

# **The HL7 Europe Laboratory Report FHIR IG**

Giorgio Cangioli

Technical Lead HL7 Europe

fagforum, April 17<sup>th</sup> 2024





# Who am I

**Giorgio Cangioli**

Co-facilitator of the HL7 EU Laboratory Report FHIR IG

Technical Lead, Board member HL7 Europe

eHMSEG STF Architecture WG chair

Board member, CDA MG co-chair, EAC member at HL7 International

# Disclaimer



**Any views or opinions expressed in this presentation are those of the author and do not necessarily represent official policy or position of the organizations and/or projects mentioned.**

# Published the HL7 Europe Lab Report FHIR IG !



HL7 Europe Laboratory Report (FHIR IG)

History

### Publication (Version) History

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

The following versions have been published:

Date	IG Version	FHIR Version	Description	Links
2024-02-26 (current)	0.1.0 (last commit)	4.0.1 n/a	This is the Edition 1 STU 1 release undefined	
2024-02-26	0.1.0	4.0.1	This is the Edition 1 STU 1 release (Permanent Home)	
2023-10-22	0.1.0-ballot	4.0.1	This is the version released for the STU 1 ballot	

hl7.fhir.eu.laboratory: HL7 Europe Laboratory Report @© FHIR | (0) PUBLIC DOMAIN

HL7 FHIR PACKAGE REGISTRY

laboratory

Only FHIR Versions

Refine package results

Find matching contents by

Only in jurisdictions

Implementation Guide

Profile or Specimen

StructureDefinition

Profile or Practitioner

Profile or Bundle

Implementation Guide

Profile or Specimen

StructureDefinition

Profile or Practitioner

Profile or Bundle

European EHRxF



EHDS - Art 5 Priorities

# What this is about ?

**HL7**  
Europe

**HL7 Europe Laboratory Report**  
0.1.0 - trial-use 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: STU 1) based on FHIR (HL7® FHIR® Standard) 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  
Active as of 2024-02-26  
Computable Name: HL7EuLaboratoryIg

Copyright/Legal: Used by permission of HL7 Europe, all rights reserved Creative Commons License

**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](#).

1.1 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).

1.2 Scope  
Specify a set of rules to be applied to HL7 FHIR to define how to represent a **Laboratory Report** in the **European Context**, coherently with the European eHN Guidelines (see the European eHealth - Key documents).

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



Laboratory Results

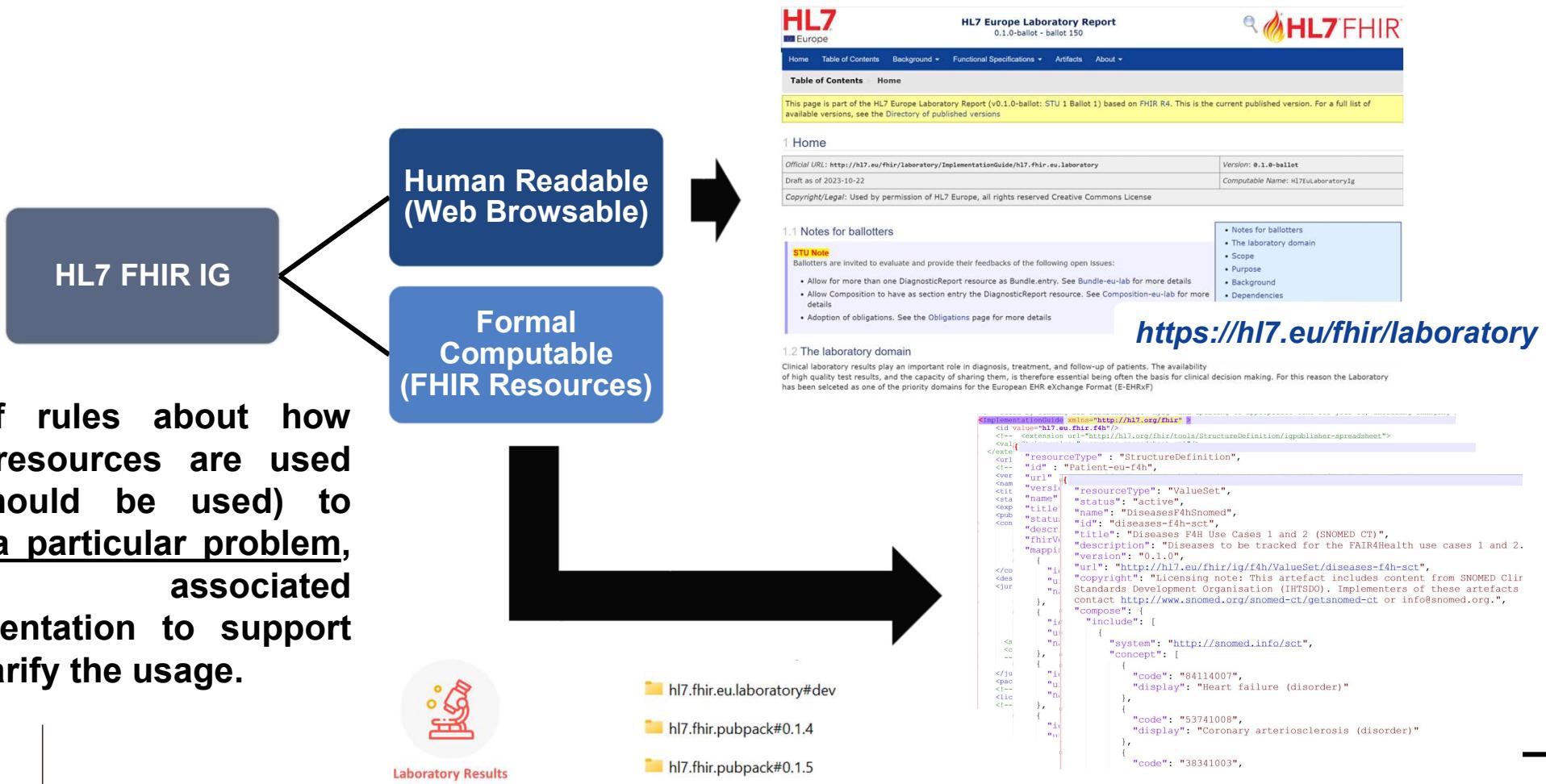


Common European rules for representing in HL7 FHIR a **Laboratory Report**

Facilitate the harmonization among the national initiatives

Support the development of the European-EHRxF

# What is a FHIR Implementation Guide (IG)



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.



## Laboratory Result

# What this guide is about..



Laboratory Results

The screenshot shows the HL7 Europe Laboratory Report website. The header includes the HL7 Europe logo, the title 'HL7 Europe Laboratory Report v0.1.0-ballot: STU 1 Ballot 1', and the FHIR logo. The navigation bar has links for Home, Table of Contents, Background, Functional Specifications, Artifacts, and About. Below the header is a yellow banner stating: '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 starts with a section titled '1.1 Notes for balloters' containing a 'STU 1' note. The note discusses ballot evaluation and provides a list of open issues related to the laboratory domain.



® Health Level Seven and HL7 are registered trademarks of Health Level Seven International, registered with the United States Patent and Trademark Office.

# A cooperative work



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

Tested and improved during the HL7 FHIR Connectathon in Athens (about 30 people in the track)



**HL7**  
Europe  
**Standard**

**HL7**  
Europe



2022

2023

2024

2025

Laboratory results and reports



Laboratory Results

Proof of Concept

April 2024

Implementation in MyHealth@EU (Wave 8)

(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

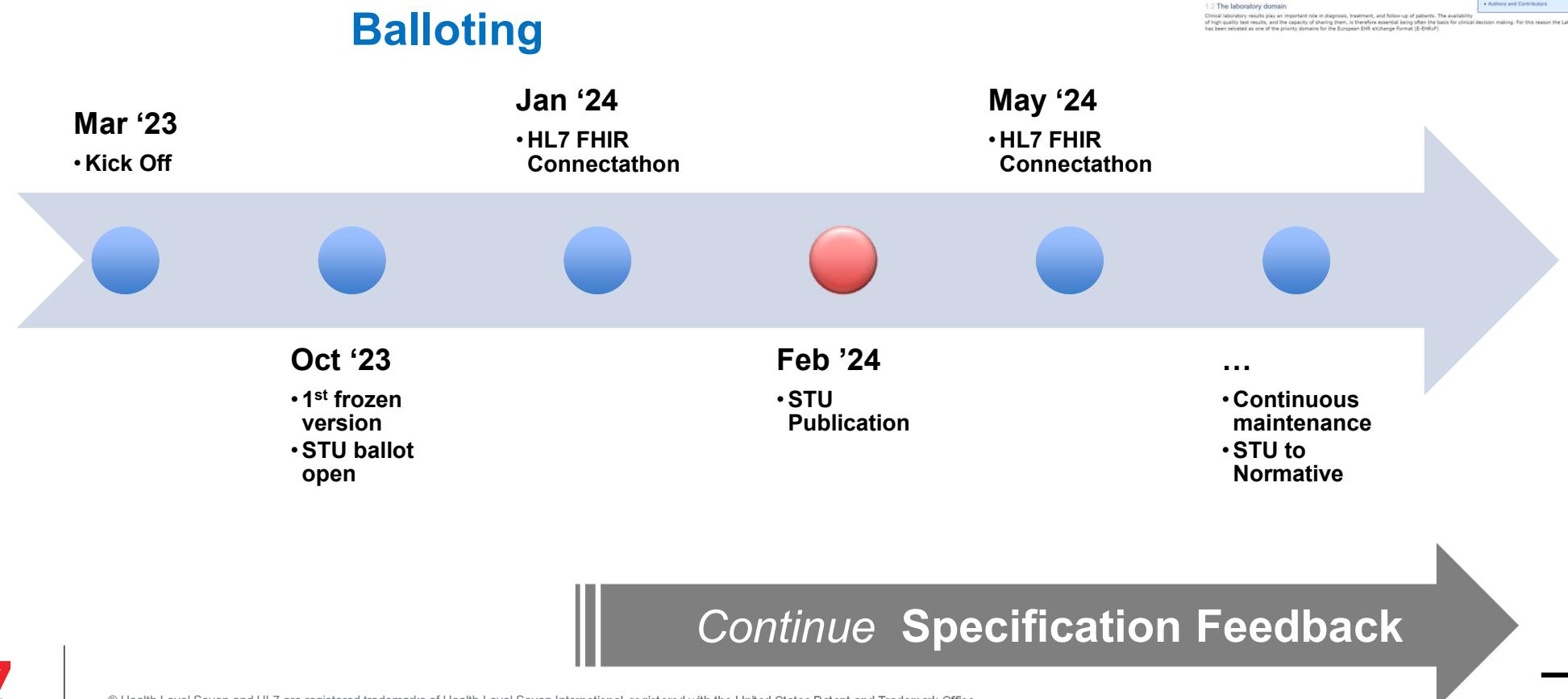
Xt-EHR (JA-09)

National Initiatives

The HL7 EU Laboratory Report FHIR IG



# When .. the timeline



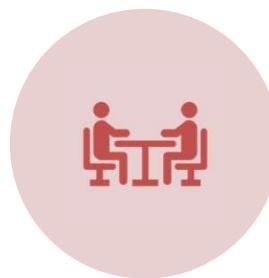
# How to be engaged ...



**STAYING TUNED  
(WEBINARS,  
TUTORIALS)**



**PROVIDING YOUR  
FEEDBACK (JIRA,  
BALLOT)**



**ATTENDING THE  
HANDS-ON EVENTS  
(HL7 FHIR  
CONNECTATHON)**



**JOINING THE  
MEETINGS**

# 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/>

The screenshot shows the Jira Software interface with a blue header bar containing the Jira logo, navigation links for Dashboards, Projects, Issues, Boards, Plans, and a 'Create' button. A red box highlights the 'Create' button. Below the header is a 'Create Issue' dialog box. The dialog has fields for 'Project' (set to 'FHIR Specification Feedback ...'), 'Issue Type' (set to 'Change Request'), and 'Default' (set to 'Advanced'). A section titled 'Submitting a Change Request' explains that it's for changes more than a simple technical correction. It includes fields for 'Specification' (set to 'EU Laboratory Report (FHIR)'), 'Raised in Version' (a search bar), 'Summary' (a text input field), and 'Related URL' (a text input field). At the bottom of the dialog are 'Create another', 'Create', and 'Cancel' buttons.

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

# WHAT IS IN THE GUIDE...

# What's in it...



A screenshot of the "HL7 Europe Laboratory Report" website. The header includes the HL7 Europe logo and the title "HL7 Europe Laboratory Report 0.1.0 - trial-use |50". Below the header is a navigation menu with links to Home, Table of Contents, Background, Functional Specifications, Artifacts, and About. A "Table of Contents" section is visible. The main content area contains a yellow banner stating: "This page is part of the HL7 Europe Laboratory Report (v0.1.0: STU 1) based on FHIR (HL7® FHIR® Standard) R4. This is the current published version. For a full list of available versions, see the Directory of published versions." Below this is a "1 Home" section with detailed information about the report's scope, purpose, and design choices. A "STU Note" box provides additional context on obligations and dependencies. The footer includes copyright information and a link to the eHN Guidelines.

## HL7 FHIR Logical Models

## eHN Guidelines



How data are  
represented in HL7  
FHIR

## Models to Profiles Mapping

## HL7 FHIR Profiles

How to use HL7  
FHIR

Obligations

# 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

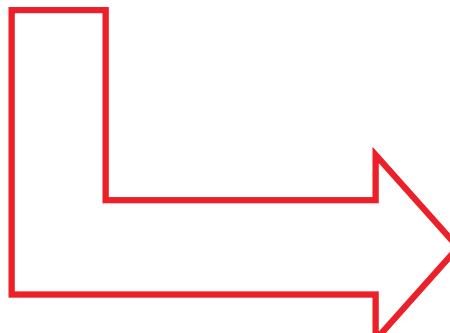
Field	Field description	Preferred Code System
<b>A.1 Report header data elements</b>		
<b>A.1.1 Identification of the patient/subject</b>		
A.1.1.1 Family name/surname	The family name/surname/last name of the patient. This field can contain more than one element or multiple fields could be present.	
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.	

HL7 FHIR  
Logical  
Models



HL7 FHIR  
Profiles

HL7  
Europe



## Logical Model

LabReport	0..*	Base	Laboratory Report
header	1..1	BackboneElement	A.1 Report header data elements
subject	1..1	Subject	A.1.1 - A.1.2 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

# Guideline data set formalization

Name	Flags	Card.
Subject		0..*
identification		1..1
familyName		0..*
givenName		0..*
dateOfBirth		0..1
identifier		0..1
gender		0..1
addressTelecom		0..*
address		0..*
telecom		0..*



eHealth Network

GUIDELINE

on

the electronic exchange of health data under

Cross-Border Directive 2011/24/EU

Laboratory Results

Release 1.1



## 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 contacts)		
Subject.addressTelecom.address (A.1.2.1 Address)		
Subject.addressTelecom.telecom (A.1.2.2 Telecom)		

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 contacts)		
Subject.addressTelecom.address (A.1.2.1 Address)		
Subject.addressTelecom.telecom (A.1.2.2 Telecom)		

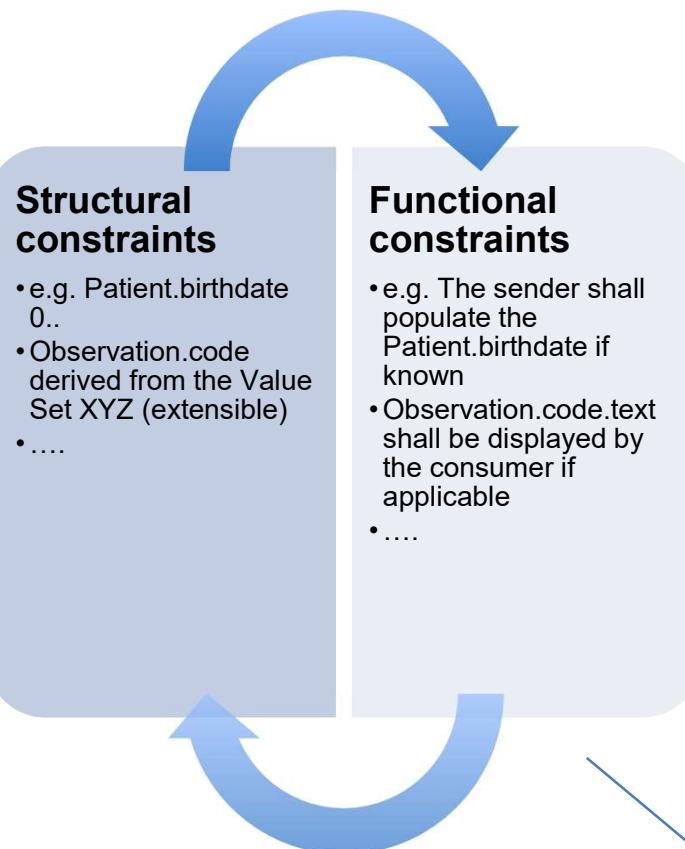


Name	Flags	Card.	Type	Description & Constraints
Patient			PatientUvIps	
identification		0..*	Identifier	Patient identifiers
name	C	1..*	HumanNameEu	Name of a human - parts and usage <b>eu-pat1:</b> Patient.name.given, Patient.name.family Text representation of the full name.
text		0..1	string	
family		0..1	string	
given		0..*	string	
telecom		0..*	ContactPoint	
gender		0..1	code	
address	C	0..*	AddressEu	
HumanName			HumanName	Human name (often called 'Surname') Example spanish name: Valero Iglesias
family		0..1	string	Extension Slice: Unordered, Open by value: Portion of family name derived from father URL: <a href="http://hl7.org/fhir/StructureDefinition/address#family">http://hl7.org/fhir/StructureDefinition/address#family</a>
given		0..*	Extension	Example spanish name: Valero Portion of family name derived from mother URL: <a href="http://hl7.org/fhir/StructureDefinition/address#given">http://hl7.org/fhir/StructureDefinition/address#given</a>
mothersFamily		0..*	string	Example spanish name: Iglesias Given names (not always 'first'). Includes middle names Example spanish name: Borja
given		0..*	string	

MAY be selected from ISO Country Alph 1-3, IF the country is not specified in v  
<http://hl7.org/fhir/ValueSet/iso3166-1>

# Obligations

Name	Flags	Card.	Type
Patient		0..*	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

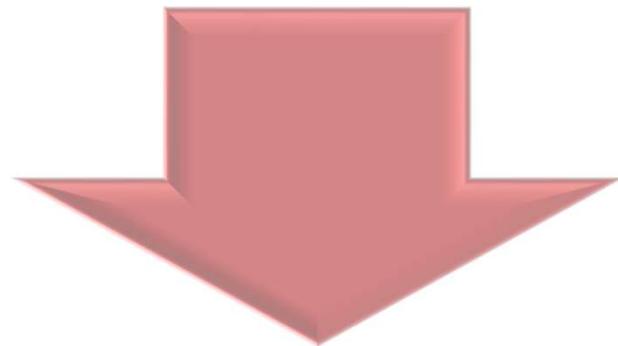


*Obligations are informative in this version of the IG*

Name	Flags	Card.	Type	Description & Constraints
Patient		0..*	Patient	Information about an individual or animal receiving health care services
identifier		0..*	Identifier	An identifier for this patient
name		0..1	string	Text representation of the full name
text		0..1	string	
family		0..1	string	Family name (often called 'Surname')
given		0..*	string	
telecom		0..*	ContactPoint	
gender		0..1	code	
address		0..*	AddressEu	
city		0..1	string	
district		0..1	string	
postCode		0..1	string	
region		0..1	string	
street		0..1	string	
type		0..1	string	
obligations		0..1	Actor	Obligations
handle		0..1	ActorLabRptConsumer	generalPractitioner
send		0..1	ActorLabRptCreator	address
send		0..1	ActorLabRptCreator	telecom
send		0..1	ActorLabRptCreator	generalPractitioner
elements		0..1	Element	
handle		0..1	ActorLabRptConsumer	
send		0..1	ActorLabRptCreator	
send		0..1	ActorLabRptCreator	

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

# Balancing different (EU) requirements



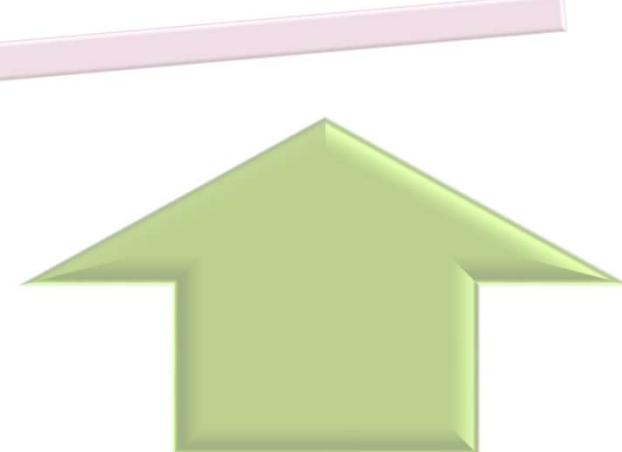
## Legally signed documents

Often structured and including different kinds of test results

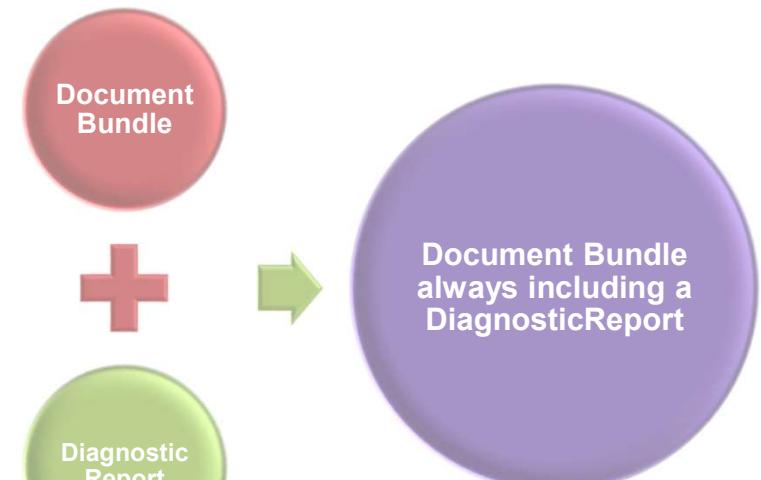
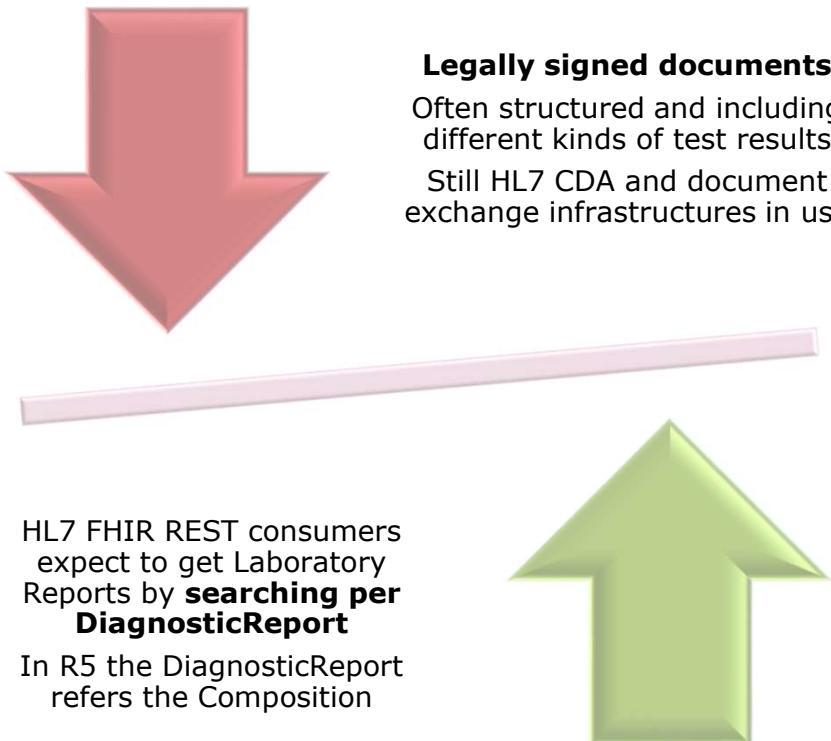
Still HL7 CDA and document exchange infrastructures in use

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

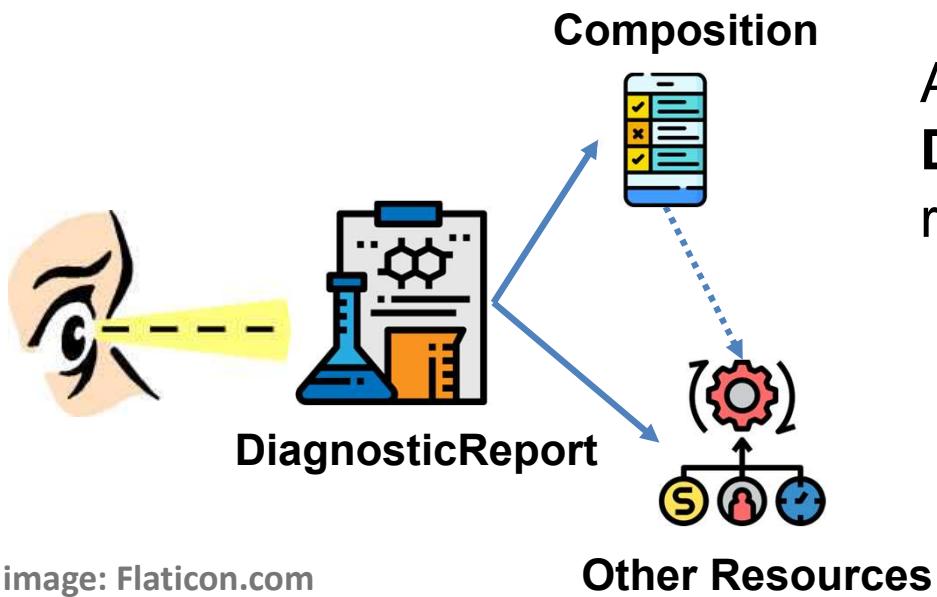
In R5 the DiagnosticReport refers the Composition



# Balancing different (EU) requirements



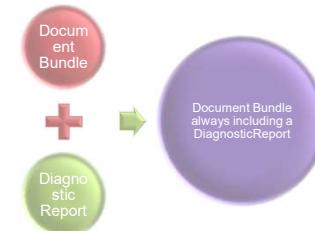
# The Laboratory Report



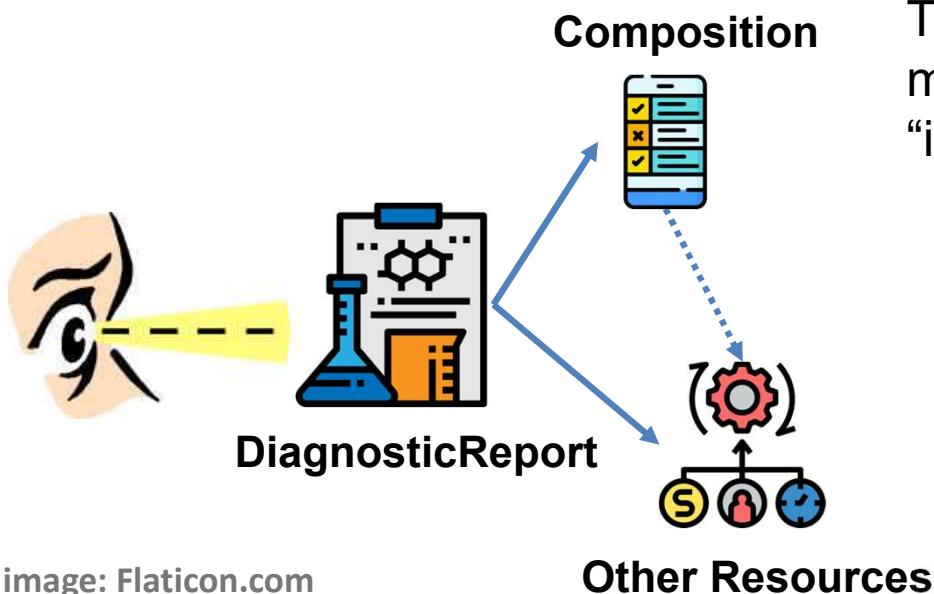
A Lab **report** is always **represented by a DiagnosticReport**. This resource always refers a Composition

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

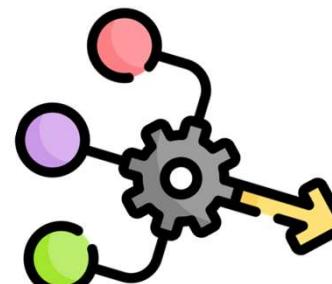
## REST Perspective



# The Laboratory Report

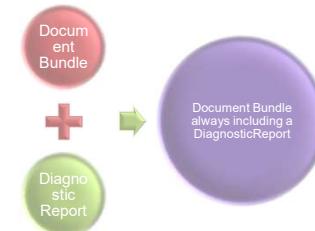


The **Composition** defines the report **structure** (it might be just a single section) and it acts as an “index” for all the used resources

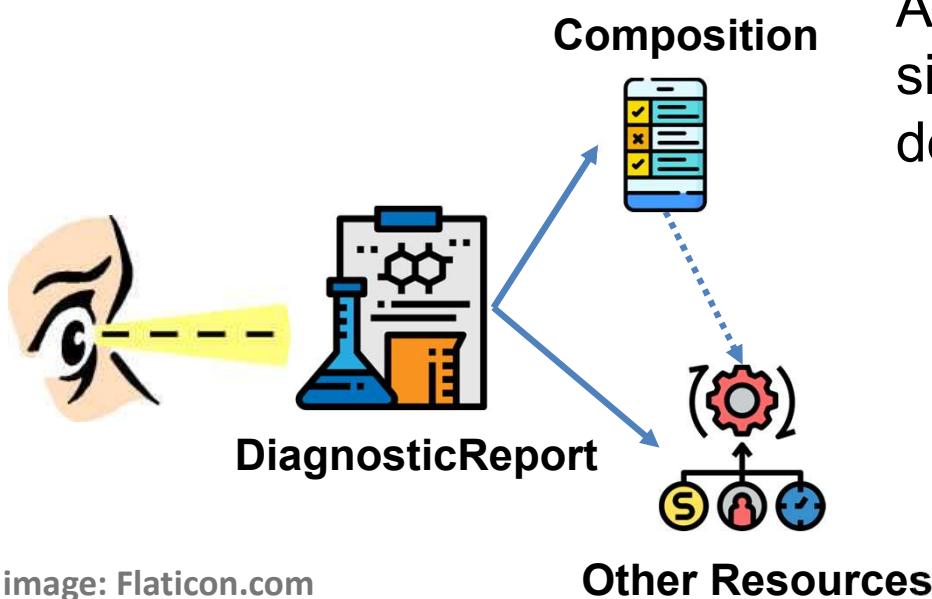


It is the mean for assembling the report as a document (**document Bundle**)

**REST Perspective**

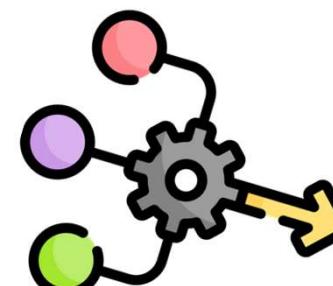


# The Laboratory Report

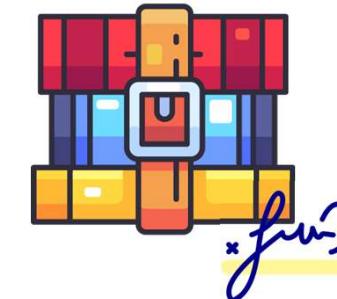


REST Perspective

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



Bundle  
[type = document]



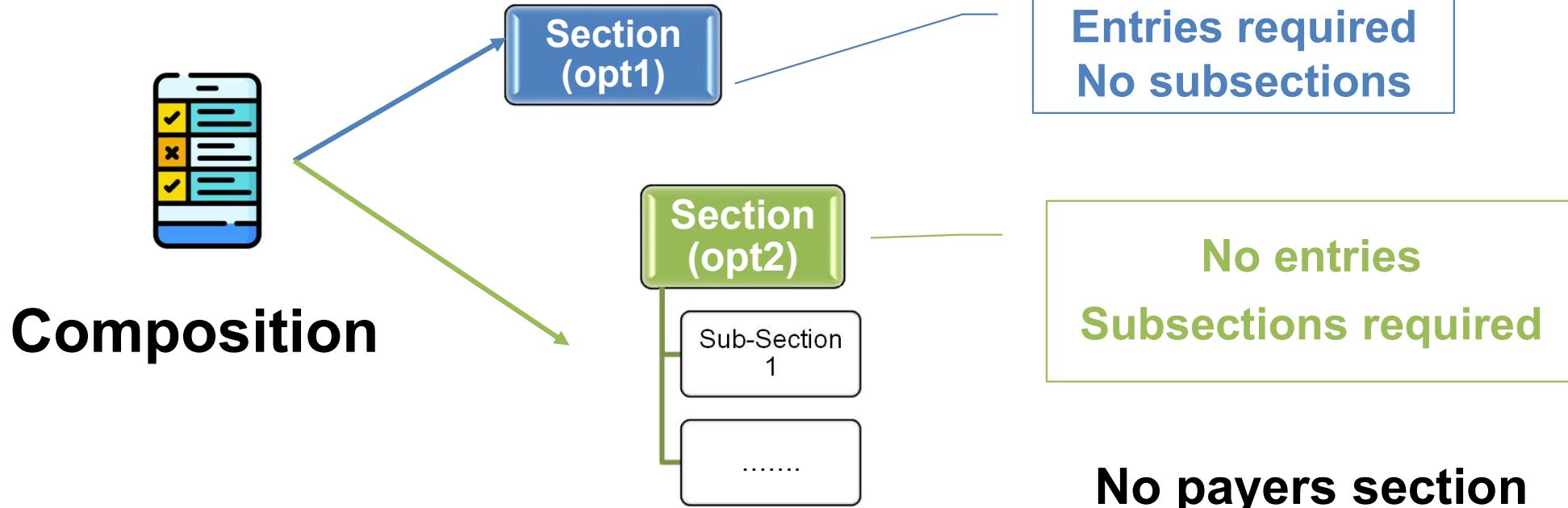
Document Perspective

# The Laboratory Report



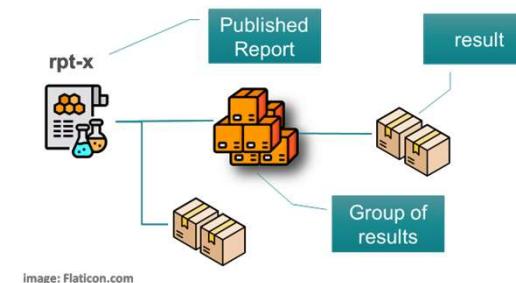
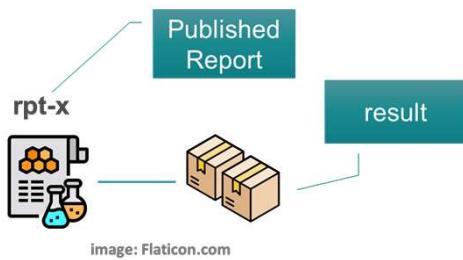
Document Bundle

(For results) Same structure of the IHE XD-LAB CDA body



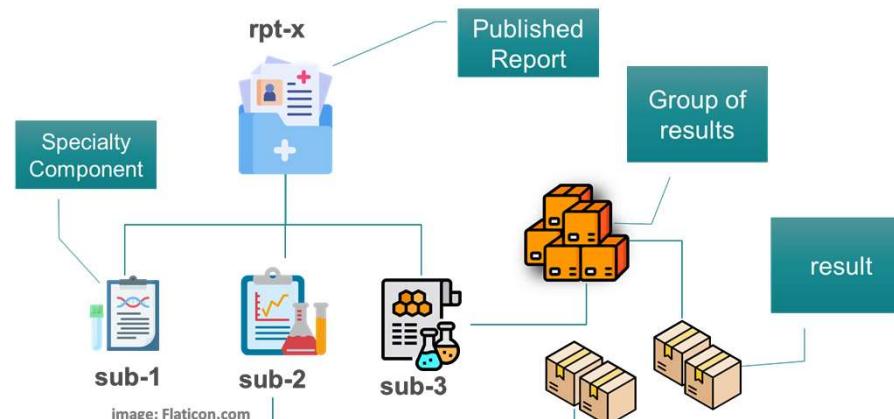
# A single solution for different structural choices

Very simple report  
(e.g. single panel)

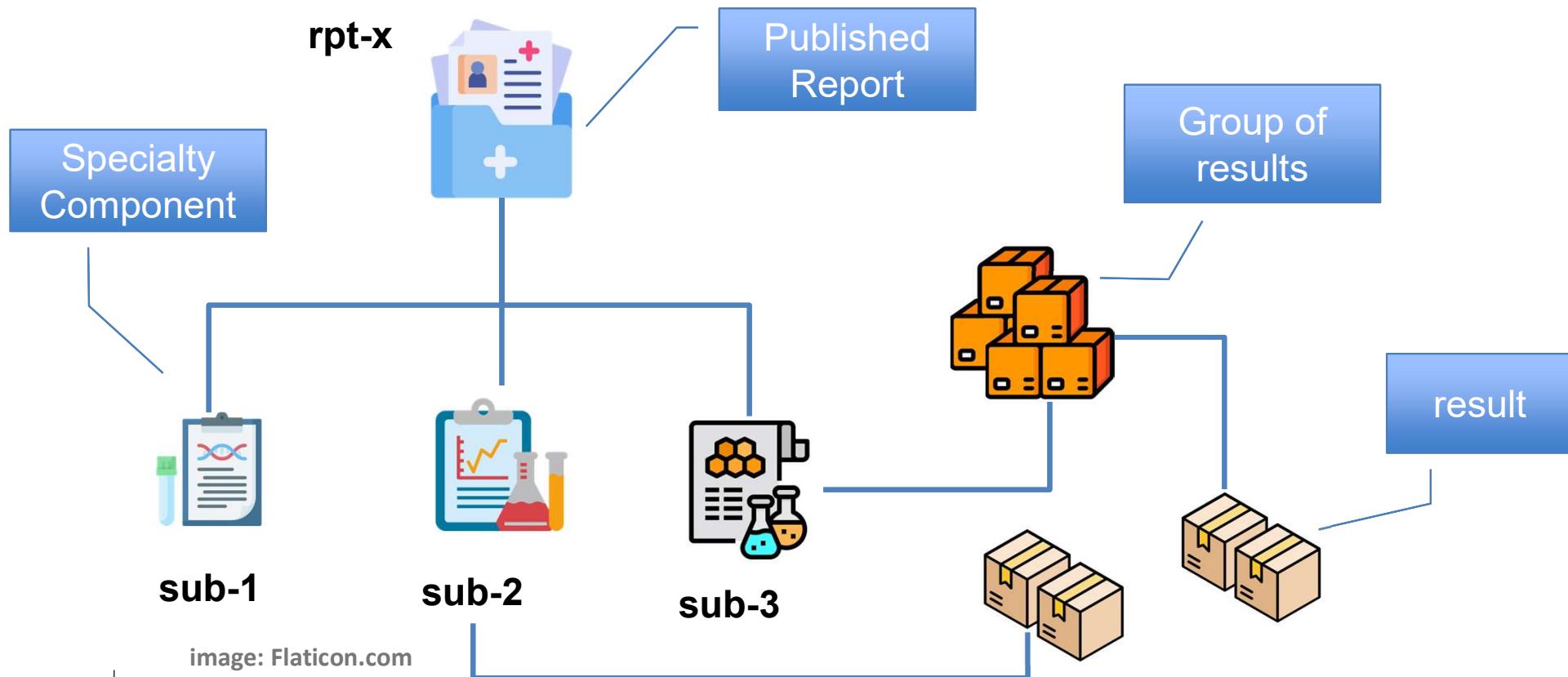


Single-specialty report

Multi-specialty report



# Multi-specialty report



# Multi-specialty report

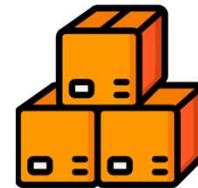


**DiagnosticReport** (→ Composition), recorded into a Document Bundle



**Composition.section**

(Set of) Composition.section



**Observation** (→ Observation)

Composition.section



**Observation**

# ..before taking a look....



HL7 Europe Laboratory Report 0.1.0 - trial-use 150

HL7 FHIR

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: STU 1) based on FHIR (HL7® FHIR® Standard) R4. This is the current published version. For a full list of available versions, see the [Directory of published versions](#)

## 1 Home

Official URL: <a href="http://hl7.eu/fhir/laboratory/ImplementationGuide/hl7.fhir.eu.laboratory">http://hl7.eu/fhir/laboratory/ImplementationGuide/hl7.fhir.eu.laboratory</a>	Version: 0.1.0
Active as of 2024-02-26	Computable Name: HL7EuLaboratoryIg

Copyright/Legal: Used by permission of HL7 Europe, all rights reserved Creative Commons License

**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

**1.1 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).

**1.2 Scope**  
Specify a set of rules to be applied to HL7 FHIR to define how to represent a **Laboratory Report** in the **European Context**, coherently with the European eHN Guidelines (see the European eHealth - Key documents [↗](#) ).

- The Laboratory Domain
- Scope
- Purpose
- Background
- Design choices
- Navigating the profiles
- Dependencies
- Cross Version Analysis
- Global Profiles
- IP statements
- Authors and Contributors



# The guide in one slide

- **The Lab FHIR IG is out !**
- **Result of a participatory** multi-stakeholders and Europe wide standardization and review **effort** (not limited to EU)
- A **flexible structure** supporting REST and document perspectives; covering different usage contexts (e.g. human and non-human subjects) and different report structural choices
- **Common rules** applicable EU-wide, aiming to help the development of the European-EHRxF

A baseline for any Laboratory Report (HL7 FHIR) specifications

# THE JOURNEY TOWARDS THE EHDS

# A complex and multiform scenario

- Needs and expectations are different and **there is not a one-fits-all solution**

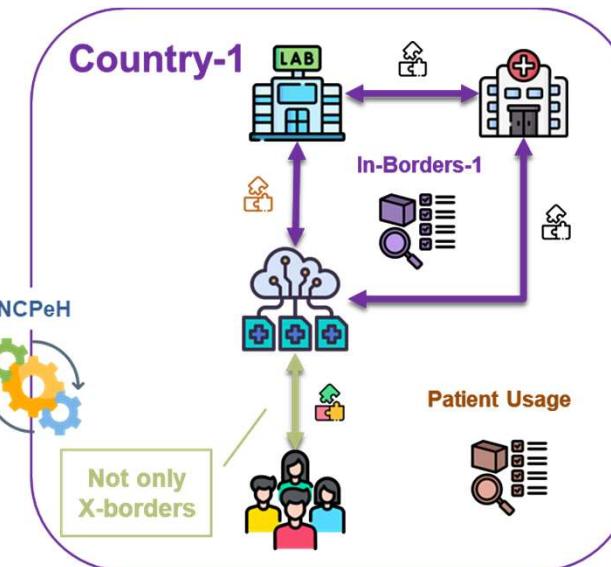
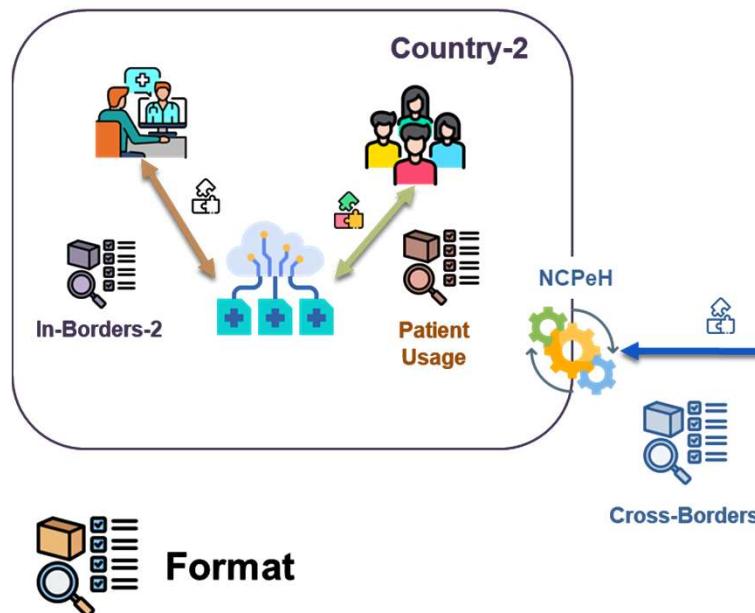
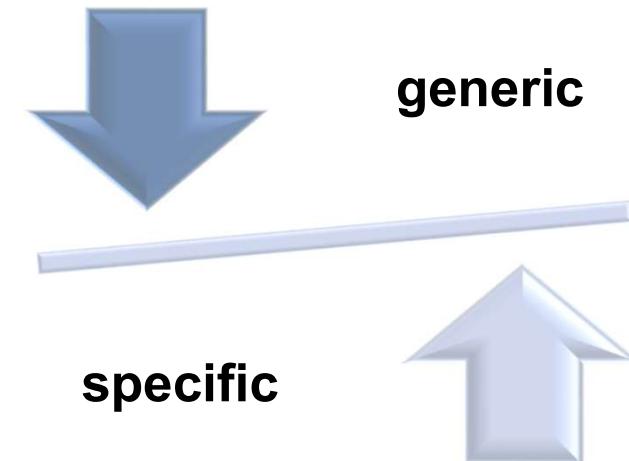
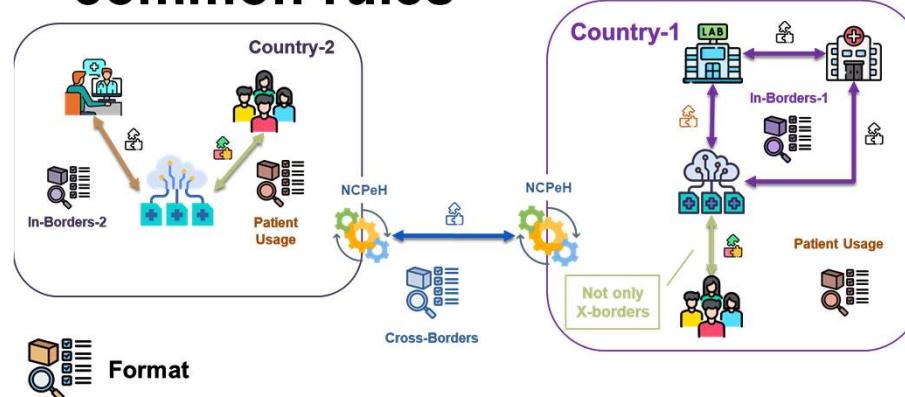


image: Flaticon.com

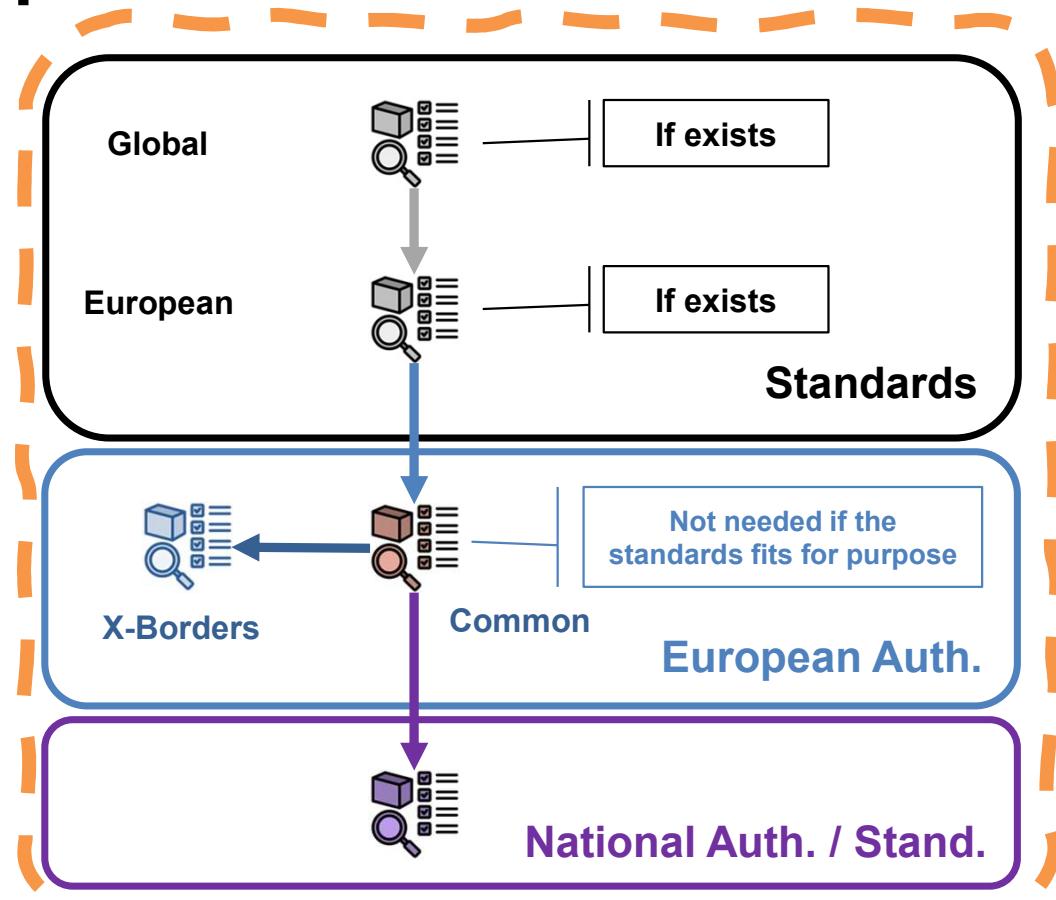
# A complex and multiform scenario



- Needs and expectations are different and there is not a **one-fits-all solution**... but.. no European interoperability without:
  - **serving and being useful in all these situations**
  - **common rules**



# The vision



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

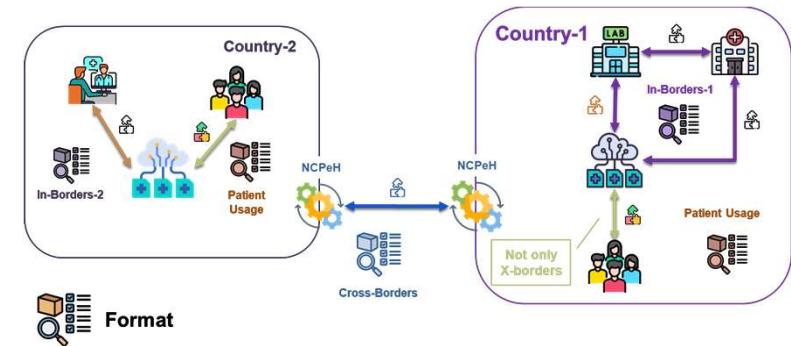
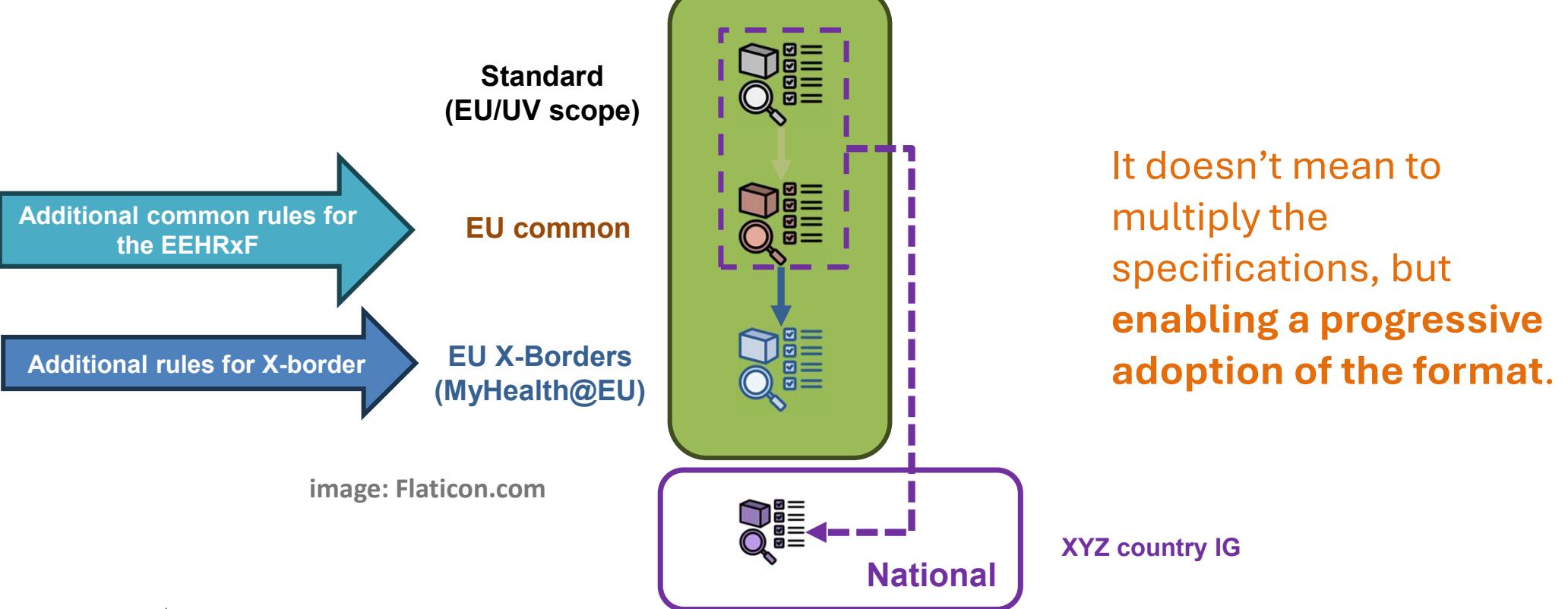
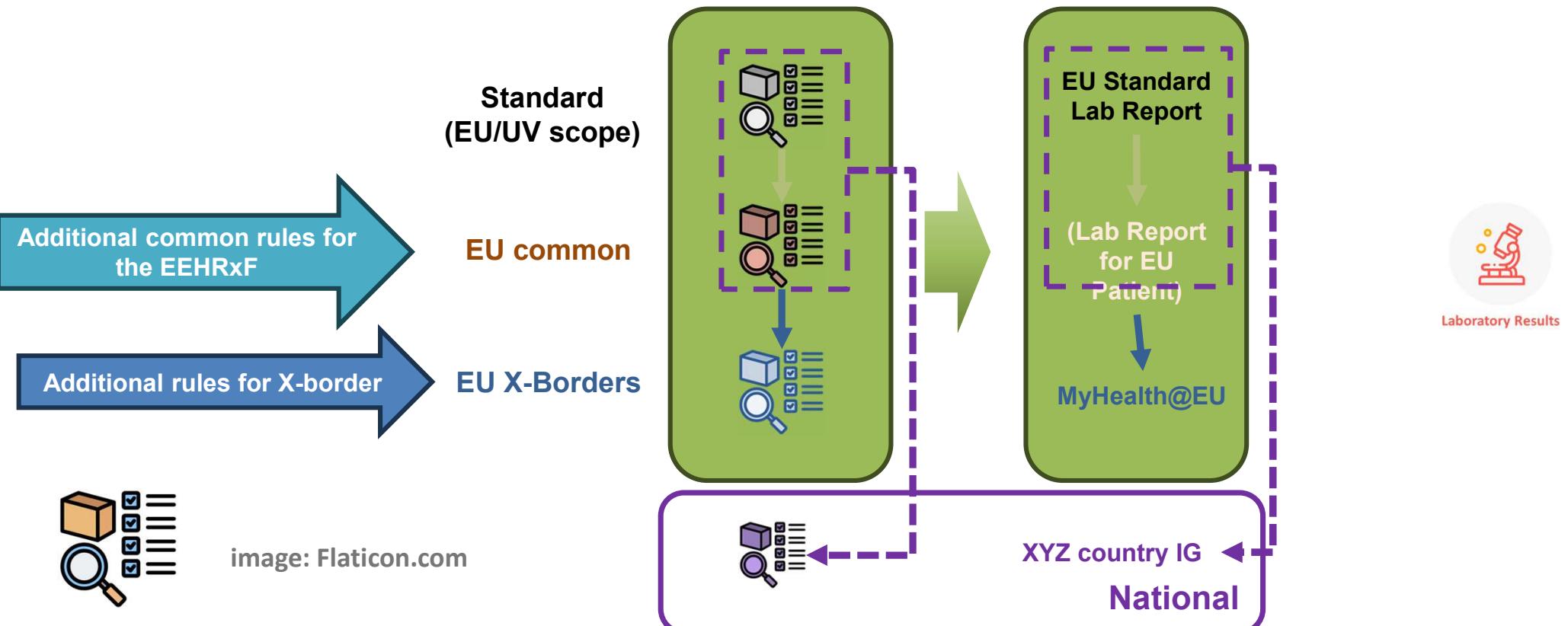


image: Flaticon.com

# The vision



# Instantiating the vision



# The vision made real..



eHealth Network

**GUIDELINE**

on

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

Laboratory Results

Release 1.1

**Standard  
(EU/UV scope)**

**EU X-Borders**

**HL7 Europe Laboratory Report**  
0.1.0 - trial-use 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: STU 1) based on FHIR (HL7® FHIR® Standard) R4. This is the current published version. For a full list of available versions, see the Directory of published versions.

Official URL: <http://hl7.eu/fhir/laboratory/ImplementationGuide/HL7-FHIR-eu.laboratory> Version: 0.1.0

Active as of 2024-02-26 Copyright/Legal: Used by permission of HL7 Europe, all rights reserved Creative Commons License

**STU 1 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.

**My health EU Domain** Laboratory results play an important role in diagnosis, treatment, and follow-up of patients. The availability of laboratory results is often a key factor in the capacity of sharing them, it 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 Health Data Space.

- The Laboratory Domain
- Scope
- Purpose
- Background
- Design choices
- Navigating the profiles
- Dependencies
- Cross Version Analysis
- Global Profiles

**MyHealthEU Laboratory Report**  
0.1.0 - trial-use 150

Home Table of Contents Examples Artifacts Downloads

Table of Contents Home

This page is part of the MyHealthEU Laboratory Report - Local Development build (v0.1.0). See the Directory of published versions.

Official URL: <http://health-eu-europe.eu/FHIR/Laboratory/ImplementationGuide/rec-ex-fhir-laboratory> Version: 0.1.0

Draft as of 2024-02-28 Copyright/Legal: CC BY-SA

**1.1 Scope** This is the HL7 FHIR Implementation Guide for Laboratory Report V4aOH project, created to assist work with pilot product for product data in FHIR.

The specification herewith documented is a demo working specification, and may not be used for any implementation purposes. No liability can be inferred from the use or misuse of this specification, or its consequences.

**1.2 The project**

orem ipsum dolor sit amet, consectetur adipiscing elit. Duis a hendrerit ante, a efficitur neque. Fusce pulvinar pellentesque risus, vel aliquet ante aliquet eu. Sed id du accumsan, feugiat augue in, sollicitudin felis. Curabitur dignissim venenatis leo, ut fribus latus ornare ut. Quisque sem diam, mollis vel luctus et. Ut id libero magna elementum leo, id molestie neque nisi fermentum odio. Supersedisse potest. Quisque luctus ligula nec sapien incidunt sodales. Orci varius natoque sit amet, consetetur sadipscing elitr, sed diam nonumy eirmod tempor invidunt ut labore et dolore magna aliquyam erat, sed diam voluptua. At vero eos et accusamus et iusto odio dignissim qui blanditiis praesentium voluptatum deleniti atque sonet, ut labore et dolore magna aliquyam erat, sed diam voluptua. At vero eos et accusamus et iusto odio dignissim qui blanditiis praesentium voluptatum deleniti atque sonet.



**Laboratory Results**



**CH ELM (R4)**

**CH ELM (R4)**

Home Laboratory Report Use Case Guidance Profiles Extensions Terminology API Artifacts

Table of Contents Home

This page is part of the CH ELM (R4) - trial-use 150. See the Directory of published versions.

Official URL: <http://ch.fhir.ch/elm> Draft as of 2023-09-29 Copyright/Legal: CC BY-SA

**1.1 Introduction** CH ELM is a project of laboratories to send FHIR as our FHIR Implementation Guide. It is based on the FHIR R4 standard and the FHIR BESTEST was the project (see graphic).

**1.2 This documentation is** This documentation is a continuous build for version 5.5.0. This documentation is based on the current content of <https://ch.fhir.ch/elm> and changes regularly. See the [Directory of published versions](#).

**1.3 Content**

Official URL: <https://ch.fhir.ch/elm> Draft as of 2023-11-24 Copyright/Legal: CC BY-SA

**1.4 Laboratori nálež**

There is also an overview of the [Laboratori nálež](#). The top menu allows quick access to multiple tabs.

**1.5 Informace o projektu**

Tato implementační specifikace určuje způsob reprezentace laboratori náleží v rámci národního projektu interoperability HZČR.

**1.6 Účel dokumentu**

Tato implementační specifikace určuje způsob reprezentace laboratori náleží v rámci národního projektu interoperability HZČR.

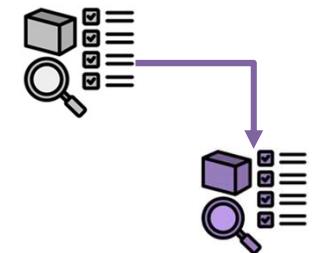
**1.7 Uprozdění**

Alternativní reprezentaci laboratori náleží je standard [DASTA](#).

**National Guides**



# A vision made real..



**HL7 Italia**

**HL7 FHIR Implementation Guide Laboratory Report**  
0.2.0 - trial-use

IG Home | Sommario | Specifiche | Indice Artefatti | Supporto

Table of Contents > Home

This page is part of the HL7 FHIR Implementation Guide Laboratory Report (v0.2.0: Release 1) based on FHIR (HL7® FHIR® Standard) R4. This is the current published version. For a full list of available versions, see the [Directory of published versions](#).

**1 Home**

Official URL: <a href="http://hl7.it/fhir/lab-report/ImplementationGuide/hl7.fhir.it.lab-report">http://hl7.it/fhir/lab-report/ImplementationGuide/hl7.fhir.it.lab-report</a>	Version: 0.2.0
Active as of 2024-03-08	Computable Name: HL7ITLabReport

**1.1 Scopo**  
L'obiettivo della seguente guida è quello di definire, secondo lo standard HL7 FHIR versione R4, le specifiche per l'implementazione dei profili che verranno utilizzati nel referto di medicina di laboratorio nel contesto italiano.

**1.2 Definizione del Referto di Medicina di Laboratorio**  
Il referto di laboratorio appartiene al nucleo minimo dei documenti del Fascicolo Sanitario Elettronico. Ai sensi dell'articolo 27, comma 1, lettera d), del decreto n. 178 del 29 settembre 2015, il referto di laboratorio e' il documento redatto dal medico di medicina di laboratorio. Il contenuto informativo del Referto di Laboratorio è disciplinato all'art.2 dal Decreto del 18 maggio 2022 del Ministero della Salute ([Decreto Contenuti](#)).

**1.3 Contesto**  
La guida intende fornire delle specifiche adeguate al contesto italiano secondo lo standard HL7 FHIR, per assicurare l'accuratezza dei risultati degli esami di lab trasmissione degli stessi, al paziente o ad altra figura professionale, in modo chiaro e corretto. Questa guida implementativa è stata creata per descrivere in modo chiaro gli elementi standard necessari per supportare lo scambio sia semantico che sintattico di informazioni inerenti al referto di laboratorio e viene sviluppata considerando la risorsa Patient.

La guida può essere utilizzata per descrivere i risultati di laboratorio nei settori chiave della diagnostica in vitro, come:

- Scopo
- Definizione del Referto di Medicina di Laboratorio
- Contesto
- Navigazione
- Dipendenze
- Details
- Autori e contributori
- Intellectual Property Statement

**HL7 Italia**

**HL7 FHIR Implementation Guide Laboratory Report**

History

**Publication (Version) History**

HL7 FHIR Implementation Guide Laboratory Report specifica come utilizzare lo standard HL7 FHIR per documentare un referto di medicina di laboratorio.

The following versions have been published:

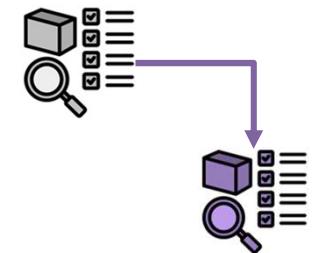
Date	IG Version	FHIR Version	Description	Links
2024-03-08	0.2.0	4.0.1	This is the Edition 1 STU 1 release	
(current)	(last commit)	n/a	undefined	
2024-03-08	0.2.0	4.0.1	This is the Edition 1 STU 1 release (Permanent Home)	
2023-07-11	0.1.0	4.0.1	This is the June 2023 STU ballot version.	

## 1.5 Dipendenze

IG	Package	FHIR
HL7 FHIR Implementation Guide Laboratory Report	hl7.fhir.it.lab-report#0.2.0	R4
HL7 Terminology (THO)	hl7.terminology.r4#5.3.0	R4
FHIR Extensions Pack	hl7.fhir.uv.extensions.r1#1.0.0	R4
HL7 Europe Laboratory Report	hl7.fhir.eu.laboratory#0.1.0	R4
International Patient Summary Implementation Guide	hl7.fhir.uv.ips#1.1.0	R4
HL7 Europe Extensions	hl7.fhir.eu.extensions#0.1.0	R4

**Officially Published**

# A vision made real..



Schweizerische Eidgenossenschaft  
Confédération suisse  
Confederazione svizzera  
Confederació suïça  
Swiss Confederation  
Fédérale Department of Home Affairs FDHA  
Federal Office of Public Health FOPH

## CH ELM (R4)

1.0.0-trialuse - trial-use

Home Laboratory Report Use Case Guidance Profiles Extensions Terminology API Artifacts

Table of Contents > Home

This page is part of the Observations of notifiable communicable infectious diseases (v1.0.0-trialuse: STU 1 Draft) 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://fhir.ch/ig/ch-elm/ImplementationGuide/ch.fhir.ig.ch-elm>  
Draft as of 2023-09-13  
Copyright/Legal: CC0-1.0

### 1.1 Introduction

CH ELM is a project of the Swiss Federal Office of Public Health (FOPH), Communicable Disease laboratories to send their observations of notifiable communicable infectious diseases to the created as a specialized Clinical Document based on the HL7® FHIR® standard. This FHIR a FHIR RESTful web API endpoint. CH ELM derives from the [Swiss implementation guides](#) project (see [graphical overview](#)).

The expected content of the FHIR document, based on the ordinance of the Federal Office ( ), is defined in the [logical model](#). A [mapping](#) shows how to access the data from the FHIR documentation for specific topics can be found on the [guidance](#) page and the use cases (Df with respective examples for specific organisms.



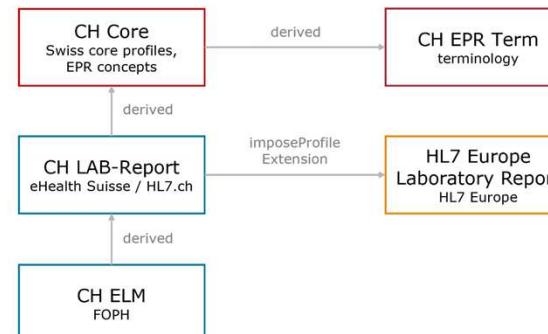
Laboratory Results

### 1.6 Dependencies

#### 1.6.1 Dependency Overview

This overview illustrates the relevant dependencies of CH ELM to the [Swiss implementation guides](#) and the European laboratory project.

#### Core profiles



#### Exchange formats

HL7 Europe Laboratory Report  
1.0.0-trialuse - trial-use

Table of Contents Home

This page is part of the HL7 Europe Laboratory Report (v1.0.0-trialuse: STU 1 Draft) based on FHIR R4. This is the current published version. For a full list of available versions, see the [Directory of published versions](#).

I Home  
Official URL: <http://fhir.ch/ig/ch-elm/ImplementationGuide/ch.fhir.ig.ch-elm>  
Draft as of 2023-09-13  
Copyright/Legal: CC0-1.0

II Notes for Implementers  
III HL7 FHIR  
IV HL7 FHIR  
V HL7 FHIR  
VI HL7 FHIR  
VII HL7 FHIR  
VIII HL7 FHIR  
IX HL7 FHIR  
X HL7 FHIR  
XI HL7 FHIR  
XII HL7 FHIR  
XIII HL7 FHIR  
XIV HL7 FHIR  
XV HL7 FHIR  
XVI HL7 FHIR  
XVII HL7 FHIR  
XVIII HL7 FHIR  
XIX HL7 FHIR  
XX HL7 FHIR  
XXI HL7 FHIR  
XXII HL7 FHIR  
XXIII HL7 FHIR  
XXIV HL7 FHIR  
XXV HL7 FHIR  
XXVI HL7 FHIR  
XXVII HL7 FHIR  
XXVIII HL7 FHIR  
XXIX HL7 FHIR  
XXX HL7 FHIR  
XXI The laboratory domain  
XXII The laboratory domain  
XXIII The laboratory domain  
XXIV The laboratory domain  
XXV The laboratory domain  
XXVI The laboratory domain  
XXVII The laboratory domain  
XXVIII The laboratory domain  
XXIX The laboratory domain  
XXX The laboratory domain

Fig. 1: Dependency Overview

# A vision made real..



eHealth Network

GUIDELINE

on

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

Laboratory Results

Release 1.1

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

**MyHealth@Eu Laboratory Result Reports**  
0.0.1 - ci-build 150

**HL7 FHIR**

Home Table of Contents HL7 EU Lab Report IG Functional Specifications Artifacts Downloads

Table of Contents Home

MyHealth@Eu Laboratory Result Reports - Local Development build (v0.0.1) built by the FHIR (HL7® FHIR® Standard) Build Tools. See the Directory of published versions.

## 1 Home

Official URL: <http://myhealth.eu/fhir/laboratory/ImplementationGuide/myhealth.eu.fhir.laboratory>

Version: 0.0.1

Draft as of 2024-03-14

Computable Name: MyHealthEuLaboratoryIg

### 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

### 1.1 Scope

Specify a set of rules to be applied to HL7 FHIR to define how to represent a **Laboratory Report** for the **European cross-borders exchange**, coherently with the European eHN Guidelines (see the European eHealth - Key documents).

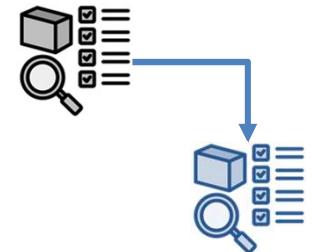
This Implementation Guide applies to laboratory reports within the core fields of in-vitro diagnostics (e.g. clinical biochemist leaving out some specialised laboratory domains like histopathology or medical genetics).

This guide is derived for the HL7 Europe Laboratory Report constraining the subject to human beings identified in the cour



Laboratory Results

*On-development FHIR IG*



**EU X-Borders**

## 1.5 Dependencies

### IG

MyHealth@Eu Laboratory Result Reports

HL7 Terminology (THO)

FHIR Extensions Pack

International Patient Summary Implementation Guide

fhir-dicom #2022-4-20221006

HL7 Europe Laboratory Report

HL7 Europe Extensions

### Package

myhealth.eu.fhir.laboratory#0.0.1

### FHIR

R4

hl7.terminology.r4#5.3.0

R4

hl7.fhir.uv.extensions.r4#1.0.0

R4

hl7.fhir.uv.ips#1.1.0

R4

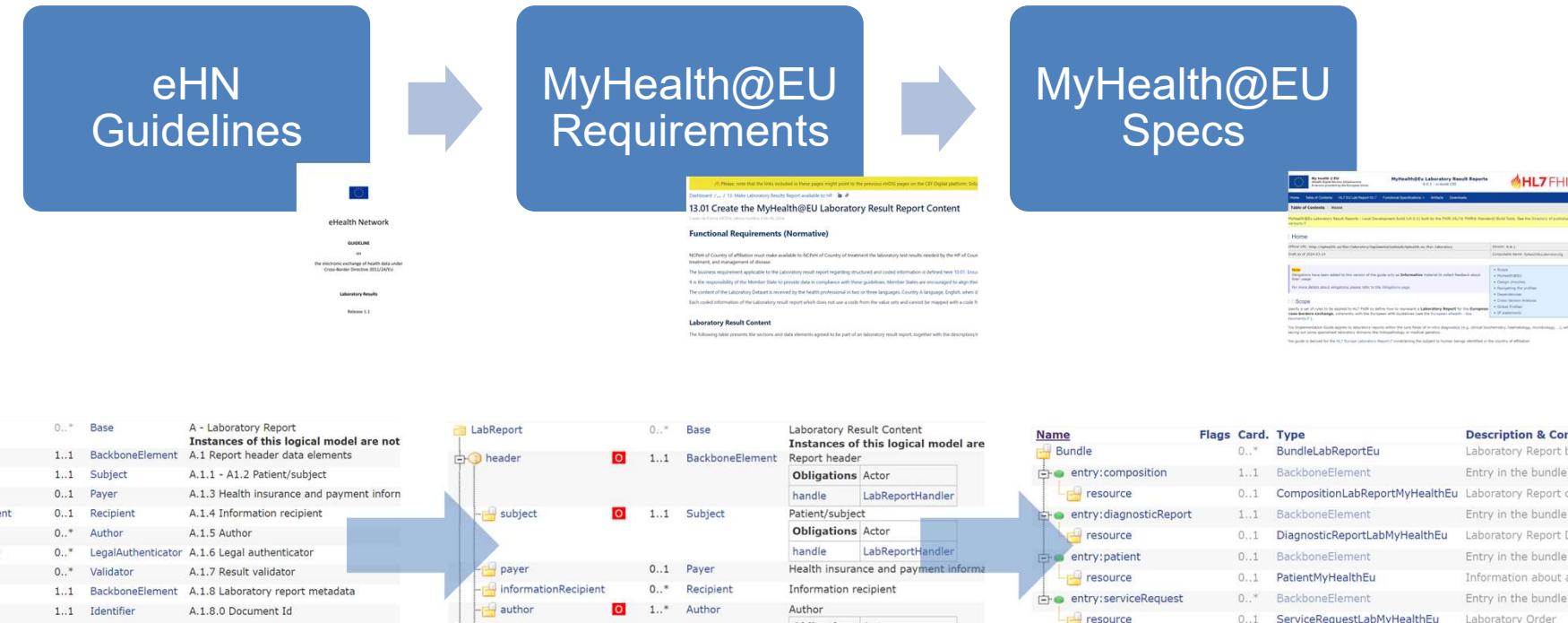
hl7.fhir.eu.laboratory#0.1.0

R4

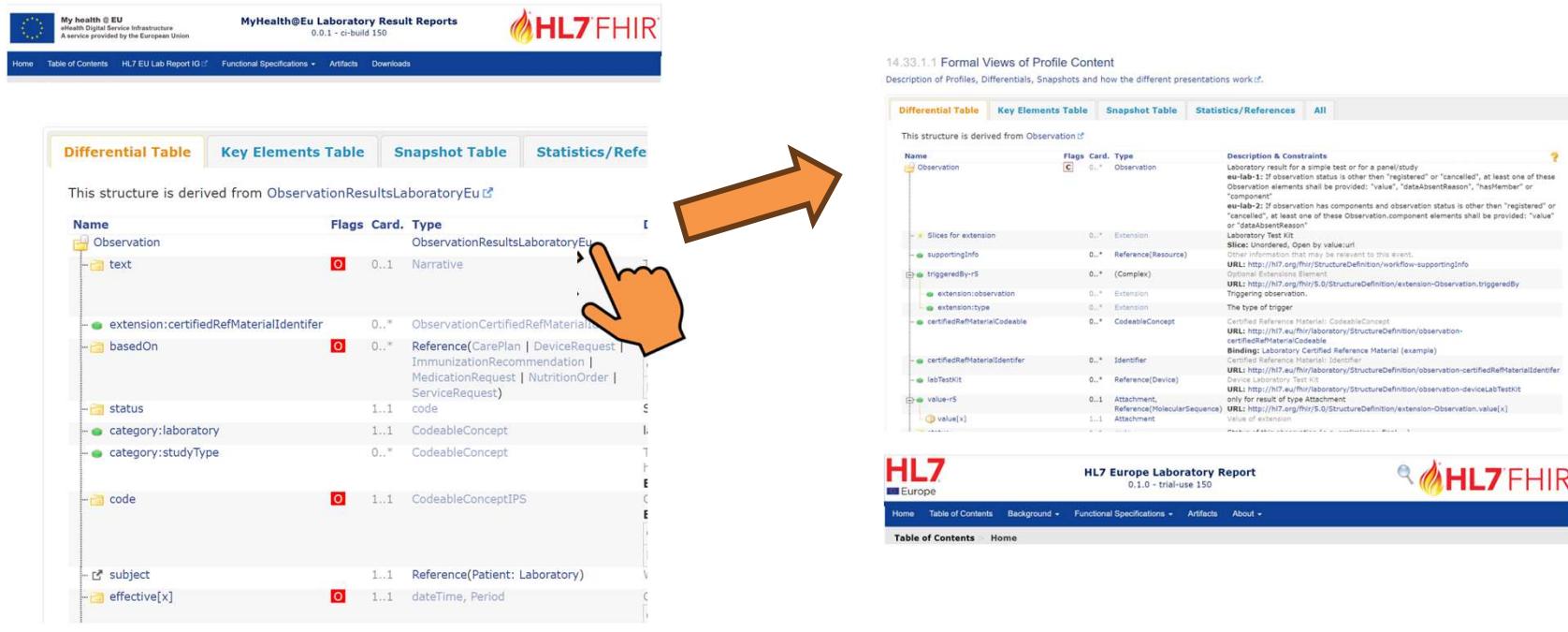
hl7.fhir.eu.extensions#0.1.0

R4

# The MyHealth@EU guide



# Easy to navigate “federated” guides



The screenshot displays two panels of the HL7 FHIR Laboratory Result Reports interface. The left panel is a 'Differential Table' showing the structure of the ObservationResultsLaboratoryEu profile. It lists various fields such as text, extension:certifiedRefMaterialIdentifier, basedOn, status, category:laboratory, category:studyType, code, subject, and effective[x]. The right panel shows a detailed view of the 'Observation' resource structure under the heading '14.33.1.1 Formal Views of Profile Content'. This view includes the 'Observation' resource itself and its extensions: supportingInfo, triggeredBy:\$s, extension:observation, extension:type, certifiedRefMaterial:codeable, certifiedRefMaterial:identifier, labTestKit, value:\$s, and value[x]. An orange arrow points from the left panel towards the right panel, indicating the interconnected nature of the profiles.

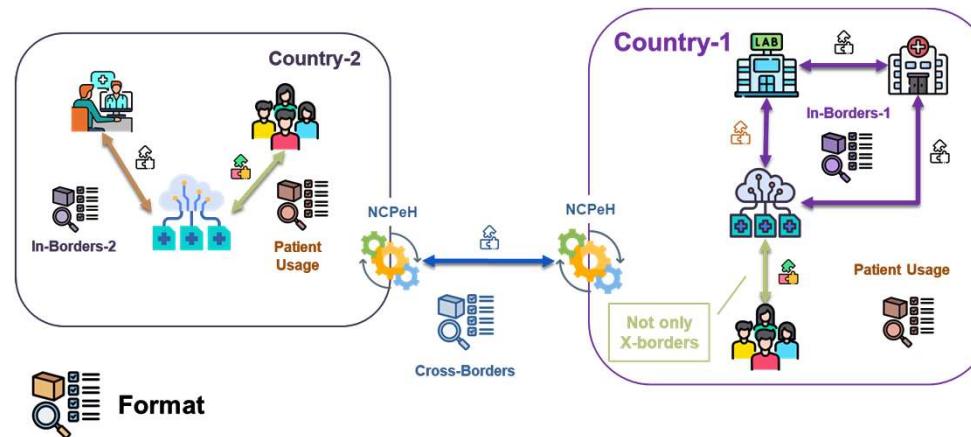


Laboratory Results

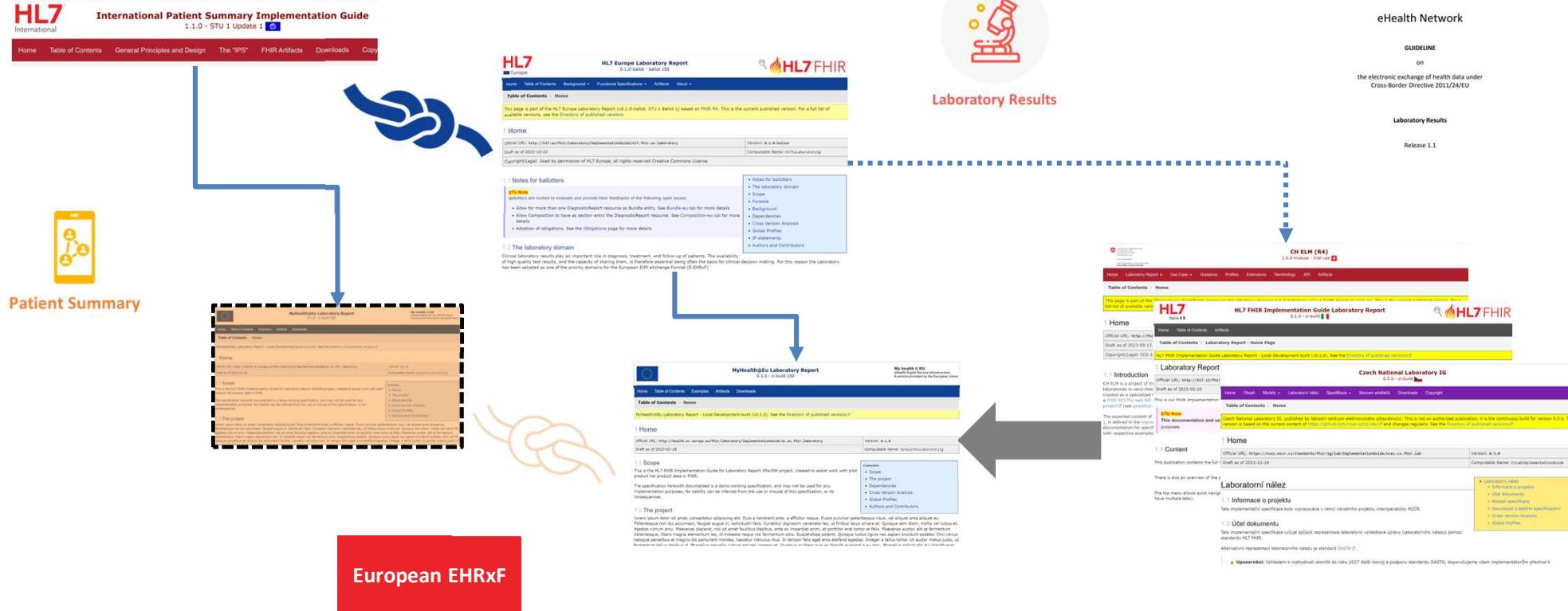
# A complex and multiform scenario



- Serving different needs for the same domain is a basic requirement... but this is not enough..
- .. data should be **reusable across domains**



# Enabled for reuse



# Enabled for reuse

European EHRxF



EHDS - Art 5 Priorities

HL7  
Europe

HL7 Europe Laboratory Report  
0.1.0-ballot - ballot 150

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

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)

HL7  
Europe

# Enabled for reuse



HL7 Europe Laboratory Report  
0.1.0-ballot - ballot 150

Home Table of Contents Background ▾ Functional Specifications ▾ Artifacts About ▾

## Laboratory Report

- Observation
  - Observation
  - Observation

## Observation



Laboratory Results

## Rad Report

Observation

Observation

## Patient Summary Result Section

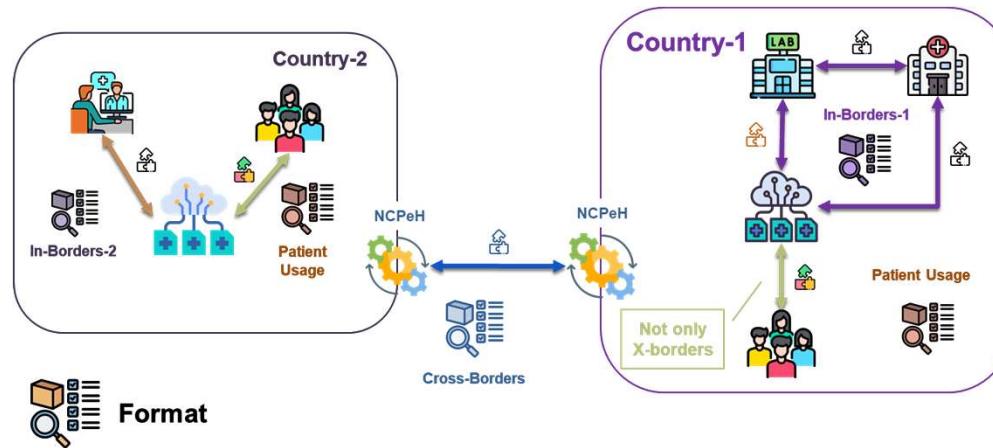
### Observation



Patient Summary

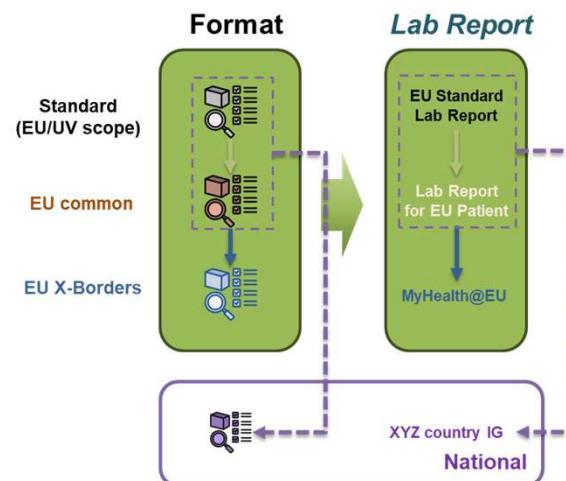
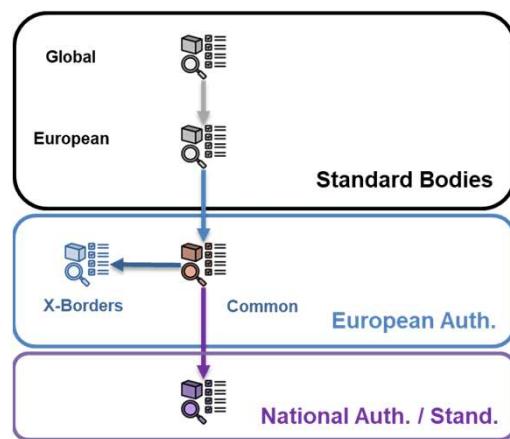
# Take-away messages

- There are **no one-fits-all solutions**
- Need of sharing common rules (i.e. standards), enabling data reuse across domains, and covering the national expectations.



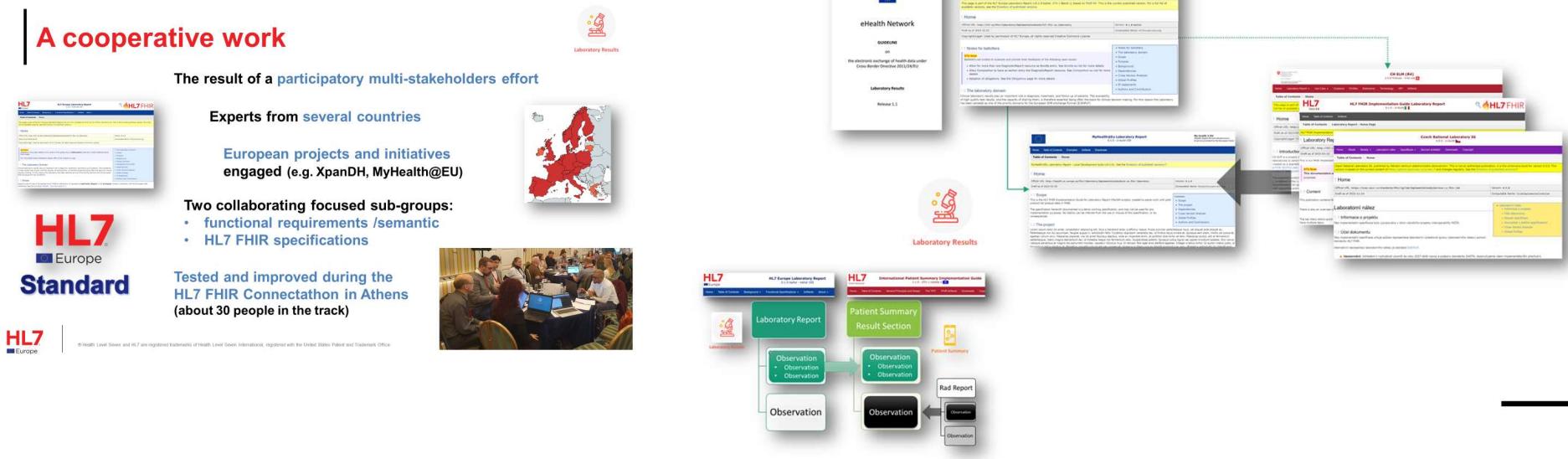
# Take-away messages

- The way to fulfill all these expectations is that of having a **system (i.e. a federation) of layered, coherent and possibly standard-based specifications enabling a progressive adoption of the format.**



# Take-away messages

- The Laboratory Report FHIR IG has been published
- This experience gives evidence of the added **value** and the **concreteness** of this approach !



# What's next

- Laboratory Report
  - Bi-weekly call working on “semantric” and functional requirements
  - Laboratory track @HL7 WGM Dallas (May)
  - Hands on session @IHE Plugathon Trieste (June)
- Medicinal Prescription and Dispense HL7 FHIR IG
  - Joint effort with IHE Pharmacy (part of the Gemini project)
  - Next meeting Thursday 18<sup>th</sup> 4 pm CEST

# Let's take a look !



**HL7**  
Europe

**HL7 Europe Laboratory Report**  
0.1.0 - trial-use 150

**HL7 FHIR**

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: STU 1) based on FHIR (HL7® FHIR® Standard) R4. This is the current published version. For a full list of available versions, see the [Directory of published versions](#)

## 1 Home

Official URL: <a href="http://hl7.eu/fhir/laboratory/ImplementationGuide/hl7.fhir.eu.laboratory">http://hl7.eu/fhir/laboratory/ImplementationGuide/hl7.fhir.eu.laboratory</a>	Version: 0.1.0
Active as of 2024-02-26	Computable Name: HL7EuLaboratoryIg

Copyright/Legal: Used by permission of HL7 Europe, all rights reserved Creative Commons License

**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

**1.1 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).

**1.2 Scope**  
Specify a set of rules to be applied to HL7 FHIR to define how to represent a **Laboratory Report** in the **European Context**, coherently with the European eHN Guidelines (see the European eHealth - Key documents [↗](#) ).

- The Laboratory Domain
- Scope
- Purpose
- Background
- Design choices
- Navigating the profiles
- Dependencies
- Cross Version Analysis
- Global Profiles
- IP statements
- Authors and Contributors



# Thank you !



® Health Level Seven and HL7 are registered trademarks of Health Level Seven International, registered with the United States Patent and Trademark Office.