

The HL7 Europe Laboratory Report FHIR IG

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Technical Lead HL7 Europe

fagforum, April 17th 2024





Who am I

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Co-facilitator of the HL7 EU Laboratory
Report FHIR IG

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eHMSEG STF Architecture WG chair

Board member, CDA MG co-chair, EAC
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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

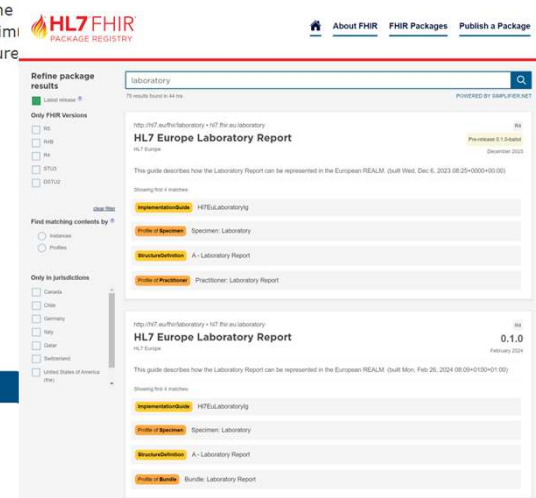
Publication (Version) History

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, immunology, 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
Current Versions				
2024-02-26	0.1.0	4.0.1	This is the Edition 1 STU 1 release	📄 📄 📄 📄 📄
(current)	(last commit)	n/a	undefined	📄 📄 📄 📄 📄
STU 1 Sequence				
2024-02-26	0.1.0	4.0.1	This is the Edition 1 STU 1 release <i>(Permanent Home)</i>	📄 📄 📄 📄 📄
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



European EHRxF



EHDS - Art 5 Priorities



What this is about ?



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

The screenshot shows the HL7 Europe Laboratory Report website. The header includes the HL7 Europe logo and the HL7 FHIR logo. The main content area features a 'Table of Contents' section with a 'Home' link. Below this, there is a 'Home' section with a table of metadata:

Official URL: http://hl7.eu/fhir/laboratory/ImplementationGuide/hl7.fhir.eu.laboratory	Version: 0.1.0
Active as of 2024-02-26	Computable Name: HL7EULaboratoryIq
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Below the table, there is an 'STU Note' section and a list of topics:

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

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

What this guide is about..



Laboratory Results

Laboratory Report

- No Pathology or Genetic Laboratory Report
- Complete reports with structured elements available for re-use

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

HL7 Europe HL7 Europe Laboratory Report v1.1.0-Balot - Series 135

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-Balot: STU 1 Balot 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/1aboratory/ImplementationGuide/137-fhir-eu-1aboratory> Version: v1.1.0-Balot 1
Draft as of 2023-10-22 Computable Name: HL7EU.Laboratory1g
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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 DRG exchange Format (E-DRG47)

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)



2022	2023	2024	2025
------	------	------	------

Laboratory results and reports





Laboratory Results

Proof of Concept

Implementation in MyHealth@EU (Wave 8)

April 2024

(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

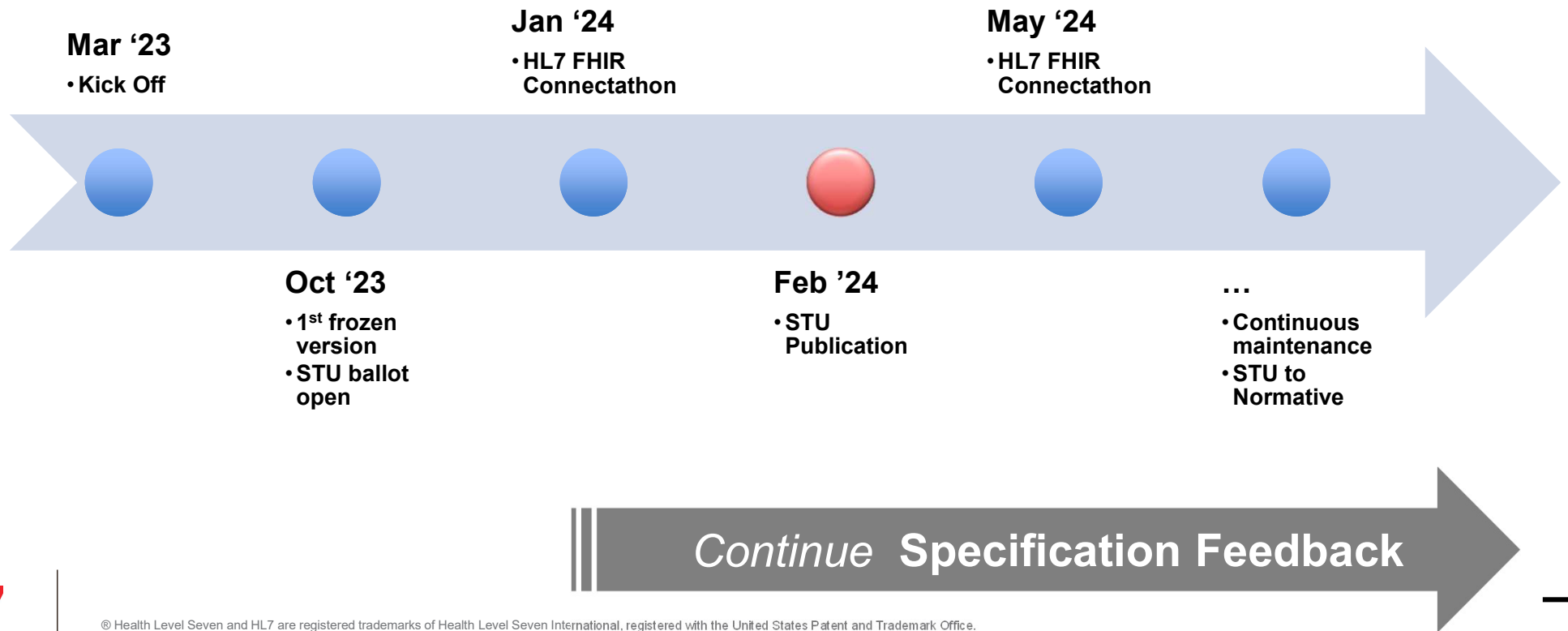
The HL7 EU Laboratory Report FHIR IG

March 2023



When .. the timeline

Balloting



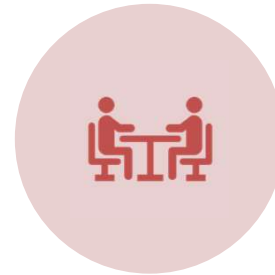
How to be engaged ...



**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/>

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

WHAT IS IN THE GUIDE...

What's in it...



HL7 FHIR
Logical
Models

eHN
Guidelines



HL7 Europe Laboratory Report
0.1.0 - trial-use 150

Home Table of Contents Background Functional Specifications Artifacts About

Table of Contents Home

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1 Home

Official URL: http://hl7.eu/fhir/1laboratory/ImplementationGuide/hl7.fhir.es.laboratory	Version: 0.1.0
Active as of: 2024-02-26	Computable Name: HL7Laboratory2g
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STU Note
Obligations have been added to this version of the guide only as **Informative** material to collect feedback about their usage.
For more details about obligations please refer to the Obligations page.

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-EHRx).

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 eHR Guidelines (see the European eHealth - Key documents(7)).

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

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
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

Element	Cardinality	Type	Description
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

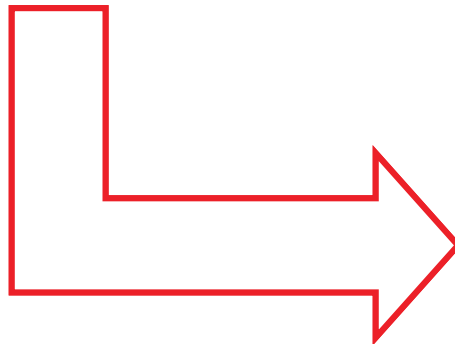
HL7 FHIR
Logical
Models



Models to
Profiles
Mapping



HL7 FHIR
Profiles



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..*

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



Name	Flags	Card.	Type	Description & Constraints
Patient			PatientUvIps	
identifier		0..*	Identifier	Patient identifiers
name	C	1..*	HumanNameEu	Name of a human - parts and usage eu-pat-1: Patient.name.given, Patient name, 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	

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

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



Release 1.1



Obligations

Obligations are informative in this version of the IG

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	D	0..*	Identifier	An identifier for this patient
name				Text representation of the full name
text	D	0..1	string	
family	D	0..1	string	Family name (often called 'Surname')

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

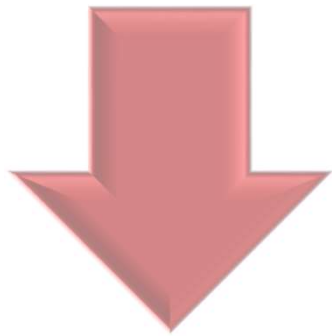
Still HL7 CDA and document exchange infrastructures in use

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

In R5 the DiagnosticReport refers the Composition



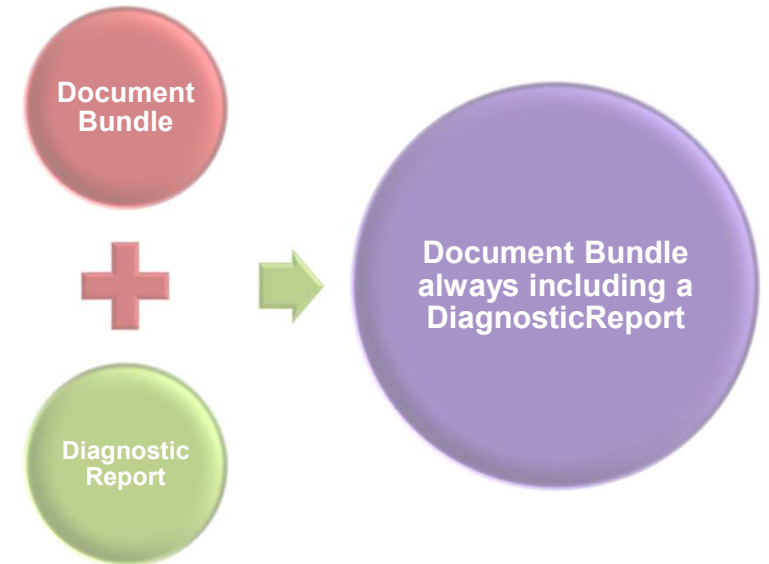
Balancing different (EU) requirements



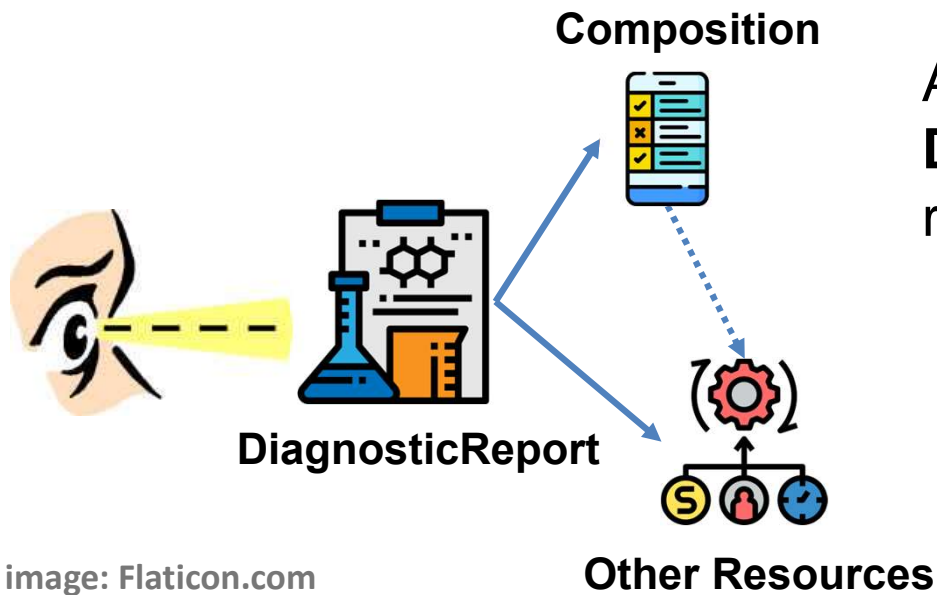
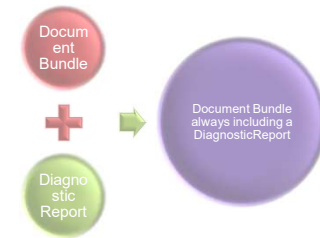
Legally signed documents
Often structured and including different kinds of test results
Still HL7 CDA and document exchange infrastructures in use



HL7 FHIR REST consumers expect to get Laboratory Reports by **searching per DiagnosticReport**
In R5 the DiagnosticReport refers the Composition



The Laboratory Report

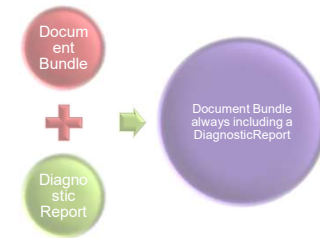


A Lab report is always **represented by a DiagnosticReport**. This resource always refers a Composition

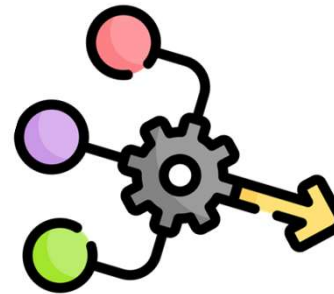
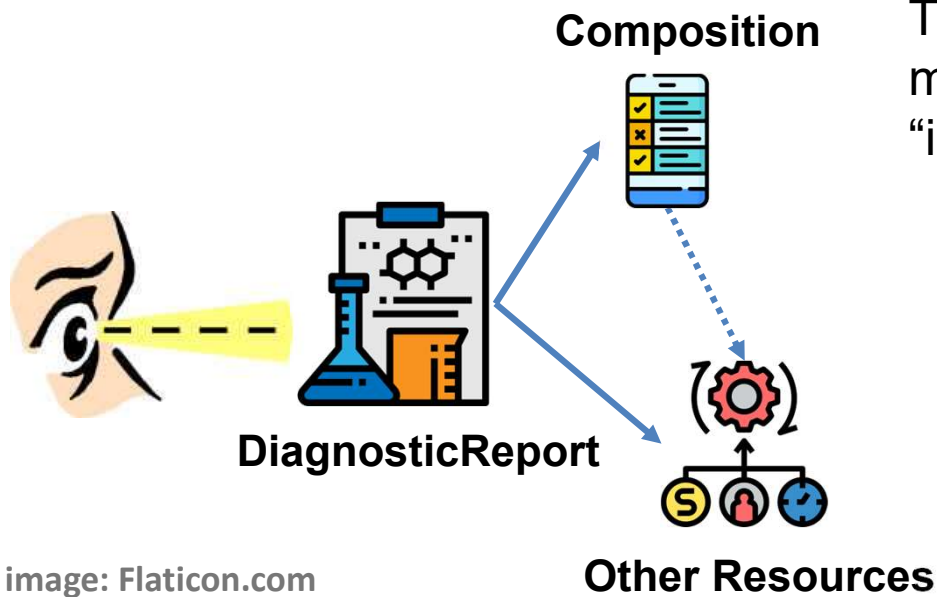
The **Composition defines** the report **structure** (it might be just a single section) and it acts as an “index” for all the used resources

REST Perspective

The Laboratory Report



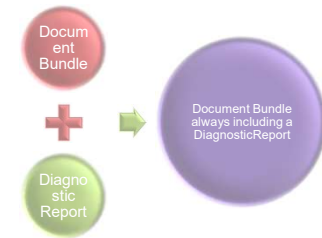
The **Composition** defines the report **structure** (it might be just a single section) and it acts as an “index” for all the used resources



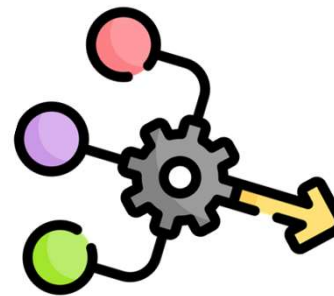
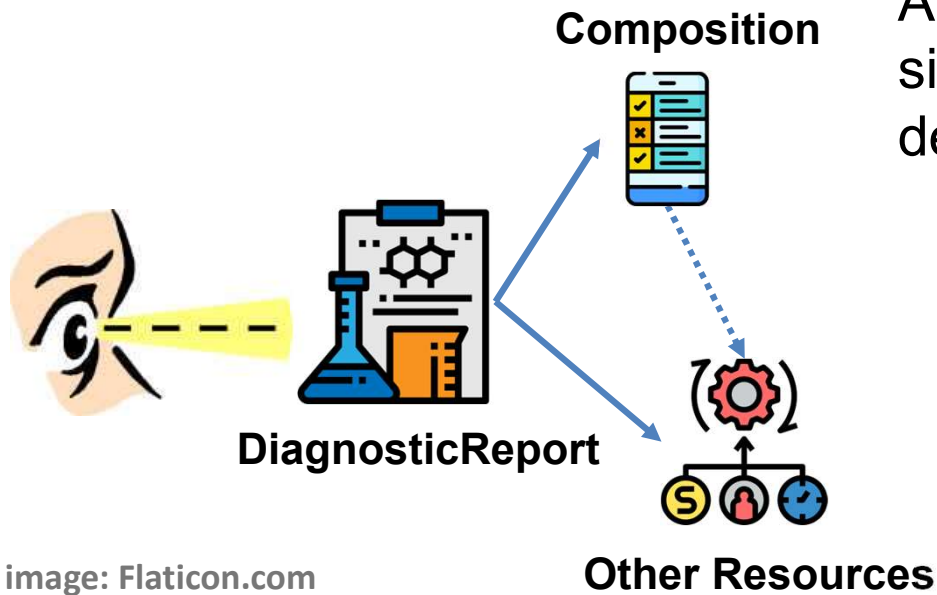
It is the mean for assembling the report as a document (**document Bundle**)

REST Perspective

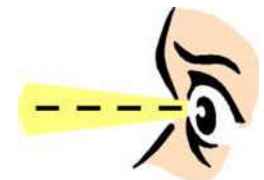
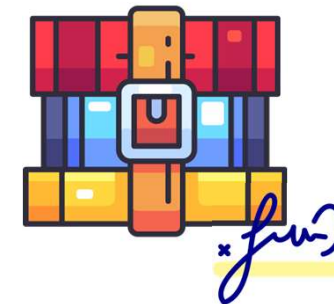
The Laboratory Report



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



Bundle
[type = document]



REST Perspective

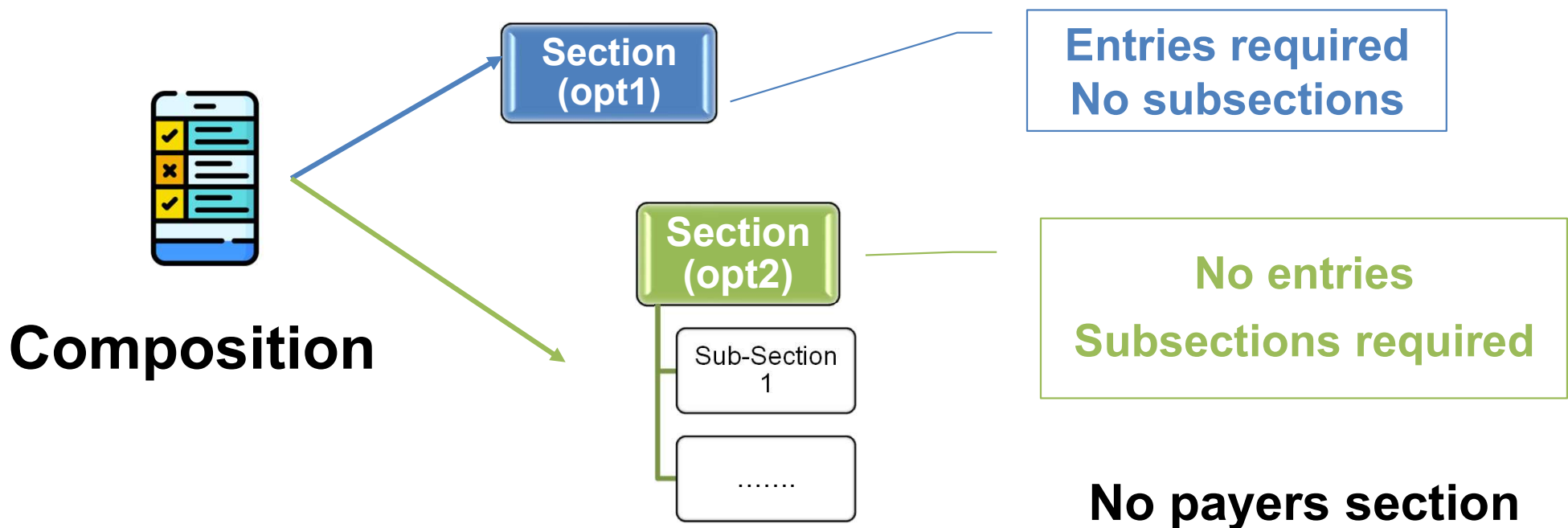
Document Perspective

The Laboratory Report



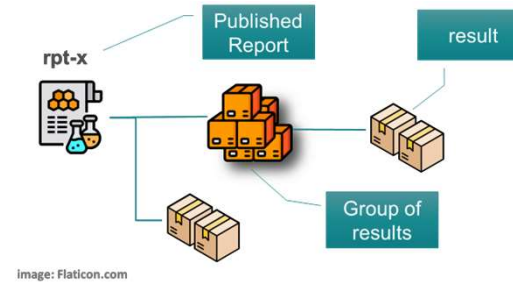
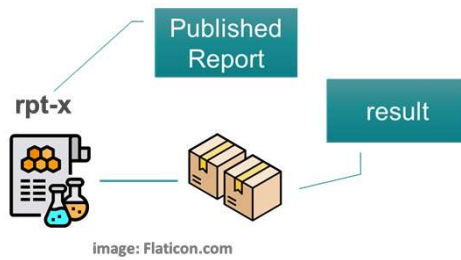
Document Bundle

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



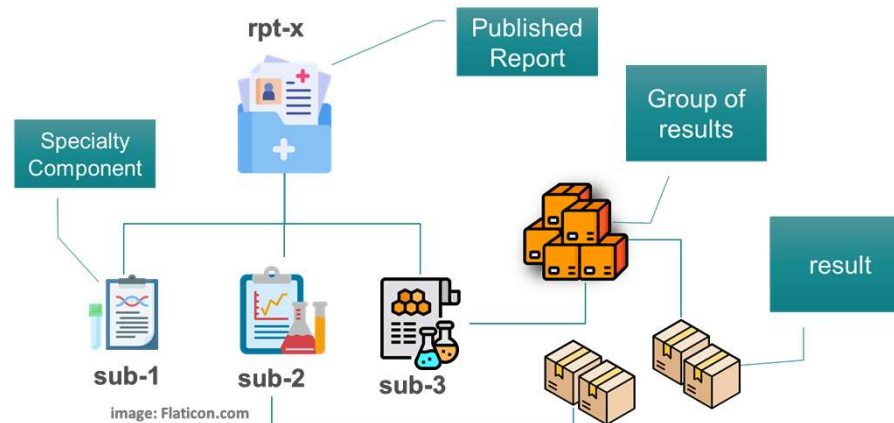
A single solution for different structural choices

Very simple report
(e.g. single panel)

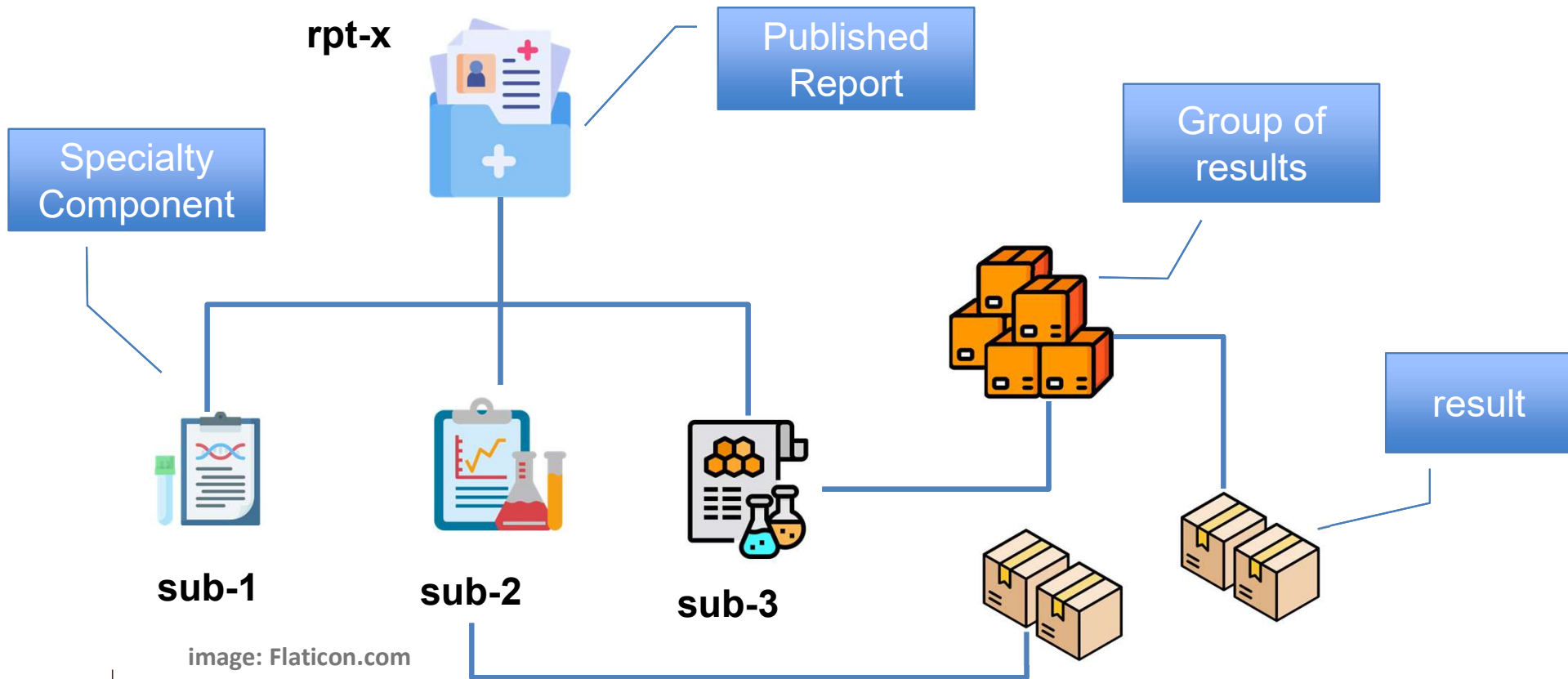


Single-specialty
report

Multi-specialty
report



Multi-specialty report



Multi-specialty report

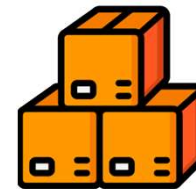


**DiagnosticReport (→
Composition), recorded
into a Document
Bundle**



Composition.section

(Set of) Composition.section



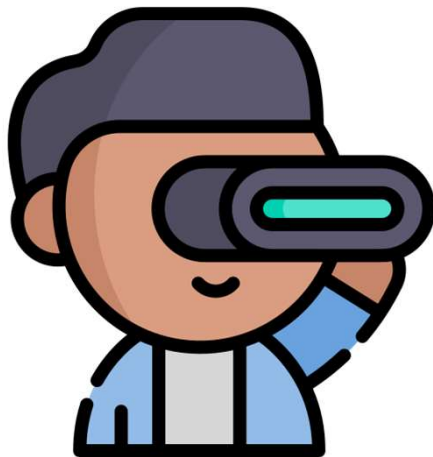
Observation(→ Observation)

Composition.section



Observation

..before taking a look....



The screenshot shows the homepage of the HL7 Europe Laboratory Report. The header includes the HL7 Europe logo, the title "HL7 Europe Laboratory Report 0.1.0 - trial-use 150", and the HL7 FHIR logo. A navigation menu contains links for Home, Table of Contents, Background, Functional Specifications, Artifacts, and About. Below the menu, a yellow banner states: "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".

The main content area is titled "1 Home" and contains a table with the following information:

Official URL: http://hl7.eu/fhir/Laboratory/ImplementationGuide/h17.fhir.eu.laboratory	Version: 0.1.0
Active as of 2024-02-26	Computable Name: H17EuLaboratoryIg
Copyright/Legal: Used by permission of HL7 Europe, all rights reserved Creative Commons License	

Below the table, there is an "STU Note" section with a yellow background, stating: "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".

On the right side, there is a blue sidebar with a list of navigation links:

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

The main content area continues with sections "1.1 The Laboratory Domain" and "1.2 Scope".

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 guide in one slide



- **The Lab FHRI 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

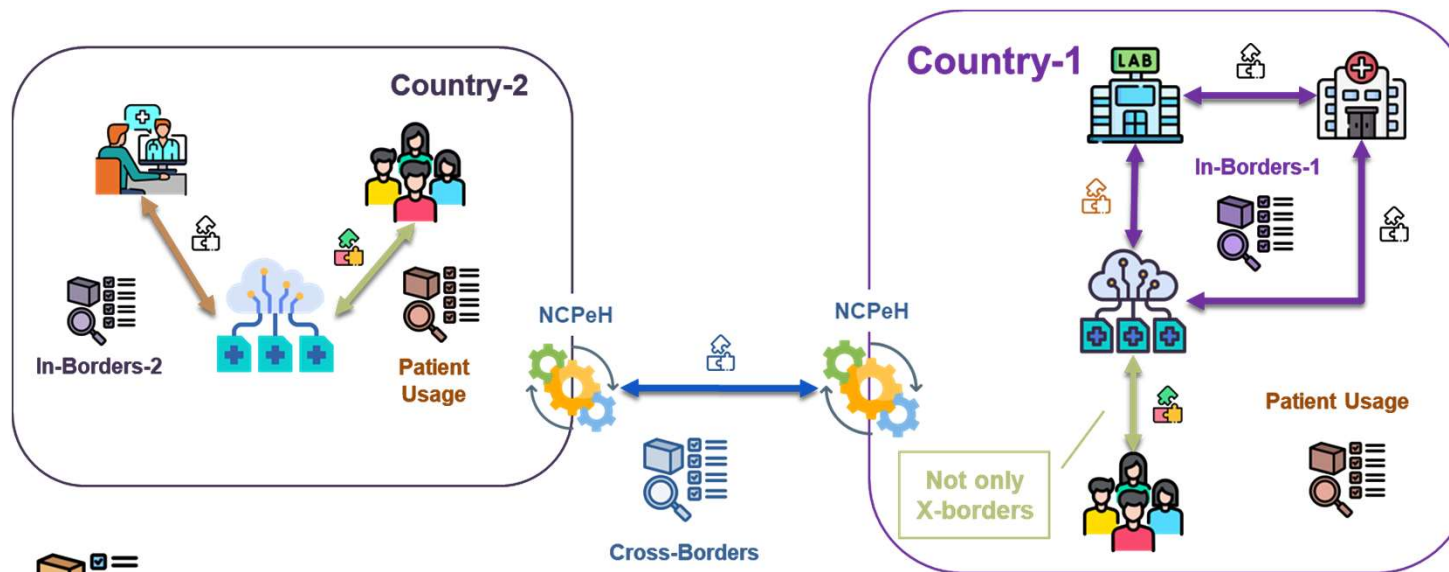
A baseline for any Laboratory Report (HL7 FHIR) specifications

THE JOURNEY TOWARDS THE EHDS

A complex and multiform scenario



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

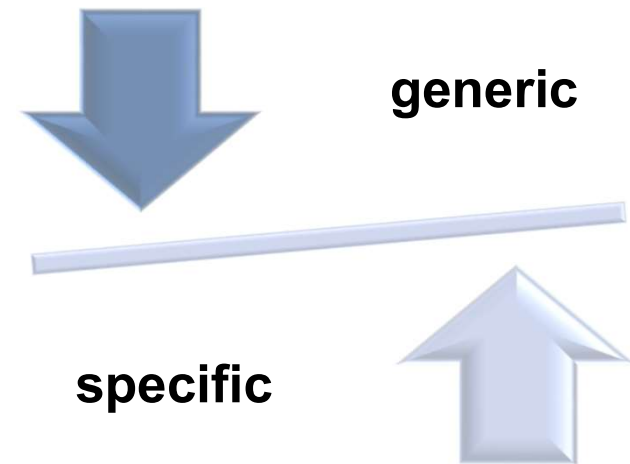
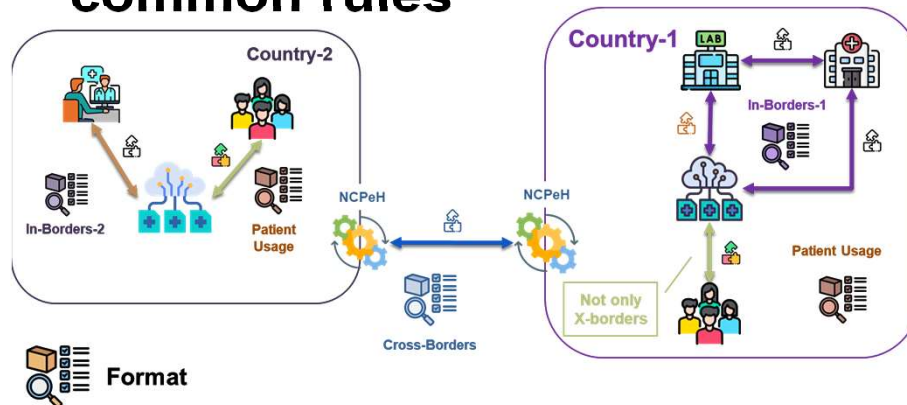


A complex and multiform scenario

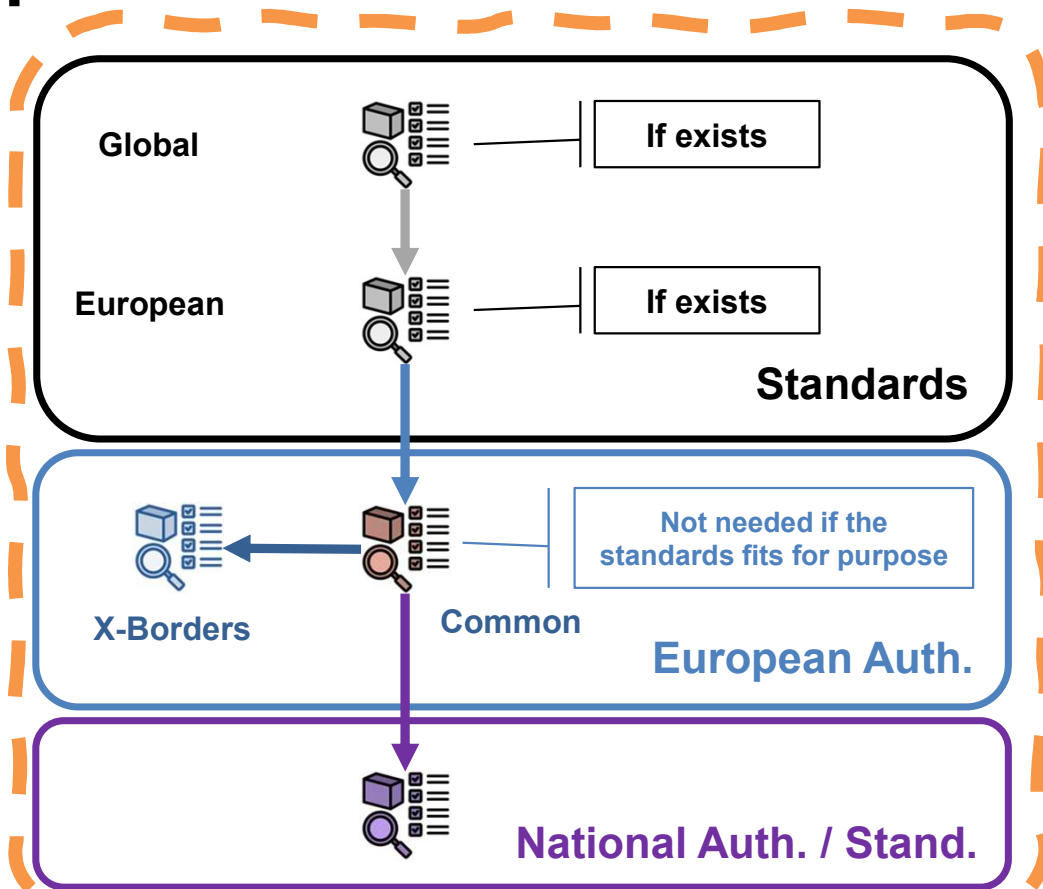


- Needs and expectations are different and there is not a **one-fits-all solution...** but.. no European interoperability without:

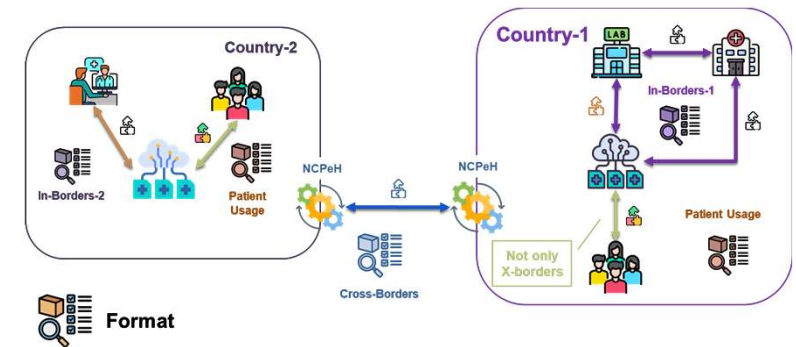
- serving and being useful in all these situations
- common rules



The vision



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



The vision



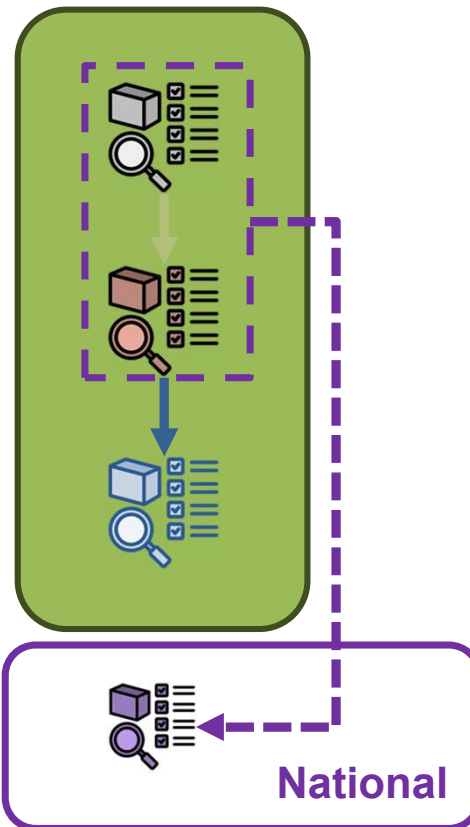
Additional common rules for the EEHRxF

Additional rules for X-border

Standard
(EU/UV scope)

EU common

EU X-Borders
(MyHealth@EU)



It doesn't mean to multiply the specifications, but enabling a progressive adoption of the format.

image: Flaticon.com

Instantiating the vision

Additional common rules for the EEHRxF

Additional rules for X-border

Standard
(EU/UV scope)

EU common

EU X-Borders

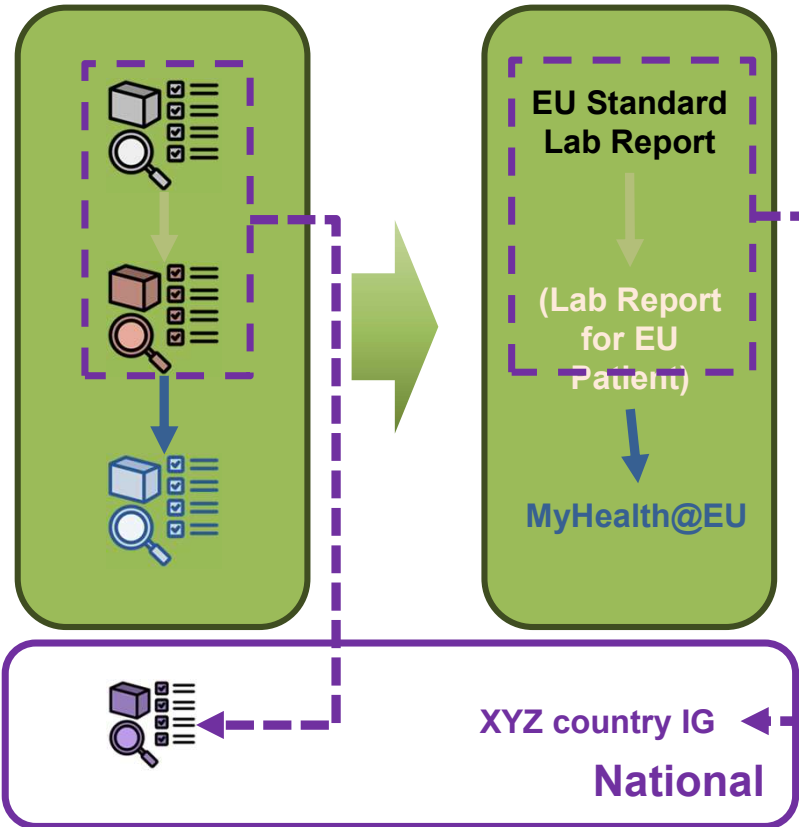


image: Flaticon.com

The vision made real..



Laboratory Results

HL7 Europe Laboratory Report
0.1.0 - build 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/0.1.0-01-build150> Version: #1.0

Active as of 2024-02-26 Computable Name: HL7EULaboratoryIg

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STU Note

Obligations have been added to this version of the guide only as **Informative** material to collect feedback about their usage.

For more detailed obligations please refer to the Obligations page

Domain

High quality laboratory data play an important role in diagnosis, treatment, and follow-up of patients. The availability of high quality laboratory data, 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 eHealth Network.

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

Standard (EU/UV scope)

MyHealth@Eu Laboratory Report
0.1.0 - ci-build 150

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MyHealth@Eu Laboratory Report - Local Development build (v0.1.0). See the Directory of published versions.

1 Home

Official URL: <http://health.ec.europa.eu/fhir/Laboratory/ImplementationGuide/0.1.0-01-build150> Version: #1.0

Draft as of 2023-02-28 Computable Name: HL7MHEULaboratoryIg

1.1 Scope

This is the HL7 FHIR Implementation Guide for Laboratory Report X9aDm project, created to assist work with pilot product test 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

This project is a part of the HL7 FHIR Implementation Guide for Laboratory Report X9aDm project, created to assist work with pilot product test 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.

EU X-Borders

CH ELM (R4)
1.0.0-01-build 150

Home Laboratory Report Use Case Guidance Profiles Extensions Terminology API Artifacts

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HL7 FHIR Implementation Guide Laboratory Report
0.1.0 - ci-build 150

1 Home

Official URL: <http://hl7.ch/fhir/ImplementationGuide/0.1.0-01-build150> Version: #1.0

Draft as of 2023-02-28 Computable Name: HL7CHELMLaboratoryIg

1.1 Introduction

This HL7 FHIR Implementation Guide for Laboratory Report X9aDm project, created to assist work with pilot product test 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 Content

This publication contains the following information:

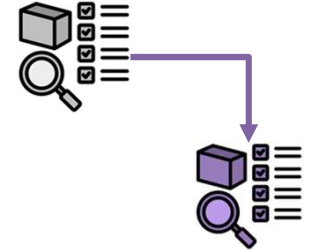
- Information about the project
- User documents
- R4a01 specifications
- Scenarios and use cases
- Cross Version Analysis
- Global Profiles

National Guides

eHealth Network
GUIDELINE
on
the electronic exchange of health data under
Cross-Border Directive 2011/24/EU
Laboratory Results
Release 1.1



A vision made real..



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

IG Home | Sommario | Specifiche | Indice Artefatti | Support

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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: <http://hl7.it/fhir/lab-report/ImplementationGuide/hl7.fhir.it.lab-report> | 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).

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

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 laboratorio, al paziente o ad altra figura professionale, in modo chiaro e corretto. Questa guida implementativa è stata creata per descrivere in modo elementi standard necessari per supportare lo scambio sia semantico che sintattico di informazioni inerenti al referto di laboratorio e viene sviluppata con la risorsa Patient.

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

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 medici

The following versions have been published:

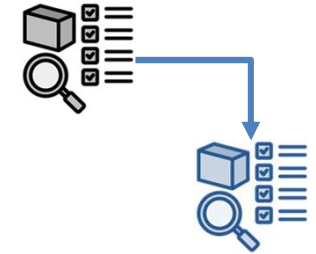
Date	IG Version	FHIR Version	Description	Links
Current Versions				
2024-03-08	0.2.0	4.0.1	This is the Edition 1 STU 1 release	📄 📄 📄 📄
(current)	(last commit)	n/a	undefined	📄 📄 📄 📄
Release 1 Sequence				
2024-03-08	0.2.0	4.0.1	This is the Edition 1 STU 1 release (Permanent Home)	📄 📄 📄 📄
2023-07-11	0.1.0	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.r4#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
🔥 FHIR Implementation Guide for Diagnostic Reports	hl7.fhir.uv.implementationguideforreports#2023.1.20231006	R4
🔥 HL7 Europe Extensions	hl7.fhir.eu.extensions#0.1.0	R4

Officially Published

A vision made real..



EU X-Borders

eHealth Network

 on

 the electronic exchange of health data under

 Cross-Border Directive 2011/24/EU

 Laboratory Results

 Release 1.1

MyHealth@EU Laboratory Result Reports

 0.0.1 - ci-build 150

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

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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

- Scope
- My
- De
- Na
- De
- Crc
- Gic
- IP

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

1.5 Dependencies

IG	Package	FHIR
MyHealth@Eu Laboratory Result Reports	myhealth.eu.fhir.laboratory#0.0.1	R4
HL7 Terminology (THO)	hl7.terminology.r4#5.3.0	R4
FHIR Extensions Pack	hl7.fhir.uv.extensions.r4#1.0.0	R4
International Patient Summary Implementation Guide	hl7.fhir.uv.ips#1.1.0	R4
	fhir.dicom#2022.4.20221006	R4
HL7 Europe Laboratory Report	hl7.fhir.eu.laboratory#0.1.0	R4
HL7 Europe Extensions	hl7.fhir.eu.extensions#0.1.0	R4

Laboratory Results

On-development FHIR IG

The MyHealth@EU guide



eHN Guidelines

MyHealth@EU Requirements

MyHealth@EU Specs



Name	Card.	Type	Code	Description
LabReport	0..*	Base	A - Laboratory Report	
header	1..1	BackboneElement	A.1 Report header data elements	Instances of this logical model are not
subject	1..1	Subject	A.1.1 - A1.2 Patient/subject	
payer	0..1	Payer	A.1.3 Health insurance and payment inform	
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	
documentId	1..1	Identifier	A.1.8.0 Document Id	
type	1..1	CodeableConcept	A.1.8.1 Document type	

Name	Card.	Type	Code	Description
LabReport	0..*	Base	A - Laboratory Report	
header	1..1	BackboneElement	A.1 Report header data elements	Instances of this logical model are
subject	1..1	Subject	A.1.1 - A1.2 Patient/subject	
payer	0..1	Payer	A.1.3 Health insurance and payment informa	
informationRecipient	0..*	Recipient	A.1.4 Information recipient	
author	1..*	Author	A.1.5 Author	

Name	Flags	Card.	Type	Description & Con
Bundle		0..*	BundleLabReportEu	Laboratory Report b
entry:composition		1..1	BackboneElement	Entry in the bundle
resource		0..1	CompositionLabReportMyHealthEu	Laboratory Report c
entry:diagnosticReport		1..1	BackboneElement	Entry in the bundle
resource		0..1	DiagnosticReportLabMyHealthEu	Laboratory Report d
entry:patient		0..1	BackboneElement	Entry in the bundle
resource		0..1	PatientMyHealthEu	Information about a
entry:serviceRequest		0..*	BackboneElement	Entry in the bundle
resource		0..1	ServiceRequestLabMyHealthEu	Laboratory Order



HL7 Europe Laboratory Report
0.2.0-ci - ci-build 150

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



Easy to navigate “federated” guides

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

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

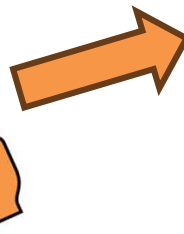
HL7 FHIR

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Differential Table Key Elements Table Snapshot Table Statistics/Refs

This structure is derived from ObservationResultsLaboratoryEu

Name	Flags	Card.	Type
Observation		0..1	ObservationResultsLaboratoryEu
text		0..1	Narrative
extension:certifiedRefMaterialIdentifier		0..*	ObservationCertifiedRefMaterialIdentifier
basedOn		0..*	Reference(CarePlan DeviceRequest ImmunizationRecommendation MedicationRequest NutritionOrder ServiceRequest)
status		1..1	code
category:laboratory		1..1	CodeableConcept
category:studyType		0..*	CodeableConcept
code		1..1	CodeableConceptIPS
subject		1..1	Reference(Patient: Laboratory)
effective[x]		1..1	dateTime, Period



14.33.1.1 Formal Views of Profile Content

Description of Profiles, Differentials, Snapshots and how the different presentations work.

Differential Table Key Elements Table Snapshot Table Statistics/References All

This structure is derived from Observation

Name	Flags	Card.	Type	Description & Constraints
Observation		0..*	Observation	Laboratory result for a simple test or for a panel/study eu-lab-1: If observation status is other than "registered" or "cancelled", at least one of these Observation elements shall be provided: "value", "dataAbsentReason", "hasMember" or "component" eu-lab-2: If observation has components and observation status is other than "registered" or "cancelled", at least one of these Observation.component elements shall be provided: "value" or "dataAbsentReason"
Slices for extension		0..*	Extension	Laboratory Test Kit
supportingInfo		0..*	Reference(Resource)	Slice: Unordered, Open by value:url Other information that may be relevant to this event.
triggeredBy-rS		0..*	(Complex)	URL: http://hl7.org/fhir/StructureDefinition/workflow-supportingInfo
extension:observation		0..*	Extension	URL: http://hl7.org/fhir/5.0/StructureDefinition/extension-Observation.triggeredBy
extension:type		0..*	Extension	Triggering observation.
certifiedRefMaterialCodeable		0..*	CodeableConcept	The type of trigger
certifiedRefMaterialIdentifier		0..*	Identifier	Certified Reference Material: CodeableConcept URL: http://hl7.org/fhir/laboratory/StructureDefinition/observation-certifiedRefMaterialCodeable
labTestkit		0..*	Reference(Device)	Binding: Laboratory Certified Reference Material (example) Certified Reference Material: Identifier URL: http://hl7.org/fhir/laboratory/StructureDefinition/observation-certifiedRefMaterialIdentifier
value-rS		0..1	Attachment, Reference(MolecularSequence)	Device Laboratory Test Kit URL: http://hl7.org/fhir/laboratory/StructureDefinition/observation-deviceLabTestkit
value[x]		1..1	Attachment	only for result of type Attachment URL: http://hl7.org/fhir/5.0/StructureDefinition/extension-Observation.value[x]

HL7 Europe Laboratory Report
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HL7 FHIR

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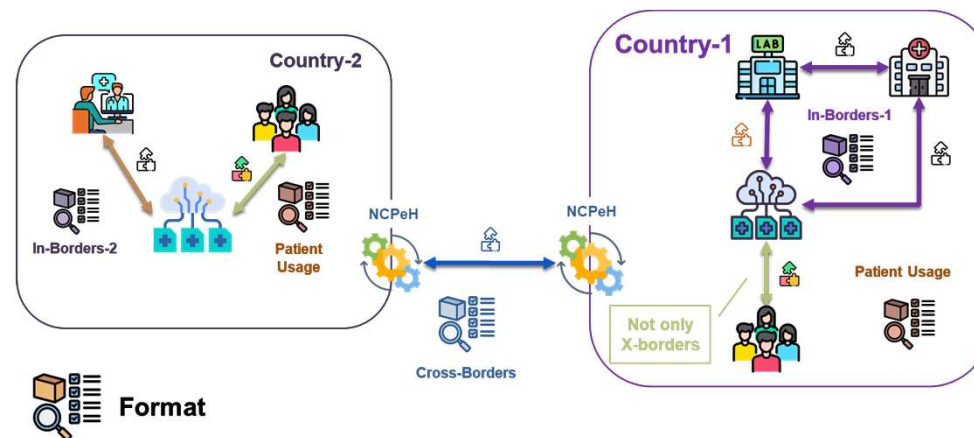


Laboratory Results

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

European EHRxF



EHDS - Art 5 Priorities

HL7
Europe

HL7 Europe Laboratory Report
0.1.0-ballot - ballot 150

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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

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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)

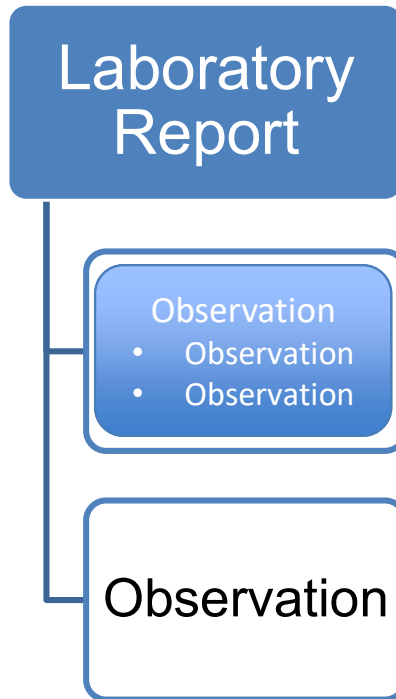
HL7
Europe

Enabled for reuse

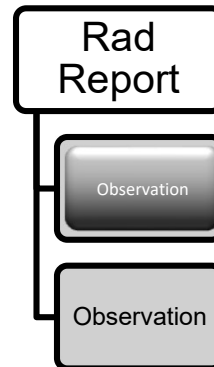


HL7 Europe Laboratory Report
0.1.0-ballot - ballot 150

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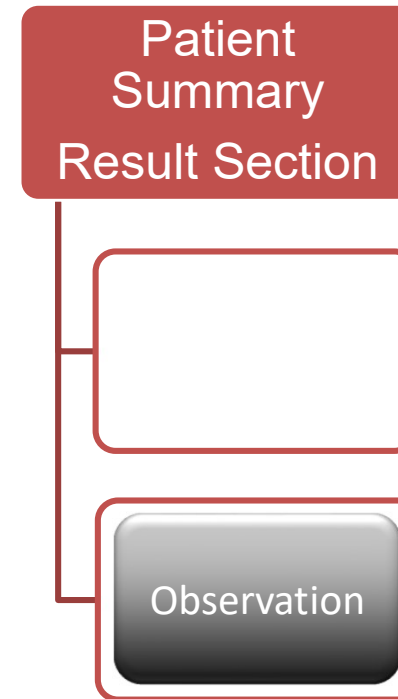


Laboratory Results



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

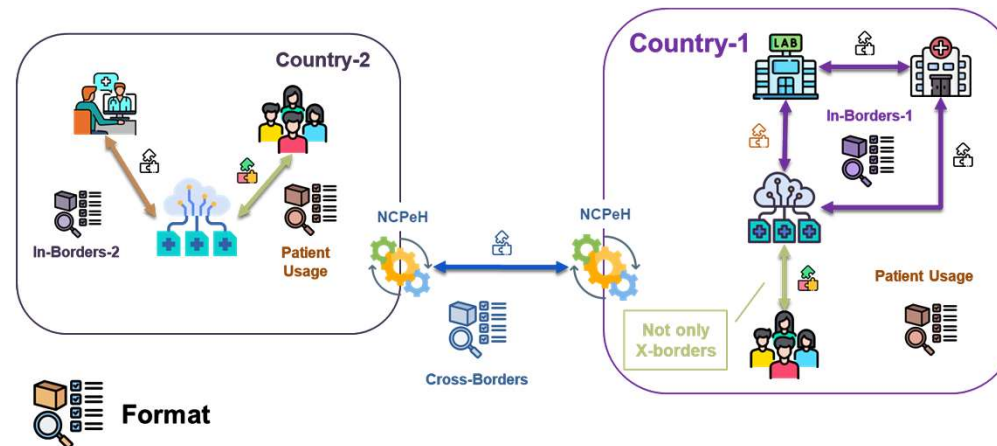


Patient Summary



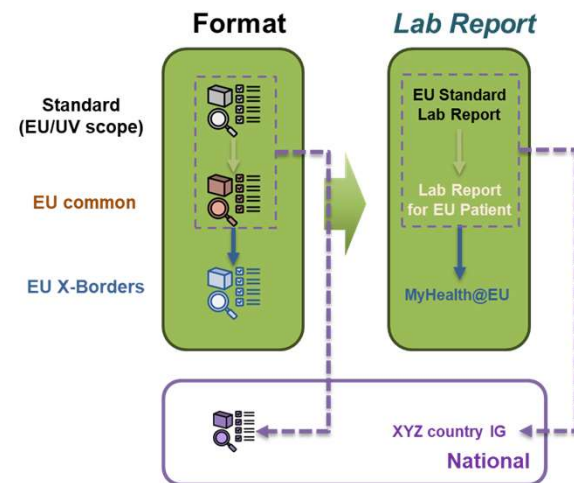
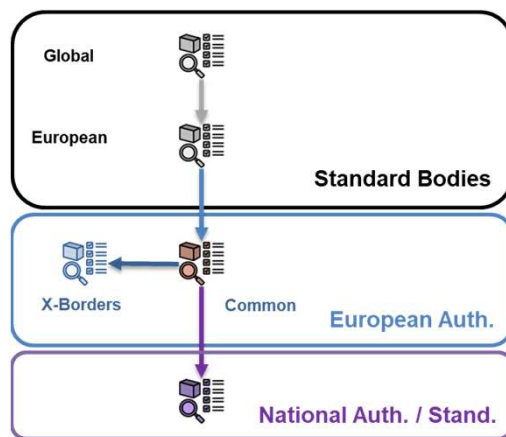
Take-away messages

- 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 !

A cooperative work

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

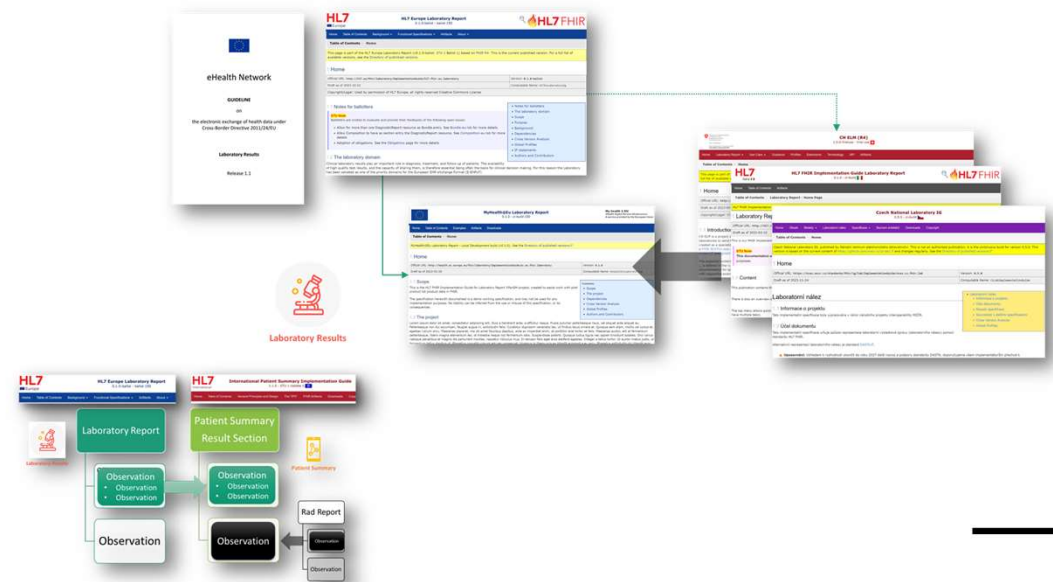
Tested and improved during the **HL7 FHIR Connectathon in Athens** (about 30 people in the track)



HL7
Europe
Standard

HL7
Europe

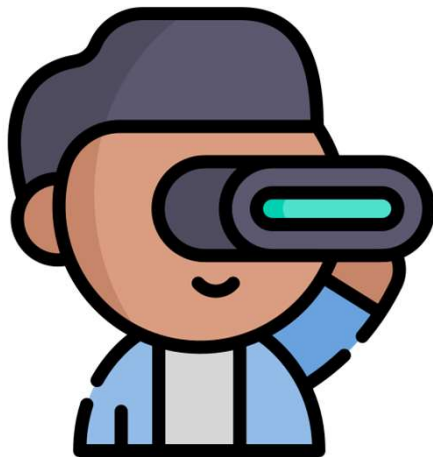
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What's next

- Laboratory Report
 - Bi-weekly call working on “semantic” 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 18th 4 pm CEST

Let's take a look !



The screenshot shows the homepage of the HL7 Europe Laboratory Report. At the top, there is a navigation bar with the HL7 Europe logo on the left, the title "HL7 Europe Laboratory Report 0.1.0 - trial-use 150" in the center, and the HL7 FHIR logo on the right. Below the navigation bar is a "Table of Contents" section with a link to "Home". A yellow banner below the navigation bar states: "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".

The main content area is titled "1 Home" and contains a table with the following information:

Official URL: http://hl7.eu/fhir/Laboratory/ImplementationGuide/h17.fhir.eu.laboratory	Version: 0.1.0
Active as of 2024-02-26	Computable Name: H17EuLaboratoryIg
Copyright/Legal: Used by permission of HL7 Europe, all rights reserved Creative Commons License	

Below the table is a "STU Note" section with a yellow header. The text reads: "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".

On the right side of the page, there is a blue sidebar with a list of navigation links:

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

The main content area continues with two sections:

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 [↗](#)).

Thank you!

