aderenti allo standard HL7 FHIR per i documenti sanitari e socio-sanitari previsti nelle linee guida per il potenziamento del Fascicolo Sanitario Elettronico (FSE 2.0). Di seguito sono illustrati l'approccio metodologico e il tool stack.

1.2 Introduzione

Le IG HL7 FHIR, formalizzate attraverso metodologie formali previste dallo standard HL7, includeranno i profili HL7 FHIR e tutti gli elementi (e.g. modelli logici, value set, code system, etc.) necessari allo sviluppo dei vari scenari di uso previsti per FSE 2.0.



Workflow



Name	Flags	Card.	Type	Description & Constraints
Bundle	0..*		Bundle	Bundla Referto di Laboratorio
identifier	1..1		Identifier	Identificativo del PMID Document.
id	1..1		id	Hashcode del codice identificativo.
value	1..1		string	Valore univoco di identificazione della bundle all'interno dei dataset.
type	1..1		code	Indica cosa rappresenta l'obiettivo del Bundle.
timestamp	1..1		instant	Quando la Bundle è stata assemblata.
entry	0..*		BackboneElement	Risorse contenute nel documento PMID.
entryComposition	1..1		BackboneElement	Entry in the Bundle - will have a resource or information
resource	1..1		CompositionReferenceable	Composition Referto di Laboratorio
entryDiagnosticReport	1..1		BackboneElement	Entry in the Bundle - will have a resource or information
resource	1..1		DifferentialTableReferenceable	DifferentialTable Referto di Laboratorio
entryObservation	1..1		BackboneElement	Entry in the Bundle - will have a resource or information
resource	1..1		Referenceable	Report Referto di Laboratorio
entryObservation	0..*		BackboneElement	Entry in the Bundle - will have a resource or information
resource	0..*		ObservationReferenceable	Observation Referto di Laboratorio
entrySpecimen	0..*		BackboneElement	Entry in the Bundle - will have a resource or information
resource	0..*		SpecimenReferenceable	Specimen Referto di Laboratorio
entryServiceRequest	0..*		BackboneElement	Entry in the Bundle - will have a resource or information
resource	0..*		ServiceRequestReferenceable	ServiceRequest Referto di Laboratorio
entryOrganization	0..*		BackboneElement	Entry in the Bundle - will have a resource or information
resource	0..*		Organization	Organization Referto di Laboratorio

Logical models are intended for non-technical users to express and validate functional requirements for information exchange, from a functional or clinical perspective. These support a stable and common understanding of interoperability data needs.

Logical models

A profile is an extension of existing FHIR resources used in a specific use case. Depending on the information content of the logical models identified, it was necessary to make some FHIR resources more specific.

Name	Flags	Card.	Type	Description & Constraints
RefertoLaboratorio	0..*		Base	2 - Referto di Laboratorio
header	1..1		BackboneElement	A.1.3 header del Referto di Laboratorio
soggettoReferto	1..1		string	A.1.1.1.1.2 Paciente/Soggetto del Referto di Laboratorio
destinatario	0..1		string	A.1.4 Destinatario delle informazioni
autore	0..*		string	A.1.5 Autore
firmatario	0..*		string	A.1.6 Firmatario del documento
validatore	0..*		string	A.1.7 Validatore del documento
metadati	1..1		BackboneElement	A.1.8 Metadati del Referto di Laboratorio
tipo	1..1		CodeableConcept	A.1.8.1 Tipo di documento
stato	1..1		CodeableConcept	A.1.8.2 Stato del Referto
data	1..1		dateTime	A.1.8.3 Data e ora della creazione del referto
idDocumento	0..1		string	A.1.8.4 ID del documento
numero	0..1		BackboneElement	A.1.8.5 Codice del referto
ordine	0..*		string	A.2-4.3 Ordine
campione	0..*		string	A.4 Informazioni sul campione
risultato	0..*		string	A.5 Risultati dell'esame
organismi	0..*		string	A.5.1 Batteri e esami
risultato	1..*		string	A.5 Risultati dell'esame

Profiles

To verify that the identified profiles conformed to the use case, instances of them were created.

Example

4.4.3.1 Example Bundle: Bundle document - Referto di Medicina di Laboratorio
Mara Rossi Female: DoB: 1971-05-01 (it: RSSUR47E191F205E)

```

Generated Narrative: Composition
Resource Composition: "Zaef5a7c-9094-41a3-af31-c6b5d4c35d91" (Language: "it-IT")
Profile: Composition - Lab Report
Security Labels:
DataEntered:
url
dataEntered:
value: See above (PractitionerRole/65842d1-8266-43c7-90c3-75a9998080c)
url
tempoCompilazione:
value: 2023-02-25 10:45:00-0300
  
```

Document Based On Order: See above (ServiceRequest/463a6f9-024-463b-8463-100a90265763)
Information required: See above (PractitionerRole/Lab-Examits)
Identifier: id: urn:uuid:10925ea-725c-446d-8a65-8a654444d8f3 (use: OFFICIAL)
status: FINAL

Round of stakeholders

- Hynek Kružík
National eHealth Center, Czech Republic
- Patrizio Fonzi
Sogei (Ministry of Economy and Finance), Italy
- Manel Domingo Falcón
Ministry of Health, Spain
- George Karapetakos
Computer Control Systems, Greece
- Audience Q&A



PRESIDENCIA
ESPAÑOLA
CONSEJO DE LA
UNIÓN EUROPEA

Laboratory Results FHIR IG

- Manel Domingo -



European Projects Technical Office
Vice-directorate of Digital Health Services
Directorate General of Digital Health and Information Systems for the National Health System

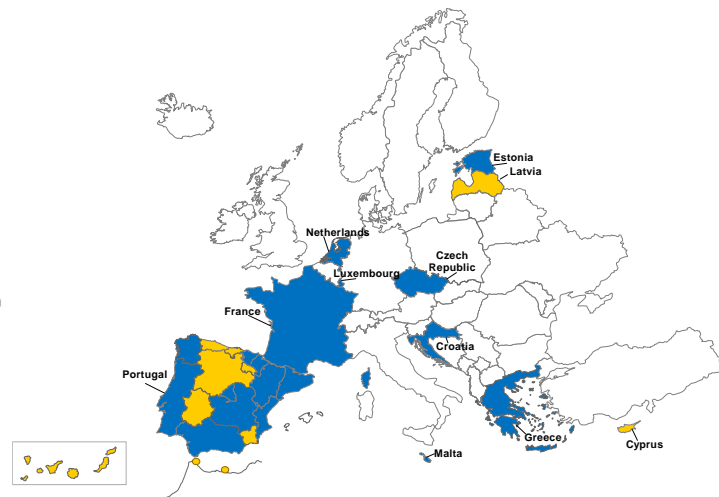
24/11/2023

Personal Introduction



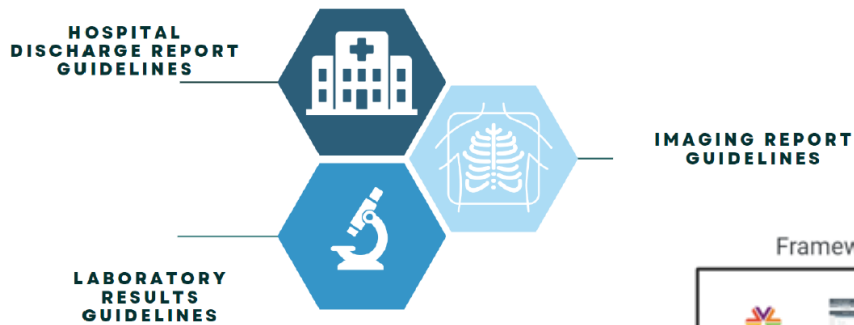
- 1 Spanish Ministry of Health - Interoperability EU Office
- 2 Roche – Building a Global Data Platform based on FHIR and AWS
- 3 Public Health Government of Catalonia – Defining regional standards based on HL7
- 4 HL7 Spain – Former Technical Director, Proctor and Educational courses professor
- 5 Interoperability Office of Catalonia – Defining regional PHR, EHR and IGs
- 6 Public Hospital – Leading the interoperability of each service

Summary. MyHealth@EU/eHDSI Services



MyHealth@EU/eHDSI new services. Implications

Working on:



Frameworks

A white box with a black border containing three logos: SMART (with a colorful star icon), IHE FHIR Profiles (in a yellow box), and HL7 CDS Hooks (with the HL7 logo).

IGs and use cases

A white box with a black border containing three logos: US Core Implementation Guide (with a small US flag icon), DA VINCI (with a small robot icon), and IPS (The International Patient Summary).

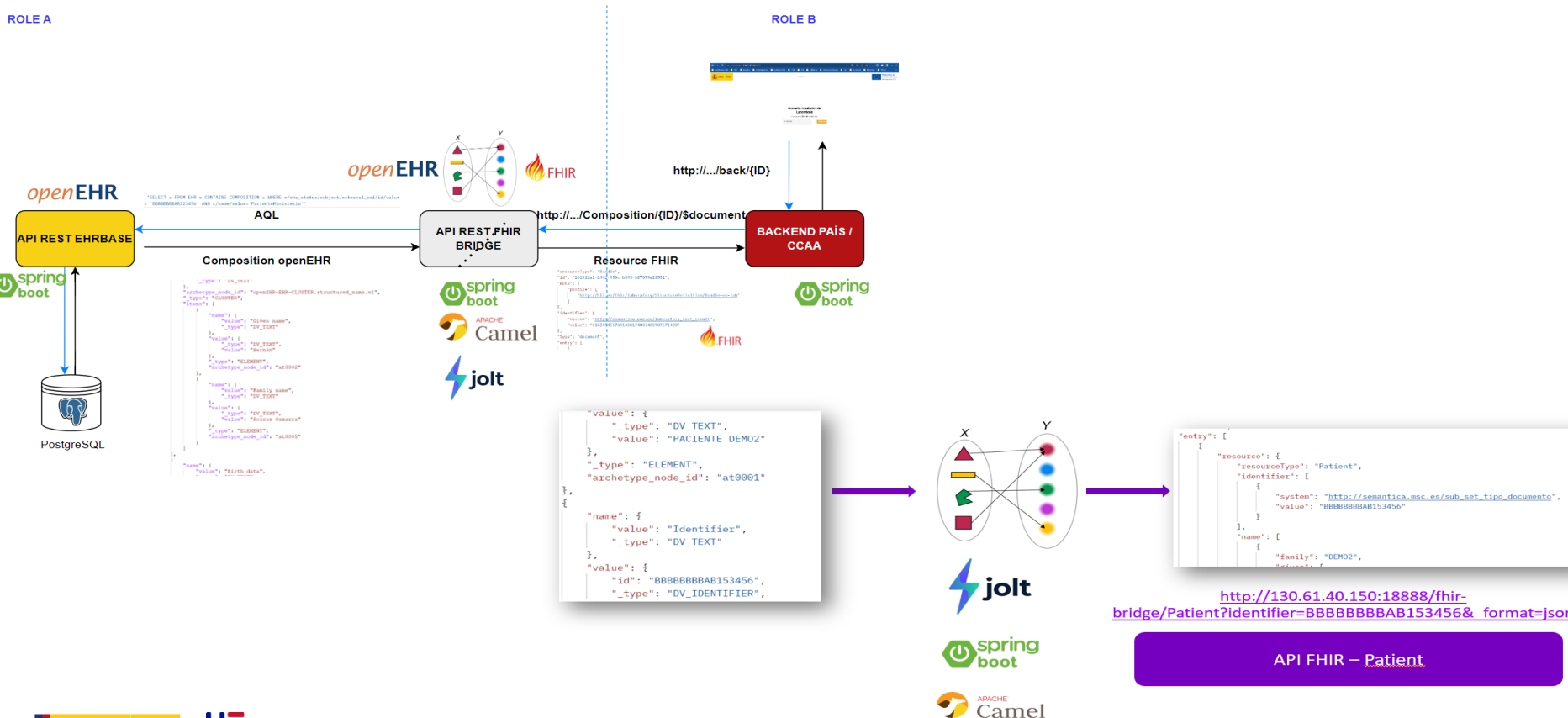
Tooling

A white box with a black border containing five logos: KODJIN BY EEBLAE, Azure API for FHIR (in a yellow box), SIMPLIFIER.NET (in a yellow box), HAPI FHIR (with a cat icon), and Forge (with a gear icon).

MyHealth@EU/eHDSI Laboratory Report new service. Prototype.

ROLE A

ROLE B



http://130.61.40.150:18888/fhir-bridge/Patient?identifier=BBBBBBBBB153456&_format=json

API FHIR – Patient

THANK YOU!



Round of stakeholders

- Hynek Kružík
National eHealth Center, Czech Republic
- Patrizio Fonzi
Sogei (Ministry of Economy and Finance), Italy
- Manel Domingo Falcón
Ministry of Health, Spain
- George Karapetakos
Computer Control Systems, Greece
- Audience Q&A

About CCS

With over a 30-year history, CCS is leading the healthcare informatics sector in Greece, driving improved care across Public, Military and Private Hospitals. CCS software, as well as e-Health and m-Health solutions, are currently implemented in more than 80 hospitals and a plethora of other sites (Insurance Funds, Diagnostic Centers, Microbiology Labs) across SE Europe and Middle East.

CCS main products are
MediLab LIS, e-AIMA (Blood Bank) and H-C LIS (Anatomic Pathology)

ISO CERTIFIED

Certified with **ISO 9001:2015** and **ISO 27001:2013** for the «design, development, installation, support of software products, solutions and services».



Why FHIR?

- It offers easier integration with various other systems.
- It is designed to be flexible, scalable, and easily extensible.
- It reduces development time.
- It encourages innovation.

Round of stakeholders

- Hynek Kružík
National eHealth Center, Czech Republic
- Patrizio Fonzi
Sogei (Ministry of Economy and Finance), Italy
- Manel Domingo Falcón
Ministry of Health, Spain
- George Karapetakos
Computer Control Systems, Greece
- Audience Q&A



The HL7 FHIR Implementation Guide for laboratory results Agenda

16.00 Welcome (Michael Strübin, *HL7 Europe*)

16.05 The policy context (Henrique Martins, *former chair of the eHealth Network*)

16.15 The HL7 EU Lab Report FHIR IG (Giorgio Cangioli, *HL7 Europe*)

16.30 Q&A with stakeholders and the audience

- Hynek Kružík, *National eHealth Center, Czech Republic*
- Patrizio Fonzi, *Sogei (Ministry of Economy and Finance), Italy*
- Manel Domingo Falcón, *Ministry of Health, Spain*
- George Karapetakos, *Computer Control Systems, Greece*

16.50 Next steps on the Lab Report FHIR IG (Catherine Chronaki, *HL7 Europe*)

17.00 End

HL7 Working Group Meeting

Europe



HL7 Europe WGM and HL7 FHIR Marathon

Preliminary program



- Sunday January 14, 2024: Joint Initiative Council
- Monday January 15, 2024
 - Q1: Athens Digital Health Week Opening
 - Q2, Q3: HL7 European Strategic Advisory Board
 - Lunch meeting: JIC listening Session
 - Q4, Q5: HL7 Europe Board Meeting
 - 19:30 Joint Dinner
 - Tutorials
- Tuesday January 16, 2024
 - Q1: Plenary
 - Tutorials
 - HL7 FHIR Marathon
 - HL7 WGM Thematic Workshops
- Wednesday January 17, 2024
 - Q1: Plenary
 - Tutorials
 - HL7 FHIR Marathon
 - Gravitate-Health Hackathon
 - HL7 WGM Thematic Workshops
 - xShare/xt-EHR Launch Event
- Thursday January 18, 2024
 - Q1 Plenary Joint with 2nd EuroVulcan
 - EuroVulcan conference
 - HL7 WGM Thematic Workshops
 - HL7 FHIR Marathon
 - Gravitate-Health Hackathon
 - Joint launch event xt-EHR & xShare (under ADHW)
- Friday January 19, 2024
 - Q1 Closing Plenary
 - Gravitate-Health Hackathon
 - HL7 WGM Thematic Workshops

HL7 Europe WGM and FHIR Marathon

HL7 Europe Working Group Meeting and HL7 FHIR Marathon 15-19 January 2024, Athens, Greece



Register now: HL7 Europe Working Group Meeting and FHIR Marathon January 15 to 19, 2024

We are happy to announce our first event of this kind. From January 15 to 19, 2024, we will hold an **HL7 Europe Working Group Meeting** along with an **HL7 FHIR Marathon**.

[Register for the conference here](#)

[Book a room in the conference hotel](#)



During Tuesday to Thursday before lunch, a EU centric HL7 FHIR Marathon will be conducted. Topics/tracks planned are the European Lab Report, International Patient Summary IPS, European Cancer Mission, Electronic Product Information (ePI) and Identification of Medicinal Products (IDMP).

During Wednesday to Friday afternoons, a Gravitate-Health Hackathon and Thursday the EU edition of the Vulcan Accelerator is planned.

There will be plenaries with with outstanding Keynote speakers and Roundtables on:

- Monday January 15, 2024

The HL7 FHIR Implementation Guide for laboratory results Agenda

16.00 Welcome (Michael Strübin, *HL7 Europe*)

16.05 The policy context (Henrique Martins, *former chair of the eHealth Network*)

16.15 The HL7 EU Lab Report FHIR IG (Giorgio Cangioli, *HL7 Europe*)

16.30 Q&A with stakeholders and the audience

- Hynek Kružík, *National eHealth Center, Czech Republic*
- Patrizio Fonzi, *Sogei (Ministry of Economy and Finance), Italy*
- Manel Domingo Falcón, *Ministry of Health, Spain*
- George Karapetakos, *Computer Control Systems, Greece*

16.50 Next steps on the Lab Report FHIR IG (Catherine Chronaki, *HL7 Europe*)

17.00 End

Wrap up

- HL7 will share with all registered attendees:
 - Link to HL7 FHIR lab report (<https://hl7.eu/fhir/laboratory/>)
 - Webinar slides and recording
 - Jira instructions and other relevant information and links
- All attendees are invited to
 - Become or stay involved
 - Offer feedback in Jira
 - Follow HL7 Europe on LinkedIn



Thank you!