



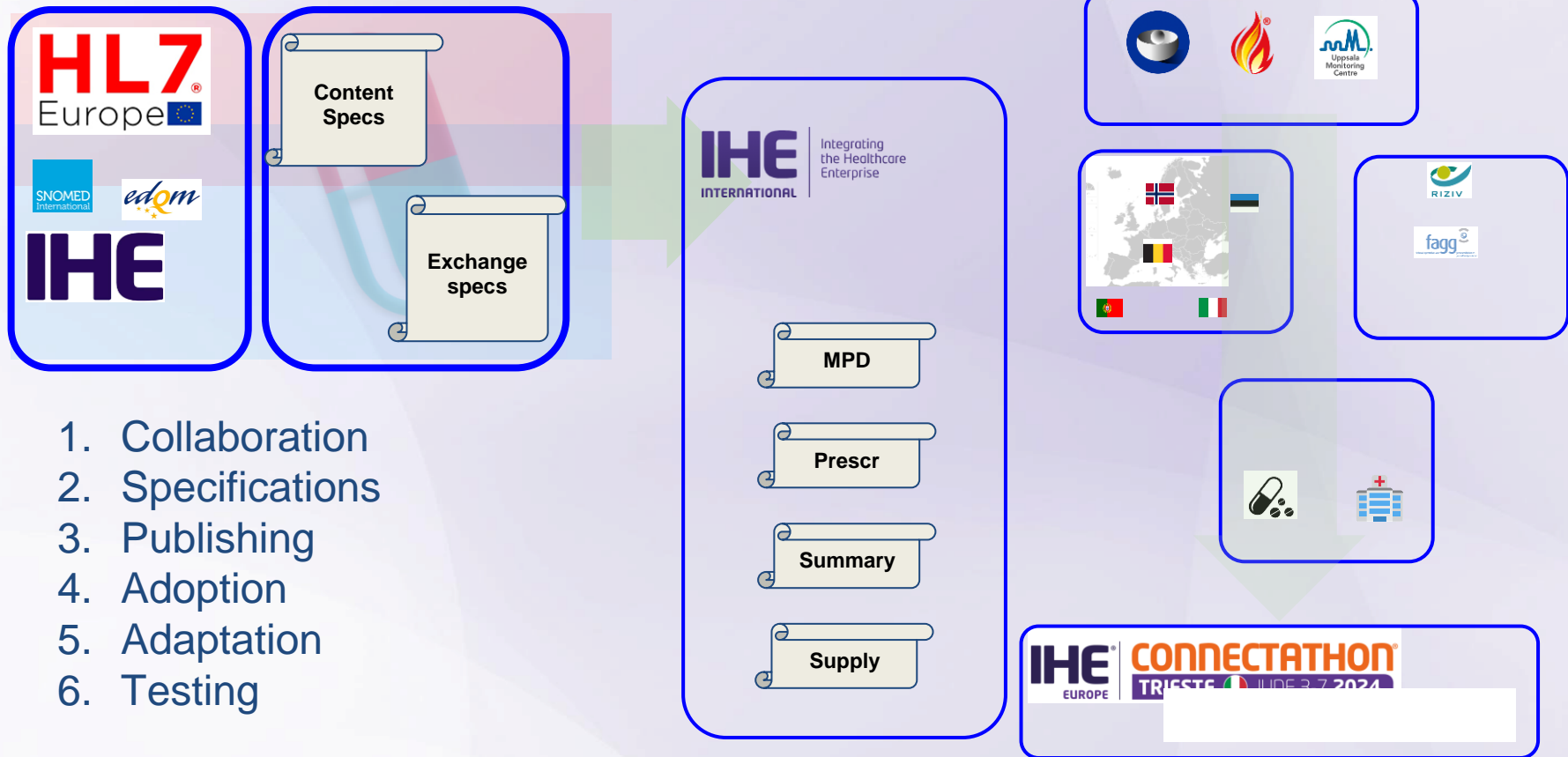
# UN COM

**IHE** | Integrating  
the Healthcare  
Enterprise

Handover to industry

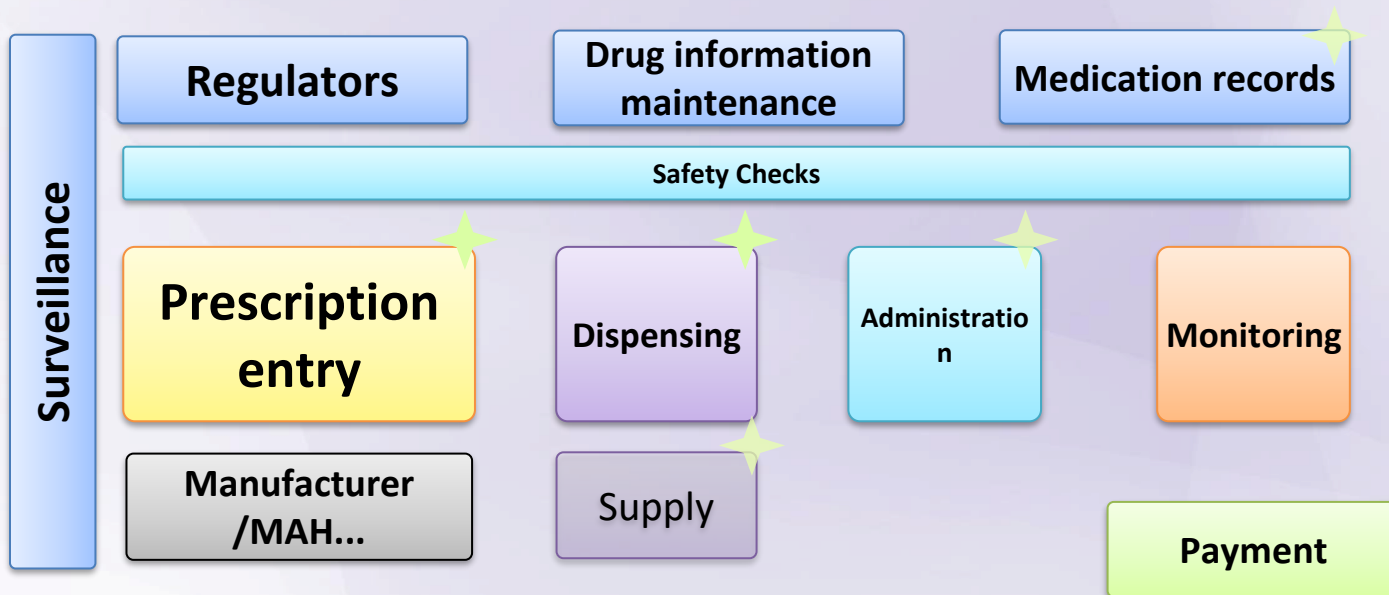
*José Costa Teixeira, IHE Pharmacy co-chair, UNICOM contributor*

## Agenda: From UNICOM to standardised data exchange



1. Collaboration
2. Specifications
3. Publishing
4. Adoption
5. Adaptation
6. Testing

# Interoperability



(adapted from ISO WG6 internal documentation)

## UNICOM and product identification

Not just a cross-border need

- Equivalents for dispensing
- Creating and reconciling medication lists
- Pharmacovigilance

**75 avoidable hospital admissions per day  
due to medication errors !!!**

**MPID**

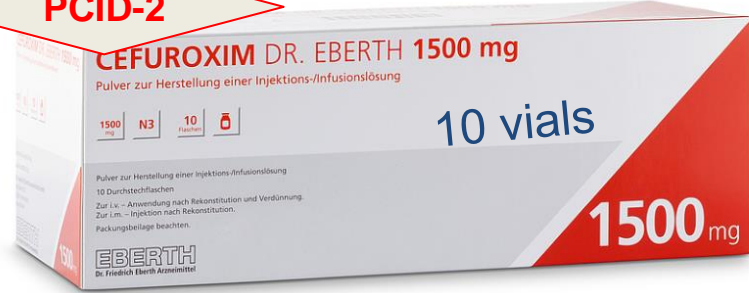
**Medicinal product**

**PCID-1**



**Packaged product 1**

**PCID-2**



**Packaged product 2**

x1

x10

**Manufactured item**

Powder for  
solution in vial

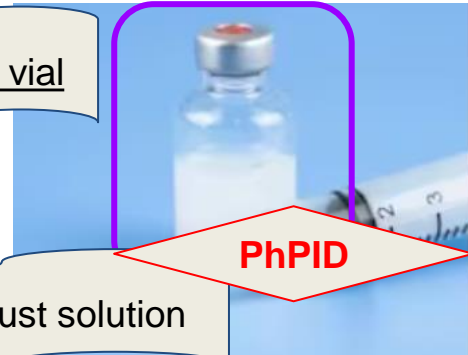


**Pharmaceutical product**

Solution in vial

**PhPID**

PhPID for just solution

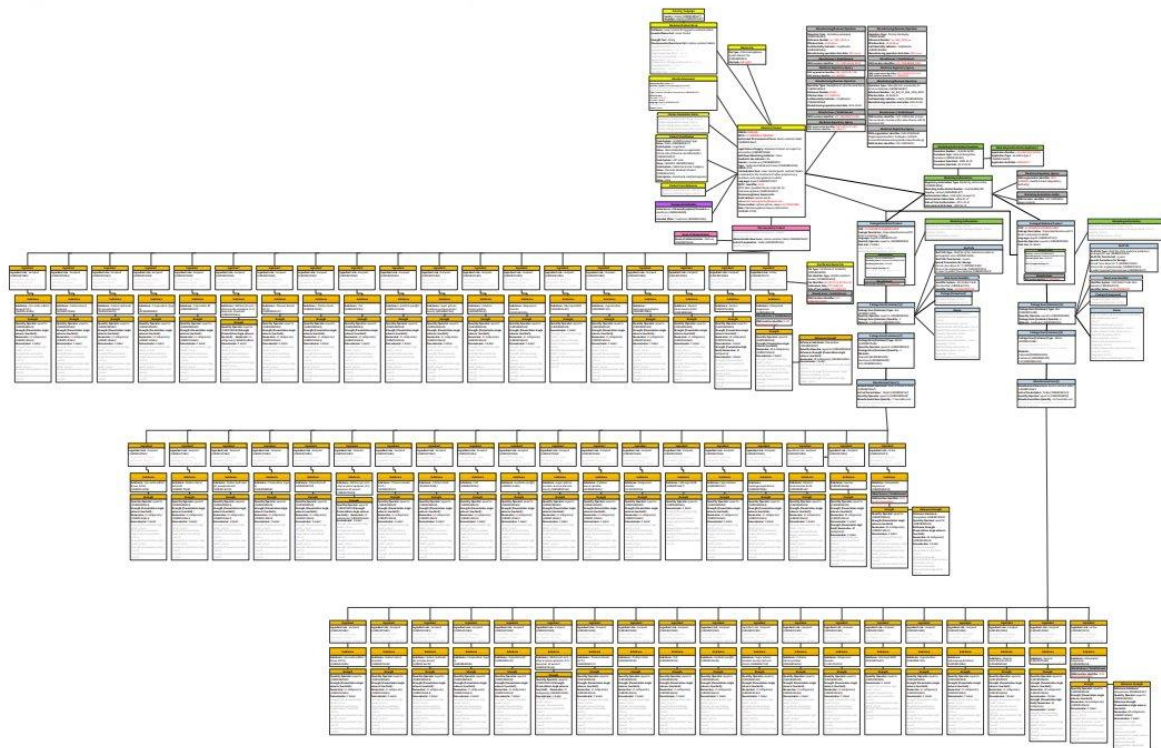


# Full IDMP for regulatory

Full ISO IDMP representation  
of one product. EMA IDMP IG  
[Annex 8](#).



## 1. Example 1: Losec Control 20mg gastro-resistant tablets <sup>1</sup>



# Reduced IDMP (clinical)

## CEFUROXIME 1500mg

Powder for solution for injection.

1 or 10 vials in a package.



### Medicinal Product

**MPID:** [EE-100009199-27834]

**Full name:** Cefuroxime MIP 1500 mg, süste-/infusioonilahuse pulber

**Classification:** J01DC02

**Authorised dose form:** Powder for solution for injection/infusion

### Marketing Authorisation

**MA number:** 805813

**Status:** Valid – Renewed/Varied

**Country:** Estonia

**Holder:** Mip Pharma GmbH

### Pharmaceutical Product

**PhPID:** [...]

**Administrable dose form:** Solution for injection/infusion

**Unit of presentation:** Vial

**Route of administration:** Intramuscular use  
Intravenous use

### Packaged Product (I)

**PCID:** [EE-100009199-27834-1529940]

**Outer package:** 1 - Box - Cardboard

**Inner package:** 1 - Vial - Glass type I

**Package item quantity:** 1 Vial

### Packaged Product (II)

**PCID:** [EE-100009199-27834-1529962]

**Outer package:** 1 - Box - Cardboard

**Inner package:** 10 - Vial - Glass type I

**Package item quantity:** 10 Vial

### Manufactured Item

**Manufactured dose form:** Powder for solution for  
injection/infusion

**Unit of presentation:** Vial

**Quantity:** N/A

### Ingredient

**Role:** active

**Substance:** Cefuroxime sodium

**Presentation strength:** 1578mg/vial

**Reference strength:**

**Substance:** Cefuroxime

**Strength:** 1500mg/vial

# Collaboration

IHE and HL7 worked together with other SDOs (and agencies) to compile specifications that meet the UNICOM needs

Within those SDOs, we found and covered gaps in the standards - specifications, terminology

Tooling

Lessons learned

Collaboration also extended to EMA, WHO, ....

# Specifications

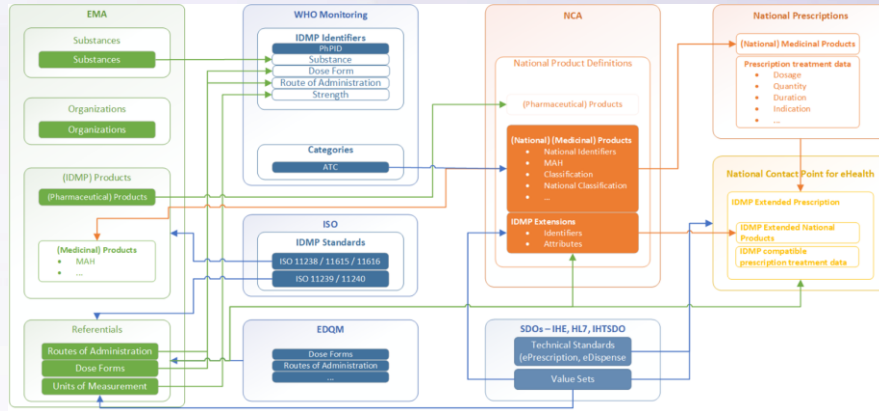
UNICOM IG - for FHIR-based specifications, a specification of

- Content that MAY be exchanged
- The conditions and constraints applying to the exchanged data

## IHE Transactions

- A set of “prototypical” data exchange in different scenarios
  - Exchange IDMP-compatible product data (Catalogues)
  - Exchange product data in clinical documents (prescriptions, summaries)
  - Substitution component (exchange data to inquire substitutes)

# How does it work?



- FHIR improvements R4b- R5
- FHIR Implementation Guide
- EMA FHIR specifications as FHIR IG
- Testable Specifications
  - Master Content specifications IHE+HL7
  - Adaptation and compliance testing IHE
- Testing infrastructure
- Tooling
- Sample content
- Community

# Medication in Europe

## Domain: Pharmacy

- IHE Pharmacy has been mostly driven by European participants
- National and cross-border specifications
- Standards (HL7 V2, CDA, FHIR)
- IHE Pharmacy
  - Current profiles:
    - Prescription
    - Dispense
    - Administration
    - Medication Lists



Integrating  
the Healthcare  
Enterprise

# Publishing

IHE hosts the transactions

# Adoption

Adoption consists of creating systems that conform to those specifications.

# Adaptation

- UNICOM specifications are EU-driven
- IHE specifications are global
- A EU flavour of the UNICOM specifications will be retained
- Each country will have their own specifications
- IHE has “Volume 4” - national extensions
- Each industry may still derive their own customisation

Example of Volume 4: IHE MPD

# Testing

IHE has testing infrastructure that can be reused:

- Test content and test cases - Test design should be consistent. IHE provides that baseline
- Testing process and infrastructure - testing on validated tools for test processes
- Community and events - to test data interoperability, identify gaps in the specifications or upstream standards, help shape the roadmap

# Link to ePI - cross country information

GTIN

PCID/MPID

PhPID

MPID target

ePI

Placing the pharmacy in the loop: a pharmacy system needs to look up a cross-border medication, either for prescribing or for dispensing – how would that integrate into the workflow provided by the pharmacy system? Explore the use of GTINs in the context of dispensation and plan for future FHIR connectathons. Explore connections to the PhPID Operating model in relation to the Query/Retrieval PhPIDs from different countries.

I have this Information: GTIN ▾ Show 10 ▾ entriesSearch: 

Nr° ▲	Name	Identifier	ePI ▾
1	<a href="#">Folitrax [Ipca Laboratories] (India)</a>	<a href="http://www.who-umc.org/whodrug/productid#1B93DFBAD671">http://www.who-umc.org/whodrug/productid#1B93DFBAD671</a>	<a href="#">View ePI</a>
2	<a href="#">Folitrax [Ipca Laboratories] (India)</a>	<a href="http://www.who-umc.org/whodrug/productid#1B93D53A1A91">http://www.who-umc.org/whodrug/productid#1B93D53A1A91</a>	<a href="#">View ePI</a>
3	<a href="#">Methotrexat teva onco [Teva Pharma AG] (Switzerland)</a>	<a href="http://www.who-umc.org/whodrug/productid#1B887DB2FEC4">http://www.who-umc.org/whodrug/productid#1B887DB2FEC4</a>	<a href="#">View ePI</a>
4	<a href="#">Methotrexate [Hospira] (Bangladesh)</a>	<a href="http://www.who-umc.org/whodrug/productid#1B7E891D1941">http://www.who-umc.org/whodrug/productid#1B7E891D1941</a>	<a href="#">View ePI</a>
5	<a href="#">Methotrexate [Pfizer] (Canada)</a>	<a href="https://health-products.canada.ca/dpd-bdpp#02182971 http://www.who-umc.org/whodrug/productid#1B7E88754E84">https://health-products.canada.ca/dpd-bdpp#02182971 http://www.who-umc.org/whodrug/productid#1B7E88754E84</a>	<a href="#">View ePI</a>

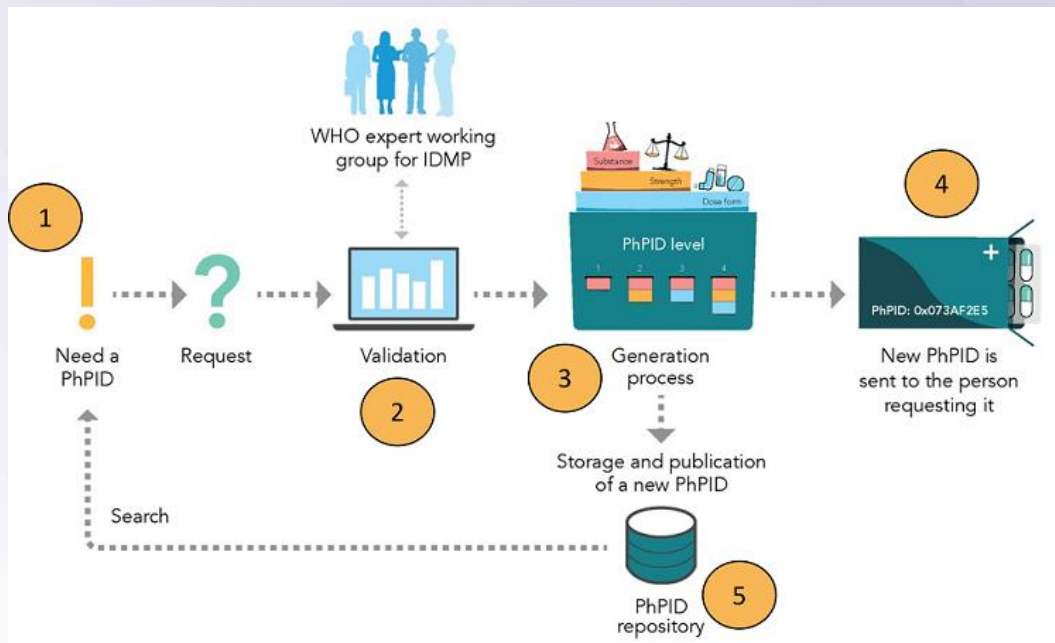
Showing 1 to 5 of 5 entries

[Previous](#)

1

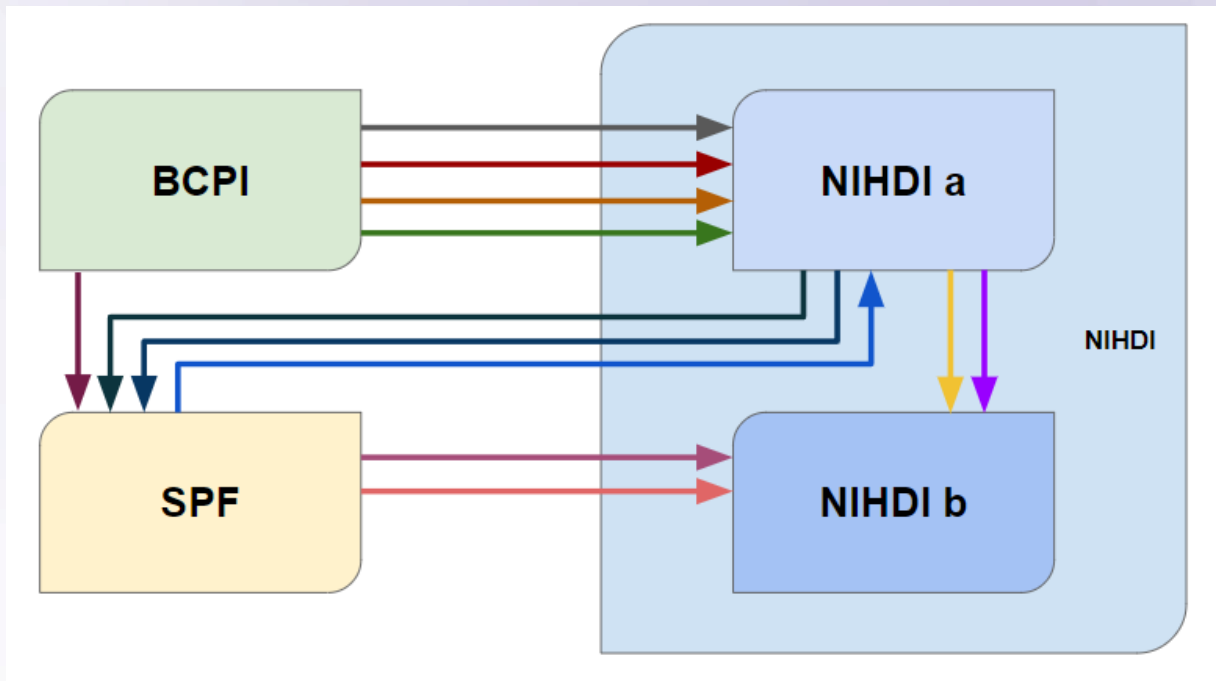
[Next](#)

# Example Operating model



# The Belgian case

....



# UNICOM FHIR IG

## UNICOM FHIR Implementation Guide

- Profiles for validation rules
- Example data
- CodeSystems and ValueSets (EMA RMS, EDQM)
- Visualisation template

The toolbox contains UNICOM Implementation Guide, but it can also be used with any other specification.

### Additional data:

- Sweden (from UFIS, provided by SEMPA)
- Estonia (from UFIS, provided by EESAM & TEHIK)
- Portugal (provided by Infarmed)

UnicomIG, published by UNICOM. This guide is not an authorized publication; it is the continuous build for version 0.1.0 CI Build. This version is based on the current content of <https://github.com/hl7-eu/unicom-ig/> and changes regularly.

## 7 Artifacts Summary

This page provides a list of the FHIR artifacts defined as part of this implementation guide.

### 7.0.1 Logical models

Logical data models as FHIR resources

Medicinal Product Logical Model	Logical model for a pilot product list's medicinal product
------------------------------------	--

### 7.0.2 Regulatory profiles

Profiles for regulatory data, EMA IG and IDMP compliant

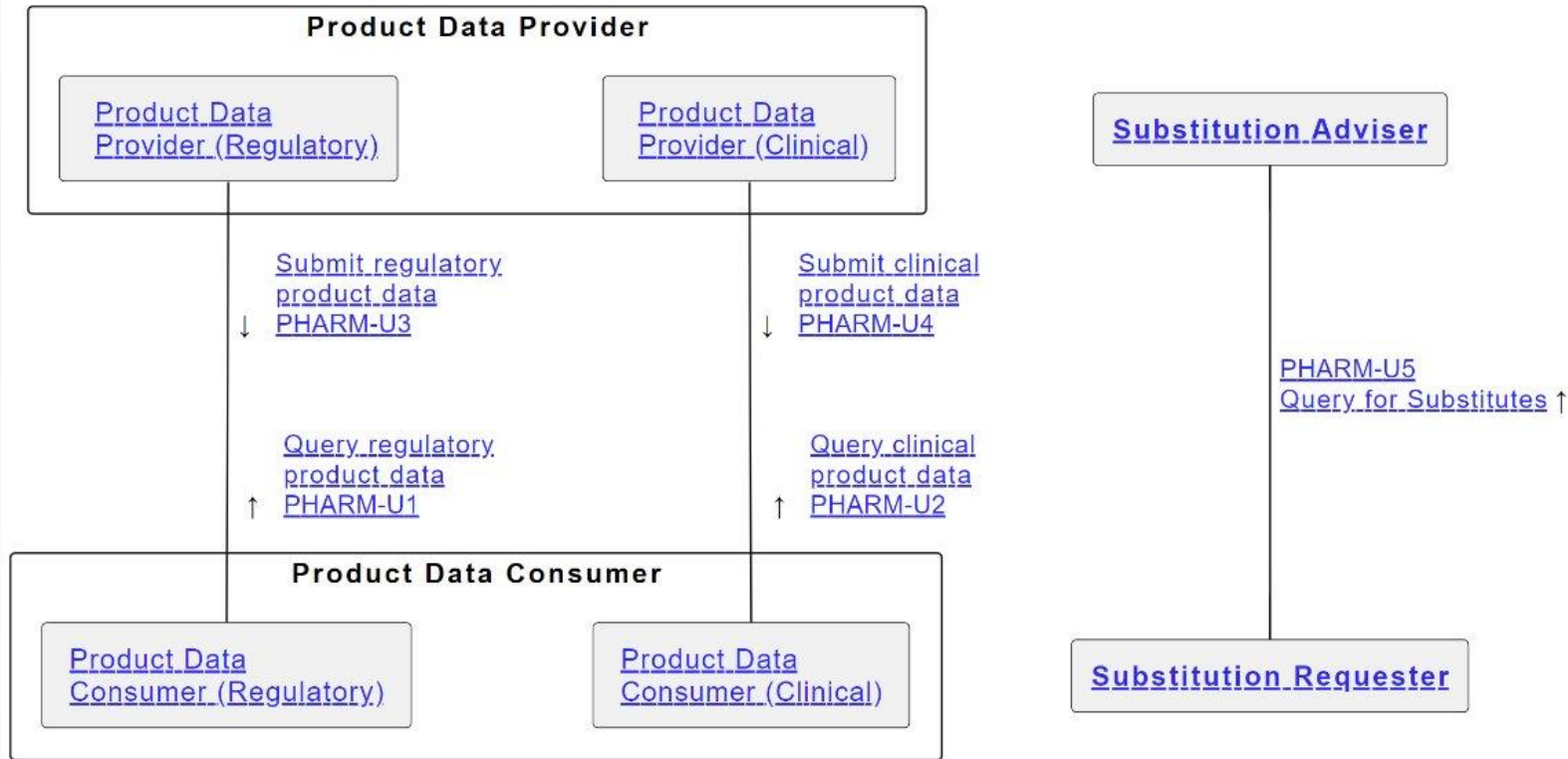
PPL Administrable Product profile	Administrable product profile defines the ISO IDMP Pharmaceutical Product concept
PPL Ingredient profile	Ingredient for the medicinal product, pharmaceutical product and/or manufactured item
PPL Manufactured Item profile	Manufactured item is the countable element inside the package

#### 7.0.13 Example: Example Instances

These are example instances that show what data produced and consumed by systems conforming with this implementation guide might look like.

001-Agen5mg-EE-FullProduct	Agen 5mg Tablet. Estonia. Simple example of one full product as a bundle. Packages, PCIDs, differ by material.
002-Agen10mg-EE-FullProduct	Agen 10mg Tablet. Estonia. Simple example of one full product as a bundle. Packages, PCIDs, differ by material.
003-CefuroximStragen-1-5g-Powder-SE-FullProduct	Cefuroxim Stragen 1.5g Powder for solution for injection/infusion. Sweden. Strength in grams; man. item quantity unknown; transformation before administration.
004-Cefuroxime-MIP-1500mg-EE-FullProduct	Cefuroxime MIP 1500mg Powder for solution for injection/infusion. Estonia. Strength in milligrams; man. item quantity unknown; transformation before administration.

# UNICOM Transactions



# UNICOM Toolbox

UNICOM toolbox is an **open-source platform** containing technical resources used/developed by UNICOM to help with IDMP adoption: from data creation to rapid prototyping of innovative apps.

It combines common and innovative features and lessons learned throughout the UNICOM project into a platform that implementers can use.

Unless specified, all the components in the UNICOM toolbox are open source and free to use.

## The key features and components:

- IDMP-compatible server with standard FHIR API
- Medicinal product browser, for browsing medicinal products data
- IDMP data visualiser for data modeling help and visual validation
- FHIR validation, to validate IDMP data against the relevant FHIR specifications
- ... other features - check out [our repository](#) and feel free to contribute!

# UNICOM IDMP on FHIR test server

[Home](#)[Server: Local Tester](#)[Source Code](#)[About This Server](#)

Options

Encoding (default) XML JSON

Pretty (default) On Off

Summary (none) true text data count

Server

Server Home/Actions

Resources

[Account](#)

[ActivityDefinition](#)

[ActorDefinition](#)

[AdministrableProductDefinition](#)

[AdverseEvent](#)

[AllergyIntolerance](#)

[Appointment](#)

[AppointmentResponse](#)

[ArtifactAssessment](#)

[AuditEvent](#)

[Basic](#)

[Binary](#)

[BiologicallyDerivedProduct](#)

[BiologicallyDerivedProductDispense](#)

[BodyStructure](#)

UNICOM

HAPI FHIR

UNICOM Test Server

Home page

Product Browser

Server	HAPI FHIR R5 Server
Software	HAPI FHIR Server - 6.8.3
FHIR Base	<a href="http://localhost:8080/fhir">http://localhost:8080/fhir</a>

Server Actions

Retrieve the server's **conformance** statement.

Conformance

Retrieve the update **history** across all resource types on the server.

History

Since




Limit # (opt)


Post a bundle containing multiple resources to the server and store all resources within a single atomic transaction.

Transaction

Bundle\* (place transaction bundle body here)

# Inbuilt Product Browser





Refresh

Product Browser

Search:

ID	Name	Country	Viewer	Source	Validation
ABASAGLAR-100eml-Solution-SE-IS-MedicinalProductDefinition	ABASAGLAR 100 enheter/ml Injektionsvätska, lösning i cylinderampull	Sweden	<a href="#">Viewer</a> <a href="#">Ext. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>
Agen-10mg-Tablet-EE-MPD	Agen, 10 mg tabletid	Republic of Estonia	<a href="#">Viewer</a> <a href="#">Ext. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>
Agen-5mg-Tablet-EE-MPD	Agen, 5 mg tabletid	Republic of Estonia	<a href="#">Viewer</a> <a href="#">Ext. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>
Airomir0.1Spray-SE-PLC-MedicinalProductDefinition	Airomir 0,1 mg/dos inhalationsspray, suspension	Sweden	<a href="#">Viewer</a> <a href="#">Ext. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>
Alburex-200g-L-Solution-SE-AJ-MedicinalProductDefinition	Alburex 200 g/l Infusionsvätska, lösning	Sweden	<a href="#">Viewer</a> <a href="#">Ext. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>
Alburex-50g-L-Solution-SE-AJ-MedicinalProductDefinition	Alburex 50 g/l infusionsvätska, lösning	Sweden	<a href="#">Viewer</a> <a href="#">Ext. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>
Altermol-500mg30mg-Tablet-SE-IS-MedicinalProductDefinition	Altermol 500 mg/30 mg Tablett	Sweden	<a href="#">Viewer</a> <a href="#">Ext. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>
Alvedon250mgMunsonderTablett-SE-PLC-MedicinalProductDef	Alvedon 250 mg Munsönderfallande tablett	Sweden	<a href="#">Viewer</a> <a href="#">Ext. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>

# 2 display options

FHIR resource URL: <http://fhir.hl7.pt:8787/fhir/MedicinalProductDefinition/BuprenorphineOri-2mg-Tablet-SE-t> [Display Product](#)

## Product

**Name:** Buprenorphine Orifarm 2 mg resoriblett, sublingual

Scientific name part: Buprenorphine Orifarm

Strength name part: 2 mg

Pharmaceutical dose form name part: Resoriblett, sublingual

Country: Sweden

Language: Swedish

Identifier: SE-100002342-00043164

Identifier: 461

Domain: Human use

Status: Current

Dose Form (combination of all parts): Sublingual tablet

Legal Status of Supply: Medicinal product subject to special medical prescription

Classification - ATC: N07BC01

Indication(s) text: Substitutionsbehandling vid opioidberoende i samband med medicinsk, social och psykologisk behandling.

## Package

Identifier: (no identifier)

Description: Blister, 7 tabletter

Marketing Status

Country: Sweden

Status: Marketed

Contained Items: 7 Tablet

Packaging

Type: Box

Quantity: 1

Material: Cardboard

Packaging

Type: Blister

Quantity: 1

Material: Aluminium, PolyVinyl Chloride

Amount: 7 Tablet

## Manufactured Item

Dose Form: Sublingual tablet

Unit of presentation: Tablet

## Ingredient

Role: Active

Substance: Buprenorphine hydrochloride

Strength

Presentation Strength: 2.16 milligram(s) per 1 tablet

Reference Substance: Buprenorphine

Strength: 2 milligram(s) per 1 tablet

NProgram IDMP Viewer. Free (not open source). Based on core FHIR specification, good for debugging the data and handling unexpected content.

## Agen, 10 mg tabletid

MPID: EE-100002580-15548

Full name: Agen, 10 mg tabletid

- Invented Name Part: Agen

- Strength part: 10 mg

- Pharmaceutical dose form part: tabletid

Name usage: Estonian (Republic of Estonia)

Authorised dose form: Tablet

Legal status of supply: Medicinal product subject to medical prescription

Domain: Human use

Resource status: Current

Product classification:

- 100000095065 amlodipine
- C08CA01 amlodipine

## Marketing Authorisation 1 of 1

Authorisation number: 418403

Region: Republic of Estonia

Marketing authorisation holder: Zentiva k.s.

Identifier:

- LOC-100002580

Status: Valid - Renewed/Varied (2013-06-07)

Package 1 of 2

PCID: EE-100002580-15548-1109900a

Description:

Tabletid on pakendatud PVC/PVDC/Al blistrisse (valged) või PVC/Al blistrisse (valged).

Marketing status:

- Republic of Estonia: Marketed

Pack size:

- 30 tablet

Package: 1 Box (Cardboard)

Containing:

Package: Blister (PolyVinyl Chloride) (PolyVinylidene Chloride) (Aluminium)

Containing: 30

## Manufactured Item

Dose form: Tablet

Unit of presentation: Tablet

## Ingredient

Role: Active

Substance: Amlodipine besilate

Presentation strength: 13.87 milligram(s) / 1 tablet

Reference strength:

Amlodipine 10 milligram(s) / 1 Tablet

Open-source viewer developed by UNICOM and usable inside FHIR IG. Tailored to present the data in a clean readable way, customisable by users.

## Validation outcome: PASS

Details

Warnings (27)

Informations (7)

## Information: Terminology\_TX\_NoValid\_3\_CC

None of the codings provided are in the value set 'PublicationStatus' (<http://hl7.org/fhir/ValueSet/publication-status>), and a coding is recommended to come from this value set) (codes = <https://spor.ema.europa.eu/v1/lists/200000005003#200000005004>)

Bundle.entry(0).resource ofType(MedicinalProductDefinition).statusLine 1, Col 1430

## Information:

This element does not match any known slice defined in the profile <http://unicom-project.eu/fhir/StructureDefinition/PPLMedicinalProductDefinition>

Bundle.entry(0).resource ofType(MedicinalProductDefinition).identifier[1]Line 1, Col 1220

## Validation outcome: Issues Detected

Details

Errors (4)

Warnings (27)

Informations (51)

```
{
  "classification": [
    {
      "coding": [
        {
          "system": "https://spor.ema.europa.eu/v1/lists/100000093533",
          "code": "100000095065",
          "display": "amlodipine"
        },
        {
          "system": "https://www.whooc.no/atc",
          "code": "C08CA01",
          "display": "amlodipine"
        }
      ]
    }
  ],
  "name": [
    {
      "productName": "Agen, 10 mg tabletid",
      "part": [
        {
          "part": "Agen",
          "type": {
            "coding": [
              {
                "system": "http://spor.ema.europa.eu/v1/lists/220000000000",
                "code": "220000000002",
                "display": "Invented Name Part"
              }
            ]
          }
        },
        {
          "part": "10 mg",
          "type": {
            "coding": [
              {
                "system": "http://spor.ema.europa.eu/v1/lists/220000000000",
                "code": "220000000004",
                "display": "Strength part"
              }
            ]
          }
        },
        {
          "part": "tablet",
          "type": {
            "coding": [
              {
                "system": "http://spor.ema.europa.eu/v1/lists/220000000000",
                "code": "220000000005",
                "display": "Pharmaceutical dose form part"
              }
            ]
          }
        }
      ]
    }
  ]
}
```

# UNICOM Toolbox

Home Server: Local Tester Source Code About This Server

Options  
Encoding (default) XML JSON  
Pretty (default) On Off  
Summary  
(none) true text data count  
Server  
Server Home/Actions  
Resources  
Account  
ActivityDefinition  
ActorDefinition  
Admin  
Adverse  
Allergy

## UNICOM

## HAPI FHIR

### UNICOM Test Server

Home page Product Browser

Server	HAPI FHIR R5 Server
Software	HAPI FHIR Server - 6.8.3

```
{
  "substance": {
    "code": {
      "concept": {
        "coding": {
          {
            "system": "https://spor.azure-api.net/sms/api/v2/SubstanceDefinition",
            "code": "10000000079",
            "display": "Amlodipine besilate"
          }
        }
      }
    }
  },
  "strength": {
    "presentationRatio": {
      "numerator": {
        "value": 13.87,
        "unit": "milligram(s)",
        "system": "https://spor.ema.europa.eu/v1/lists/100000110633",
        "code": "100000110655"
      },
      "denominator": {
        "value": 1,
        "unit": "tablet",
        "system": "https://spor.ema.europa.eu/v1/lists/200000000014",
        "code": "2000000002152"
      }
    },
    "referenceStrength": {
      "substance": {
        "code": {
          "concept": {
            "coding": {
              {
                "system": "https://spor.azure-api.net/sms/api/v2/SubstanceDefinition",
                "code": "1000000005259",
                "display": "Amlodipine"
              }
            }
          }
        }
      },
      "strengthRatio": {
        "numerator": {
          "value": 10,
          "unit": "milligram(s)",
          "system": "https://spor.azure-api.net/sms/api/v2/SubstanceDefinition",
          "code": "10000000079"
        },
        "denominator": {
          "value": 1,
          "unit": "tablet",
          "system": "https://spor.ema.europa.eu/v1/lists/200000000014",
          "code": "2000000002152"
        }
      }
    }
  }
}
```

UNICOM Product Browser Refresh

Search: Sweden

ID	Name	Country	Viewer	Source
ABASAGLAR-100eml-Solution-SE-IS-MedicinalProductDefinition	ABASAGLAR 100 enheter/ml injektionsvätska, lösning i cylinderpall	Sweden	<a href="#">Viewer</a> <a href="#">Ext.</a> <a href="#">Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>
Airomir0.15pray-SE-PLC-MedicinalProductDefinition	Airomir 0,1 mg/dos inhalationsspray, suspension	Sweden	<a href="#">Viewer</a> <a href="#">Ext.</a> <a href="#">Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>
Alburex-200g-L-Solution-SE-AJ-MedicinalProductDefinition	Alburex 200 g/l infusionsvätska, lösning	Sweden	<a href="#">Viewer</a> <a href="#">Ext.</a> <a href="#">Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>
Alburex-50g-L-Solution-SE-AJ-MedicinalProductDefinition	Alburex 50 g/l infusionsvätska, lösning	Sweden	<a href="#">Viewer</a> <a href="#">Ext.</a> <a href="#">Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>

Pack size:

- 1 Canister

Package: 1 Box (Cardboard)

Containing: 1 Canister

Manufactured Item

Dose form: **Pressurised inhalation, suspension**Unit of presentation: **Canister**

Ingredient

Role: **Active**Substance: **Salbutamol sulfate**Presentation strength: **0.12 milligram(s) / 1 Actuation**

Reference strength:

**salbutamol 0.1 milligram(s) / 1 Actuation**

Thank you!

# IHE's Volume-4... so what?

Operationalizing market-making ***governance*** over digital health specifications, so they can be taken to ***scale***.

Derek Ritz, P.Eng., CPHIMS-CA

UNiCOM-to-Industry “Hand-off” Meeting, Brussels

May-14 2024




# Story arc...

- ❑ *Super-brief introduction*
- ❑ **What** is the role of Volume-4 in an IHE Profile?
- ❑ **How** will this be employed re: UNICOM?
- ❑ **Why** should you care?
- ❑ Q&A



# Mandatory apologies...



**Derek Ritz** 1st

Principal Consultant, ecGroup Inc.  
Toronto, Canada Area | Information Technology and Services

Current ecGroup Inc., The University of Edinburgh, ISO TC215

Previous Université de Sherbrooke, Canada Health Infoway Standards Collaborative, MARC HI

Education The University of Edinburgh


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Contact Info

**Background**

 Summary

Trusted advisor to global public and private sector clients regarding m/eHealth architecture, strategy, implementation and adoption.

Specialties: eHealth technology & strategy, health enterprise architecture, big data analytics, health informatics standards, lean healthcare, patient safety & quality of care, EHR implementation, security, privacy, supply chain management (SCM), BPR, IT systems analysis, SOA



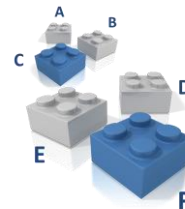
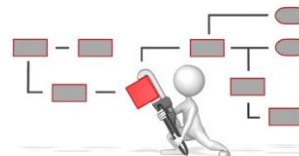
What is Vol-4, anyway?



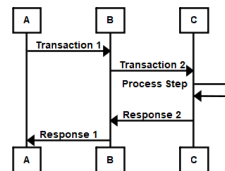
# IHE Profile (“xBundle”)



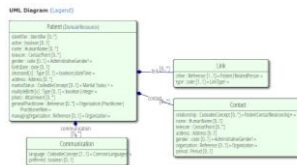
**Volume 1:**



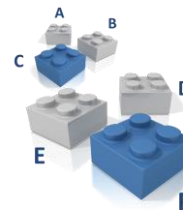
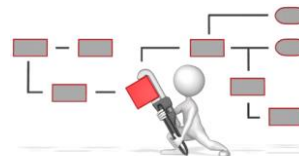
**Volume 2:**



**Volume 3:**



**Volume 4:**



```

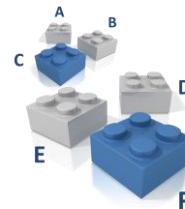
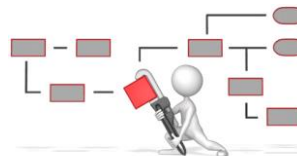
sequenceDiagram
    participant A
    participant B
    participant C
    Note over A,B: Transaction 1
    A->>B: Transaction 1
    Note over B,C: Transaction 2
    B->>C: Transaction 2
    Note over C: Process Step
    C->>B: Process Step
    Note over B,A: Response 2
    B->>A: Response 2
    Note over A,B: Response 1
    A->>B: Response 1
  
```

[illegible]

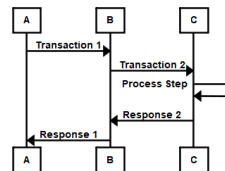
# IHE Profile (“xBundle”)



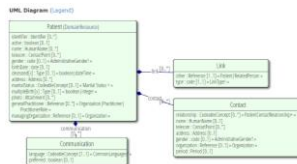
**Volume 1:**



**Volume 2:**



**Volume 3:**



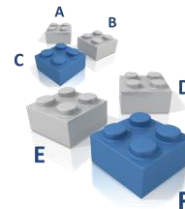
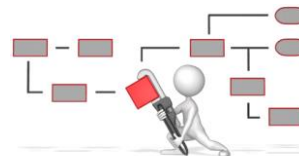
**Volume 4:**



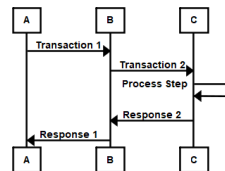
# IHE Profile (“xBundle”)



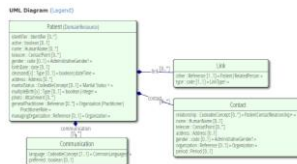
**Volume 1:**



**Volume 2:**



**Volume 3:**



**Volume 4:**



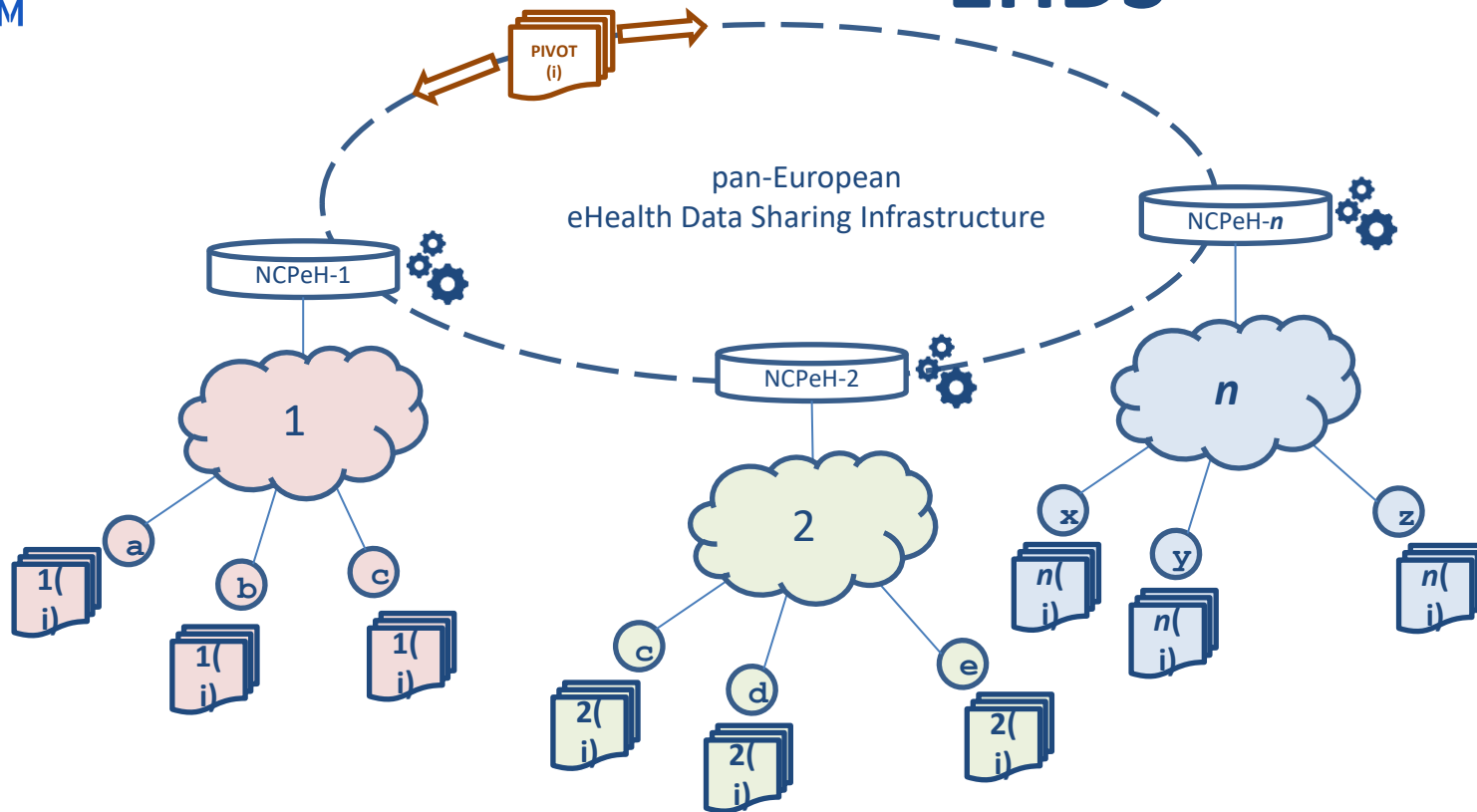


- ❑ All IHE Profiles are ***global public goods***.
- ❑ They describe ***actor-transaction pairs*** and the normative, ***conformance-testable behaviours*** of these actors as they “interoperate” with each other.
- ❑ The Volume-4 section of an IHE Profile describes how the global specification is ***contextualized*** for a particular region or use case.
- ❑ The Volume-4 sections are ***governed*** by their respective IHE Deployment Committees.

How will this work for  
**UNiCOM's** specifications?



# EHDS



# UNiCOM example

- ❑ There will be an xBundle for document (i)... e.g. **ePrescriptions**. The xBundle will reference global standards.
- ❑ ePrescriptions (i) will be **interoperable** across multiple digital health solutions operating within multiple care national delivery networks.
- ❑ For **national care continuity**, the ePrescription content spec that has been nationalized for country-1, e.g. **1(i)**, must be sharable by all relevant digital health **solutions** (e.g. a, b, c).
- ❑ For **pan-EU care continuity**, ePrescription content must be sharable from country-1 to country-2. This means **1(i)** must map to **PIVOT(i)** and **PIVOT(i)** must map to **2(i)**... and vice versa.
- ❑ The mapping from nationalized versions to the relevant document type's PIVOT will be operationalized by each country's **NCPeH**.

# Roles for xBundle “Vol-4” specs

- ❑ Based on the IHE Methodology, Vol-4 specs are used to express **contextualizations** on the “base” spec.
- ❑ Where an xBundle references a **global** standard, this will be referenced in Vol-2 and Vol-3 of the spec.
- ❑ **EEHRxF** contextualizations (e.g. to define PIVOT(i)) can be expressed in a **European Vol-4** section.
- ❑ **Nationalizations** of the EEHRxF (e.g. 1(i), 2(i), etc.) can be expressed in relevant **national Vol-4** sections.
- ❑ **Conformance-testing** can ensure **digital health solutions** correctly adhere to nationalized content specs (e.g. 1(i), 2(i), etc.).
- ❑ **Conformance-testing** can ensure **NCPeH instances** correctly map nationalized specs to European ones (e.g. PIVOT(i)) and vice versa.



- ❑ **UNiCOM's** artefacts will be taken up by IHE Pharmacy. They will be balloted as global public goods with a Volume-4 that expresses the European requirements.
- ❑ Conformance-testing (IHE Catalyst) will confirm adherence of products to the EHDS specifications.
- ❑ European member states can nationalize the specifications. This will also be in Vol-4.

Why should you *care*?





Industry are the ***heroes*** of this story!



European Commission  
Directorate-General for Health  
and Food Safety (DG SANTE)

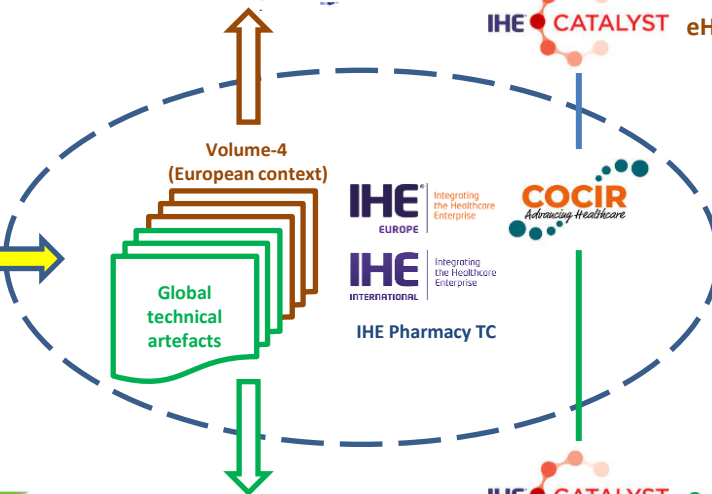


COCIR members who are demonstrably conformant to the European Volume-4 aspects will bid on EC-funded projects that leverage the IHE specifications.

**IHE CATALYST eHDSI Projectathon**



With EC funding,  
UNICOM has developed  
digital health technical  
specifications.



In collaboration with industry and government, the IHE Pharmacy TC will develop and publish global digital health specifications based on the UNICOM work. IHE Europe will govern the European (UNICOM-related) aspects of these global specs.

**IHE CATALYST Connectathon**

COCIR members who are demonstrably conformant will bid on international projects that leverage the IHE global specifications.



# Thank you!



# From UNICOM... .. to the “*format*”

**Giorgio Cangioli**

Technical Lead HL7 Europe

eHMSEG STF Architecture WG chair

UNICOM workshop @COCIR  
May 14<sup>th</sup> 2024

UN  COM

HL7<sup>®</sup>

 Europe

 **XpanDH**  
Expanding Digital Health through a  
pan-European EHRx-based Ecosystem

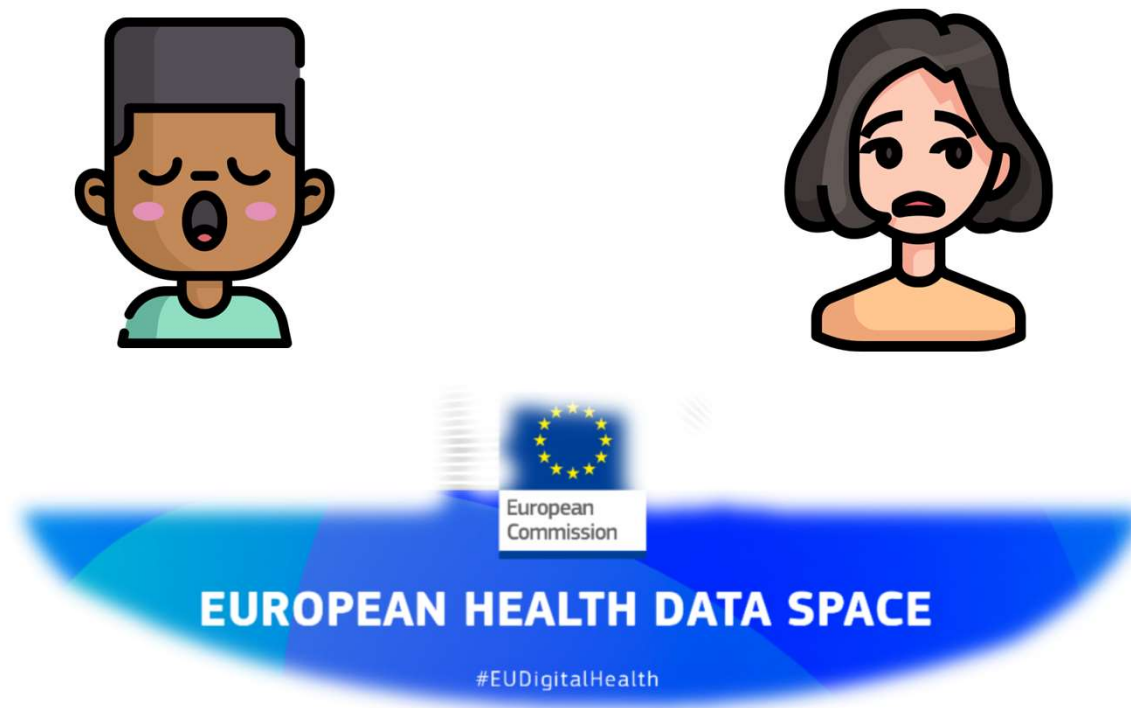
 **Share**  
EHR Xchange Format

# 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.**

(not) just another presentation about the “format”..

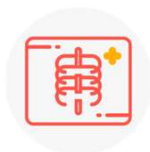


# UNICOM and the “format”

## UNICOM

### EHDS - Art 5 Priorities

European  
EHRxF



Medical Imaging  
and reports



Laboratory Results



Hospital Discharge  
report



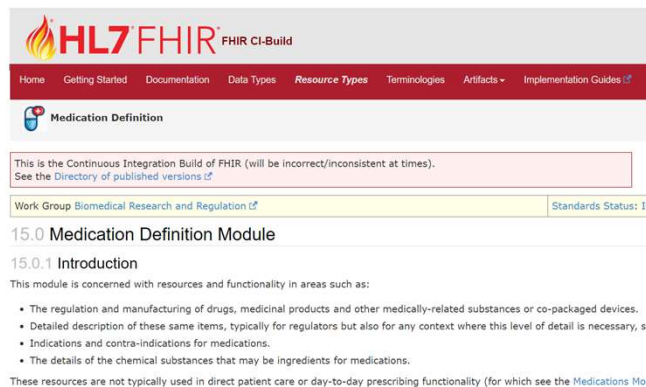
Patient Summary



ePrescription



# Contribution to Standards



CDAR2\_IG\_PHARM\_TEMPLATES\_R1\_D3\_2023APR



**HL7 CDA® R2 Implementation Guide:**  
**Pharmacy Templates**  
 Edition 1 (Universal Realm)  
 Ballot 3



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



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# Implemented in MyHealth@EU

Lantus Solostar

Canesten Combi

Qlaira

- **Outer package:** box
- **Content:** 3 x blister (used to be calendar package)  
Each blister contains:
  - 2 tablets of **3mg** estradiol valerate and **0mg** of dioneigest,
  - 5 tablets of **2mg** estradiol valerate and **2mg** of dioneigest,
  - 17 tablets of **2mg** estradiol valerate and **3mg** of dioneigest,
  - 2 tablets of **1mg** estradiol valerate and **0mg** of dioneigest,
  - 2 tablets of **0mg** estradiol valerate and **0mg** of dioneigest.



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



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Europe

HL7  
Europe

HL7  
Europe

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**eHDSI - Templates**

Project Datasets Scenarios Terminology Templates Issues

Templates

eHDSI eP/eD Manufactured Material –

Issues (1)

<b>Id</b>	1.3.6.1.4.1.12559.11.10.1.3.1.3.30	<b>Effective Date</b>	2024-04-10 10:19:06
<b>Status</b>	Active	<b>Version Label</b>	
<b>Name</b>	eHDSIePeDManufacturedMaterial	<b>Display Name</b>	eHDSI eP/eD Manufactured Material
<b>Classification</b>	CDA Entry Level Template		
<b>Open/Closed</b>	Open (other than defined elements are allowed)		
<b>Associated with</b>	▶ Associated with 14 concepts		
<b>Used by / Uses</b>	▶ Used by 0 transactions and 3 templates, Uses 3 templates		
<b>Relationship</b>	Version: template 1.3.6.1.4.1.12559.11.10.1.3.1.3.30 eHDSI eP/eD Manufactured Material (2023-04-21 13:59:56) Version: template 1.3.6.1.4.1.12559.11.10.1.3.1.3.30 eHDSI eP/eD Manufactured Material (2022-08-26 09:43:11) Version: template 1.3.6.1.4.1.12559.11.10.1.3.1.3.30 eHDSI eP/eD Manufactured Material (2022-07-12 12:23:25) Version: template 1.3.6.1.4.1.12559.11.10.1.3.1.3.30 eHDSI eP/eD Manufactured Material (2022-06-23 07:12:23) Version: template 1.3.6.1.4.1.12559.11.10.1.3.1.3.30 eHDSI eP/eD Manufactured Material (2022-02-04 17:30:00) Generalization: template 2.16.840.1.113883.10.12.311 CDA Material (2005-09-07) rdl: ad1bbr		

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HL7  
Europe



**Vision comes to live  
through 4 main scopes**



Establishing a scalable  
public infrastructure for  
digital health innovation



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



Establishing a Pan-  
European ecosystem of  
digital health



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

# Expanding Digital Health through a pan-European EEHRxF-based Ecosystem

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



**Funded by  
the European Union**

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

# XpanDH – a collaborative project

XpanDH intends to build up the EEHRxF through a **collaborative process** with the different actors that compose the eHealth community

- Identify the needs, barriers
- Co-create solutions and develop the EEHRxF
- Engage projects, stakeholders and health actors on the x-Nets and Community of doers



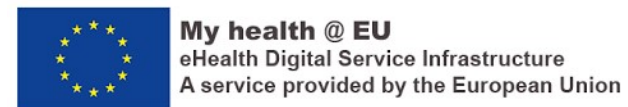
# Who's who



**Innovation**



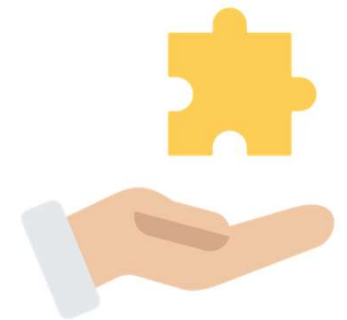
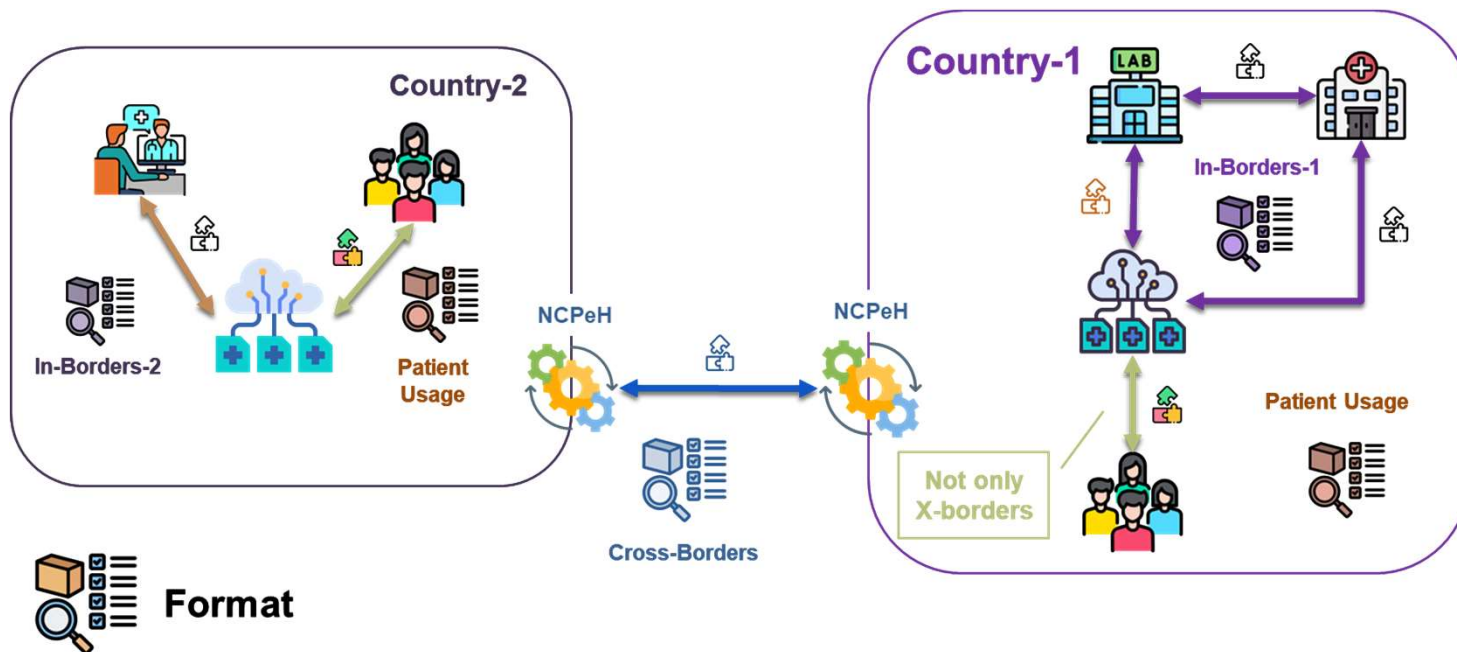
**Joint Action**



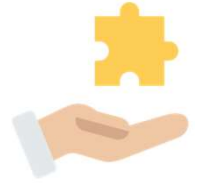
**Cross-Border Services**

# A complex and multiform scenario

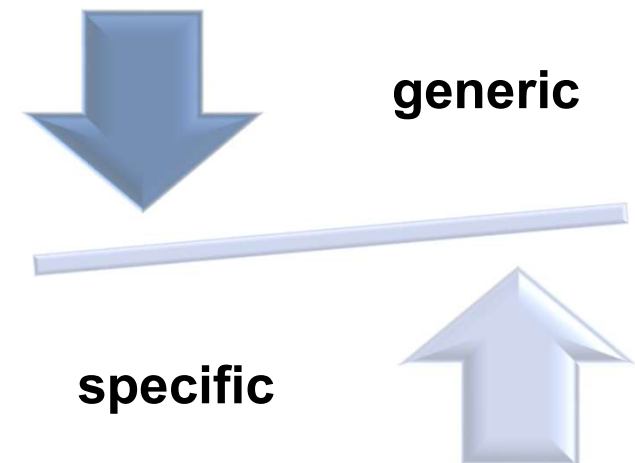
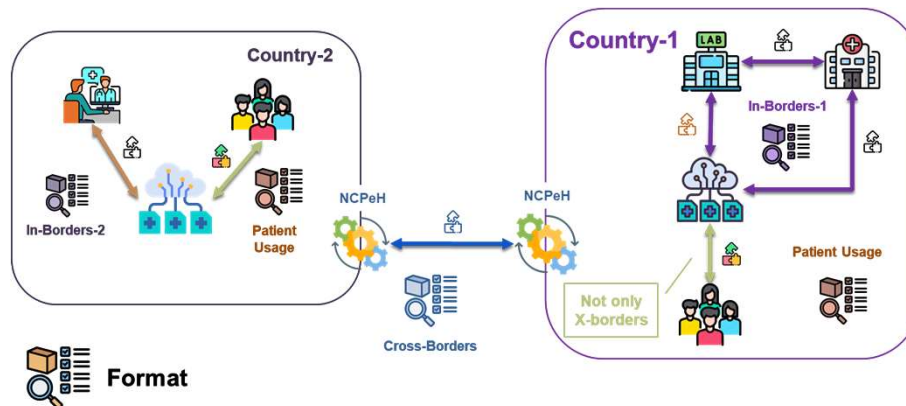
Needs and expectations are different and **there is not a one-fits-all solution**



# A complex and multiform scenario



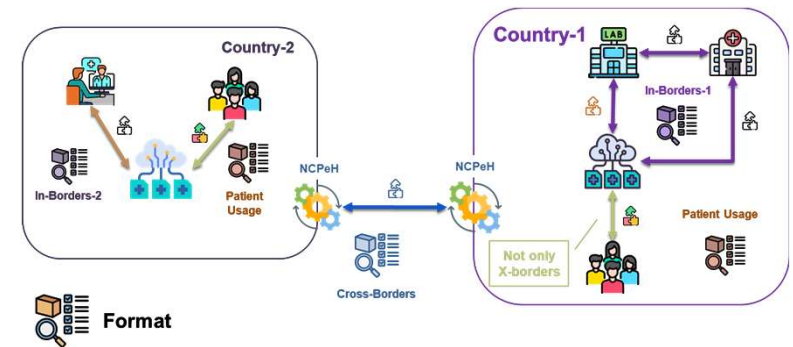
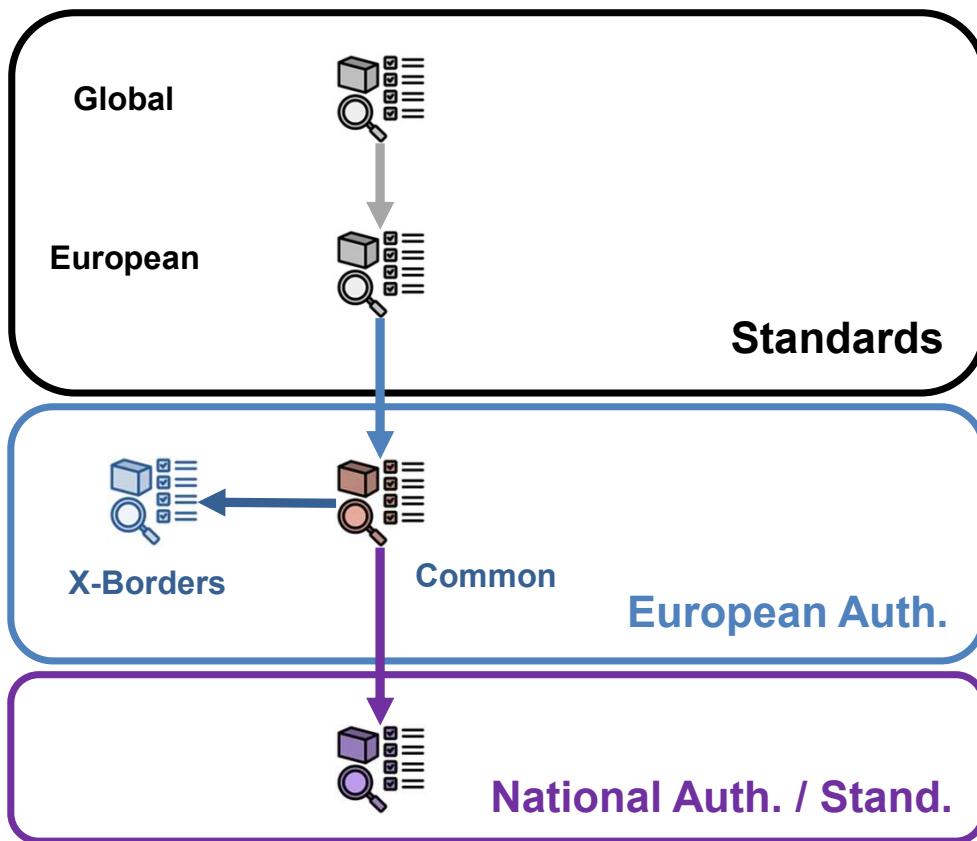
- Needs and expectations are different and there is not a **one-fits-all solution**... but.. no European interoperability without:
  - **serving and being useful in all these situations**
  - **common rules**



# The strategy



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



# The strategy



Additional common rules for  
the EEHRxF

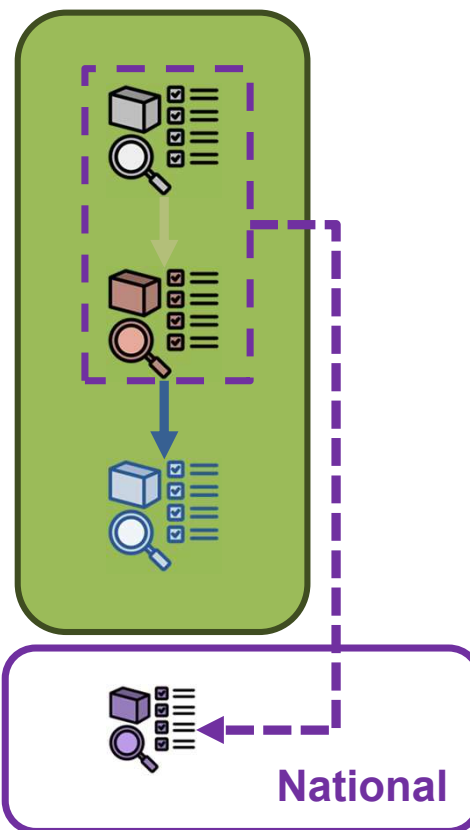
Standard  
(EU/UV scope)

EU common

Additional rules for X-border

EU X-Borders  
(MyHealth@EU)

image: Flaticon.com



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

# The strategy

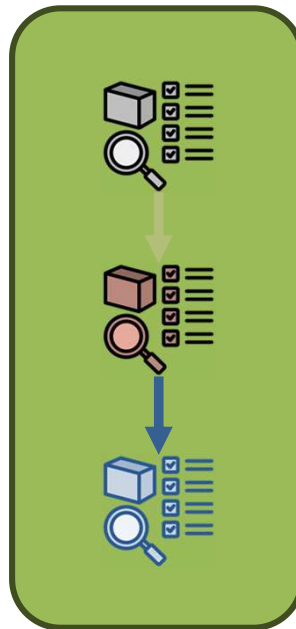


Standard  
(EU/UV scope)

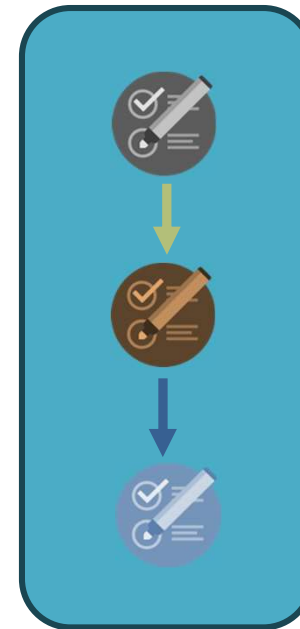
EU common

EU X-Borders  
(MyHealth@EU)

National



Progressing adoption



Progressing validation



image: Flaticon.com

# The strategy



Standard  
(EU/UV scope)

EU common

EU X-Borders  
(MyHealth@EU)

National

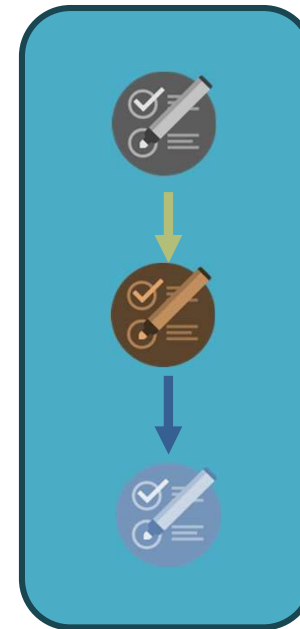
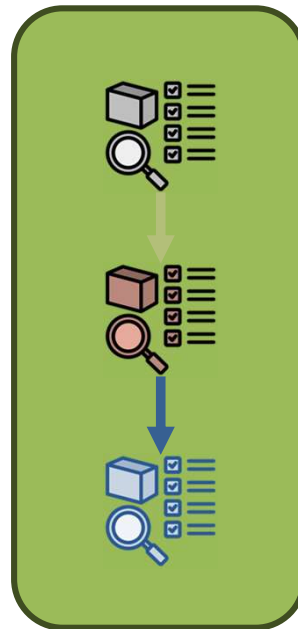


image: Flaticon.com

Progressing adoption

Progressing validation

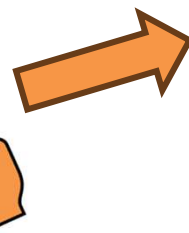


# The strategy



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.

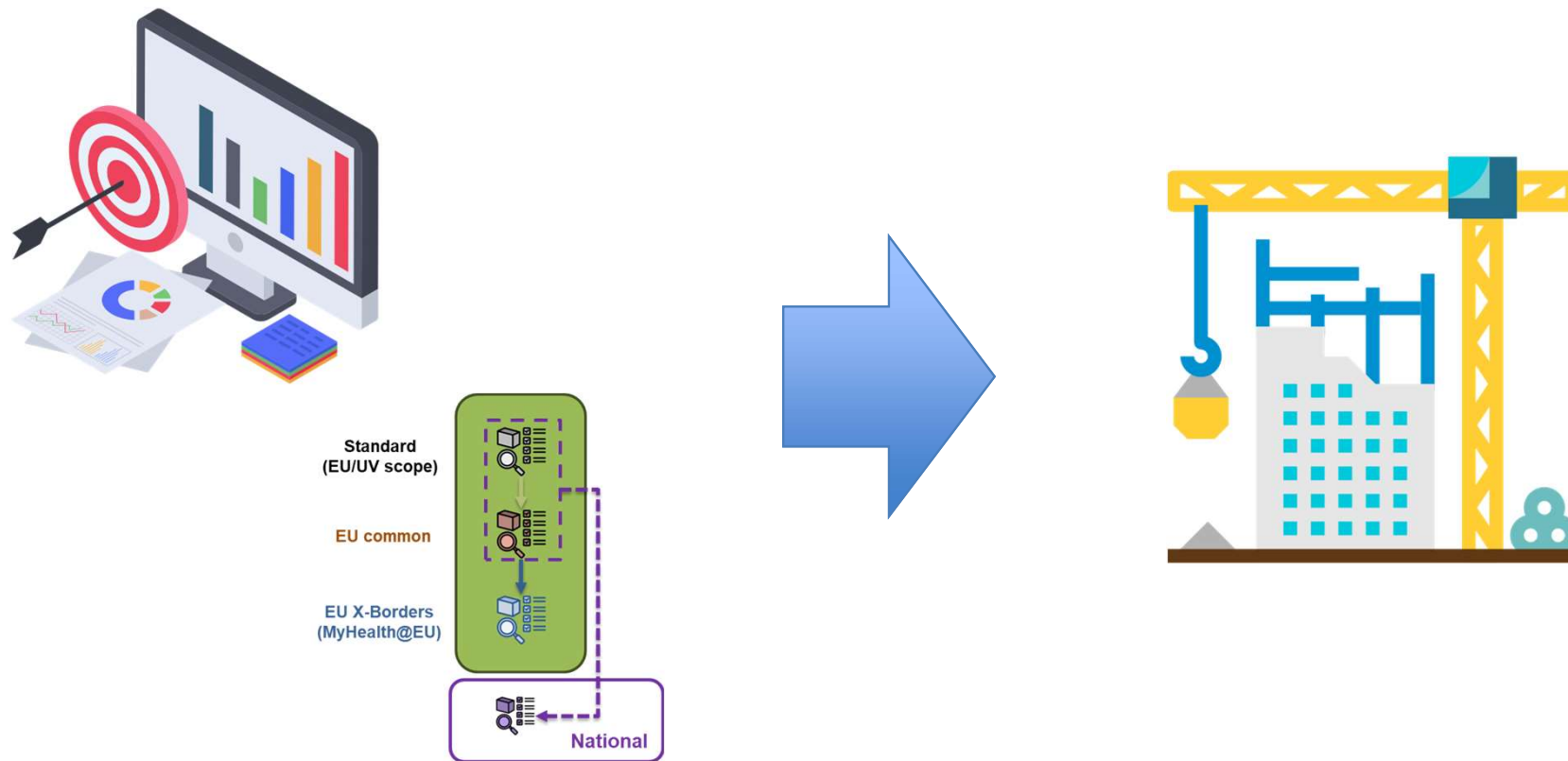
This structure is derived from Observation

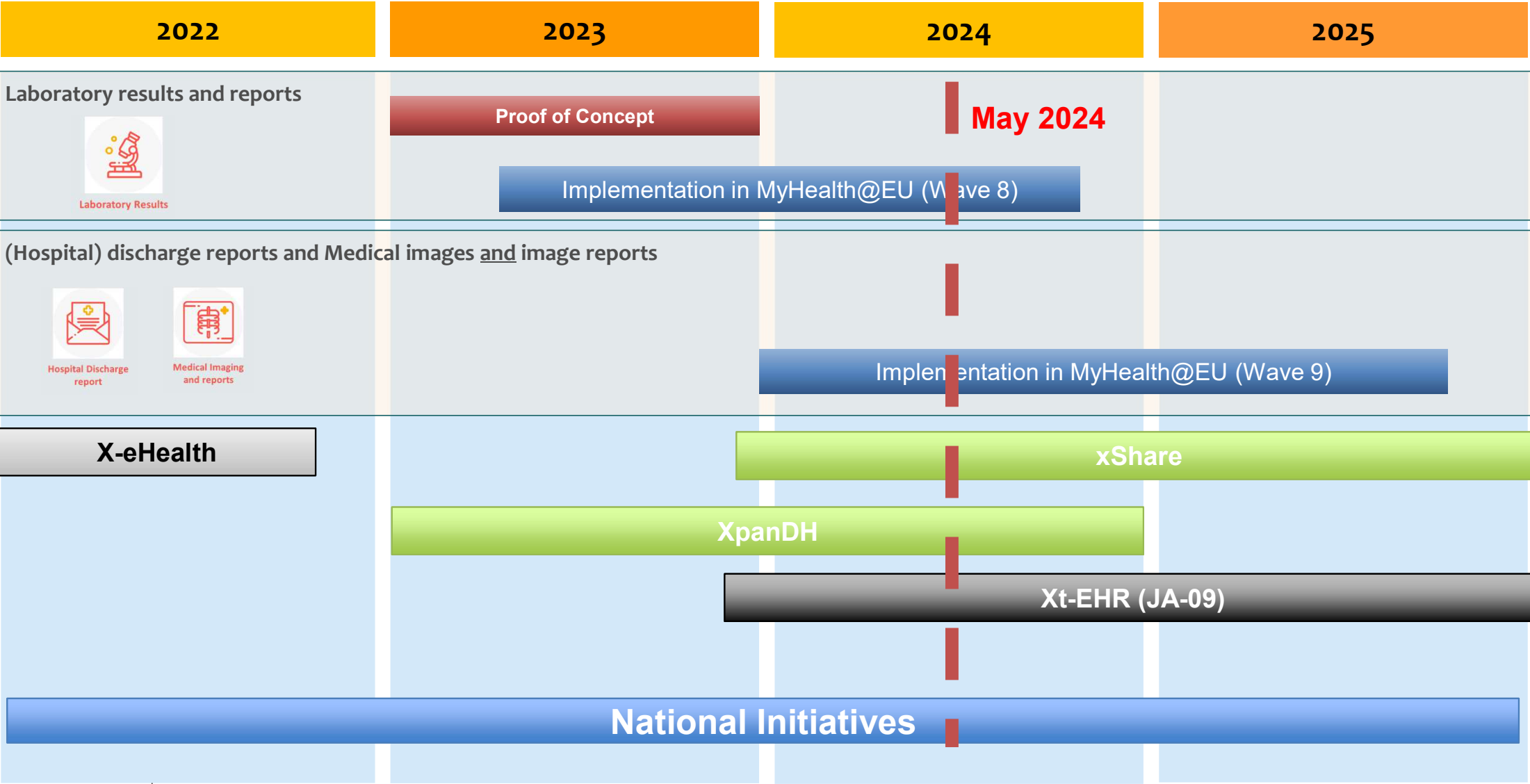
Name	Flags	Card.	Type	Description & Constraints
Observation		0..1	Observation	Laboratory result for a simple test or for a panel/study eu-lab-1: If observation status is other than "registered" or "cancelled", at least one of these Observation elements shall be provided: "value", "dataAbsentReason",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



Laboratory Results

# From strategy to reality





# From strategy to reality



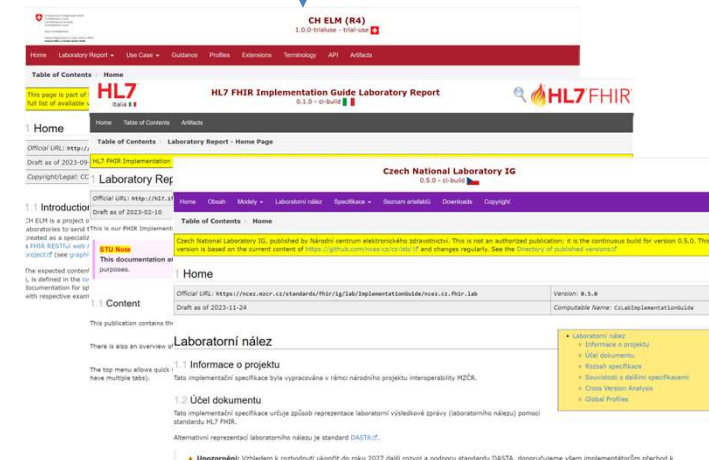
Laboratory Results



**Standard  
(EU/UV scope)**

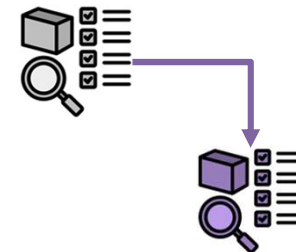


**EU X-Borders**



**National Guides**

# A vision made real..



HL7

Italia

HL7 FHIR Implementation Guide Laboratory Report

0.2.0 - trial-use

HL7 FHIR

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](#)).

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 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 medici

The following versions have been published:

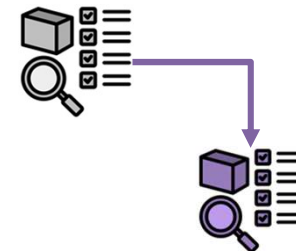
Date	IG Version	FHIR Version	Description	Links
<b>Current Versions</b>				
2024-03-08	0.2.0	4.0.1	This is the Edition 1 STU 1 release	<a href="#">Download</a> <a href="#">View</a> <a href="#">Feedback</a> <a href="#">Report Issue</a>
(current)	(last commit)	n/a	undefined	<a href="#">Download</a> <a href="#">View</a> <a href="#">Feedback</a> <a href="#">Report Issue</a>
<b>Release 1 Sequence</b>				
2024-03-08	0.2.0	4.0.1	This is the Edition 1 STU 1 release ( <i>Permanent Home</i> )	<a href="#">Download</a> <a href="#">View</a> <a href="#">Feedback</a> <a href="#">Report Issue</a>
2023-07-11	0.1.0	4.0.1	This is the June 2023 STU ballot version.	<a href="#">Download</a> <a href="#">View</a> <a href="#">Feedback</a> <a href="#">Report Issue</a>

## 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	hl7.fhir.uv.implementation#2023.1.20231006	R4
HL7 Europe Extensions	hl7.fhir.eu.extensions#0.1.0	R4

Officially Published

# A vision made real..





Schweizerische Eidgenossenschaft  
 Confédération suisse  
 Confederaziun Svizra  
 Confederaziun Svizra  
 Swiss Confederation  
 Federal Department of Home Affairs FOHA  
 Federal Office of Public Health FOPH

**CH ELM (R4)**  
 1.0.0-trialuse - trial-use

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[Laboratory Report](#)
[Use Case](#)
[Guidance](#)
[Profiles](#)
[Extensions](#)
[Terminology](#)
[API](#)
[Artifacts](#)

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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

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## 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](#).

## 1.1 Introduction

CH ELM is a project of the Swiss Federal Office of Public Health (FOPH), Communicable Diseases, to send their observations of notifiable communicable infectious diseases to the HL7® FHIR® standard. This FHIR is 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 of Public Health (FOPH), 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 (DRAFT) with respective examples for specific organisms.

### Core profiles

### Exchange formats

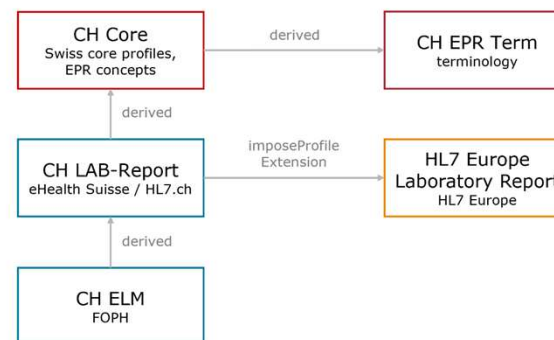


Fig. 1: Dependency Overview



HL7 Europe Laboratory Report  
 5.0.0 - draft - latest



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[Laboratory Report](#)
[Use Case](#)
[Guidance](#)
[Profiles](#)
[Extensions](#)
[Terminology](#)
[API](#)
[Artifacts](#)

This page is part of the HL7 Europe Laboratory Report (v5.0.0 - draft - latest). This is the current published version. For a full list of available versions, see the [Directory of published versions](#).

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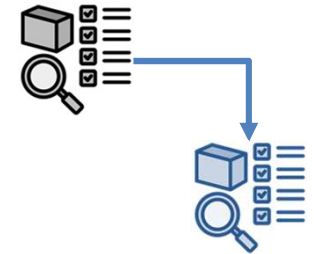
1.1: Notes for implementers

1.1: The laboratory domain




Laboratory Results

# A vision made real..




EU X-Borders

  
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



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

- Scope
- My
- De
- Na
- De
- Crc
- Glc
- IP

## 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 Disposition Implementation Guide	fhir.discom#2022.4-20231006	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

## Release Candidate

# 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)**



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



**Next hands-on events: HL7 FHIR  
Connectathon Dallas May; IHE  
Plugathon Trieste, June**



# Support the adoption (examples, sandbox)

examples

Simple viewer

UNCOM Product Browser

ID	Name	Country	Viewer	Source	Validation
Airomir0.15spray-SE-PLC-MPD	Airomir 0,1 mg/dos inhalationsspray, suspension	Kingdom of Sweden	<a href="#">Viewer</a> <a href="#">Est. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>
Alvedon500mgBrustablett-SE-PLC-MPD	Alvedon 500 mg Brustablett	Kingdom of Sweden	<a href="#">Viewer</a> <a href="#">Est. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>
AMLaurabindo-10mg-Tablet-SE-IS-MPD	Amlodipin Aurebindo 10 mg Tablett	Kingdom of Sweden	<a href="#">Viewer</a> <a href="#">Est. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>
AMLurika-10mg-Tablet-SE-IS-MPD	Amlodipin Krka 10 mg Tablett	Kingdom of Sweden	<a href="#">Viewer</a> <a href="#">Est. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>
AMLsandoz-5mg-Tablet-SE-IS-MPD	Amlodipin Sandoz 5 mg Tablett	Kingdom of Sweden	<a href="#">Viewer</a> <a href="#">Est. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>
AMLvitabalans-10mg-Tablet-SE-IS-MPD	Amlodipine Vitabalans 10 mg Tablett	Kingdom of Sweden	<a href="#">Viewer</a> <a href="#">Est. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>
AMLvitabalans-5mg-Tablet-SE-IS-MPD	Amlodipine Vitabalans 5 mg Tablett	Kingdom of Sweden	<a href="#">Viewer</a> <a href="#">Est. Viewer</a>	<a href="#">XML</a> <a href="#">JSON</a>	<a href="#">Report</a>

Amoxicillin-ratiopharm-750mg-Film-coated-tablet-EE-MPD

**Airomir 0,1 mg/dos inhalationsspray, suspension**  
MPID: SE-100001594-00012324  
EURDID: 10330

Full name: **Airomir 0,1 mg/dos inhalationsspray, suspension**  
- Invented name part: **Airomir**  
- Strength part: **0,1 mg/dos**  
- Pharmaceutical dose form part: **inhalationsspray, suspension**  
Name usage: **Swedish (Kingdom of Sweden)**

Authorised dose form: **Pressurised inhalation, suspension**  
Legal status of supply: **Medicinal product subject to medical prescription**  
Domain: **Human use**  
Resource status: **Current**

Product classification:  
• 100000098065 salbutamol

Marketing Authorisation 1 of 1  
Authorisation number: **12324**  
Region: **Kingdom of Sweden**  
Marketing authorisation holder: **Teva Sweden AB**  
Identifier:  
• LOC-100001602  
Status: **Valid (1996-04-03)**

Administrable Product (1 of 1)  
Dose form: **Pressurised inhalation, suspension**  
Unit of presentation:  
Route of administration:  
• **Inhalation use**  
Ingredients:

Validator

Validation outcome: PASS

UNCOM

# Support the adoption (examples, sandbox)



<http://sandbox.hl7europe.eu/laboratory/>



A  
P  
I



HL7 Europe Laboratory Data Browser				
ID	Name	Viewer	Source	Validation
895	Laboratory Report	<a href="#">View</a> <a href="#">Ext. View</a>	<a href="#">JSON</a>	<a href="#">Report</a>
BundleHepatitisPanel	Laboratory Report Hepatitis Panel - 27 Dec, 2020 14:30	<a href="#">View</a> <a href="#">Ext. View</a>	<a href="#">JSON</a>	<a href="#">Report</a>
BundleLabResultMicroCultureSus	Laboratory Report Bacterial Aerobic & Anaerobic Culture and Susceptibility - 27 Dec, 2020 14:30	<a href="#">View</a> <a href="#">Ext. View</a>	<a href="#">JSON</a>	<a href="#">Report</a>
BundleLabResultReportPOC	Laboratory Report - 10 March, 2023 14:30	<a href="#">View</a> <a href="#">Ext. View</a>	<a href="#">JSON</a>	<a href="#">Report</a>
IT-CD3FHIR-17e2cad1-c3e3-4901-adb1-c35a0b2b883	REFERTO DI LABORATORIO	<a href="#">View</a> <a href="#">Ext. View</a>	<a href="#">JSON</a>	<a href="#">Report</a>
SimpleChemistryResultReport	Laboratorní zpráva	<a href="#">View</a> <a href="#">Ext. View</a>	<a href="#">JSON</a>	<a href="#">Report</a>

Laboratory Report Hepatitis Panel - 27 Dec, 2020 14:30 (FINAL)

Author: MUDr. Aleš Procházka  
Date: 2022-10-25T14:30:00+01:00  
Confidentiality: N

Name: František Očkovaný  
Birth Date: 2000-03-21  
Gender: male

URN:OID:1.2.203.24341.1.20.2:740512852  
URN:OID:1.2.203.24341.1.20.9.1:A225961454  
URN:OID:2.16.840.1.113883.4.330.201:5484136

Results

Hepatitis screening panel

Hepatitis Panel, Acute with Reflex to HBsAg Confirmation and Reflex to HCV by Quantitative NAT

Category: laboratory  
Code: Acute Hepatitis Panel, reflex to confirmation  
Effective Date: 2022-10-25T13:35:00+01:00  
Members:

Category: laboratory  
Code: Hepatitis B Surface Antigen  
Effective Date: 2022-10-25T13:35:00+01:00  
Value: Negative (Normal)  
Specimen Type: Serum specimen  
Specimen Collection Date: 2022-10-25T13:35:00+01:00

Category: laboratory  
Code: Hepatitis B Core Antibody, IgM  
Effective Date: 2022-10-25T13:35:00+01:00  
Value: Negative (Normal)  
Specimen Type: Serum specimen  
Specimen Collection Date: 2022-10-25T13:35:00+01:00

Category: laboratory  
Code: Hepatitis A Antibody, IgM  
Effective Date: 2022-10-25T13:35:00+01:00  
Value: Negative (Normal)  
Specimen Type: Serum specimen  
Specimen Collection Date: 2022-10-25T13:35:00+01:00

Simple viewer

Validation outcome: Issues Detected

Details

Errors (4)

Warnings (17)

Informations (2)

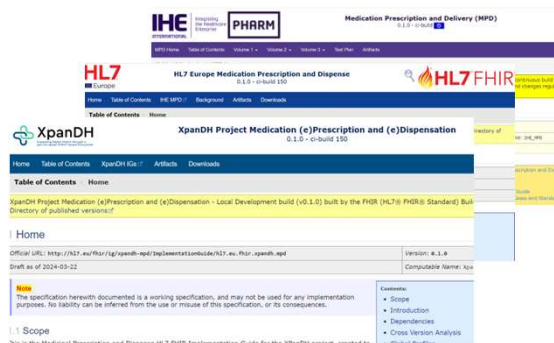
Validator

# XpanDH FHIR IGs

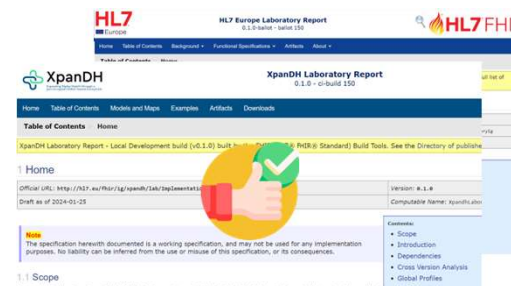
<https://build.fhir.org/ig/hl7-eu/xpandh/>



Patient Summary



ePrescription

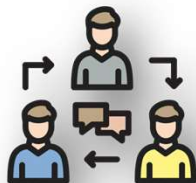


Laboratory Results



Hospital Discharge report

# XpanDH FHIR IGs



X-Bubbles  
X-Nets

## European Standard



derive



This guide



Laboratory Results

derive



X-borders (MyHealth@EU)



align

feedback

co-create

The goal of the XpanDH IGs is to support the EHDS and facilitate the E-EHRxF development.



Laboratory Results



Hospital Discharge report



Patient Summary



ePrescription



This specification has been created to contribute to the development of the European EHRxF for this domain.

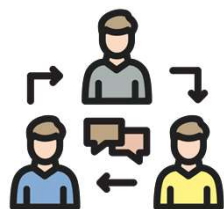
This guide is not intended to replace or override the **HL7 Europe Laboratory Report FHIR IG** or any other Implementation Guide that will be specified by **MyHealth@Eu** and/or **JA-09**

# ePrescription/eDispensation



Global

European Standard



X-Bubbles  
X-Nets

co-create

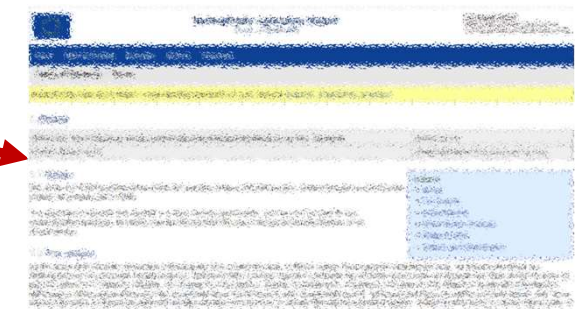
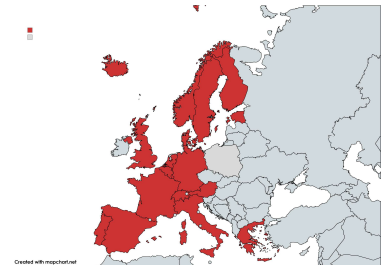
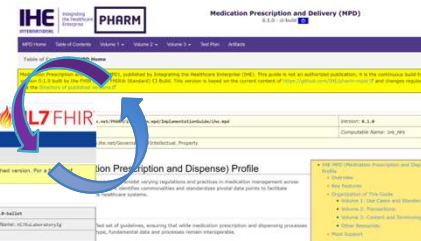
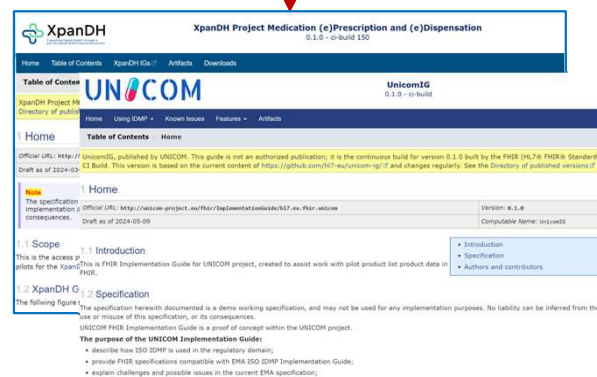
feedback

derive

derive

input for

X-borders (MyHealth@EU)



# A cooperative work

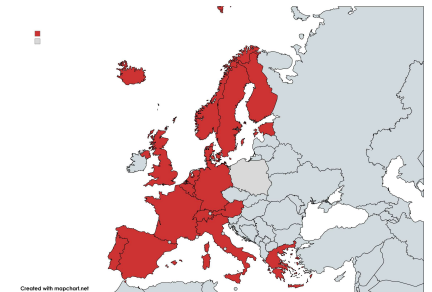


Laboratory Results

## A participatory multi-stakeholders effort

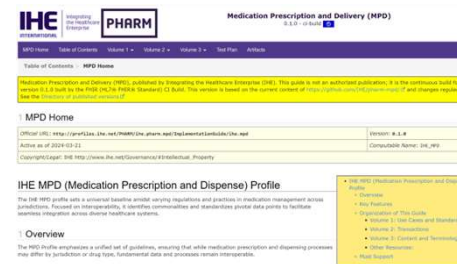
### Experts from several countries

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







Next hands-on event: IHE  
Plugathon Trieste, June

# Medication Prescription & Dispense



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# Medication Prescription & Dispense

<b>IHE MPD</b>   	<b>HL7 Europe MPD</b> 
Community pharmacy and hospital/home care	
Global	Europe
HL7 FHIR R5	HL7 FHIR R4 and R5
Supports cross border use case	Supports <b>EU</b> cross border use case
Transactions & Content	Content only
Mostly terminology-agnostic	May include preferred terminology

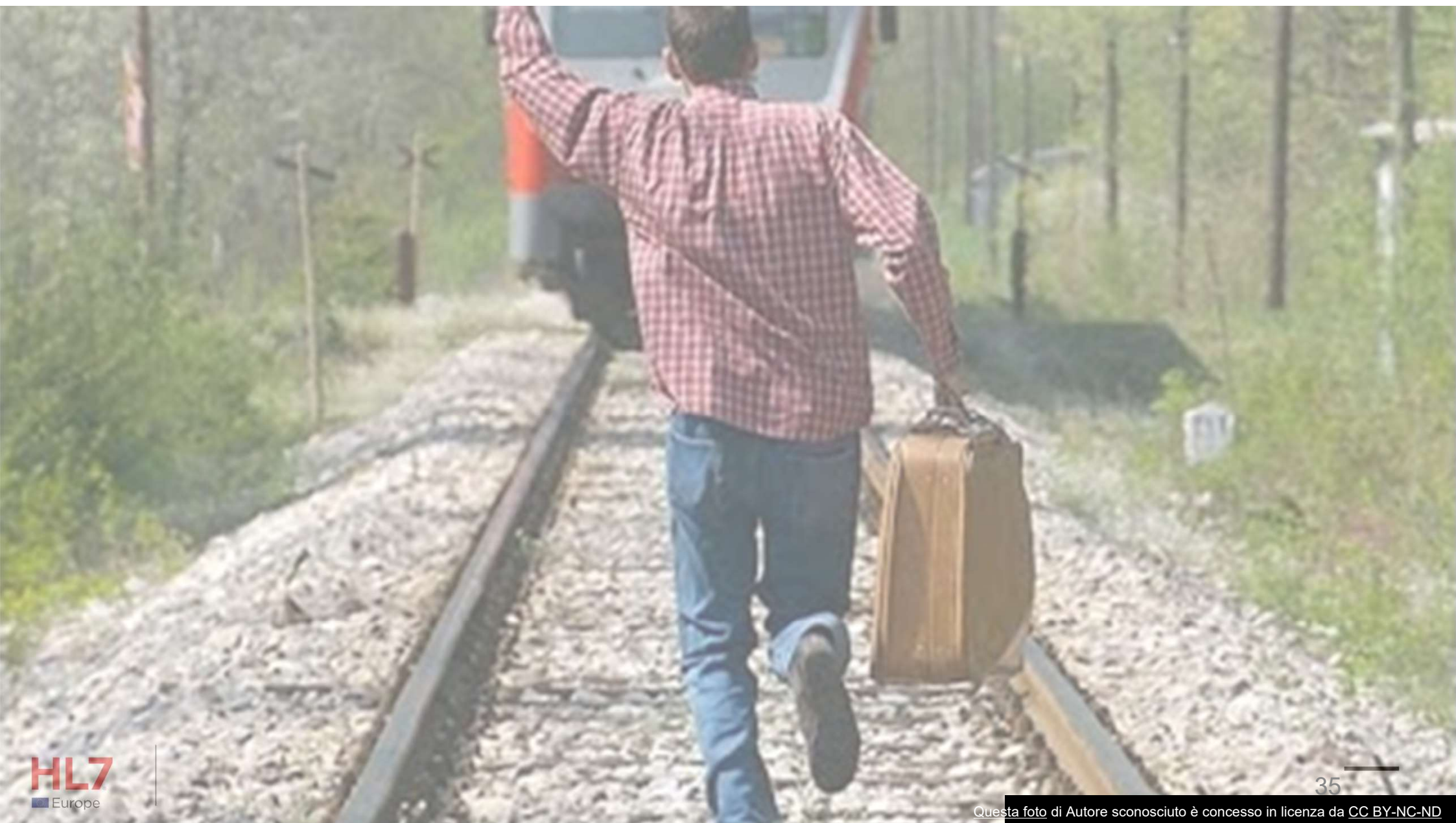
## Take-away messages

- UNICOM: a key work for the “*format*” (medications)
- Some of this work on the “*format*” is carried forward by other projects - as XpanDH, xShare – supporting the format development through a co-creation approach.
- A strategy for the “*format*” - standardization is a key - has been proposed to support and enable a **progressive adoption**

## Take-away messages

- This strategy has been successfully applied for the Laboratory Report and is replicated for **Medication Prescription and Dispense**; and hopefully extended also to the other domains: next in line Hospital Discharge Report.
- ...





# Next Stop



**IHE**<sup>®</sup>  
EUROPE

**CONNECTATHON**<sup>®</sup>  
**TRIESTE**  **JUNE 3-7 2024**



Thank you!



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