Putting resources developed by UNICOM to the test - to your benefit

The conference starts at 09:30

UNICOM Day

Rennes
28 September 2023

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Agenda for this Webinar

- Welcome & Introduction
- What is the value proposition of IHE in the context of IDMP + testing tools
- Teams presentations & Open discussion about the use cases and opportunities/challenges about IDMP
- UNICOM Test lab
  - Submission of variations – Robert Stegwee *
  - Updates to the MPD – Zain Ishfaq
  - NCA to NCPeH – Robert Vander Stichele
  - Including substitution in eDispensation – Angela Ferrara
  - Product lookup for patient facing apps – Nicole Veggiotti
- Discussion

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Welcome

Alexander and Esther (representing WP1 and WP6)

How the UNICOM Test Lab works

- Scope: work on specific use cases to advance and demonstrate the practical use of the Unicom Assets

- Each use case has been served by one or more teams
  - Each team self organised and worked together to demonstrate and test the use case

- UNICOM Test Lab organisation
  - WP6 provided a technical Helpdesk
  - Each team has (if needed) a dedicated space in Github
  - Each team has been comprised with UNICOM Partners and associated entities (third parties)

  - **Still open:**
  - Other use cases relevant to UNICOM and Third Parties are allowed and welcomed.
  - Collaboration with other projects would be beneficial, e.g. Gravitate Health?

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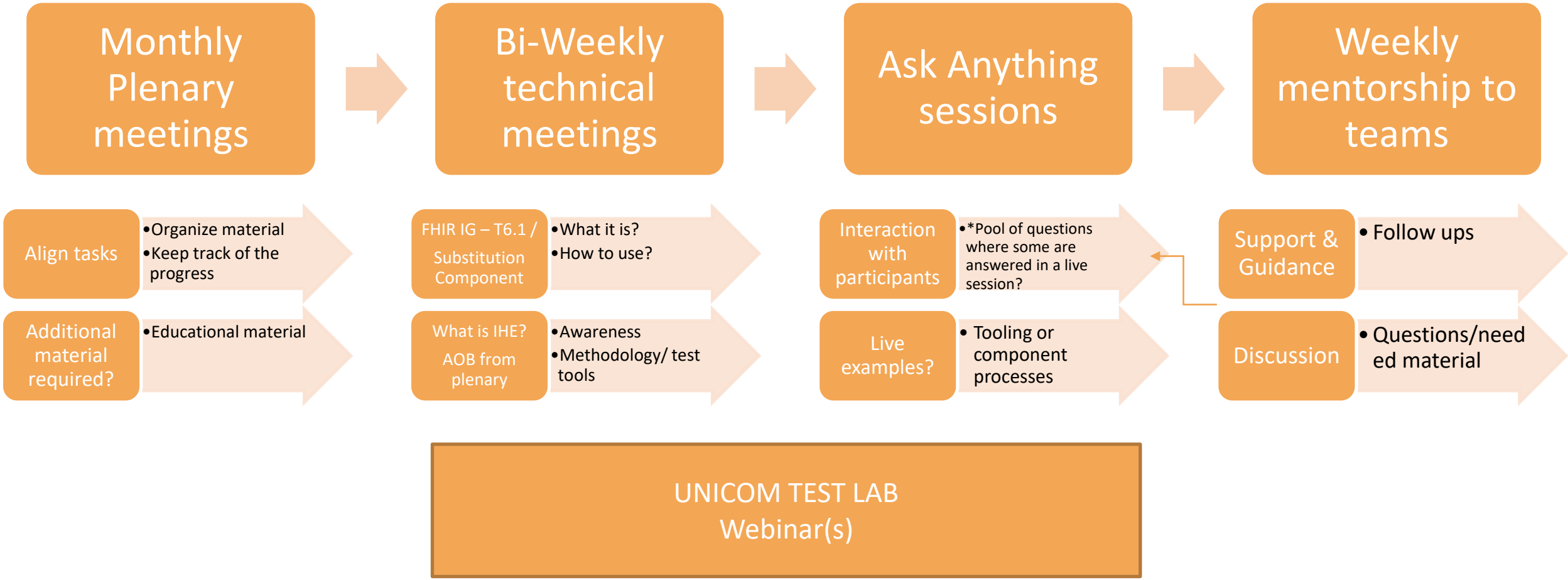
UNICOM Test Lab is about Collaboration and Co-creation



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Roadmap so far

- WP1-WP6-WP12 coordination calls at least once per month
- Plenary Meetings – all participants
  - June 20, 2pm CEST – Kick off organisation
  - July 18, 2pm CEST – Team Goals
  - August 22, 2pm CEST – Progress and open issues
  - September 19, 20m CEST – Progress and open issues -> UNICOM Day
- Educational Sessions on IHE and UNICOM Assets
  - Proposed topics IHE
  - IHE Methodology – how does IHE works?
    - IHE Testing processes – what can we test and how in the next IHE Connectathon in May/June 2024?
    - IHE Pharmacy - how and what to integrate from UNICOM into IHE Profiles
  - Proposed Topics UNICOM
    - UNICOM FHIR IG
    - UNICOM IDMP DB and API
    - UNICOM Test tools
    - GitHub session
- W6 Helpdesk supported teams at any moment with ad hoc teleconferences

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- Update software artifacts and tools in GitHub
- Track issues and document processes
  - Use Github features for open issues tracking and tasks
- Test lab teams management & support
  - Mentoring Sessions
- Support contact points via email (IHE, DW, GNOMON, ARIA) - WP6 Task Leaders
- Better documentation on the software where required
- *Align* with IHE Pharmacy (UNICOM *Profiles/transactions*?)
- Align with eHDSI Testing and Waves (WP7)
- Align with Dissemination activities (WP12)

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Key messages for today

- Testing the UNICOM resources across the landscape
  - Often N:M testing scenarios – multiple systems need to be interoperable with multiple other systems

- What are we looking for in testing
  - Testing needs across the UNICOM work packages, as coordinated by WP1
  - Coordinating testing tools and methodology, as provided by WP6
  - Testing interoperability scenarios between UNICOM resources and the systems they need to talk to
  - Testing conformance to IDMP and related standards and terminologies
  - Define what could be tested in a future Connectathon --> 2024
  - Define what need to be adopted by IHE Pharmacy

- What comes next?
  - Ghent meeting
  - 2024?

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What is the value of IHE in the context of IDMP + testing tools

Derek Ritz

UNICOM

Agenda for this section

- Unpacking: “What is the value of IHE in the context of IDMP + testing tools”
  - What does IHE “do”?
  - What are the component workflows to adopting IDMP in Europe?
  - How will an IHE-supported collaborative lab add value?
- Brief overview of IHE’s **role** in the digital health standards **ecosystem**
- Brief overview of the **IHE Methodology** and its resulting artefacts
- High level “superset” list of our UNICOM **use case participants**
- Connecting the use cases into a UNICOM **data pipeline**
- Implications for the Test Lab and its **value proposition**
- Q&A

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What role does IHE play in the digital health SDO **ecosystem**?

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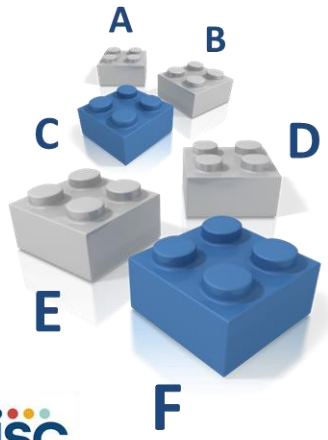
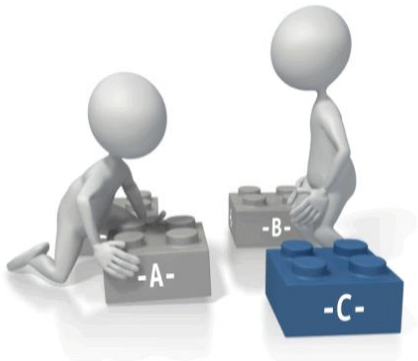
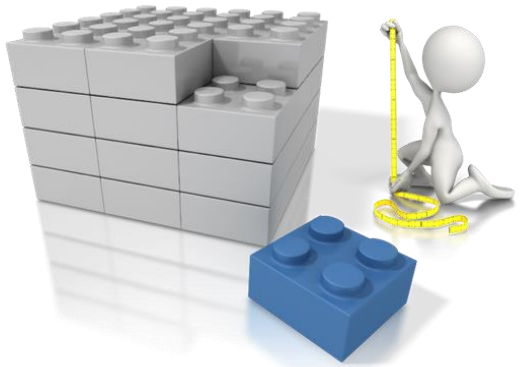
IHE INTERNATIONAL

Making Healthcare Interoperable







Base Standards → Interoperability Specifications → Conformance Testing → System-wide Interoperability

How does IHE play this role?

IHE INTERNATIONAL

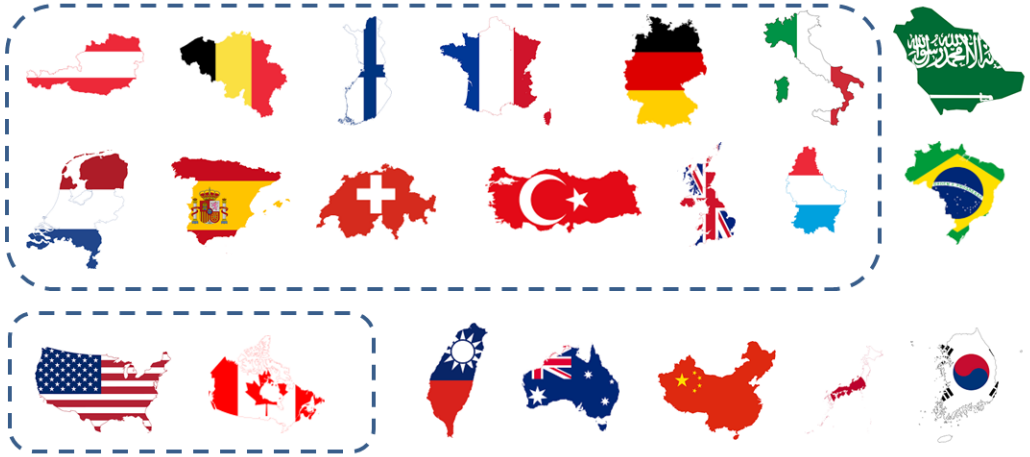
Making Healthcare Interoperable

Domain Committees

Radiology
IT Infrastructure
Pharmacy
Quality, Research & Public Health
Cardiology
Devices
Eye Care
Dental
Pathology and Laboratory Medicine
Radiation Oncology
Patient Care Coordination
Dental

Create engineering artefacts.
boring

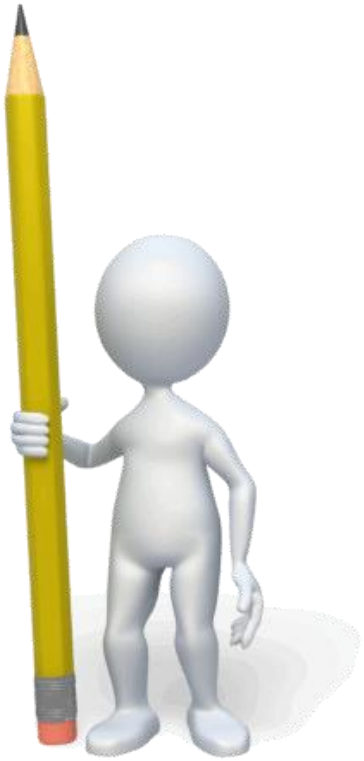
Deployment Committees



Nationalize artefacts.
Conformance-test.
Exert governance.

What is the **value proposition** in creating **boredom**?

Scale is the *innovation*.



Maybe we at IHE should change its marketing “tag line”…

IHE INTERNATIONAL

Taking all the *fun* out of digital health for over 20 years.

What is the **IHE Methodology** and how does it help?

There are **three** key pillars to the Methodology.

1. IHE **Profiles** (implementable actor-transaction specifications)
2. IHE **reference models** (technical frameworks defined in Gazelle)
3. IHE **conformance assessment** (testing events)

IHE Profiles follow a prescriptive **format** and **governance** process

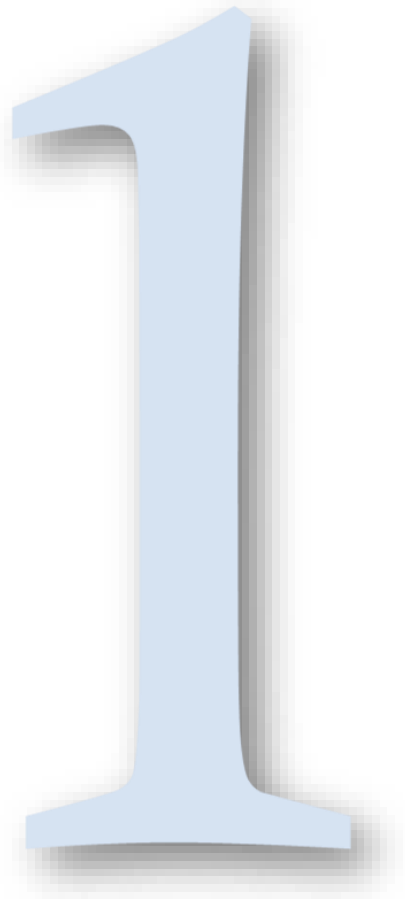
Volume 1:

Volume 2:

Volume 3:

Volume 4:

In Volume-1, the **use case** is described in simple terms.



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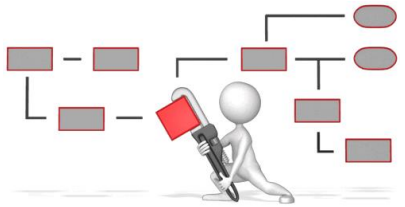
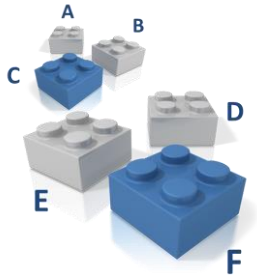


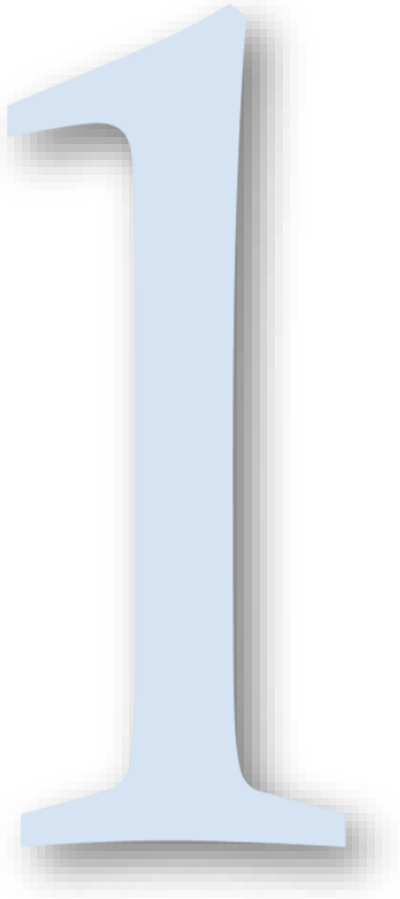


Volume 2:

Volume 3:

Volume 4:

In Volume-2, **actor-transactions** are unambiguously defined.



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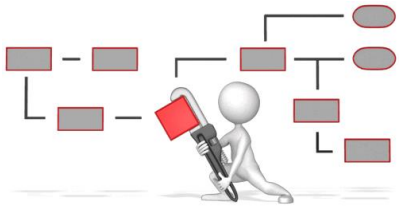

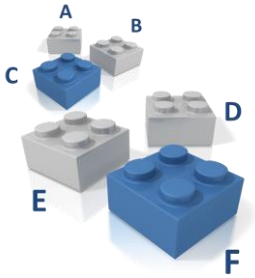

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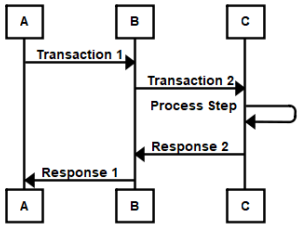
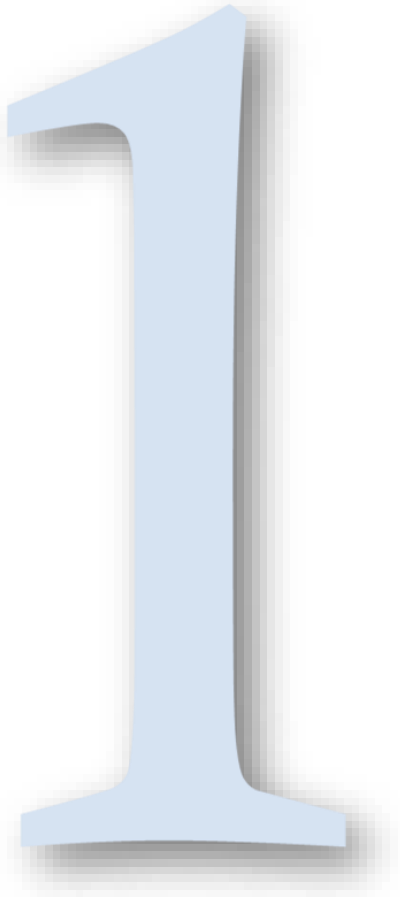


Volume 3:

Volume 4:

In Volume-3, **data content definitions** are normatively documented.



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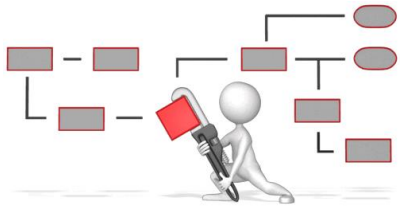

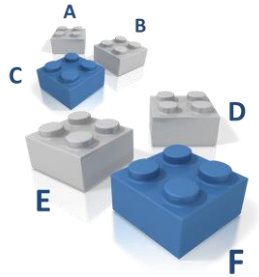

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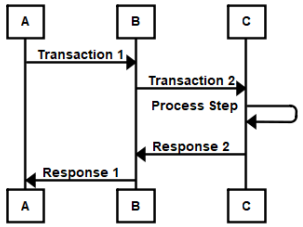

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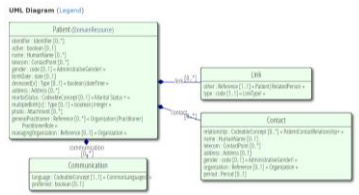
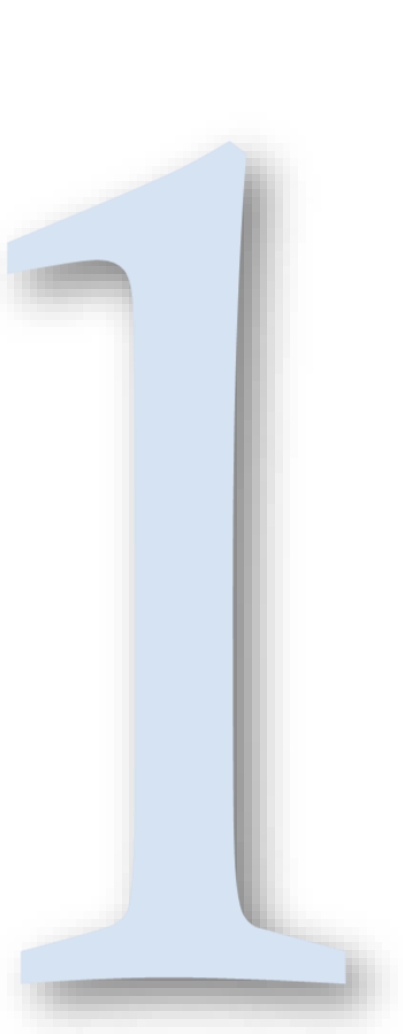


HL7 FHIR HL7 CDA

Volume 4:

It is possible to have a **content-only** IHE Profile.



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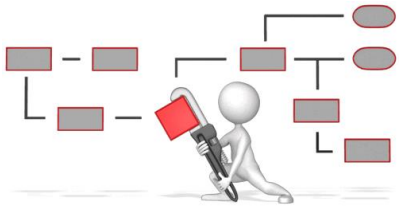

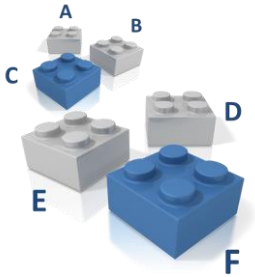

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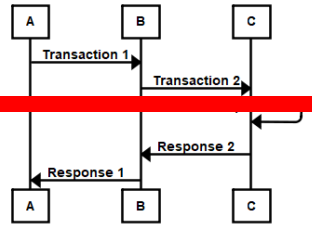
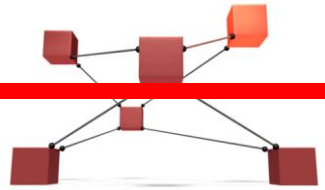
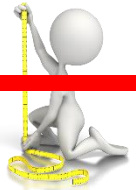
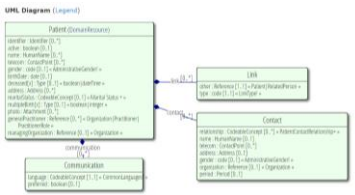






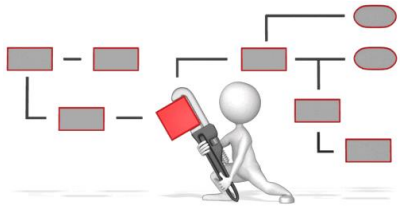
Volume 3:

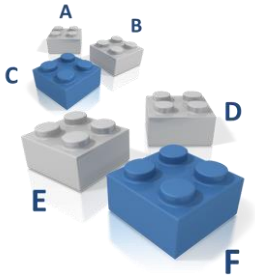


Volume 4:

Volume-4 contains ***regional*** or ***national*** constraints on the **global** spec.

Volume 1:





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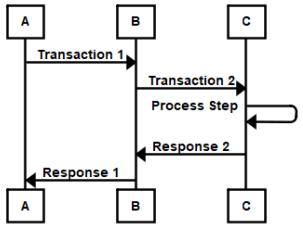

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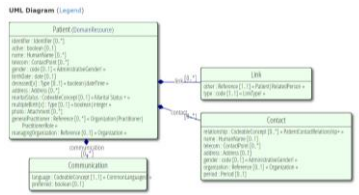
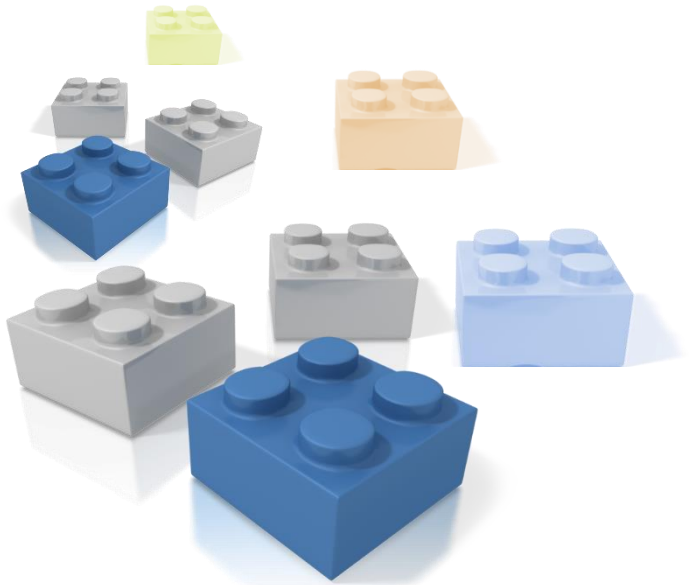


Volume 4:

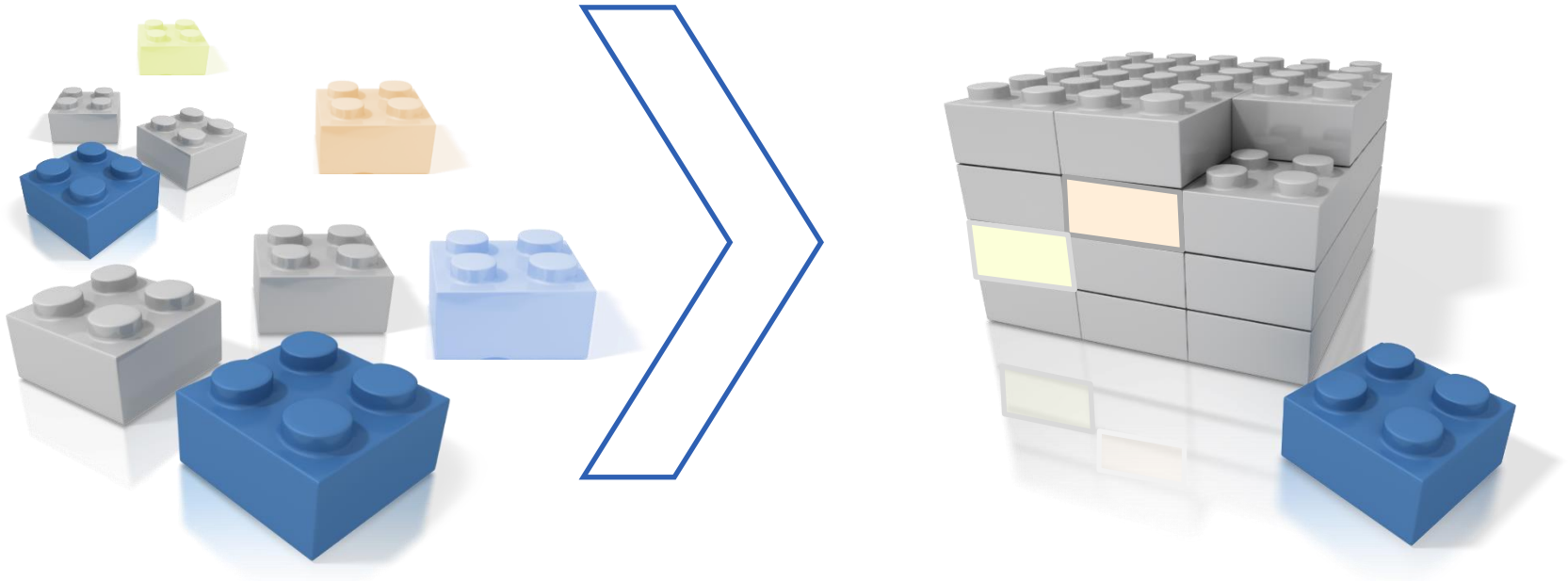
Pillar 2 is **reference models**. These are built from the **IHE Profiles**.

2



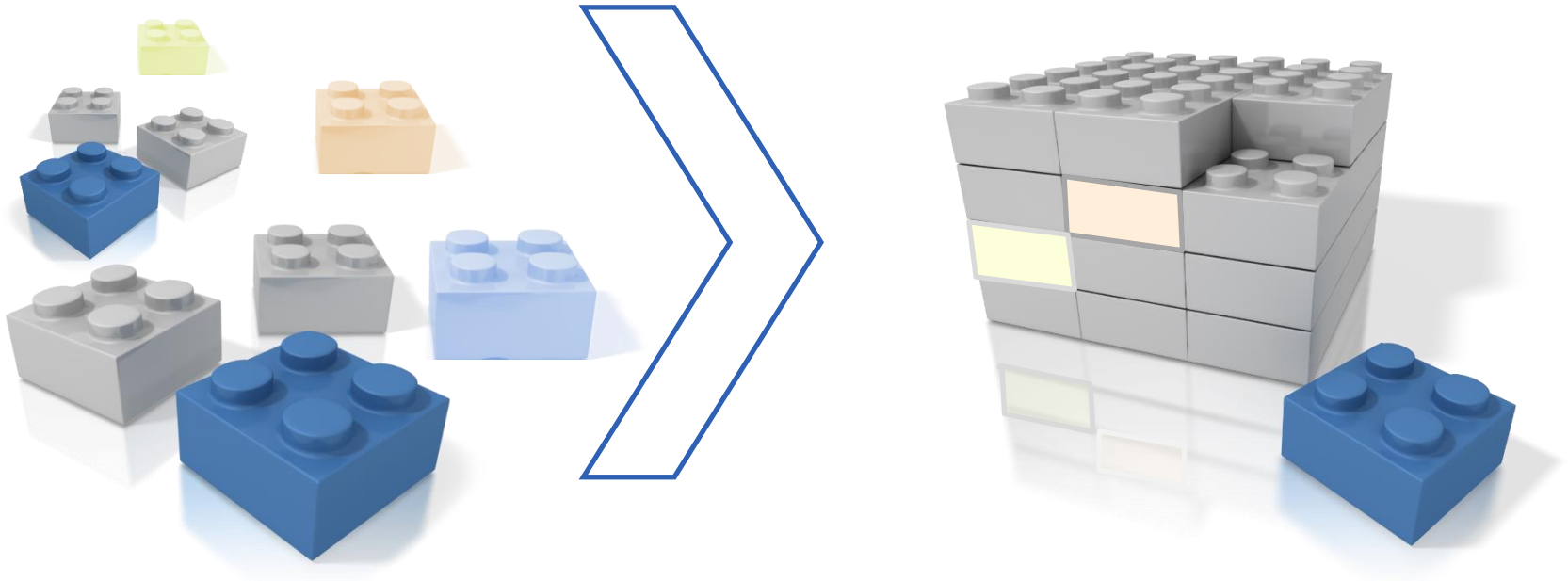
The **models** can be thought of as **assemblies** of Lego® blocks.

2



Their **boringly** engineered dimple patterns means blocks **fit** together.

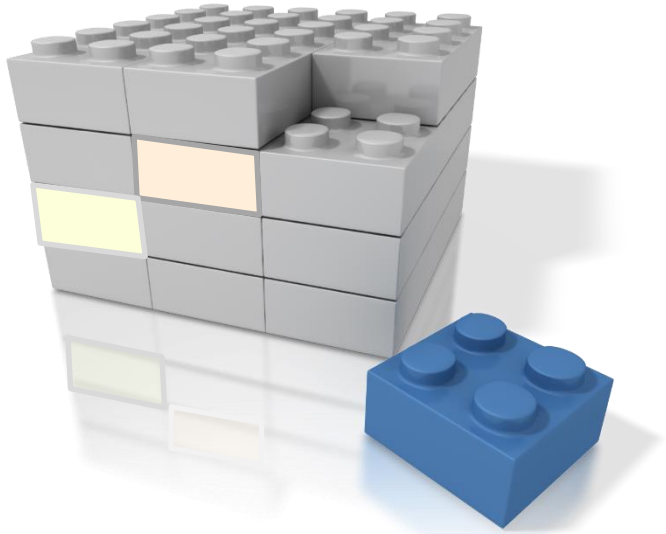
2



The **reference models** are described in **IHE Gazelle**.

2

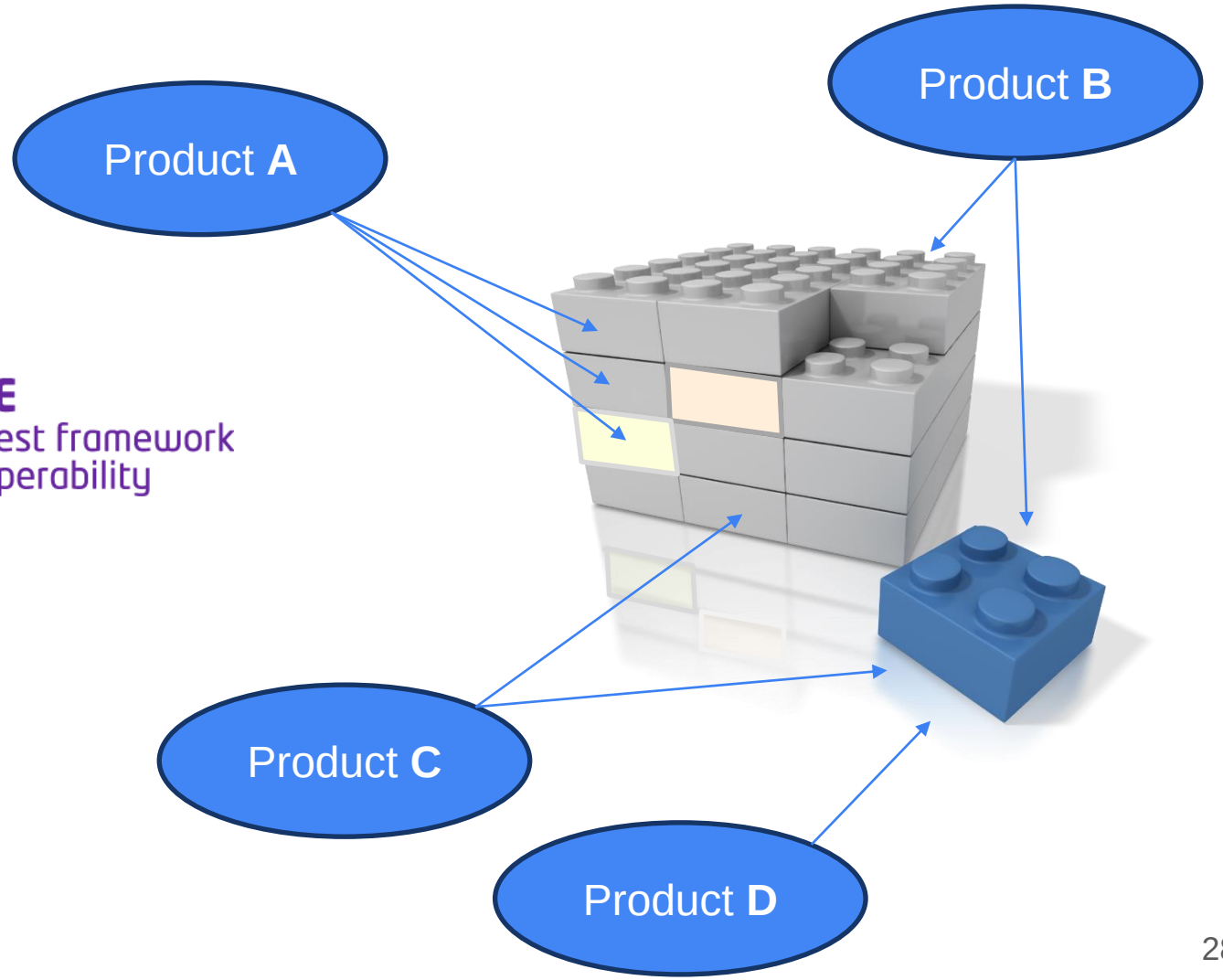
IHE | GAZELLE
eHealth test framework
for interoperability



Software solutions **operationalize** one or more building blocks.

2

IHE | GAZELLE
eHealth test framework
for interoperability

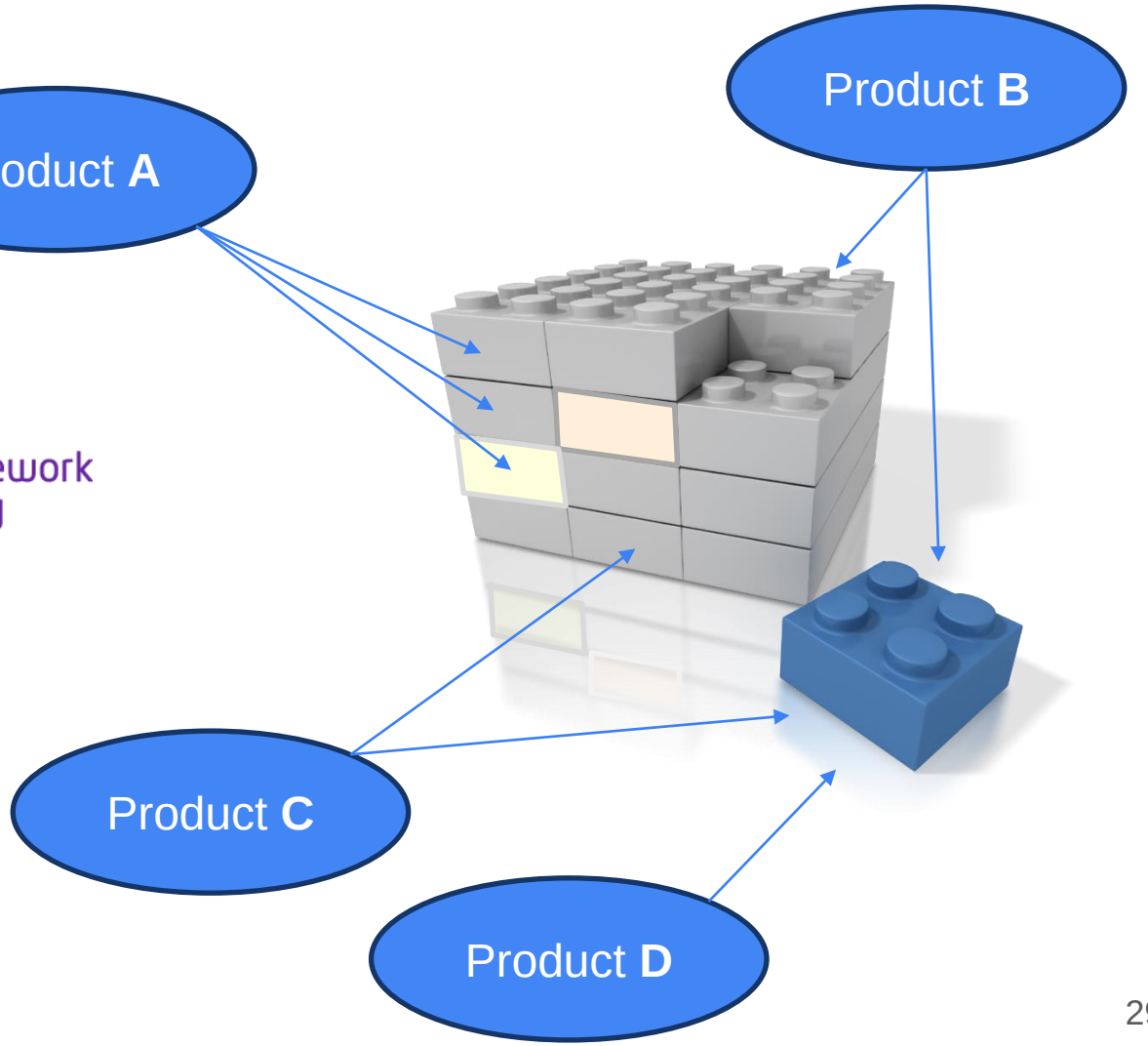


Engineering events can be leveraged to **iterate** the reference models.

2

Gazelle as an instrument of ***innovation***.

IHE | GAZELLE eHealth test framework for interoperability

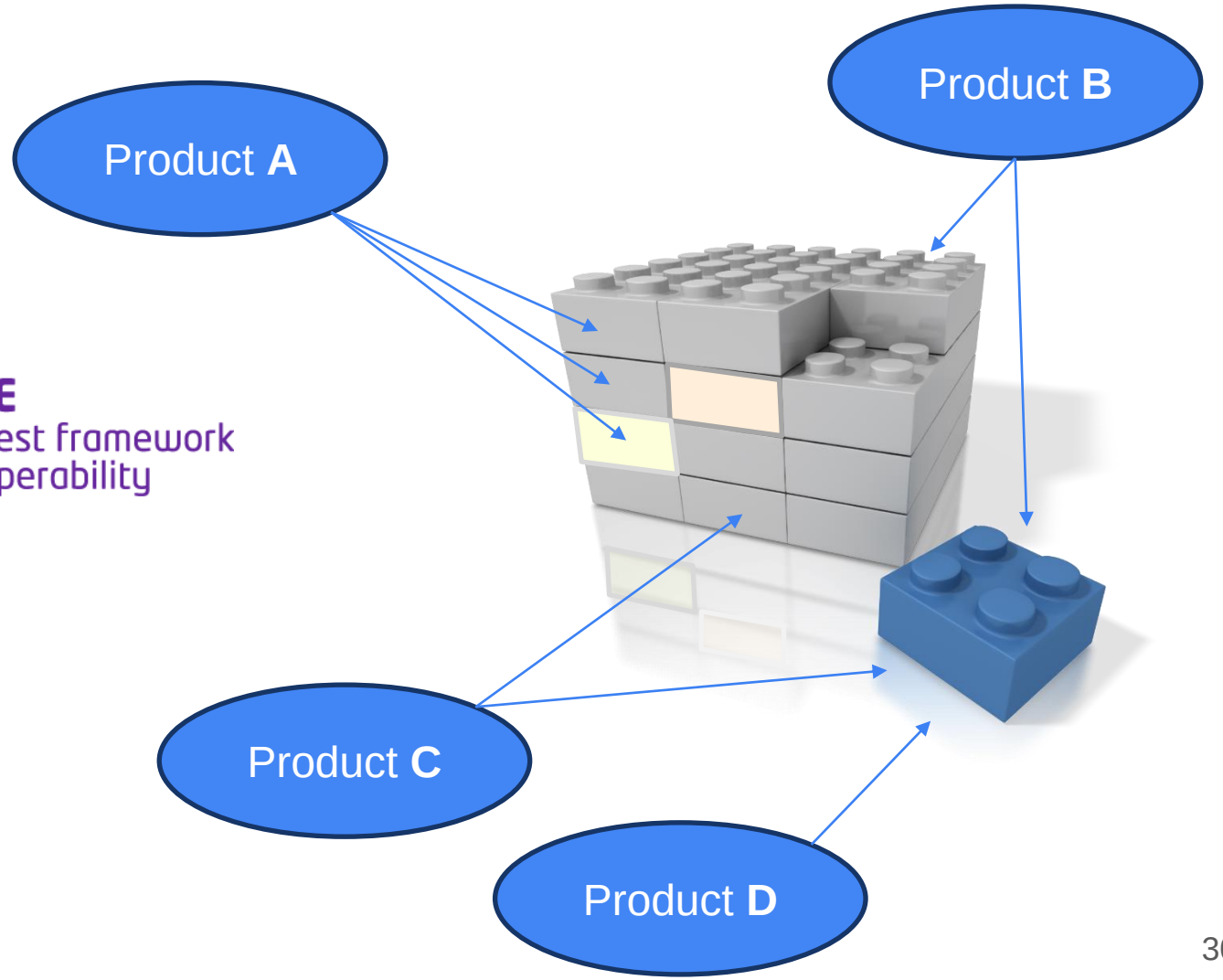


Pillar 3 takes these events a further step – to **conformance** testing.

3

Gazelle as an instrument of ***governance***.

IHE | GAZELLE eHealth test framework for interoperability

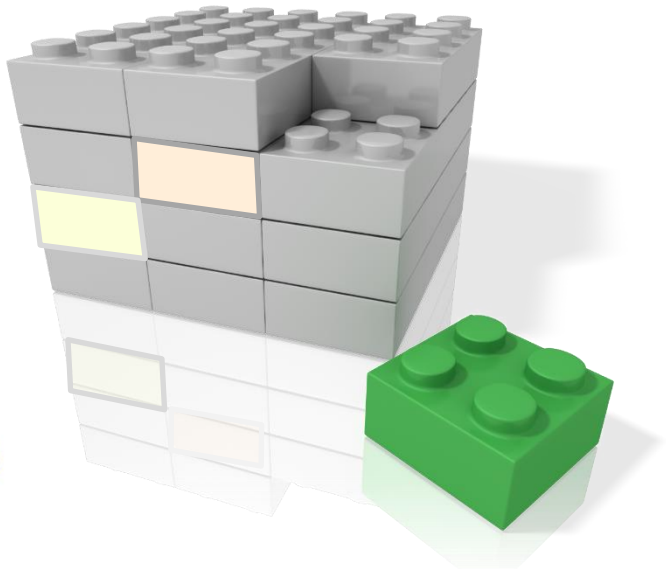


Products that pass the tests **“fit”** with the framework.

3

Gazelle as an instrument of ***governance***.

IHE | GAZELLE eHealth test framework for interoperability



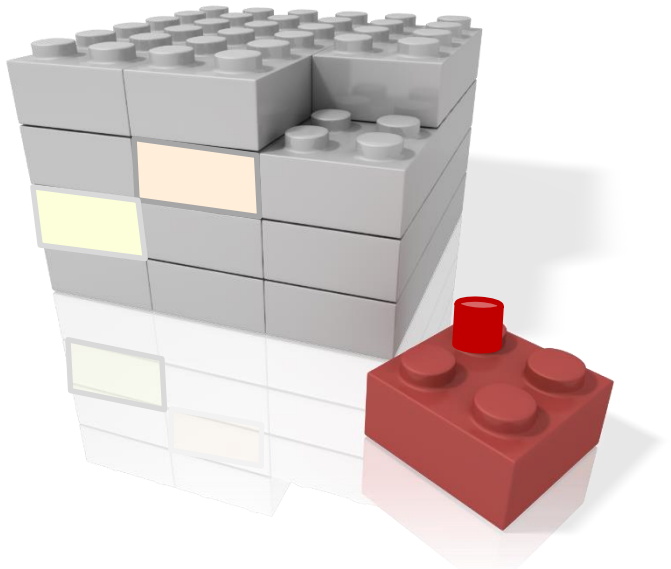
Vendor-1

Products that are **non-conformant** are identified and told what to **fix**.

3

Gazelle as an instrument of ***governance***.

IHE | GAZELLE eHealth test framework for interoperability



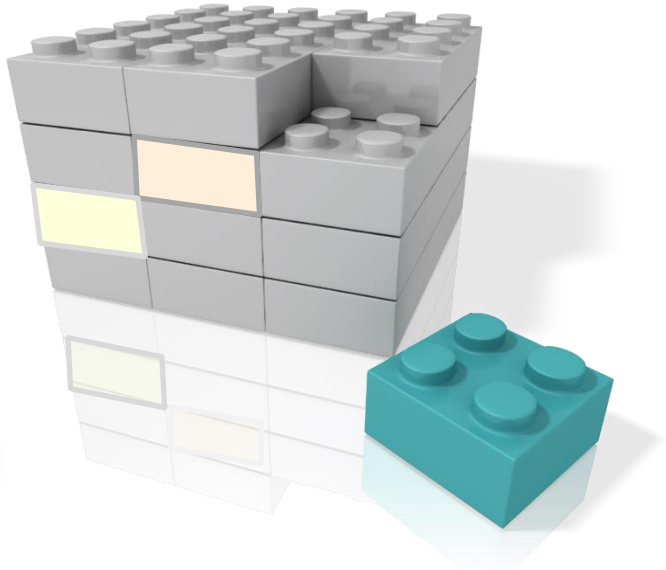
Vendor-2

This process ensures conformant solutions **plug-and-play**.

3

Gazelle as an instrument of ***governance***.

IHE | GAZELLE eHealth test framewo for interoperability



Vendor-3

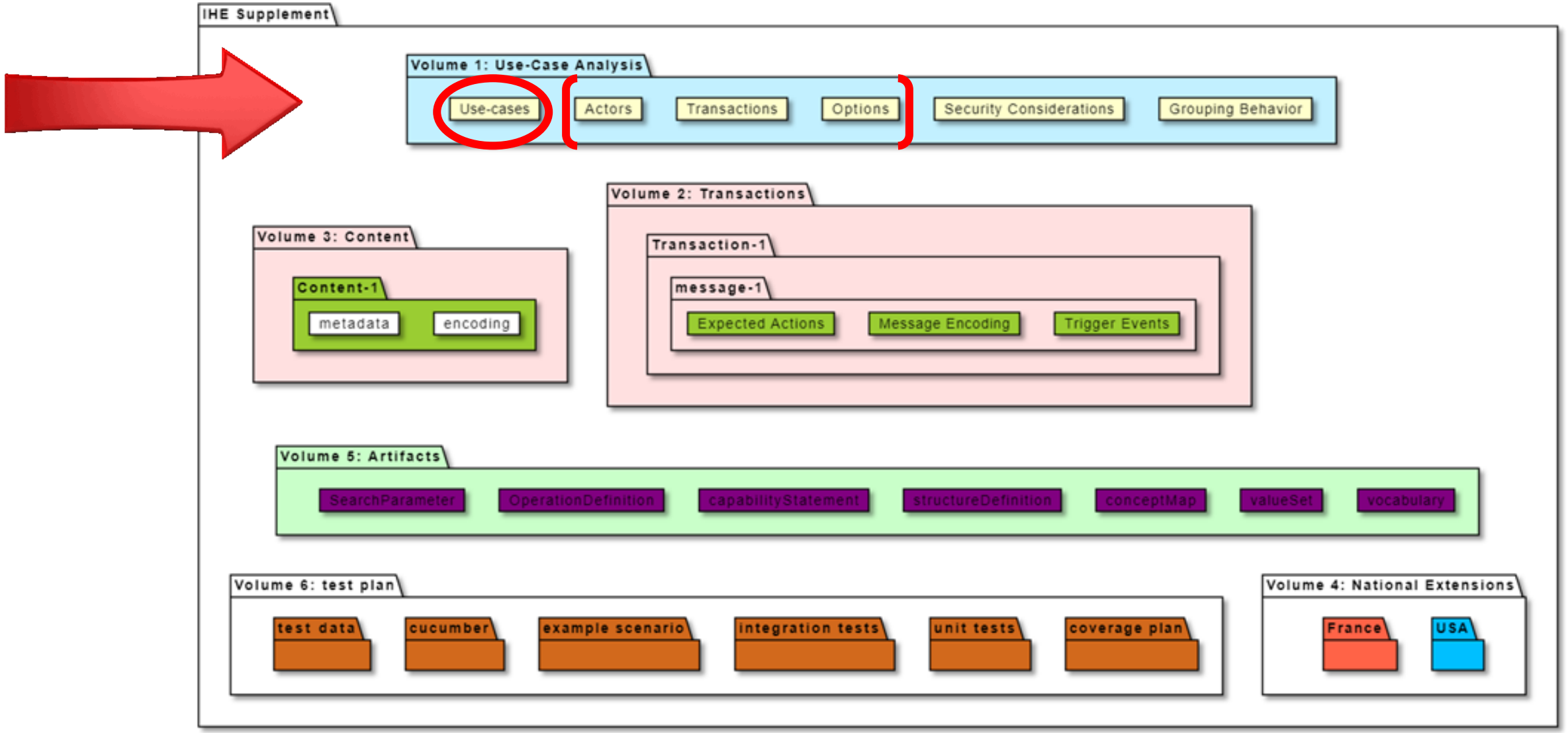
Key takeaways

IHE's mature processes give us a way to take IDMP to **scale** in Europe.

IHE does **not** define new standards. The IHE Methodology is employed to describe how a portfolio of standards are **implemented** to support **interoperability**.

What are our component IDMP workflows and how do they “***connect***”?

We leveraged a “template” to help us define IHE **Volume-1** content.



A checklist of relevant content created consistency **across** use cases.

Section	Notes	✓
Title	Name of the UNICOM use case	
Title description	1-sentence description of the UNICOM use case	
Title version # and date	Update these for each iteration of the document	
Profile Introduction	Fill in the use case name (highlighted in yellow)	
Vol-1 : Introduction	One or two sentences to describe the UNICOM use case workflows; similar to title description.	
Vol-1 : Overview : Concepts	Leverage content developed in the Antilope form to populate a description of the use case context and its business importance.	
Vol-1 : Overview : Participants	List and describe the relevant participants in the use case. NOTE: these should correspond to the participants in any use case sequence diagrams.	
Vol-1 : Overview : Content	List and describe artefacts / documents exchanged by the workflow participants.	
Vol-1 : Overview: References	List complementary or supporting UNICOM documents, deliverables, and/or artefacts	
Vol-1 : Use Case : UC-#	Number and name each use case	
Vol-1 : Use Case : UC-# : Introduction	Briefly introduce the use case	
Vol-1 : Use Case : UC-# : Sequence diagram	Use a diagramming tool to illustrate the use case as a sequence diagram; the participants should coincide with those already described.	
Vol-1 : Use Case : UC-# : Narrative description	Describe the use case diagram; include important notes related to pre- and post-conditions.	
Test Plan : Introduction	Use the gherkin syntax to describe a set of normative, testable scenarios based on the defined use case(s).	

We explicitly reference supporting or **complementary** UNICOM artefacts in our use case descriptions.

Sequence diagrams leverage a consistent **participant** list, so we can see how our use cases “fit together”.

Across ***all*** our UNICOM use cases, **who are the participants**?

Across ***all*** our UNICOM use cases, **who are the participants**?

We want to list the ***systems***… and we need to know who are the relevant ***humans***.

Across ***all*** our UNICOM use cases, **who are the participants**?

Pan-European humans
- Pharmaceutical Company
- EMA

Humans in Country-A
- Patient (*domiciled* in Country-A)
- Provider of care
- National digital health agency*
- MPD governance authority*
- National Competent Authority

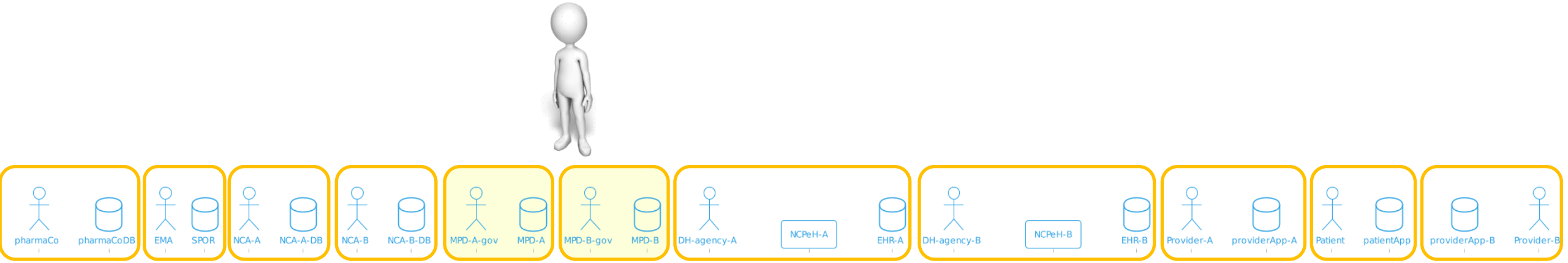
Humans in Country-B
- Provider of care
- National digital health agency*
- MPD governance authority*
- National Competent Authority

Pan-European Systems
- Pharma Company's database
- SPOR

Systems in Country-A
- Patient's app
- Provider's app
- National EHR*
- NCPeH (eHDSI gateway)
- MPD
- NCA's database*

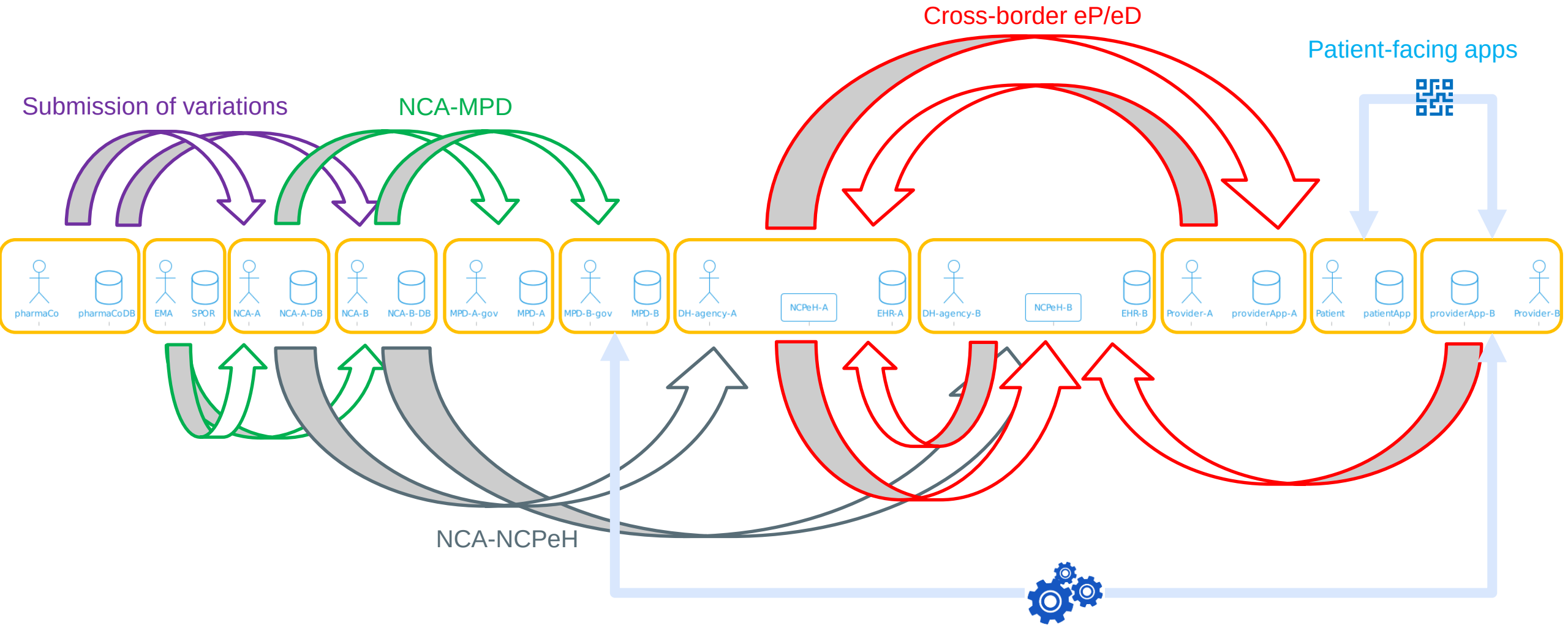
Systems in Country-B
- Provider's app
- National EHR*
- NCPeH (eHDSI gateway)
- MPD
- NCA's database*

What are the **governance** relationships between systems and humans?

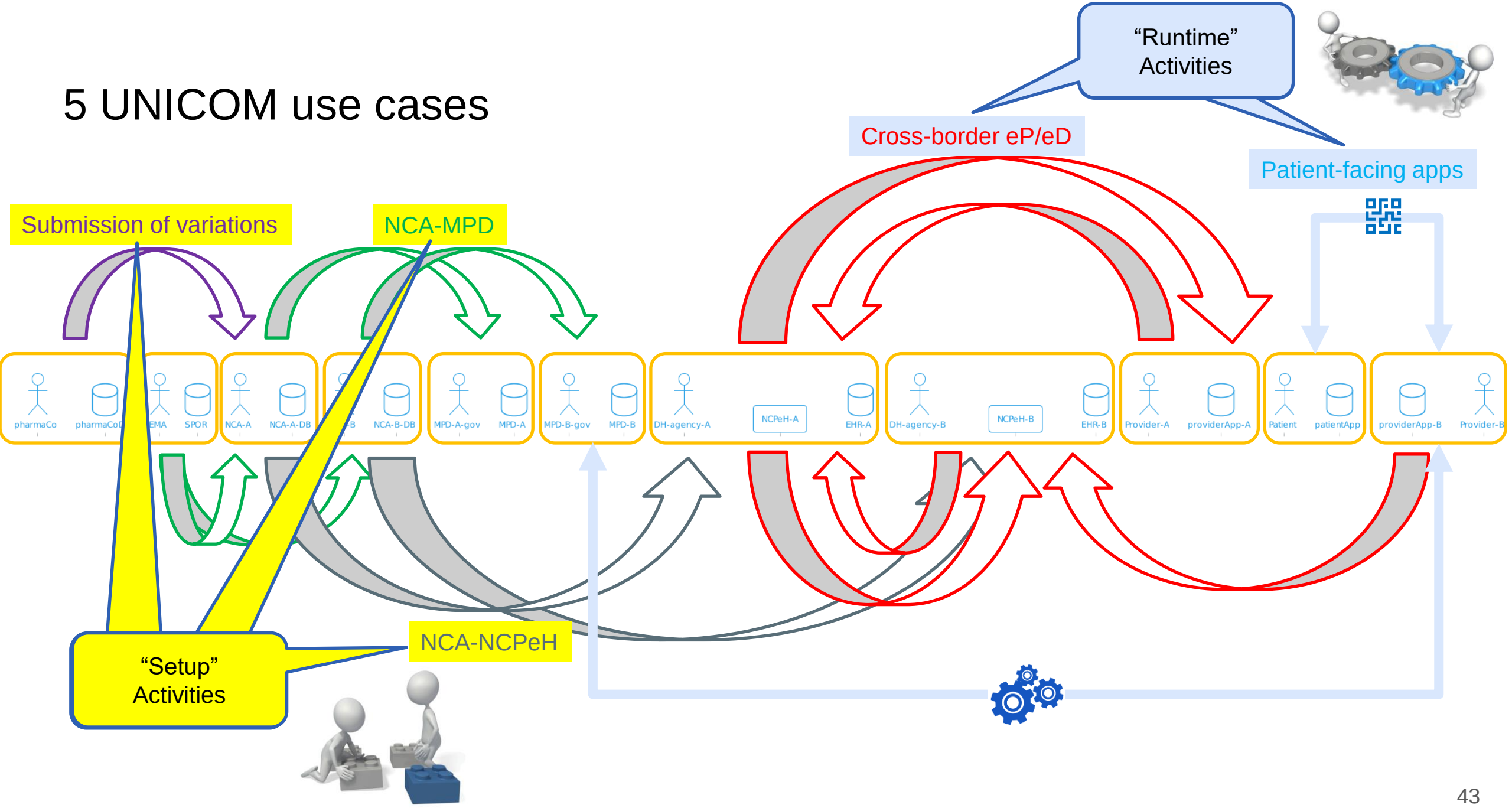


- **MPD** *governance* and *scope* seem to differ from MS to MS.
- Sometimes the MPD is governed under the auspices of the **NCA**, sometimes under the **national digital health agency**, and sometimes there is a ***separate*** MPD entity.
- Also… sometimes the MPD is a **library**, used to regularly update provider applications… and sometimes it is a **real-time OLTP service** that includes medicines substitution logic.

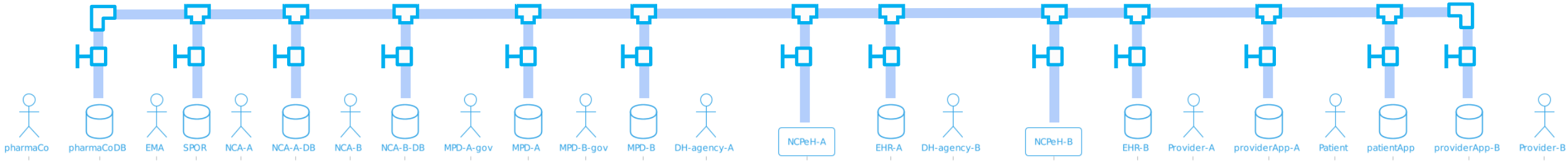
5 UNICOM use cases



5 UNICOM use cases



If we *connect* our use cases, we start to see our **UNICOM data pipeline**.



There is a predecessor-successor relationship between our use cases. Elements of our **“data pipeline”** must be *set up* before our care delivery (“*runtime*”) use cases are ***doable***.

To mitigate risk, we've been working to create test data to support use cases that rely on a pipeline that is **not yet in place** (UNICOM T6.1).

What does this tell us about our Lab's **value proposition**?

The Lab’s value chain starts well ***in advance*** of conformance testing.

Innovation

Implementability

Governance

The Lab's value chain starts well ***in advance*** of conformance testing.

Innovation

Implementability

Governance

We want to **collaborate** with the relevant stakeholders as early in the process as possible so that the **use case definitions** are correct.

We want to **prototype**, where we can, to ensure we "**want the right things**" from our technology solutions. We're actively doing this, for example with **FHIR** community members.

The Lab's value chain starts well ***in advance*** of conformance testing.

Innovation

Implementability

Governance

Scale is the innovation.

We need to involve **industry players** *early on* to ensure our normative IDMP specifications can be widely adopted and deployed.

The Lab's value chain starts well ***in advance*** of conformance testing.

Innovation

Implementability

Governance

When the time comes, we will leverage the lab to **conformance-test** digital health solutions.

Member states can reference test result evidence as a requirement in solution **procurement** documents.


Q
&
A

Test lab use cases

High level

UNICOM

The use cases that fit with the UNICOM resources developed

- Submission of variation
- Updates to the MPD
- NCA to NCPeH
- Substitution in eDispensation
- Patient-Facing Apps

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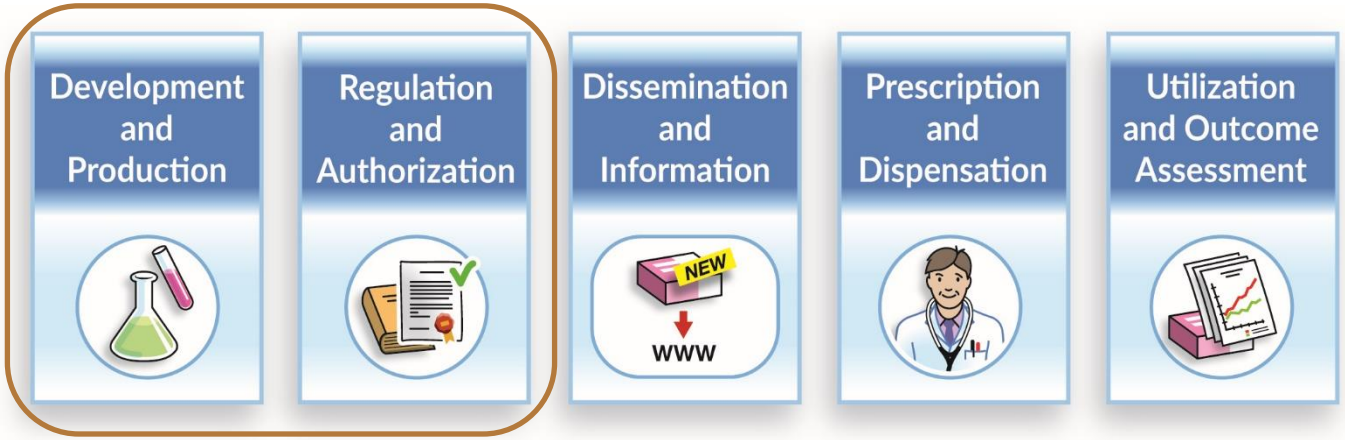
Use case : Submission of variation



Company A disposes of Marketing Autorisation for «Sweetdreams», a medicinal product sold in country A.
An excipient has to be replaced by another.
This information is communicated to the local NCA with a structured electronic message (HL7 FHIR).
Local NCA acknowledge receipt of the information with a structured electronic message (HL7 FHIR).

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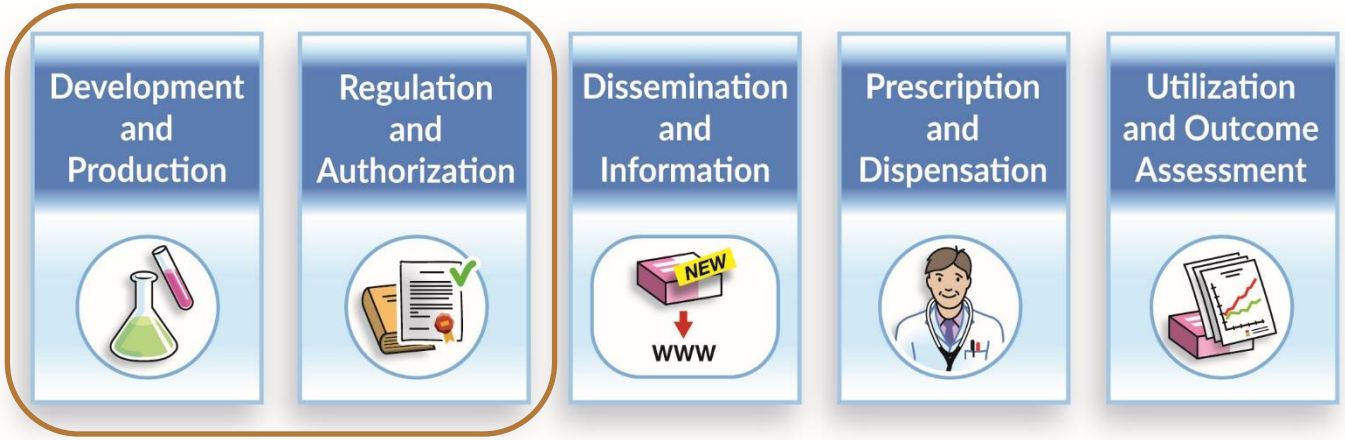
Use case : Submission of variation



The use case consists in:

- Company generates FHIR message with right information (right data regarding substance ID).
- NCA received and manages incoming structured message without alteration

- NCA sends acknowledgment structured FHIR message to Company
- Company receives and manages incoming message without alteration

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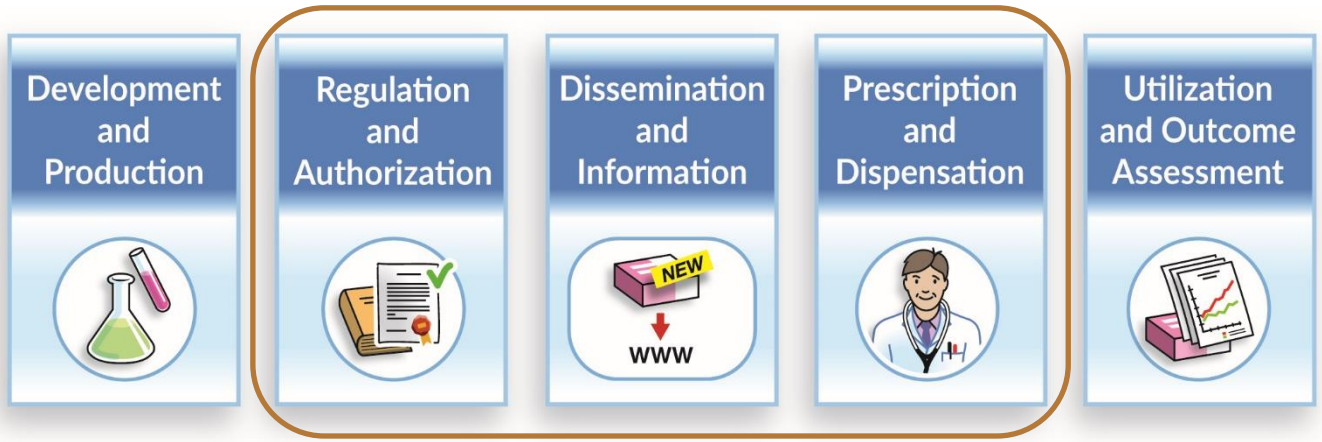
Use case : Updates to the MPD



NCA in country A publishes updates on authorized medicinal products to all MPD providers in country A
Newly authorized medicinal products need to be added, canceled authorizations need to be removed
The current authorized list of medicinal products for country A need to be integrated in the MPDs across the country
The NCA provides the detailed updates to the MPD providers in an electronic format (FHIR)
MPD providers each acknowledge receipt and processing of these updates with an electronic message (FHIR)

For consideration:
MPD provider needs to propagate the changes in the authorized medicinal products to the clinical systems
- Pharmacy Information Systems, Electronic Health Record Systems, Medication Management Systems, etc.

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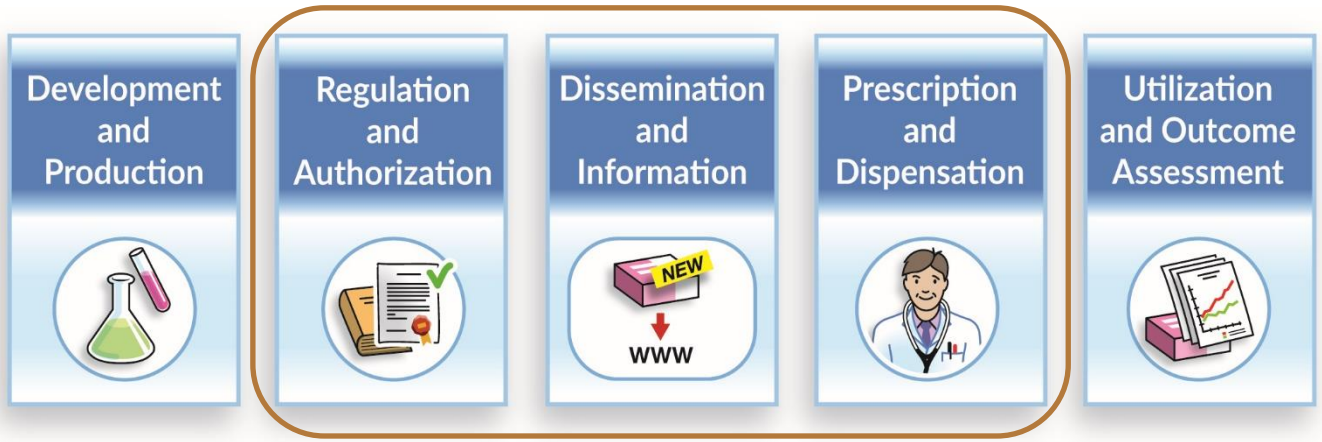
Use case : Updates to the MPD



The use case consists of:

- NCA compiles the changes to be communicated in a FHIR bundle (fully updated and identified medicinal products)
- MPD receives FHIR bundle without further alteration
- MPD processes the changes and flags any inconsistencies in e.g. product identification in its own database
- MPD provides feedback to NCA on receipt and processing of the updates provided in a FHIR bundle
- NCA receives acknowledgement and processes the feedback provided

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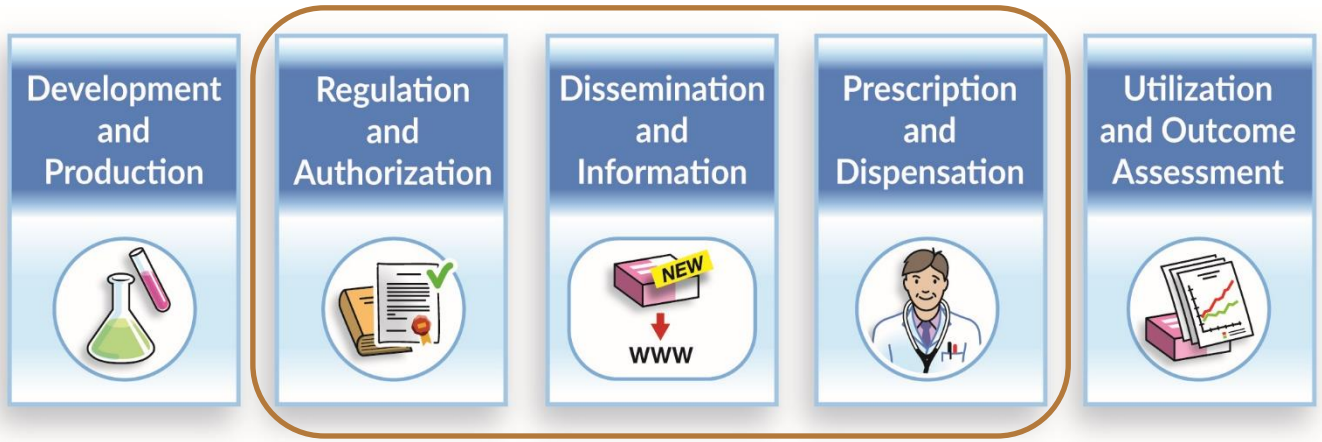
Use Case: NCA to NCPeH



- This use case is about aligning the work done in NCAs with the subset of IDMP attributes needed for the cross border eP/eD
- The idea is to analyse and propose a approach to automate this process as the MALeH will evolve between different waves of the MyHealth@EU services
- The assets provided for this use case are
  - The semantic assets defined in D6.4
  - The IDMP database and database API provided in D6.1
- The scope of this use case is to synchronise the medication list used in cross border with the NCA list with the use of IDPM

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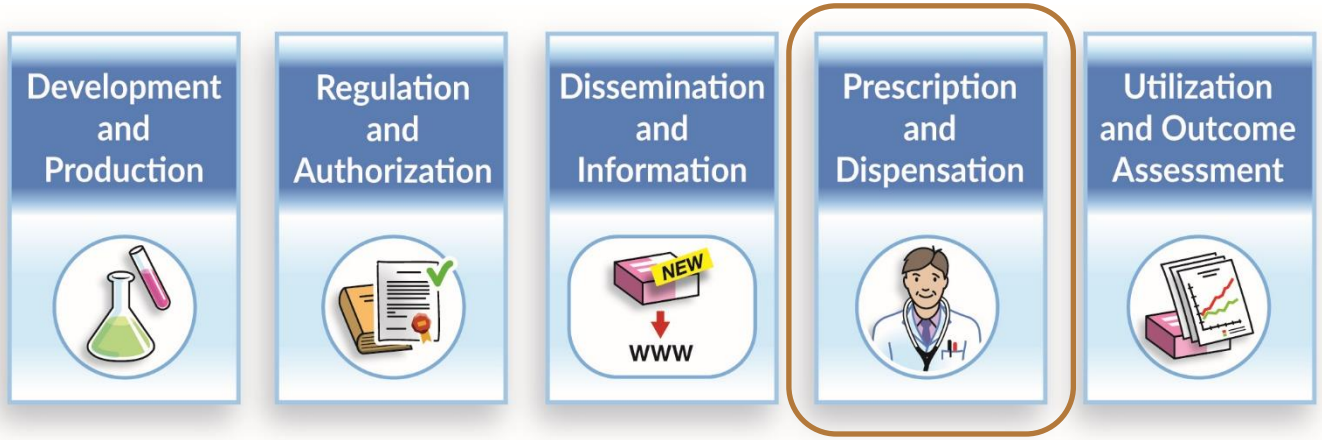
Use case : Substitution in eDispensation



What if:
a Greek patient shows up in a Belgian Pharmacy and requests to be dispensed for

αμλοδιπίνη Κάψουλα σκληρή 10mg

By identifying the IDMP data on the box, the pharmacist realizes that this about

amlodipine,

and more specifically :

amlodipine besilate capsule, hard 10mg

In Belgium available as : Amlor 10 mg (Upjohn), and in generics by a number of companies but as tablets

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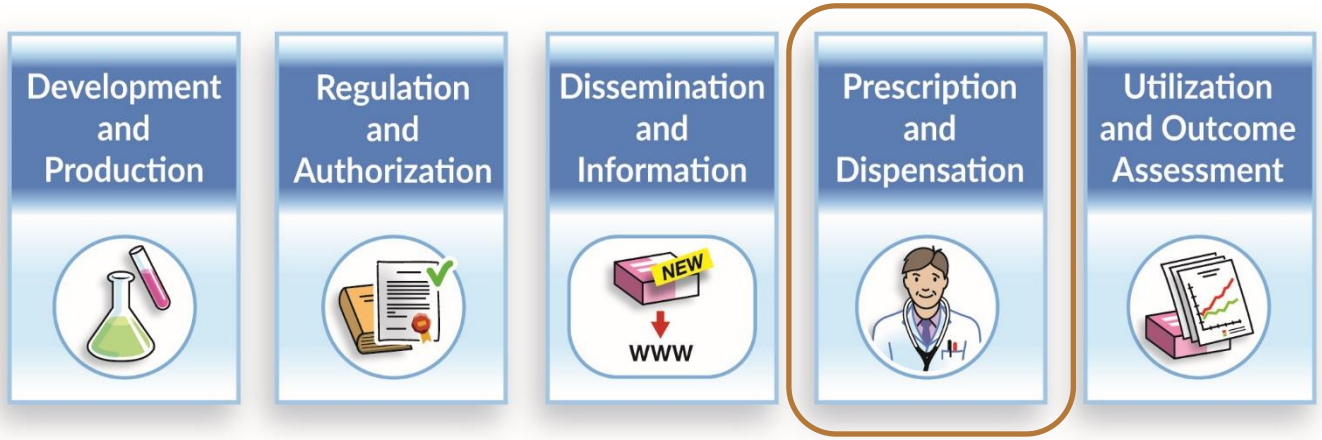
Use case : Substitution in eDispensation



The use case consists of:

- Two countries participating in eHDSI
- Cross-border exchange of enhanced ePrescription with ISO IDMP attributes (MALeH)
- Country B, country of eDispensation, applies the substitution rules and national rules if required
- Country B, sends back to Country A the updated CDA of eDispensation

- Teams created for this use case to take into consideration the testing strategy and testing processes of eHDSI (WP7)

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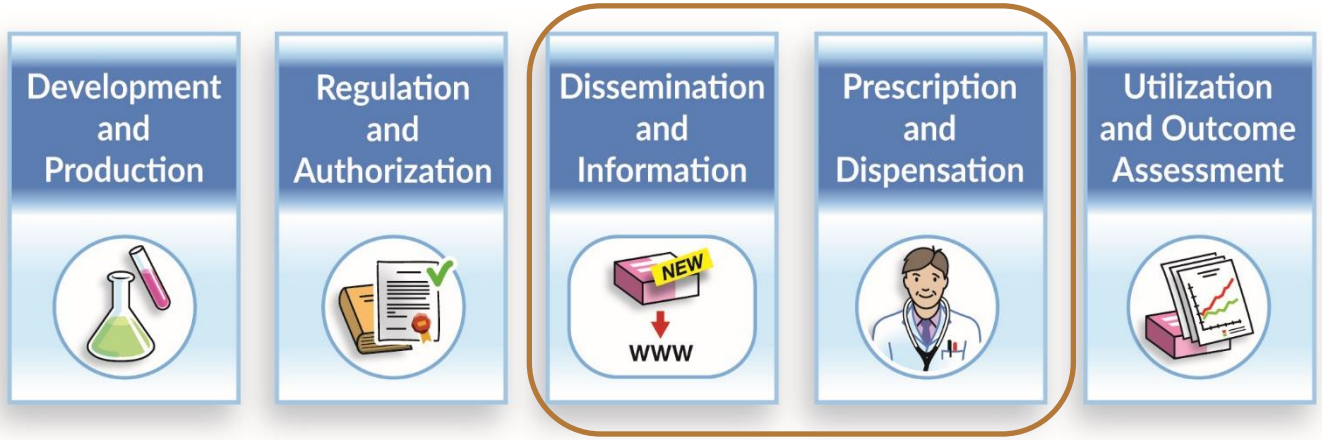
Use case : Patient-Facing Apps



Mario travelled to Greece for a trip and forgot to take his medication to treat hypertension with him.
He uses a patient-facing app to manage his medication while communicating with a pharmacist in a foreign country.

The use case consists of:

- Usage of the Smart Substitution component
- Access through FHIR API to IDMP Database
- Mobile application interaction

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Submission of variations

Robert Stegwee

UNICOM

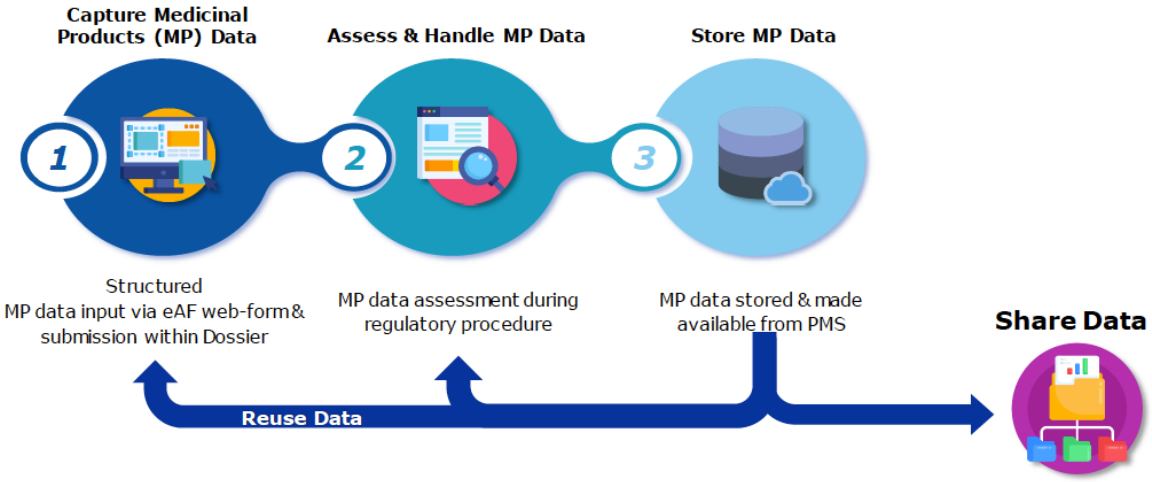
▶Submission of variations

Purpose: to support the investigation of future interoperable use of the **variations web-based electronic Application Form (eAF) for Human medicinal products** in the EMA PLM Portal, as co-developed with UNICOM WP3 (former DADI project).
The creation of the variations eAF by applicants could reuse the already existing structured data in their internal systems. The processing of the variations eAF by receiving NCA's is being implemented (WP4) but could benefit from multi-stakeholder testing.

▶Context: MP Data in Europe

▶Process: regular CAP and NAP submission

▶Main contact: Robert Stegwee



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- Future actions on the roadmap:
  - Replace forms for initial marketing authorisations (human and veterinary), variations for veterinary medicinal products and renewal forms (human only) for CAPs and NAPs
  - Support data cleansing in collaboration with PMS
  - **Explore further machine-to-machine solutions**

- Re-use structured data to decrease re-keying and subsequent errors
  - From applicant to create eAF, to be included in dossier
  - From applicant to EMA in CAP submission
  - From applicant to NCA in NAP submission

- Re-thinking the processes to eliminate and automate steps
  - Enable streamlined and simplified processes, with automated data imports facilitating procedure handling by regulators

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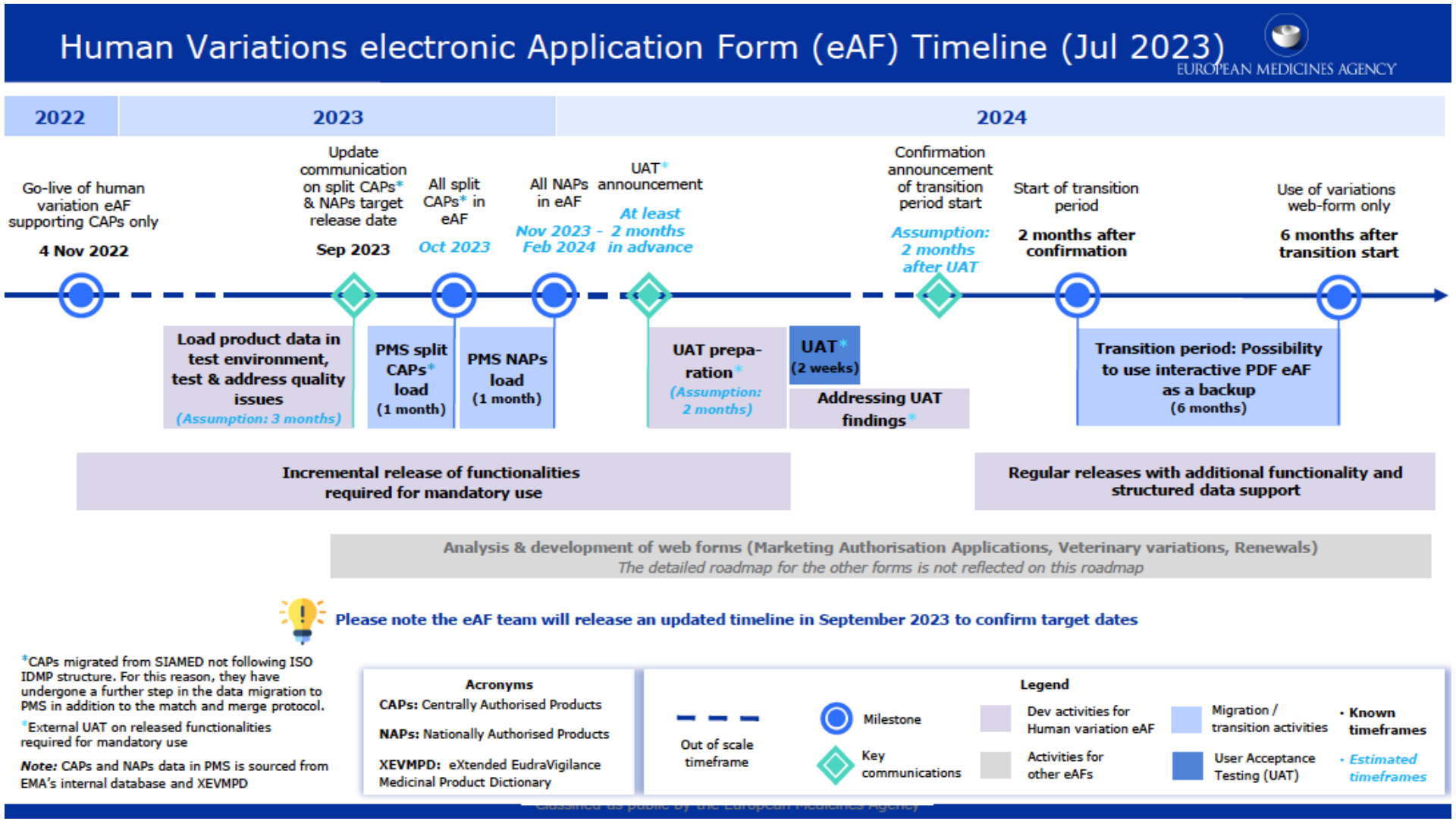
EMA timeline



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- Further contact with the Pistoia Alliance on the creation of FHIR excerpts for submission based on the IDMP Ontology that they are creating
  - The IDMP Ontology will enable industry partners to provide their internal data in an IDMP compliant format
  - By creating FHIR excerpts for submission, based on the IDMP Ontology, industry is supported in the implementation of FHIR for IDMP
  - IDMP Ontology group is looking into alignment with the UNICOM FHIR IG (linked to the IDMP Database in WP 6)

- Future testing scenarios are likely to include:
  - RIM electronic submission to NCA in HL7 FHIR format (RIM – Regulatory Information Management)
  - RIM receives submission response from NCA in HL7 FHIR format
  - IDMP Ontology is used to feed product and publishing data to RIM in HL7 FHIR format
  - IDMP Ontology is used to make HL7 FHIR response available to internal (product and publishing) systems for checking

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Questions and next steps

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Update to the MPD

Zain Ishfaq and Esther Peelen

Purpose, benefits and involved stakeholders

- **Purpose**: to support the accurate and efficient sharing of medicinal product data via the National Competent Authority to the Medicinal Product Dictionary for further distribution in clinical systems by using IDMP
- Benefits: reuse of high-quality data including IDMP-identifiers. Results in less (manual) updating: more efficiency and more accuracy.
- Role of IHE: based on a harmonised process description, IHE-profiles can be drafted for testing the standardised process including standardised data for a seamless and automated dataflow
- Process description set up in cooperation with Z-Index, CBG. Vidal
- And with the help of the material made by WP9, material shared by Rutt Lindström and the insights of the people involved with the UNICOM day.

- Main contact: zain.ishfaq@nictiz.nl esther.peelen@nictiz.nl

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EMA SPOR

- Substance Management Services (SMS)
- Product Management Services (PMS)
- Organisation Management Services (OMS)
- Referentials Management Services (RMS)

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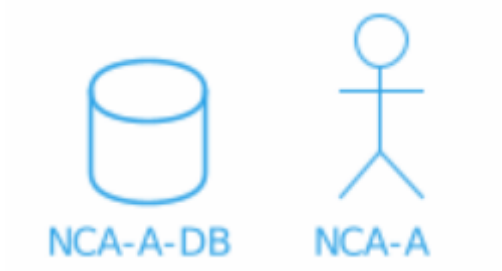
National Competent authorities



Definition:
medicines regulatory authority in a European Union member state that, according to the legal system of that member state, is responsible for the granting of marketing authorisations, clinical trial authorisations and manufacturing authorisations for medicinal products

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Medicinal product dictionary

Definition:
System that is specifically designed to support the prescription, dispensing and administration of medications in healthcare based on an accurate listing, description and identification of medicinal products

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Our crossborder nightmare

OZEMPIC: 1 pen of 3ml, 4 needles.

Pack size differs by country:

- Finland: 1 pen
- Estonia: 4 doses
- Portugal: 3 ml

SmPC text: One ml of solution contains 1.34 mg of semaglutide*. One pre-filled pen contains 4 mg semaglutide* in 3 ml solution. Each dose contains 1 mg of semaglutide in 0.74 ml solution.

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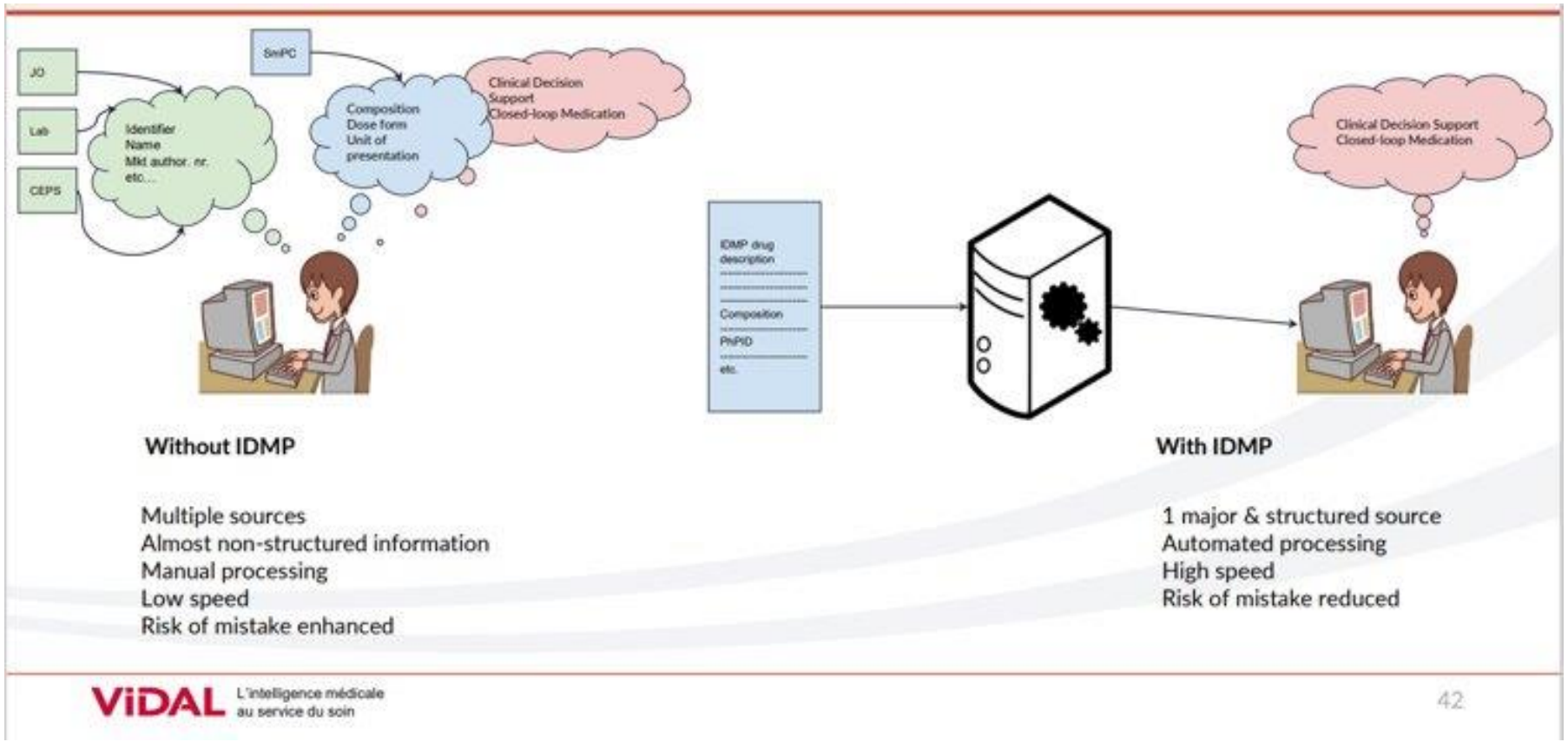
Medicinal product dictionary - needs



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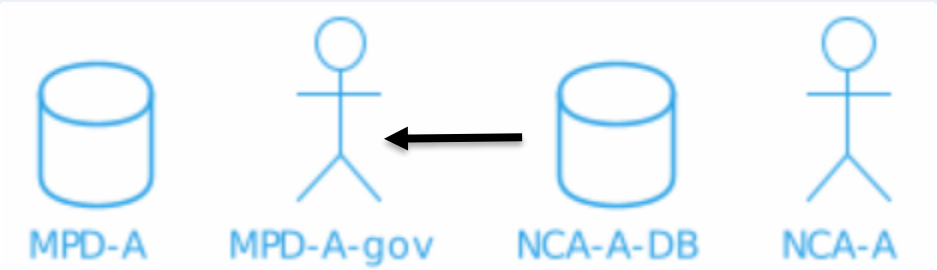
Dataflow NCA to MPD



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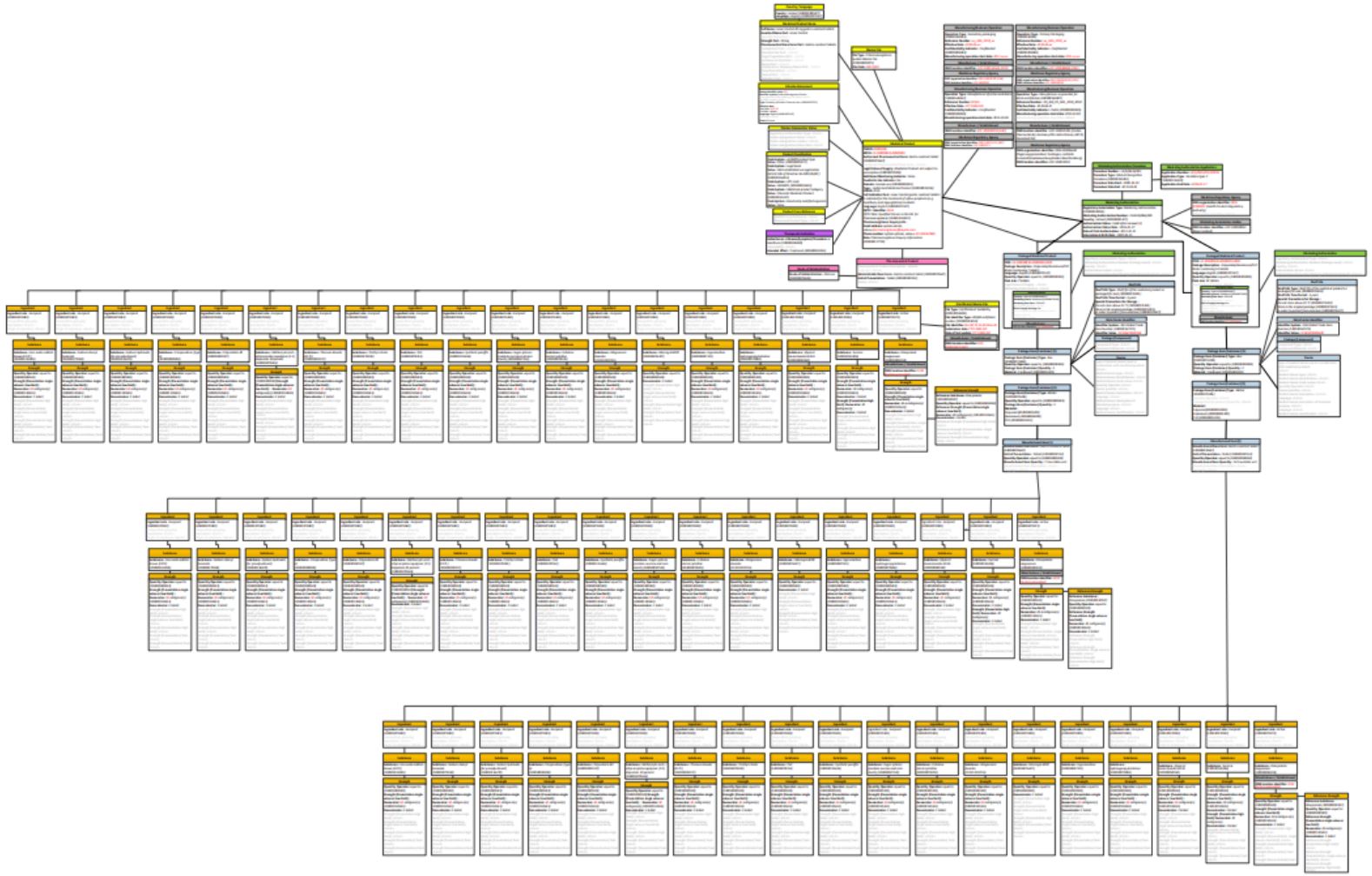
Data in NCA systems

1. **Example 1: Losec Control 20mg gastro-resistant tablets [1]**



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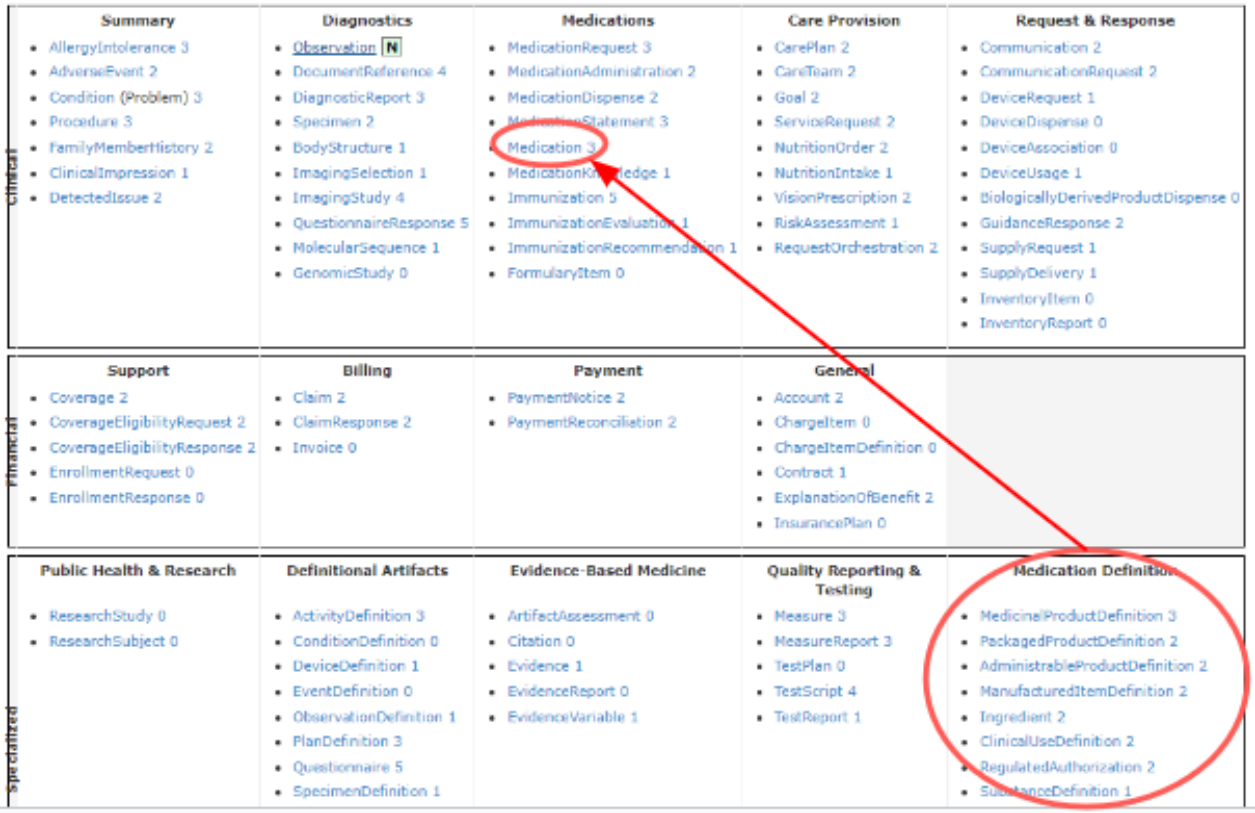
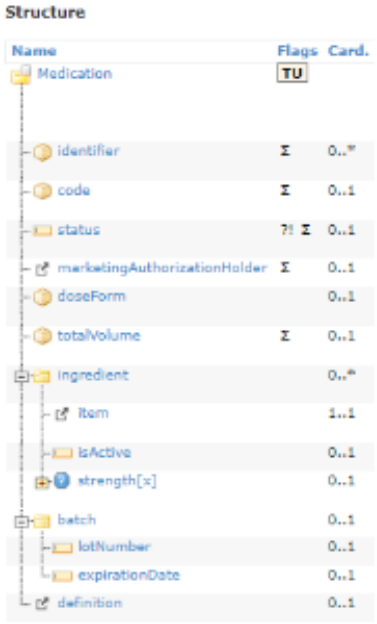
ISO IDMP on FHIR challenge

How to build a bridge from regulatory data to clinical?





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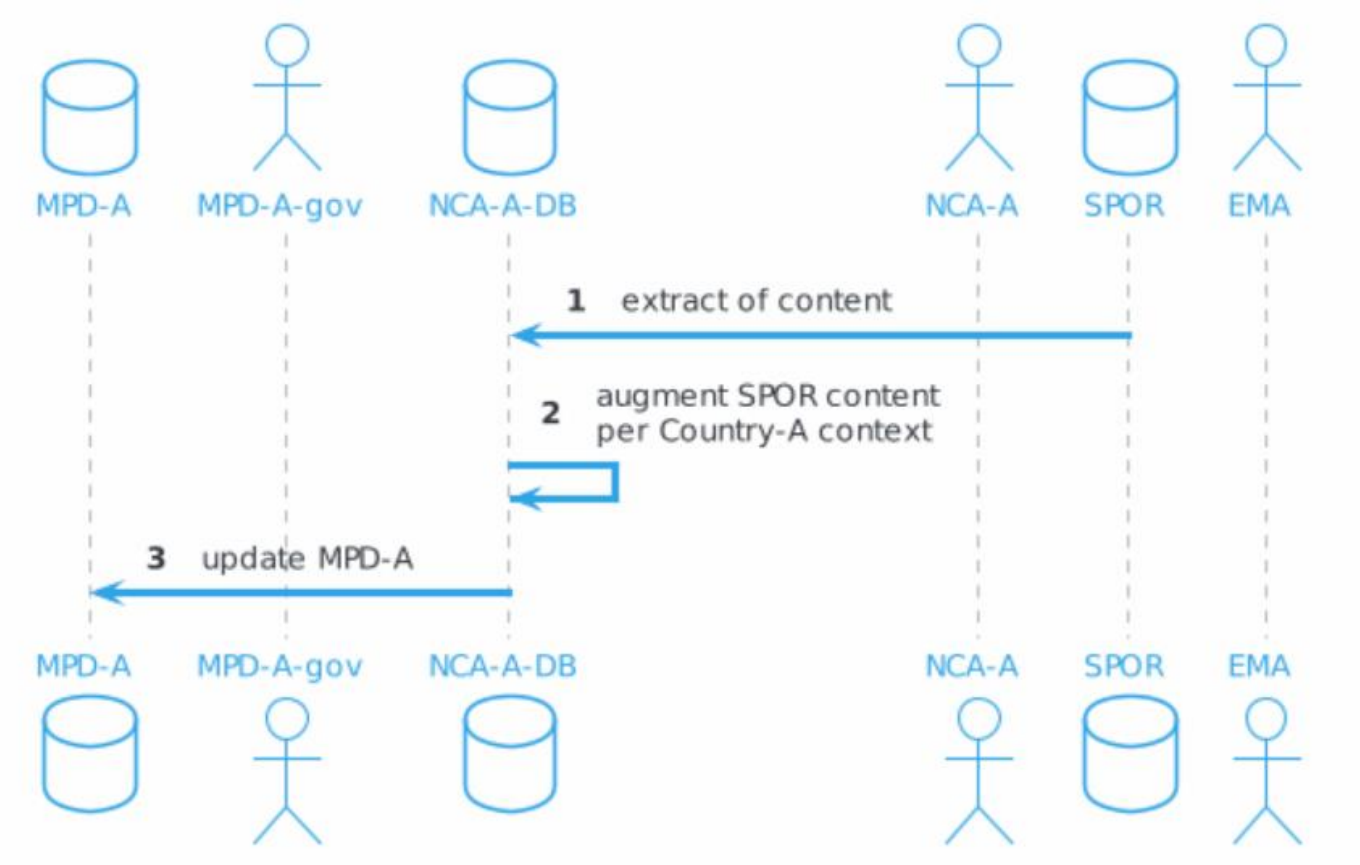
Update use case NCA to MPD – IHE volume 1 Use-case analysis



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Question:

- Should we assume and take as a starting position that IDMP-compliant model
- Is there added benefits in making a content specification between NCA to MPD

-> Or should MPD's be tasked with the capability to request the data needed

- Would the MPD's want the NCA's to have a certain terminology system

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Delivery of validated data on national medicinal product packs, compliant with IDMP, from the National Competent Authority for Marketing Authorization to the National eHealth Contact Point

Robert Vander Stichele

UNICOM

USE CASE Purpose and Context

UNICOM

Purpose:

- To test the willingness National Competent Authorities for Marketing Authorization to validate a minimal datas set of Medicinal Product Pack data, compatible with IDMP for the Mimimal Attribute list

Context:

- The EU is organising a massive infrastructure for cross-border services for ePrescription, eDispensation, and PatientSummary.
- This is coordinated by eHealth.
- The member states are invited to create National Contact Points for eHealth (NCPeH), able to send and receive prescriptions and patient summaries. A calendar has been established where each country indicates the timeframe for participating in this endeavour.
- In order to function well, these National Contact Points for eHealth must be in possession of validated information on the national medicinal products in IDMP-compliant format and compliant with the eHealth HL7 CDA Template adopted in MyHealth@EU.

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USE CASE DESCRIPTION

►Validation by NCA of the minimal data set,
produced by MPD or eHealth, and centrally standardized to IDMP

- The National Competent Authority for Market Authorization (NCA) decides to participate with a collection of all medicinal product packs for 4 substances : amlodipine, carbamazepine, ibuprofen, simvastatin)
- This collection is provided by UNICOM, as the result of a collaboration with the local MPD or eHealth Organisation, and of Central standardization to IDMP.
- The NCA validates the available data from the UNICOM T6.1 database on the (selected) national medicinal product packs, with regard to compliance with IDMP for the Minimum Attribute List (MAL). (including report on procedures of validation).
- The resulting data set is analysed for quality of IDMP implementation and for correctness of codes (EDQM, ATC, SPOR, UCUM).

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Implicated countries

- Italy
- Greece
- Belgium

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Participants

- Lead
  - Robert Vander Stichele
- Members core team
  - Members from Italy, Greece, Belgium
  - Members from HL7 and WP5

Interested persons from other countries can join, by writing an email to robert.vanderstichele@ugent.be

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Minimal Data Sets for testing implementation of IDMP

Inititally focussed on 4 substances
(amlodipine, carbamazepine, ibuprofen, simvastatin)

Focussed on Minimal Attribute List (UNICOM D5.7)
Approx. 20 IDMP variables per National Medicinal Product Pack

Aimed to support :

Use cases in UNICOM TESTLAB;
Pilots in UNICOM;
Pre-testing Cross Border Services

To be extended gradually to :

The UNICOM Pilot Product List (35 substances)
The eHSDI Critical Test Data (additional 5 substances)
The WHO Essential Medicines List (300+ substances)
All Substances (3000+ substances)

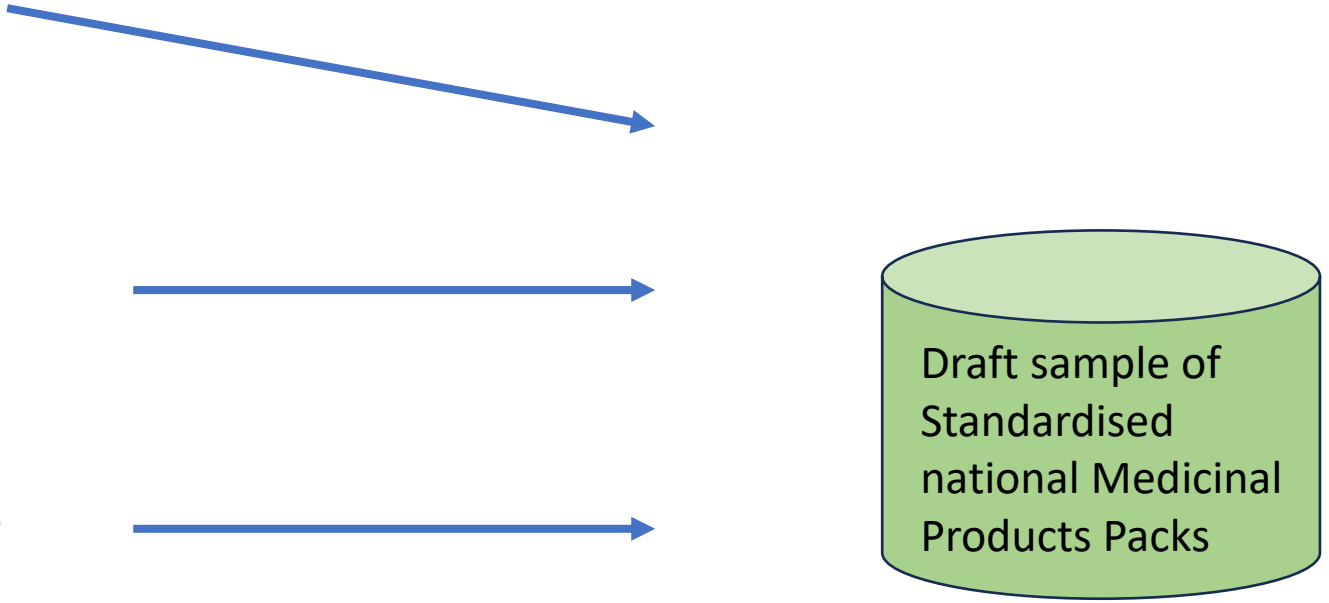
Origin of the draft Minimal Data Set submitted to validation

Internal draft by content experts
of the NCA

Export from
the authentic source of medicines,
Centrally standardised in UNICOM

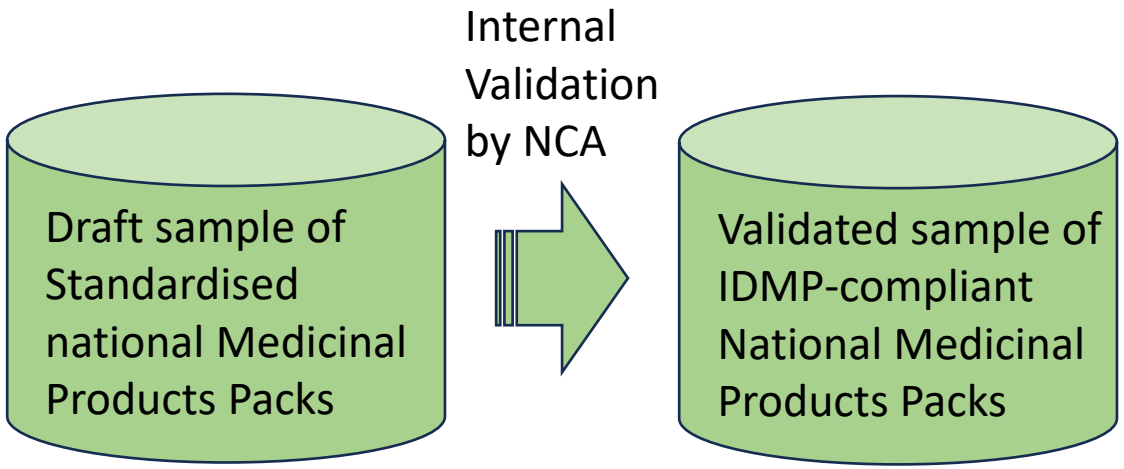
Export from
A national Medicinal Product Dictionary,
Centrally standardised in UNICOM

Export from a
Testfile, developed by eHealth,
Centrally standardised in UNICOM



EMA SPOR Terminology services

National Competent Authority for Marketing Authorisation
Director Business operations/
Director ICT/
Pharmaceutical expert



Integration with the IHE testing Process

- Starting to identify the relevant institutions and humans in the process of validation of IDMP implementation
- Get the minimal data sets ready
- Fill in the IHE Use Case Template
  - Complete Volume 1 : Use Case Description
  - Complete the test plan
    - Choose the countries
    - Get the test data
    - Apply the data quality requirements

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Conclusion of the initial phases of this use case

- This use case does not fit into the IHE approach to testing of semantic interoperability of transactions between actors.
- It is more a quality control process that needs to focus on content quality of data, produced within one organisation.

Working with the IHE testing methodology in its initial phases was considered very instrumental for the further development of this quality control program

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Renewed focus of this use case for assessing the quality of medicinal product data

a) Are all authorised and marketed medicinal products packs for the 4 substances present in the database ?

b) Are all medicinal products correctly standardized to IDMP ?
   a) Is the right substance modifier (if any) chosen for each product?
   b) Is the right EDQM administrable dose form chosen ?
   c) Are the business rules for expressing strength correctly applied ?

c) Are the correct EU-SRS, EDQM, UCUM, ATC codes used ?

d) Are the correct SPOR codes present ?

Can we formulate concrete requirements for each of these aspects of quality of data ?

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Renewed purpase of the use case

- Create a set of requirements for testing the quality of IDMP implementation
  - For internal testing of data sets provided by third parties to NCAs
  - For internal testing of data sets internally created by NCAs
  - For external testing of trusted data provided by NCAs

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Note : Perspectives on a further use case

► Survey of the transfert process of validated Medicinal Product Data from NCA to NCPeH

- A survey will be sent to The National Competent Authority for Market Authorization (NCA), already participating in data transfert to the NCPeH, requesting information on :
  - Protocol of transfert process
  - Sample of data sent by NCA to NCPeH
  - Sample of data used by NCPeH as used in the cross border pilot services

- Sample of data used by NCPeH could be tested for Quality of IDMP implementation, Semantic Interoperability, and extent of coverage of medicinal products

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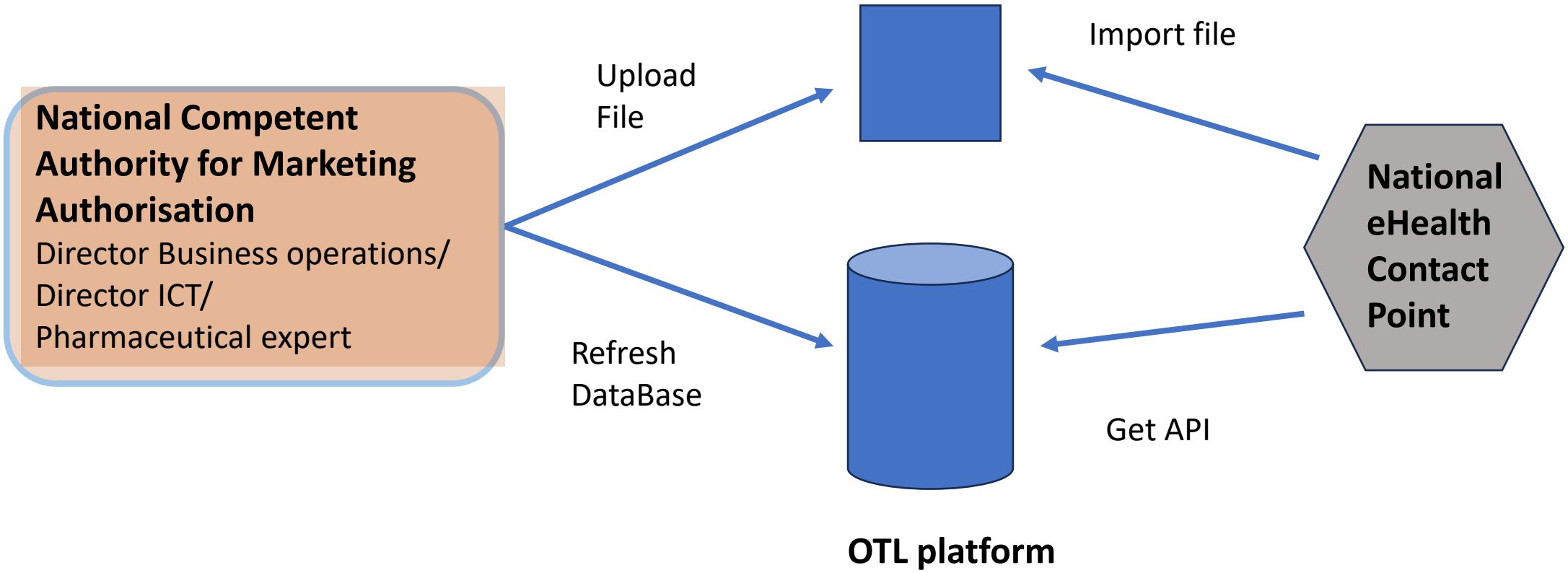
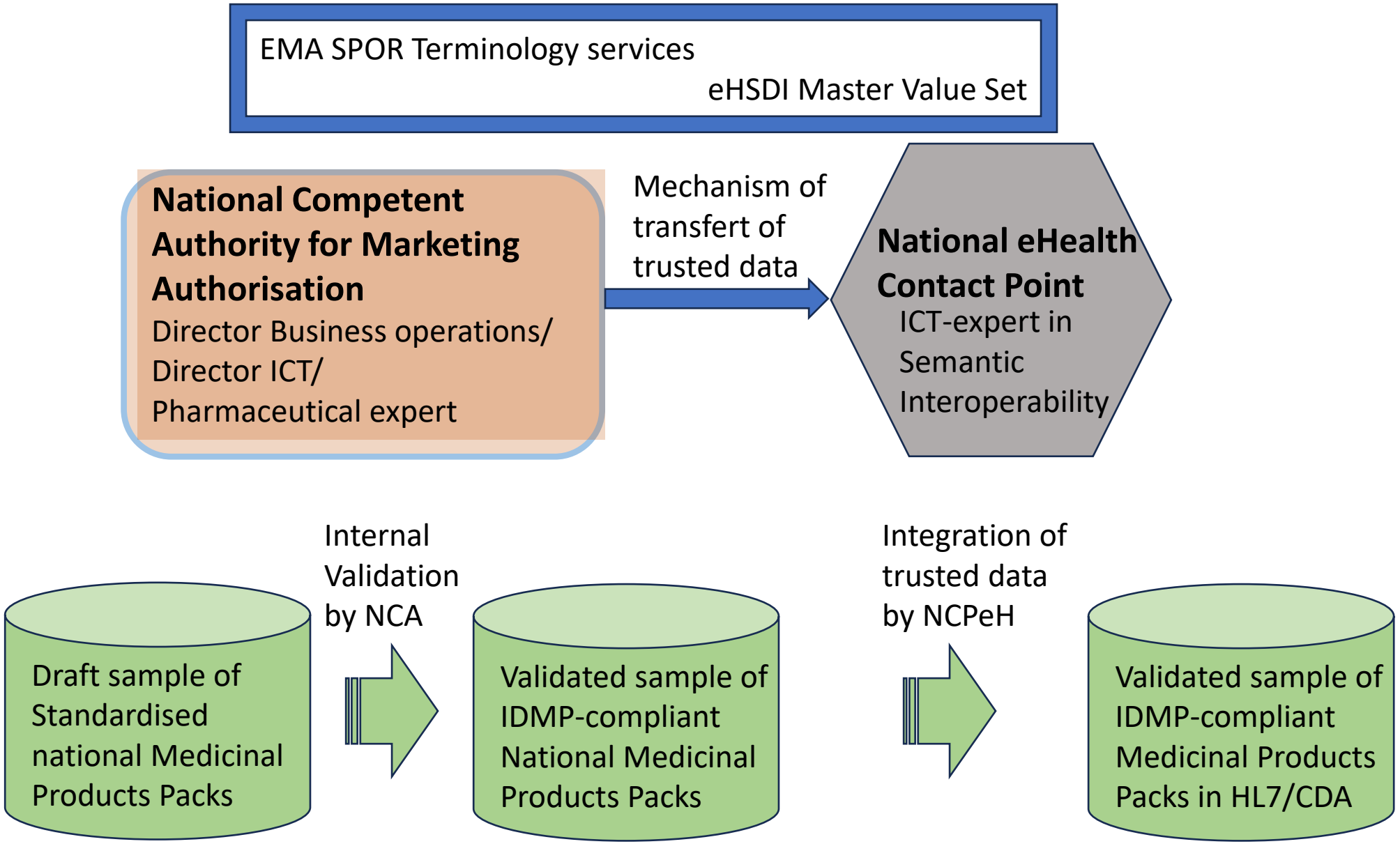
Two methods for transferring “Trusted Data” on Medicinal products From the National Competent Authority for Marketing Authorisation (NCA) to the National Contact Point in eHeallth (NCPeH)




EMA SPOR Terminology services
eHSDI Master Value Set
National Competent Authority for Marketing Authorisation
Director Business operations/
Director ICT/
Pharmaceutical expert
Mechanism of transfert of trusted data
National eHealth Contact Point
ICT-expert in Semantic Interoperability
Internal Validation by NCA
Integration of trusted data by NCPeH
Draft sample of Standardised national Medicinal Products Packs
Validated sample of IDMP-compliant National Medicinal Products Packs
Validated sample of IDMP-compliant Medicinal Products Packs in HL7/CDA

Questions and next steps

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Cross-border / Including substitution in eDispensation

Marcello Melgara, Angela Ferrara & Luca Garbarino

UNICOM

Including substitution in eDispensation

▶ Purpose

This use case aims to facilitate the exchange *and Cross-border dispensing of ePrescriptions enhanced with IDMP attributes between two countries, Country A and Country B.*

It seeks to facilitate patients' access to medications while adhering to substitution rules and national regulations in the country of dispensation.

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Including substitution in eDispensation

UNICOM

▶ Context:

The use case operates within the context of eHDSI, which entails healthcare collaboration across international borders among participating nations.

Non Technical Factors

Legal

Regulatory requirements

Privacy and data protection

Country B

Substitution Rules

▶ Main contact: *angela.ferrara@intelleraconsulting.com*

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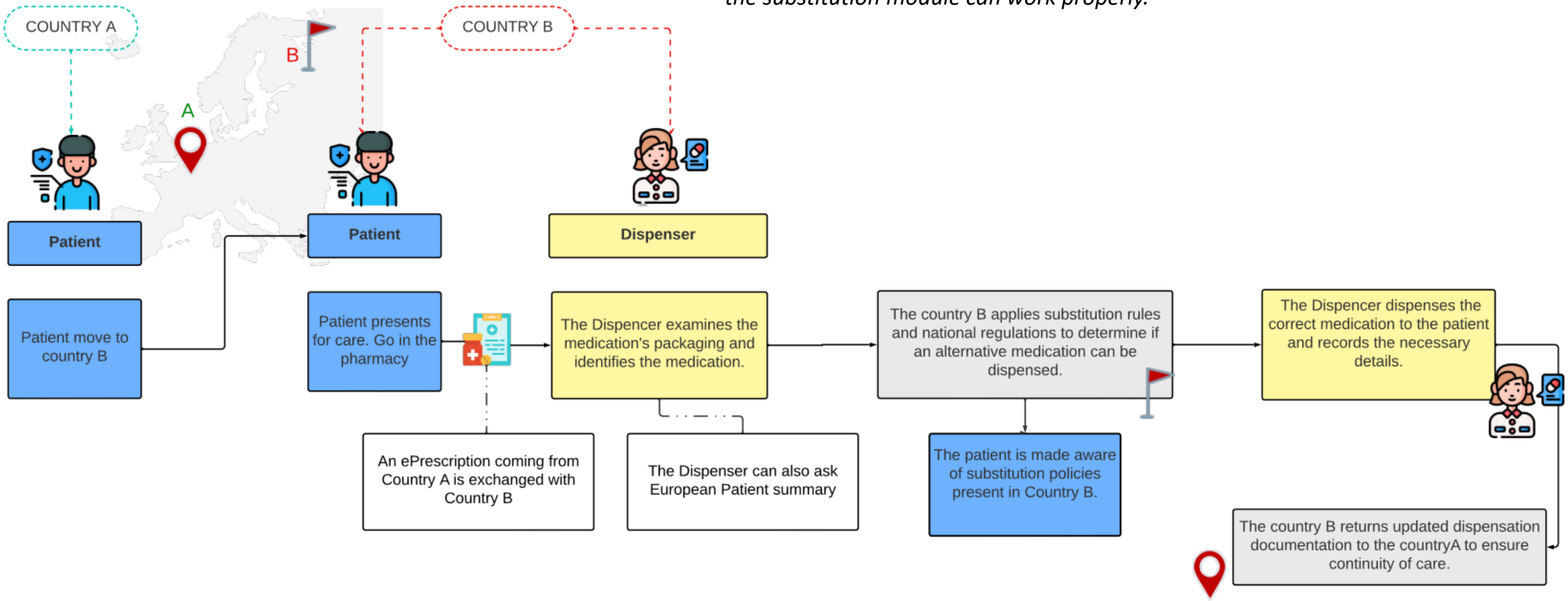
Including substitution in eDispensation

▶Functional process flow

The functional process flow prerequisite is that Country B should have a complete list of IDMP compliant medicinal product packages for ePrescription medicines, so that the substitution module can work properly.



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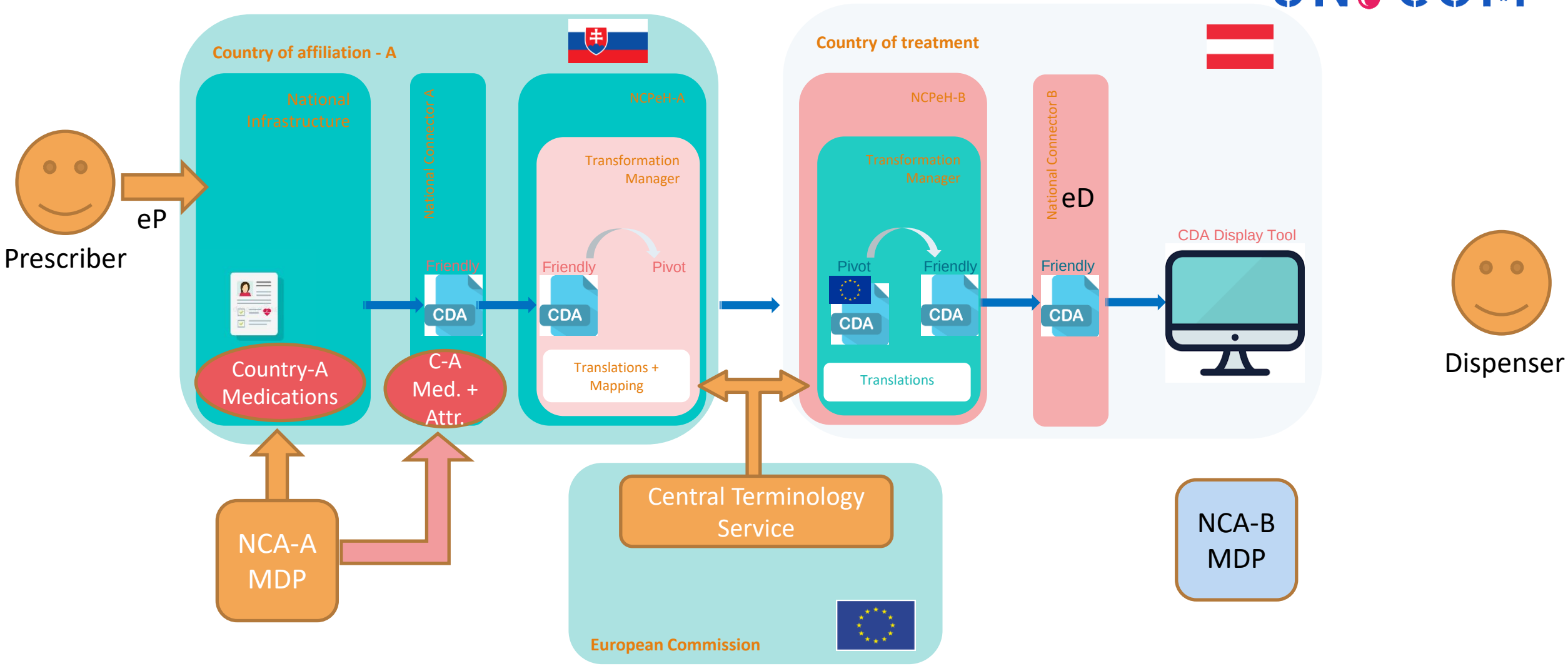
eHDSI Cross-Border Process – IDMP Minimum Attributes to DESCRIBE medications



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Participants and timeline

Including substitution in eDispensation

UNICOM

▶ Participants

▶ Use Case Subscribed

Name	Surname	Entity
Alexander	Berler	Gnomon Informatics
Kostas	Karkaletsis	Gnomon Informatics
Jose	Costa Teixeira	IHE
Alexandros	Staridas	IDIKA S.A.
Robert	Vander Stichele	I-hd
Haralampos	Karanikas	Gnomon Informatics

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Including substitution in eDispensation

UNICOM

▶ Timeline

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Cross-border/Including substitution in eDispensation Unicom

Assets & Results

Resources produced by UNICOM

Including substitution in eDispensation

▶ Results

Poland

31/03 10:00 CET ✓
PL2IT(NCPNPH80A01H501K)

Cyprus

28/03 1:30 CET ✗
Planned 07 Apr 2023
CY2IT(NCPNPH80A01H501K)

Croatia

29/03 ✓
HR2IT(NCPNPH80A01H501K)

Ireland

31/03 ✓
IE2IT(NCPNPH80A01H501K)

Greece

For the drugs of eP test, eD
in the Greek context

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- MALEH
- Wave 6, IDMP

eHDSI value set (MVC 6.1.0) + coding system	SPOR-RMS list name	EMA IG 2.1 attribute name (Preferred in RED)
Product (Brand) Name	Product Name	Product Name
eHDSIDoseForm (EDQM)	Pharmaceutical Dose Form	Authorised Pharmaceutical Form
		Manufactured Dose Form
		Administrable Dose Form
eHDSIQuantityUnit (EDQM)	Units of Presentation	Manufactured item / Unit of Presentation
		Pharmaceutical Product / Unit of Presentation
		Pack size **(CP-63)**
eHDSIPackage (EDQM)	Packaging	Package item (container) type **(CP-63)**
eHDSIUnit (UCUM)	Units of Measurement	Manufactured Item Quantity
		Strength (Presentation single value or low limit)
		Strength (Concentration single value or low limit)
		Reference Strength (Presentation single value or low limit)
		Reference Strength (Concentration single value or low limit)
eHDSIRouteofAdministration (EDQM)	Routes and Methods of Administration	Route of Administration
eHDSIActiveIngredient (WHO-ATC)	Anatomical Therapeutic Chemical classification system – Human	ATC code(s)
eHDSISubstance (SPOR-SMS)	SPOR-SMS	Substance
		Reference Substance
Marketing Authorisation Holder	Full name (SPOR-OMS (LOC ID)	Marketing Authorisation Holder (Organisation)
Medicinal Product Code	National Product ID / ~~ATC~~	Product Management Service Identifier (PMS ID)
	If available:	Medicinal Product Identifier (MPID)
	Product Management Service Identifier	Packaged medicinal product Identifier (PCID)
	PhPID, MPID, PCID	Pharmaceutical Product identifier (PhPID)

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Product lookup for Patient-Facing Apps
Use Case
Request to renew a medication on the Medication List from a patient from Country A in Country B

Nicole

UNICOM

Use case: Test Lab benefits and value propositions

- **Instrument of Innovation**

  Participants can share (or discover) important insights related to the practical aspects to realize IDMP-empowered digital health workflow

  Thanks to the developed applications

  Ground testing regarding digital health systems in Europe will inform the best directions to reach new solutions

- **Instrument of Implementability:**

  The work of the lab is to move from theory to practice

  For IDMP to go to scale, the change management and related specifications need to be practically implementable

  The lab adds value upstream of conformance testing and helps highlight interoperability specifications

- **Instrument of Governance**

  The lab will provide a trusted conformance-testing service

  Testing capacity enables EU Member States to exercise governance over digital health actors to ensure their ability to interact with each other in the service of patient care workflows that depend on shared health data

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The solution provided by the UNICOM project can represent a useful and necessary tool to help and **facilitate travelling citizens' lives and protect their health, eliminating barriers and personal fears** of forgetting their medication at home and discontinuing their therapies.

It presents benefits both for patients and healthcare providers.

Patient's health is safeguarded, since they gain information on the medications they take, no matter where they are. Moreover, their new applications are demonstrably interoperable and meet national and EU specifications.
HCPs in foreign countries can see all this information, and so they are put in a position to **rationally and safely dispense the medication** with awareness about the safety and health of foreign patients.

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This use case represents a pilot within the UNICOM Project to test the usefulness of **ISO/CEN IDMP standards** for the **univocal identification of medicinal product in a private sector real-world scenario.**

This use case aims to demonstrate the possibility for patients from Country A who are abroad **without their medicine** to obtain a **similar substitute medicine** in Country B, in order to safeguard their health and ensure their adherence and continuity of treatment.

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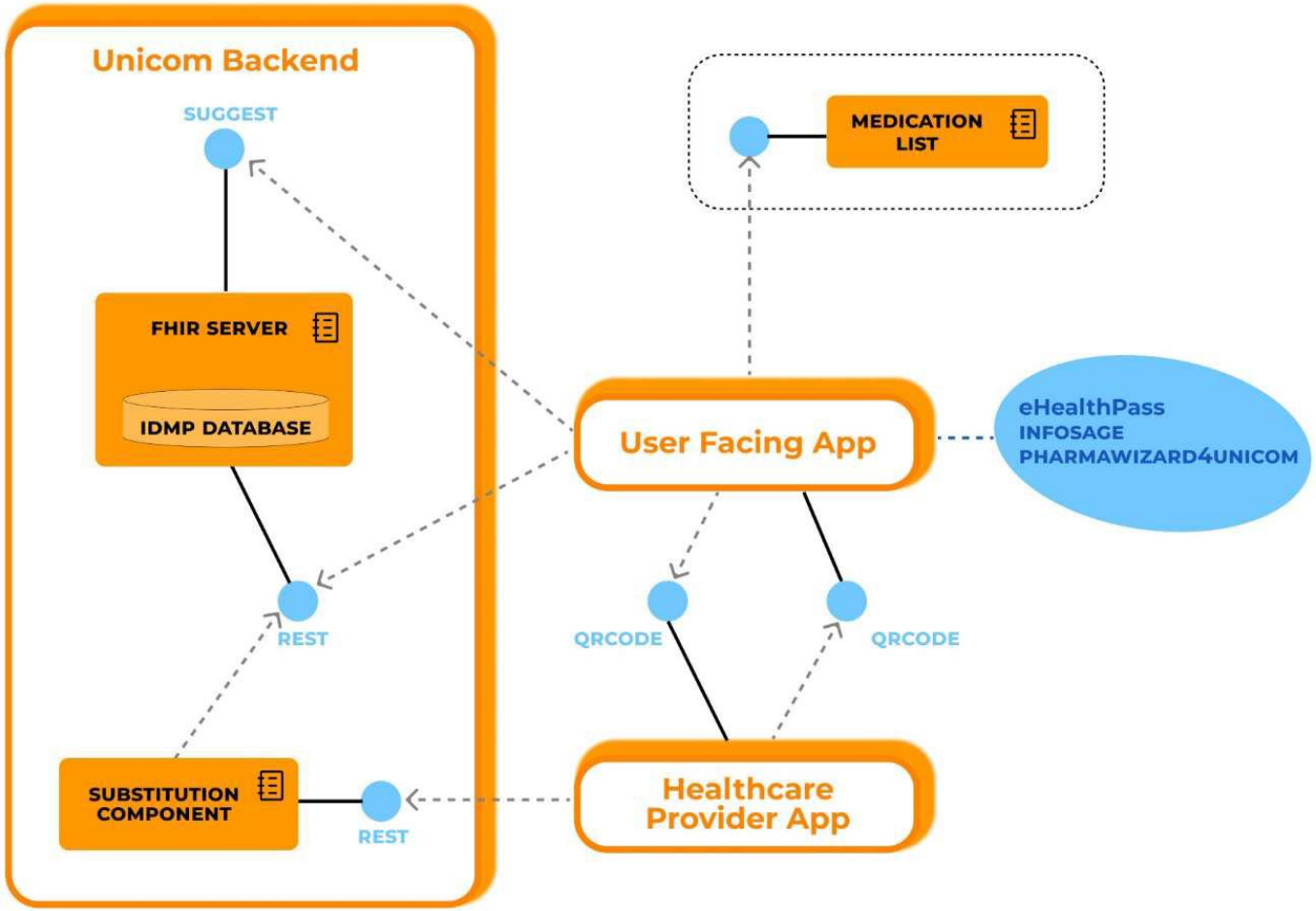
Apps Ecosystem and Repository



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Application for users
Patient-Facing Apps (PFAs)

Three applications are provided to patients:
Pharmawizard4UNICOM, eHealthPass and InfoSAGE

All present the same functionality:

- ✓ Ability of **searching for medicine** to gain information about it
- ✓ Ability of **adding medicines** to patients' Medication List
- ✓ Ability of selecting a medication from the Medication List to be refilled
- ✓ Ability of **creating a medicine data QR code** to be shown to the HCPs abroad to make them able to find a substitute drug
- ✓ Ability of **adding the identified substituted drug** to the Medication List via the QR code generated by the HCP app.

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Patient-Facing Apps aim to **empower patients' access to medicinal information** and **find substitute drugs abroad**, adding them to their Medication List.

An important purpose of these applications is to provide patients with information about the medications they are taking, put them on their personal medication list, and have a secure tool with them when travelling abroad to find the similar medications in a foreign country.

This is possible because the apps are integrated with the **IDMP Database**, developed in Task 6.1, and the **Substitution Component**, developed in Task 6.2.

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The apps carry the **Medication List** and **minimal clinical data** of the patient in the local language and with the local Medicinal Product Dictionary.

The Medication List is **IDMP-compliant**, so that can produce for each medicine on the list:

- ✓ the Pharmaceutical Product Identifier (label PhPID)
- ✓ the substance with the role of precise active ingredient
- ✓ the granular EDQM administrable dose form
- ✓ the normalized expression of strength

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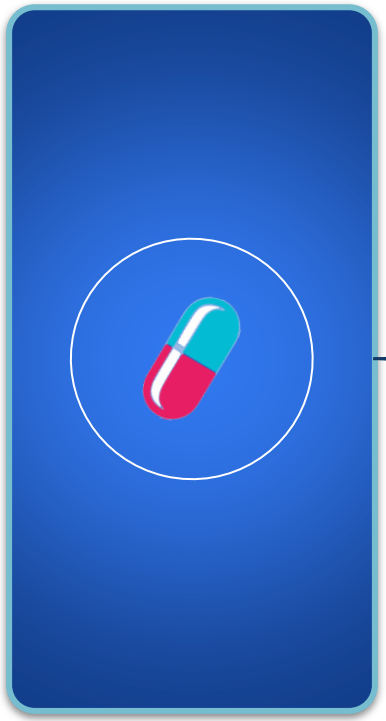
Patient-Facing App - UX Operations

With the **Patient-Facing App** the user is able to:



Create a Medication List

The patient saves Medicinal Products on his/her mobile device

Generate QR codes for the Healthcare Provider App

To communicate with the pharmacist (dispenser) about the drug to be substituted

Add substitute drugs to the Medication List

To record pharmacist's chosen medication on the app

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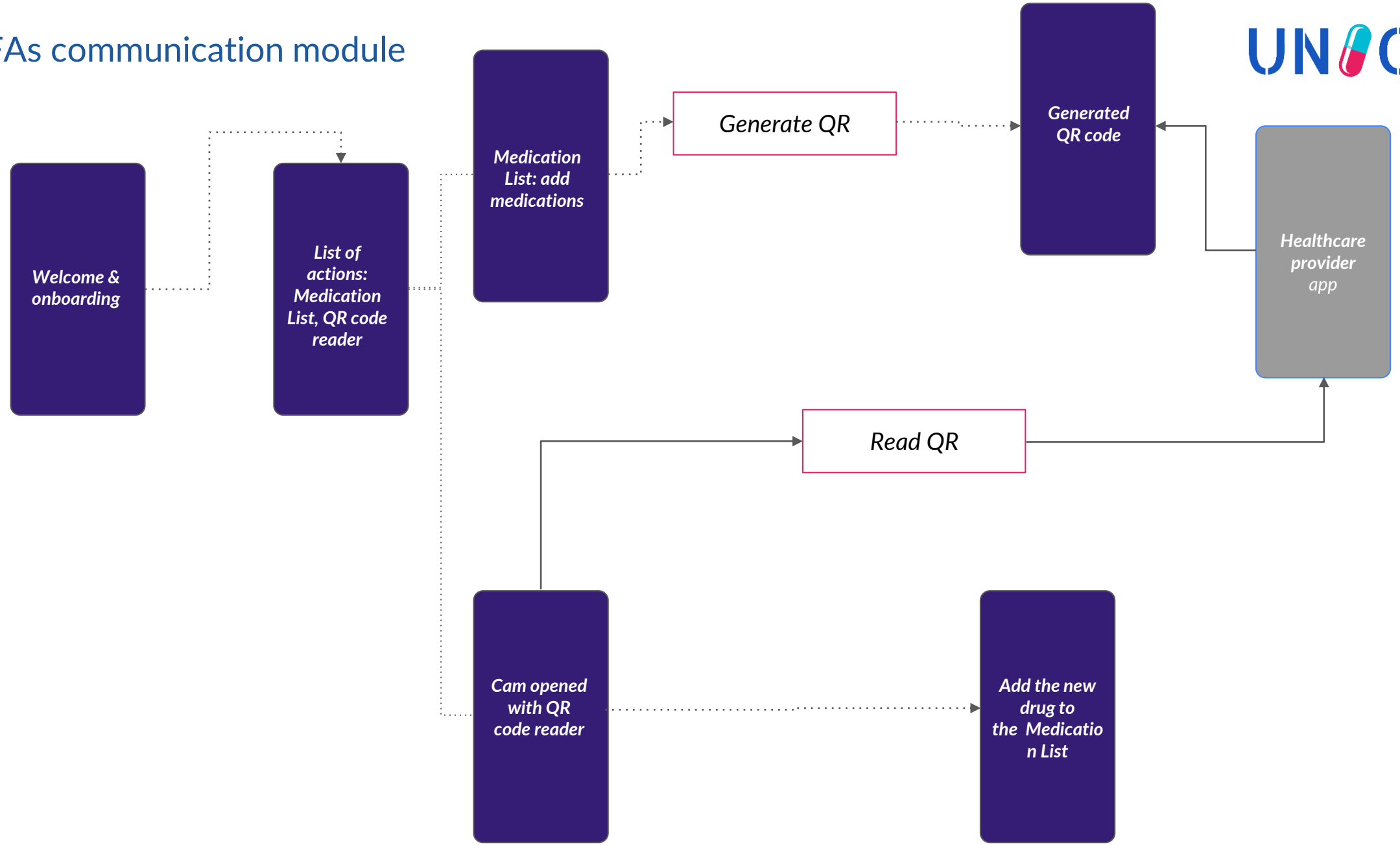
PFAs communication module



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One interface is provided to healthcare professionals (physicians, pharmacists..), with the following functionalities:

- ✓ **Scanning** the Patient-Facing App generated QR code
- ✓ **Connecting to the Substitution Component of the UNICOM server** to get a list of equivalent or similar drugs from which to choose the most appropriate medication
- ✓ **Generating a new QR code** containing the substitute drug data and information to be sent back to the Patient-Facing App

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Other interesting functionalities present in the interface are:

- Language settings (currently Italian and English)
- Font scaling and contrast management
- Substitution country settings

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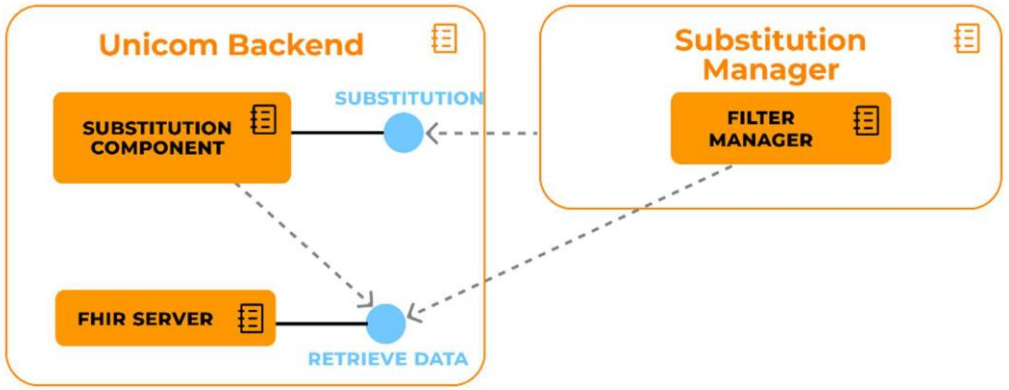
The HCPA is developed in Flutter and consists of two basic components:

A. **Substitution Manager:** an application module responsible for the integration of APIs with the Substitution Component.
B. **Filter Manager:** an internal component of the Substitution Manager making it possible to filter the results obtained by the Substitution Component

These two components combined with the UNICOM backend enable drug substitution between different countries.



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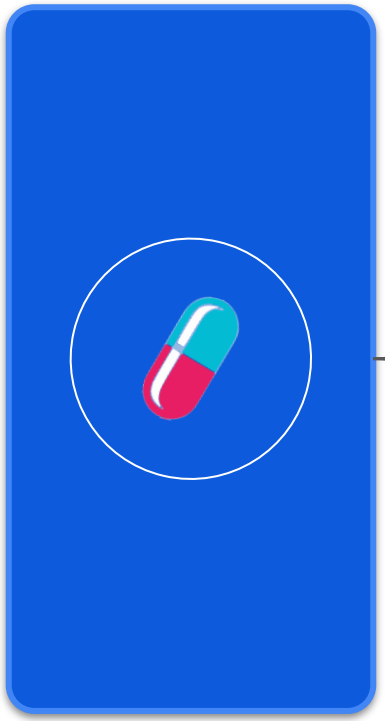
Healthcare Provider App - UX Operations

With the **Healthcare provider app** the dispenser (or prescriber) is able to:



- **Scan FPA-generated QR codes** → To obtain a list of similar medications and their characteristics
- **View the medications the patient is currently taking** → Thanks to a Medication-IDMP Multilanguage Representation
- **Consult a list of potential substitute medications** → To select the best substitute medications for the patient
  - Improved results with search bar & filters
- **Generate a QR Code to be sent back to the PFA** → To inform the patient with the chosen medication's characteristics

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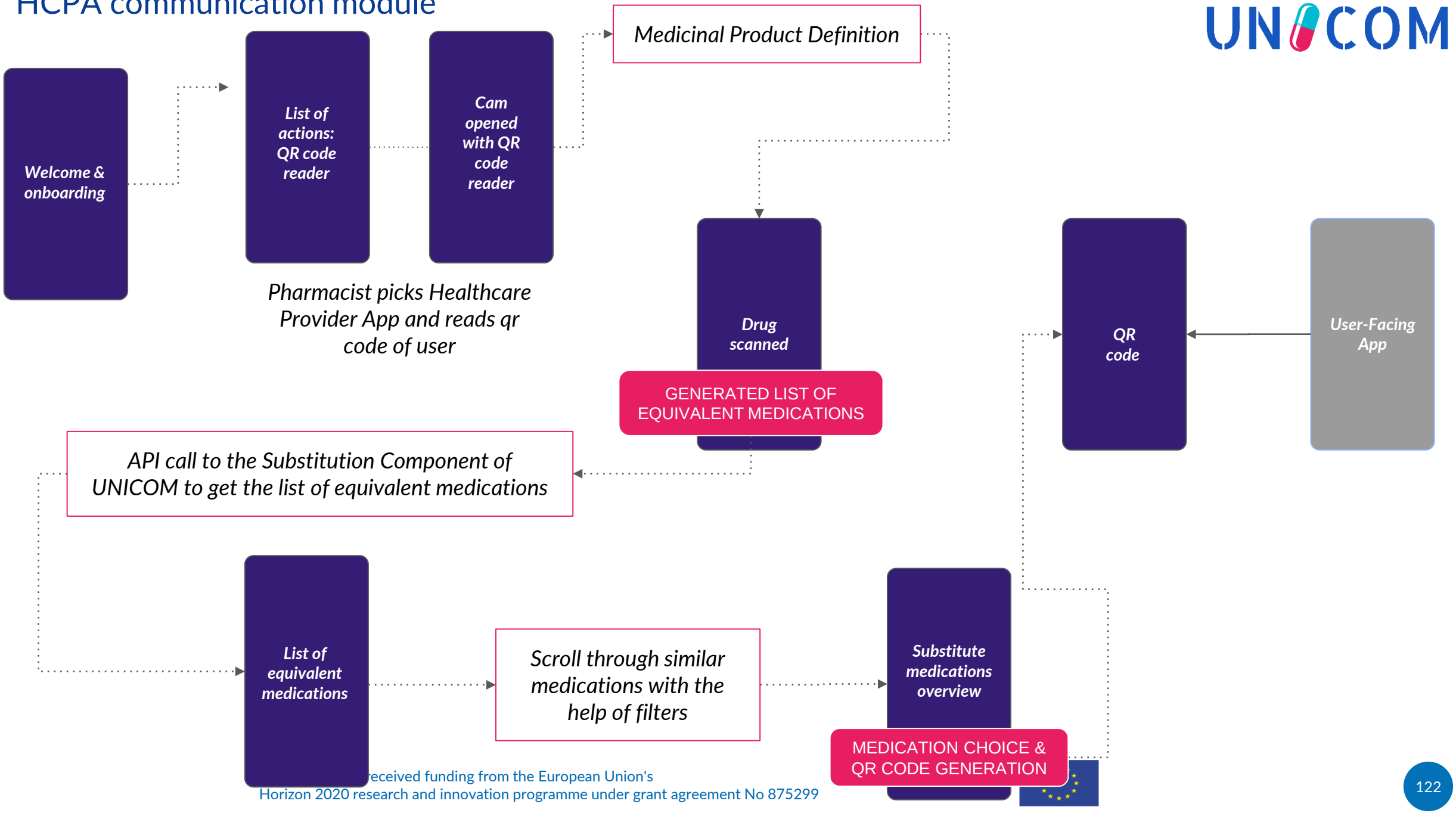
HCPA communication module



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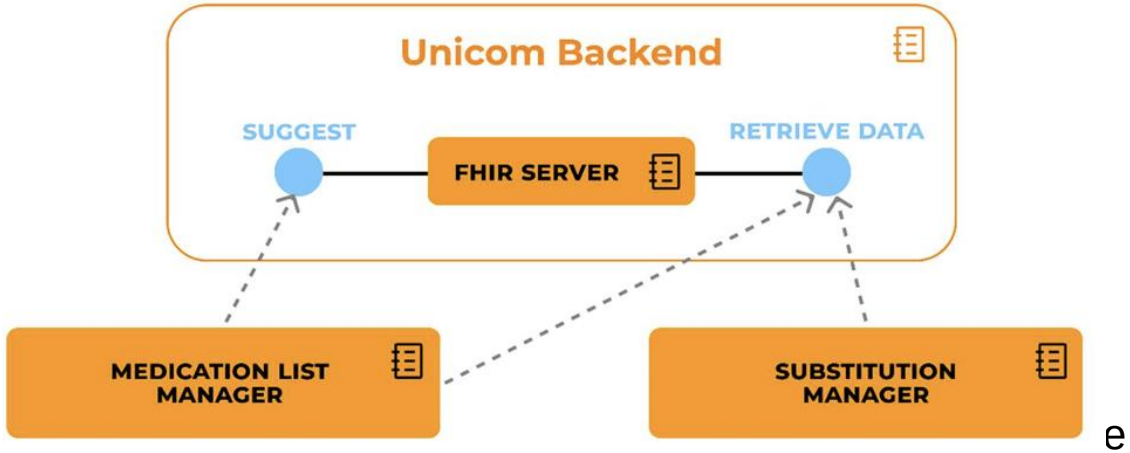
Back-end

The system back-end architecture consists of two main systems

A. **FHIR server** exposes the APIs for:
   - ✓ the IDMP to get medicinal data
   - ✓ Medication suggestion component

B. **Substitution component module** to get data on substitutions of the identified drug for different countries



e

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Use Case basic scenario

A. A patient from Country A, travelling to Country B can select a medication from the Medication List that needs refilling and present the corresponding QR code to the healthcare provider in Country B

B. The HealthCare Provider Application (HCPA) can read the PFA-generated QR code, to send information via API to the UNICOM T6.1 database and receive back a list of similar medications available in Country B, applying the local substitution rules

C. The healthcare provider makes an informed choice and provides the patient with the identifier of the chosen medication (and its labelling information) via an HCPA-generated QR code to be sent back to the PFA

D. The patient from Country A can now gain information about the similar medication available in Country B

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Communication via QRcode

Data represented via ***JSON*** (JavaScript Object Notation) format provide Patient-Facing and Healthcare Provider Applications with the ability to read or generate medication identification.

QR code generated by the Patient-Facing App

```
{
"medication": "NORVASC-tablet-5mg--65-ITA-MPD",
"substitution": null
}
```

QR code generated by the Healthcare Provider App

```
{
"medication":"NORVASC-tablet-5mg--65-ITA-MPD”,
"substitution": "amlodipine-maleate-GENERICS-TAB-10MG-TAB-173-GRC-MPD”
}
```

The medication key will correspond to the PhPID label of the user-selected medication
The substitution key will correspond to the PhPID label of the substitute medication selected by the healthcare provider.

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Use Case basic scenario – participants

A. Patient from Country A: a user with the Patient-Facing Application (PFA) in need for a medication refill in Country B

B. Healthcare provider (HCP) from Country B: a dispenser (pharmacist) able to hand over the information of the equivalent medication to the patient and possibly dispense an OTC medication or a prescriber (physician) who can prescribe an equivalent medication, according to the local rules (Country B local rules)

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Use Case basic scenario – patient's journey

A. Selection of the medicinal product for which a refill is needed
B. The PFA connects through an API with the IDMP database and retrieves the IDMP description of the national Medicinal Product from Country A.
C. PFA-generated QR code
D. Capture of the request for refill by the HealthCare Provider App (HCPA), which sends an API request to the FHIR server, requesting equivalent medicinal products from Country B
E. The FHIR server sends back the information to the HCPA
F. List of similar medicinal products, described both with national identifiers and labels and with international IDMP Ids and labels
G. After the selection of the best equivalent medication, the HCPA generates a QR code to be sent back to the PFA
H. PFA reads the HCPA-generated QR code and integrates the equivalent medicinal product to the existing Medication List

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Our patient

The use case presented involves **Haris**

- Male
- 45 years old
- 90 kg
- 175 cm
- **Hypertension**

Patient medication list:
Amlodipine 5mg 1DDD (Brand Zocor) to treat **hypertension**

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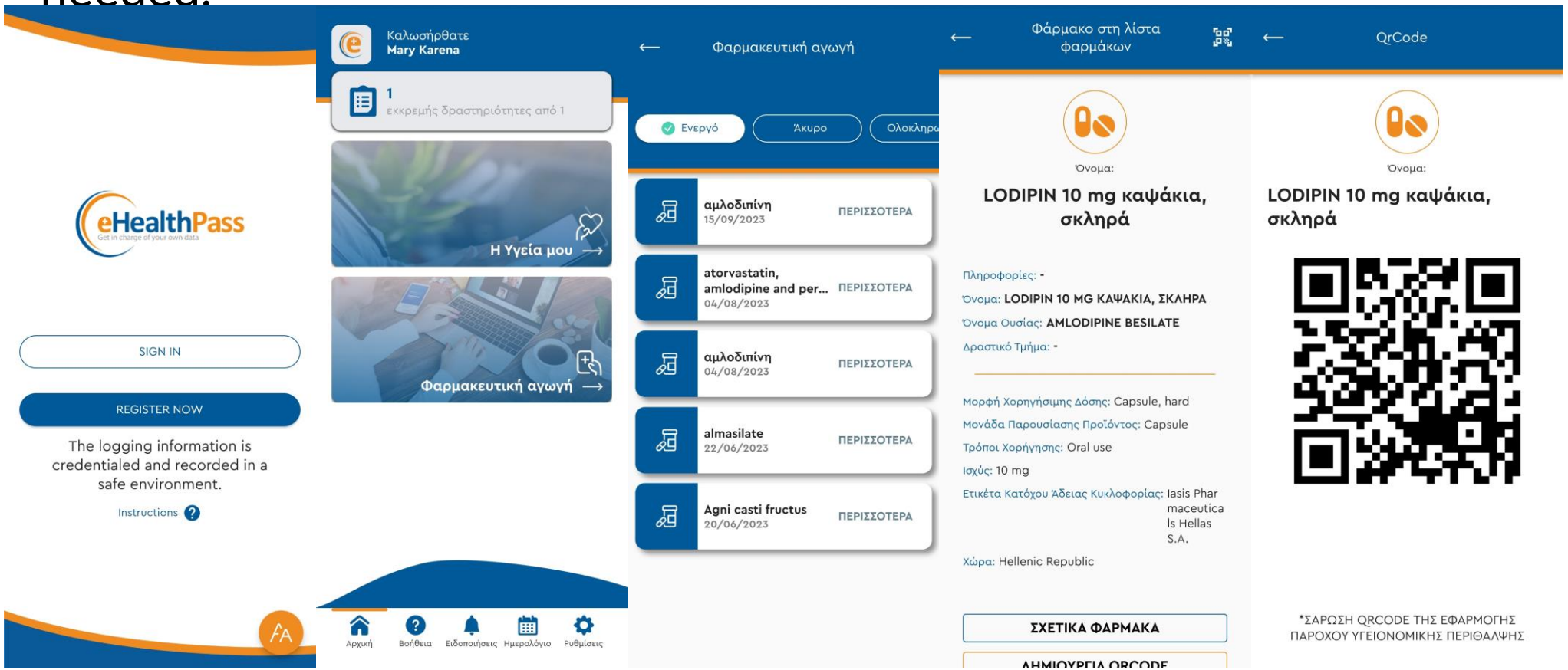
Patient to Pharmacist

During an unexpectedly extended stay in a foreign country, the patient is in need of a refill of amlodipine. He shows the pharmacist the QR code for the drug needed.



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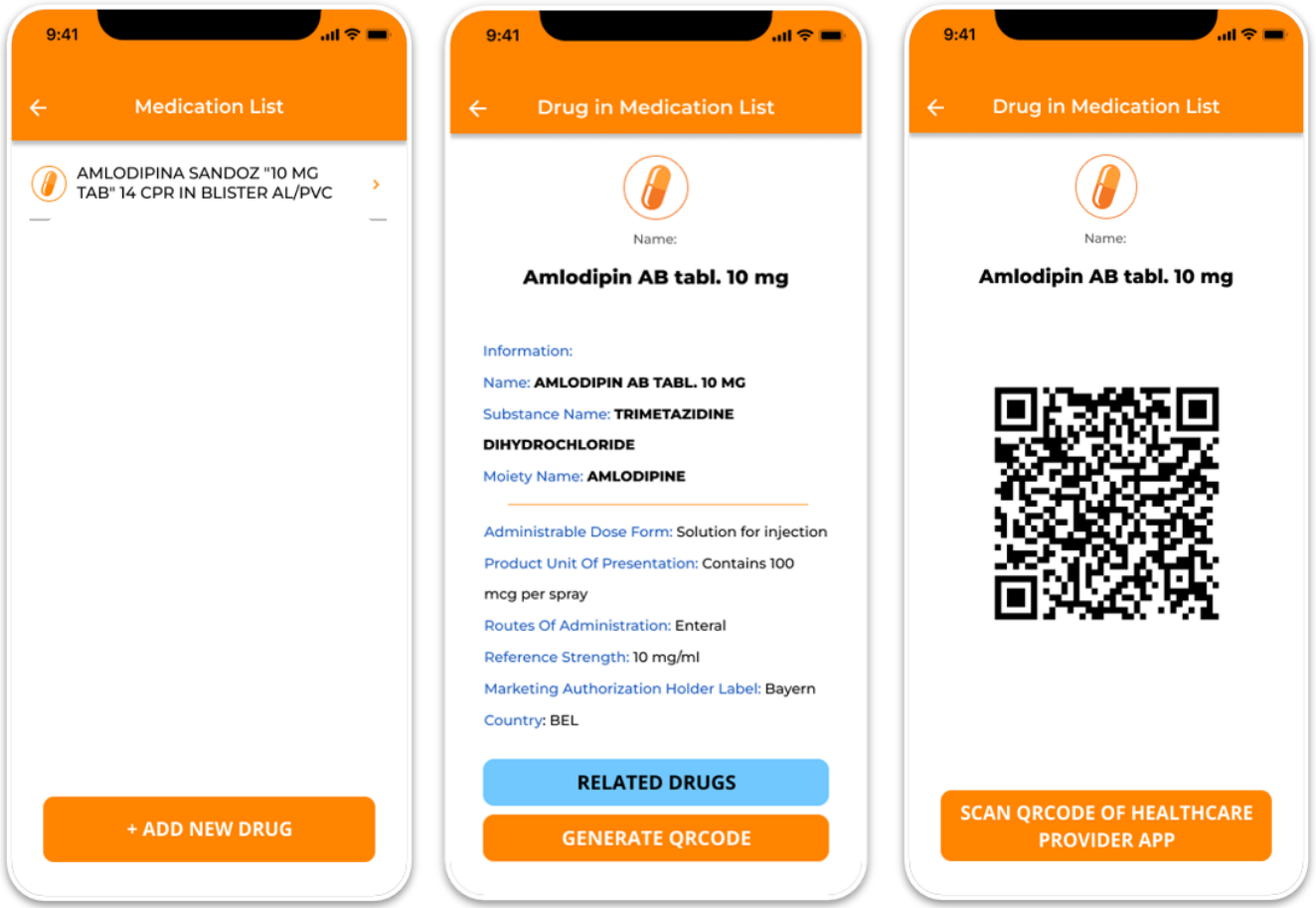

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Pharmacist to Patient

The pharmacist recognizes that the medicine comes from a foreign country. Thanks to the HCPA, he/she can identify the similar medicine marketed in his/her country. He/she shows the patient the new drug.

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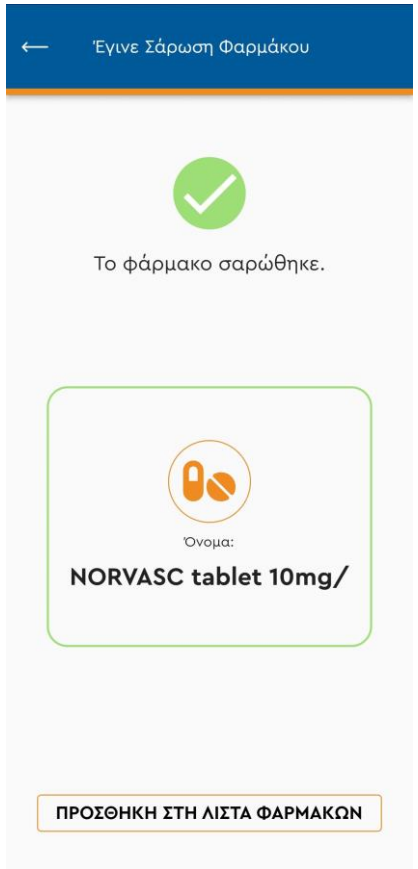
The patient scans the pharmacist's QR code and add this drug to the Medication List



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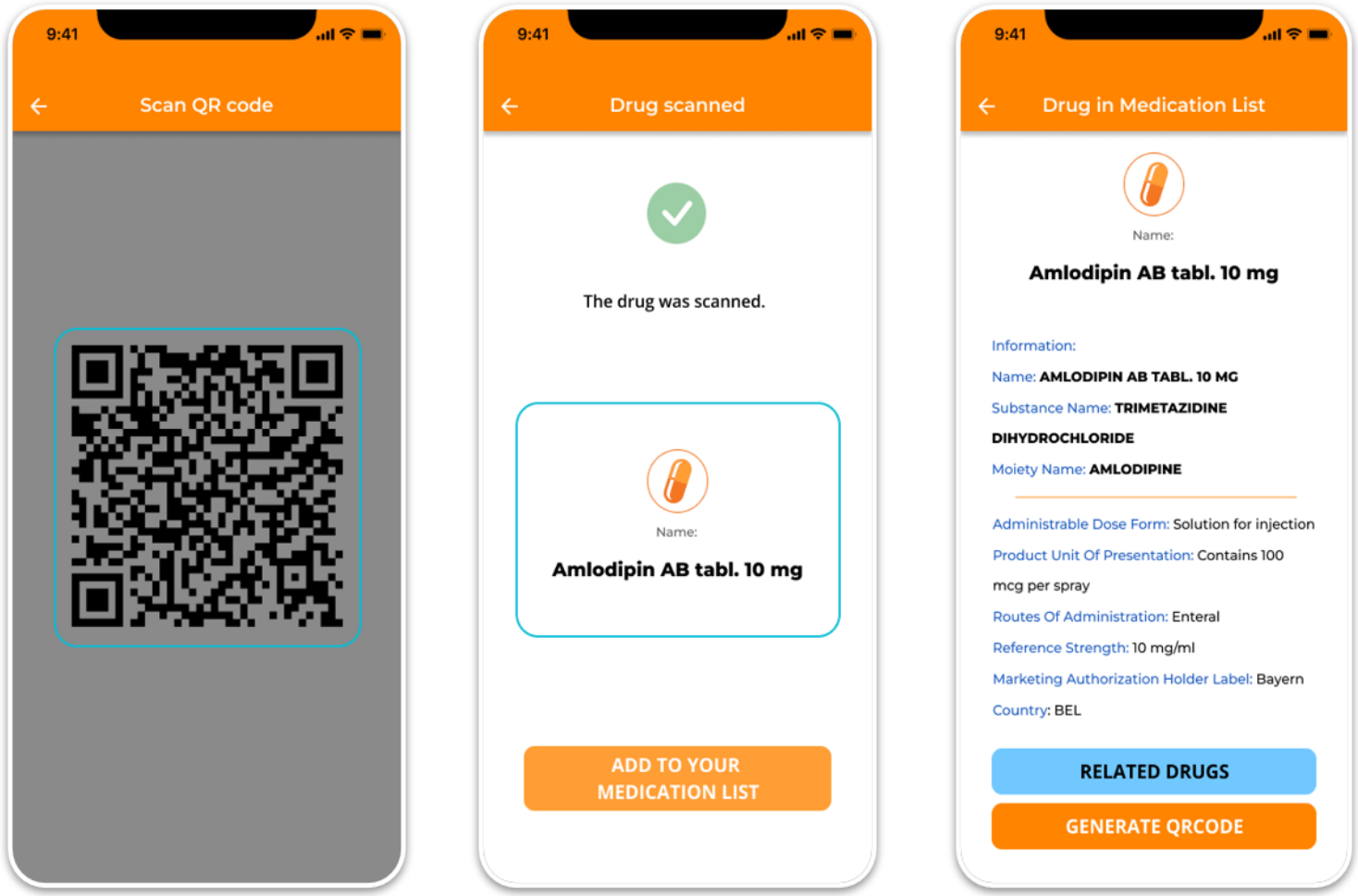

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Questions and **next steps**

T8.3
IDMP and Patient Empowerment Apps

PILOT

25 PATIENTS



4 ACTIVE INGREDIENTS

AMLODIPINE
CARBAMAZEPIN
IBUPROFEN
SIMVASTATIN

D8.6 DEMONSTRATION OF PATIENT EMPOWERMENT APPLICATION

D8.10 RESULTS OF PERSONALISED MEDICINE PILOT (T8.5) (FORTH)

T7.5
Pilot deployment and operation (ARIA)

Patient Empowerment Application validated with about **500** patients

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Questions and Answers – further discussion


Q
&
A

Thank You!

And don't forget to register for the UNICOM Test Lab meetings and the UNICOM Day on 28 September 2023

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