Creating interoperability at the source: UNICOM a global game changer !

HL7 FHIR VULCAN ACCELERATOR - PARIS MEETING
15th March 2023
Luc Nicolas (EHTEL) - Dissemination lead

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What if ?

We would be able to identify any medicinal product from anywhere in the world anywhere in the world ?

That is the ambition of 5 ISO/CEN Standards !

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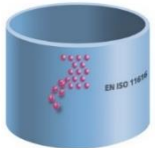
ISO standards for IDentification of Medicinal Products: IDMP

Set of 5 ISO IDMP standards establishes *definitions and concepts, common vocabularies* and describes *data elements and their structural relationships* that are required for the unique identification of medicines. Developed to ensure worldwide **interoperability** across regulatory and healthcare communities.

Substances (Substance ID/Specified Substance ID) - ISO 11238

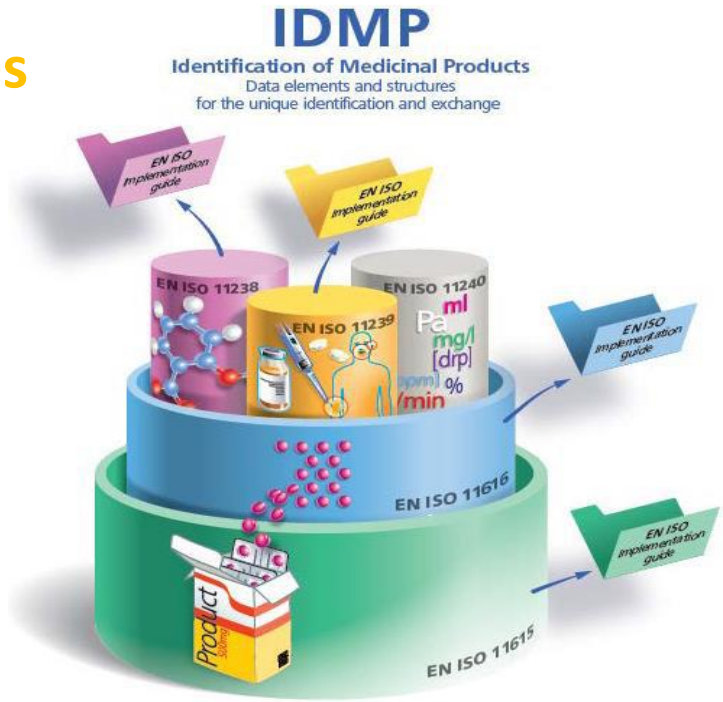
Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239

Units of measurement - ISO 11240



Pharmaceutical product (PhPID) - ISO 11616

Medicinal product (MPID/PCID) - ISO 11615



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Aims to break down barriers hindering the free flow of

- **detailed**
- **semantically coded**
- **interoperable**

medicinal product information across the globe

Objectives:

Implementation of IDMP for Marketing Authorization in EU countries and at EU level

Adaptation of Member States' cross-border digital health services to include IDMP

- ePrescribing and eDispensing
- Patient Summary

Exploration and implementation of IDMP in clinical practice:

- pharmacovigilance reporting
- medicinal product dictionaries
- digital health services

The «*wedding cake*»

What is your role in the life-cycle of a medicinal product? Which of the high-level processes are you engaged in?

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- EC supported Innovation Action on the implementation of IDMP standards
- A broad consortium of partners
  - **14 National Competent Authorities for Medicinal Products** – including support from the European Medicines Agency
  - 7 National eHealth Competence Centers / National eHealth Contact Points
  - 5 Industry Partners (Health IT)
  - 5 Research Organisations
  - 2 Medicinal Database Providers
  - 11 Standards Developing Organizations
- 4 year program: 2020-2024
- 13 work packages
- 21 M€ total budget

- **National implementations in:**
  Austria, Belgium, Croatia, Estonia, Finland, Germany, Ireland, Norway, Portugal, Spain, Sweden, The Netherlands

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Inconsistencies

- Pharmacovigilance
  - Same medicinal product
    - Different name, expression of dosage, pharmaceutical dose form, route of administration
  - Same medicinal product?
    - What about substance(s)?
- Cross border prescriptions
  - How to identify medicinal products un-ambiguously?
  - How to decide which medicinal product is identical to another?
- Decision support
  - Decision support systems based on local product master data?
  - How to develop multimarket systems?
- Shortage
  - How to aggregate medicinal products which seem to be identical/different?

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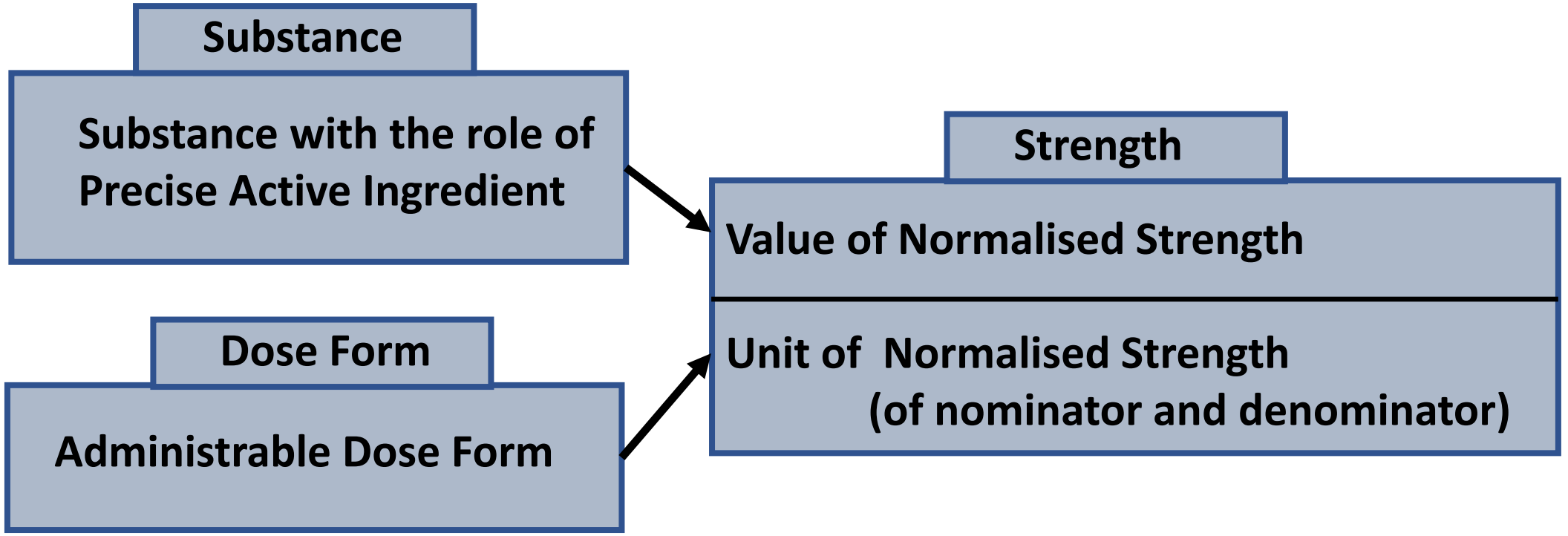
3 key elements of medicinal products

Substance, together with dose form, determines
the normalisation of strength expression of medicinal products



Note: Substance with dose form and strength determine the effect of the medication

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How to ensure interoperability in the way medicinal products are represented internationally ?

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- **For 3 core identifying concepts of medicinal products :**
  - ✓ Substance
  - ✓ Dose form
  - ✓ Strength,

We will need standardized terminologies, and business rules to govern also the relationships between these concepts

To be implemented by the national Agencies for Marketing Authorisation
In US, in Europe, and globally

To flow seamlessly into the medicinal product dictionaries, used in clinical systems all over the world

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IDMP: from data models and terminologies to identifiers

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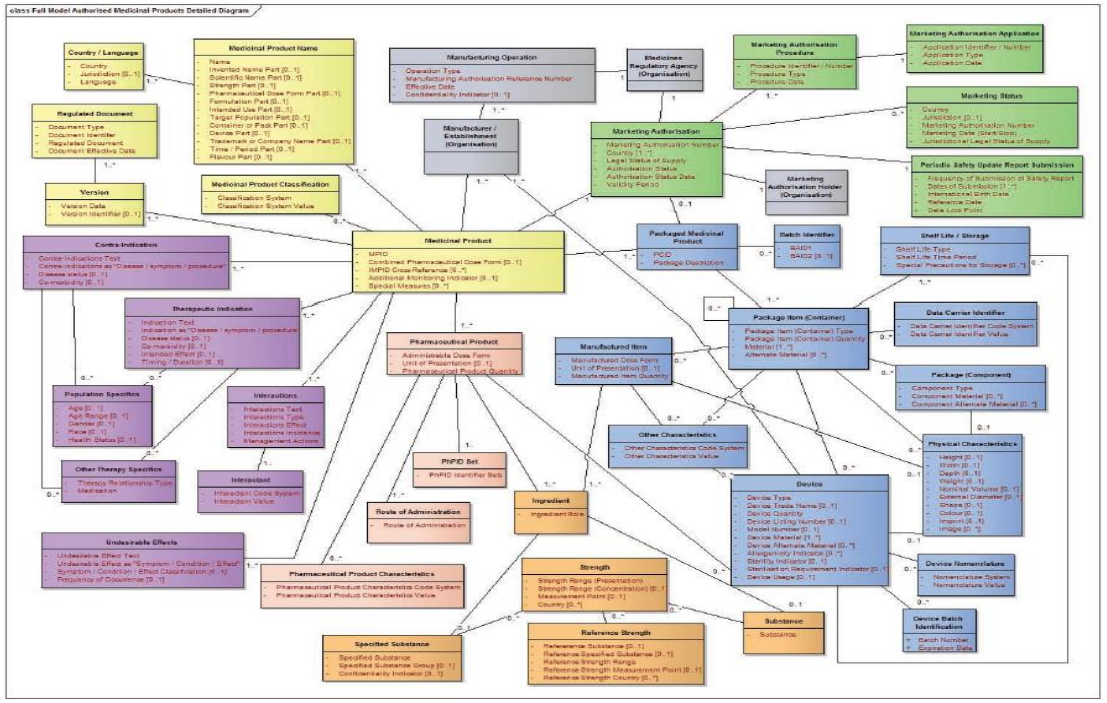
5 ISO Standards
containing ~250 data attributes



Unique Product Identifiers

PHPID	Pharmaceutical Product ID
MPID	Medicinal Product ID
SID	Substance ID
PCID	Medicinal Product Package ID
BAIDs	Medicinal Product Batch IDs

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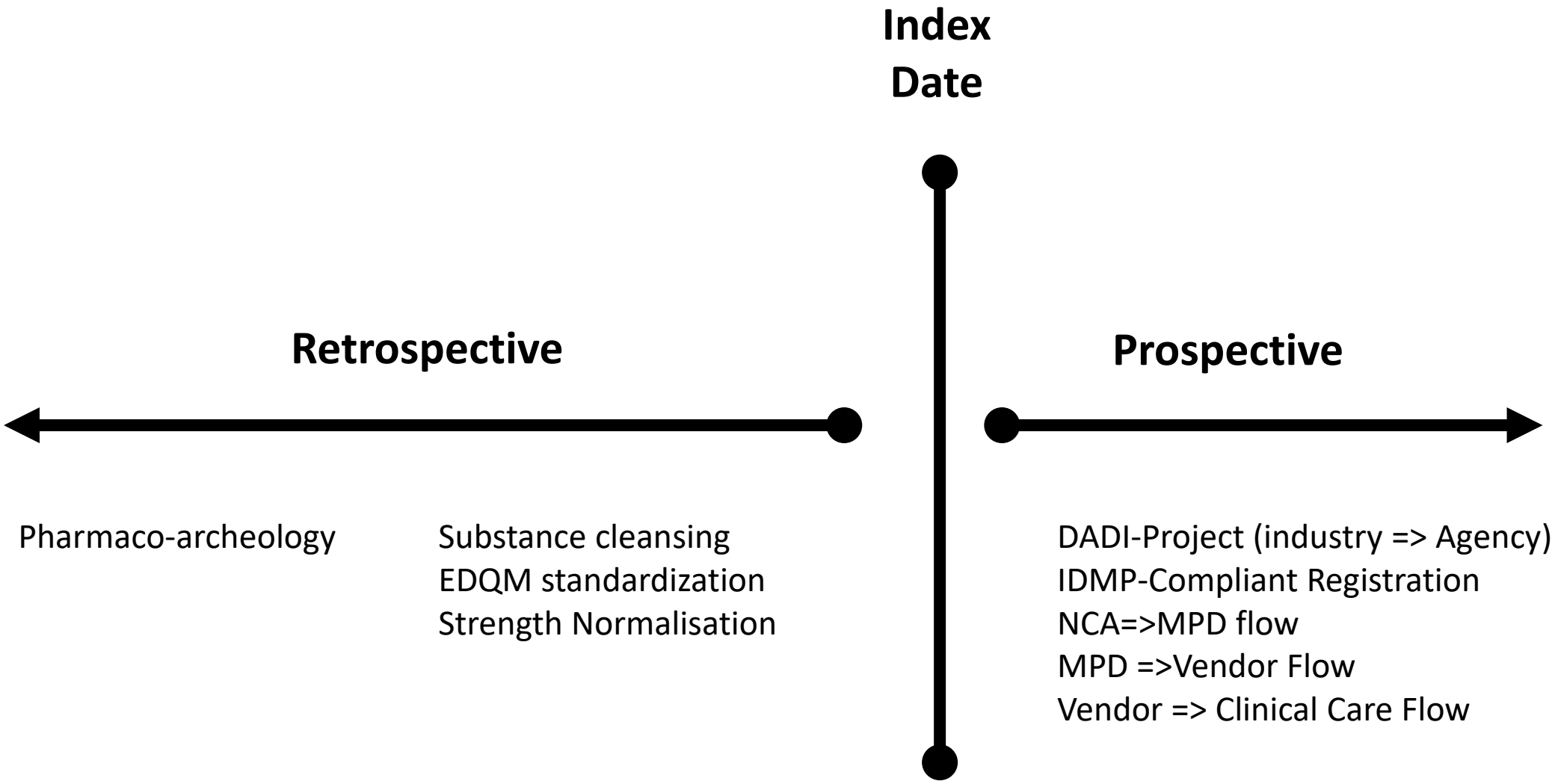
Perspective on Future and history of IDMP implementation



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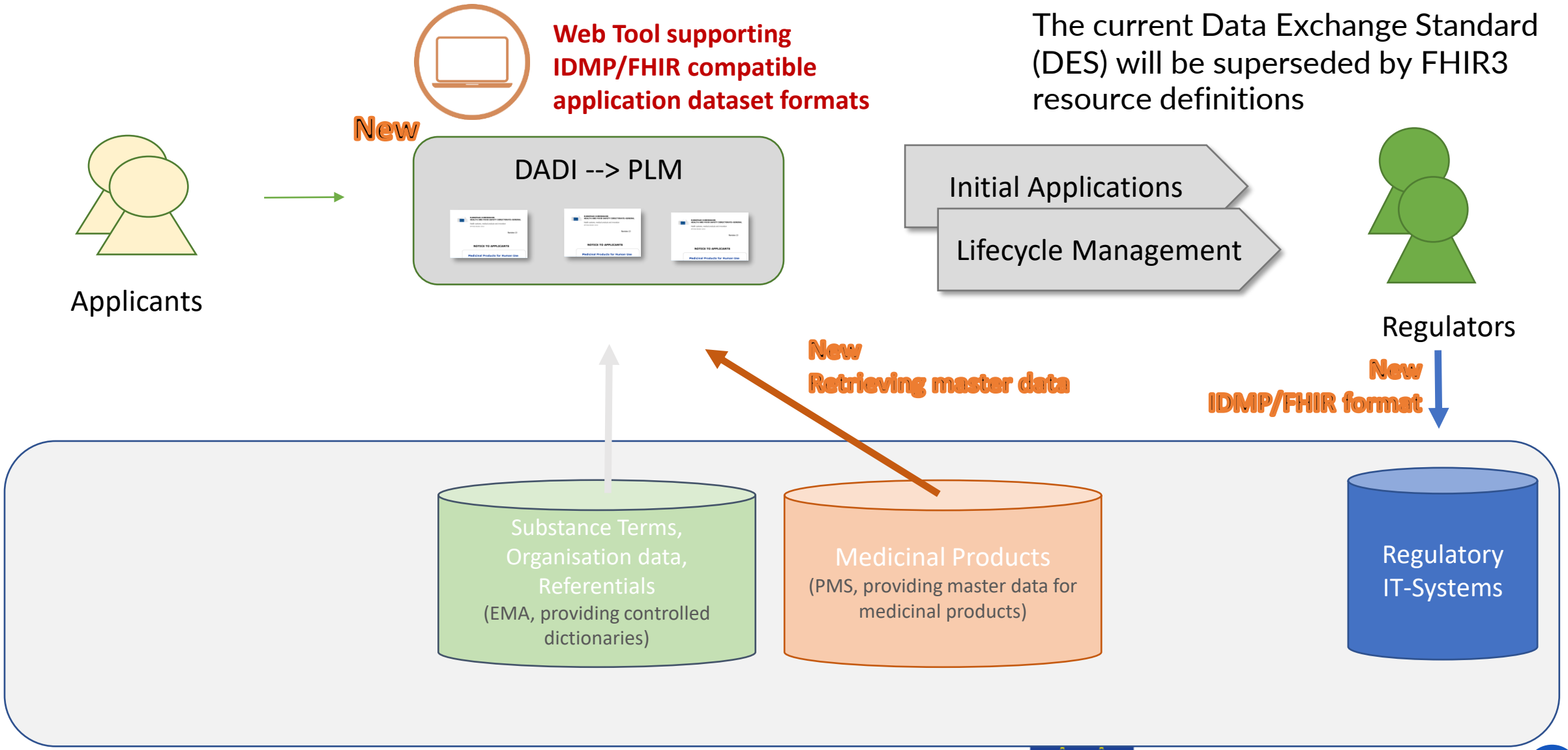
TO-BE: IDMP/FHIR compatible Electronic Application Forms



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TO-BE: Status of development

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WP 3

UAT partly achieved, **first Variation Application From release in production since 04/11/2022**

In progress

pending

Web Tool supporting IDMP/FHIR compatible application dataset formats

DADI

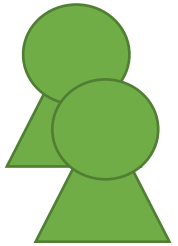
Variation Application

Initial Application

Renewal Application

Initial Applications

Lifecycle Management



Regulators

New Retrieving master data

New IDMP/FHIR format

Substance Terms, Organisation data, Referentials (EMA, providing controlled dictionaries)

Medicinal Products (PMS, providing master data for medicinal products)

Regulatory IT-Systems

See also collaboration with UNICOM WP4

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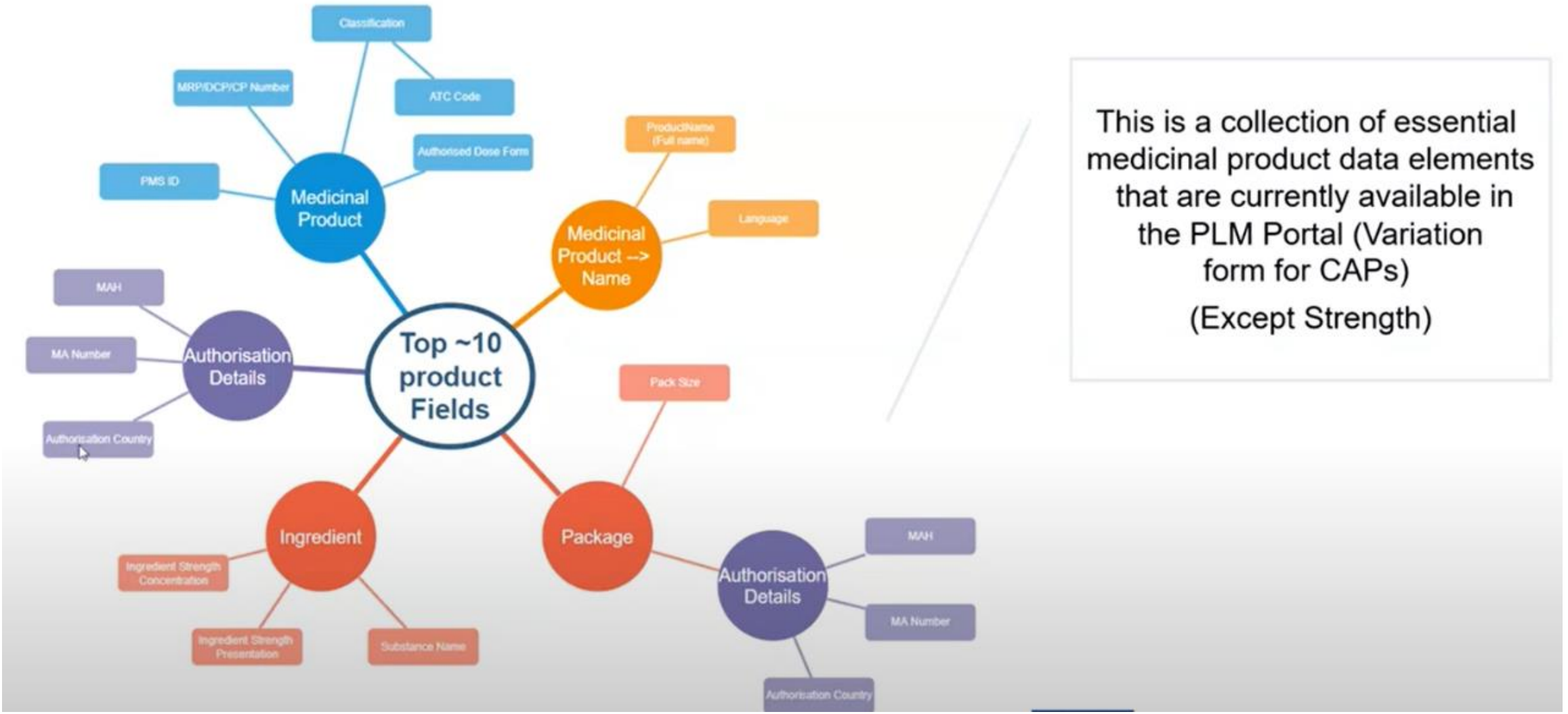
TOP 10 PRODUCT FIELDS



This is a collection of essential medicinal product data elements that are currently available in the PLM Portal (Variation form for CAPs)

(Except Strength)

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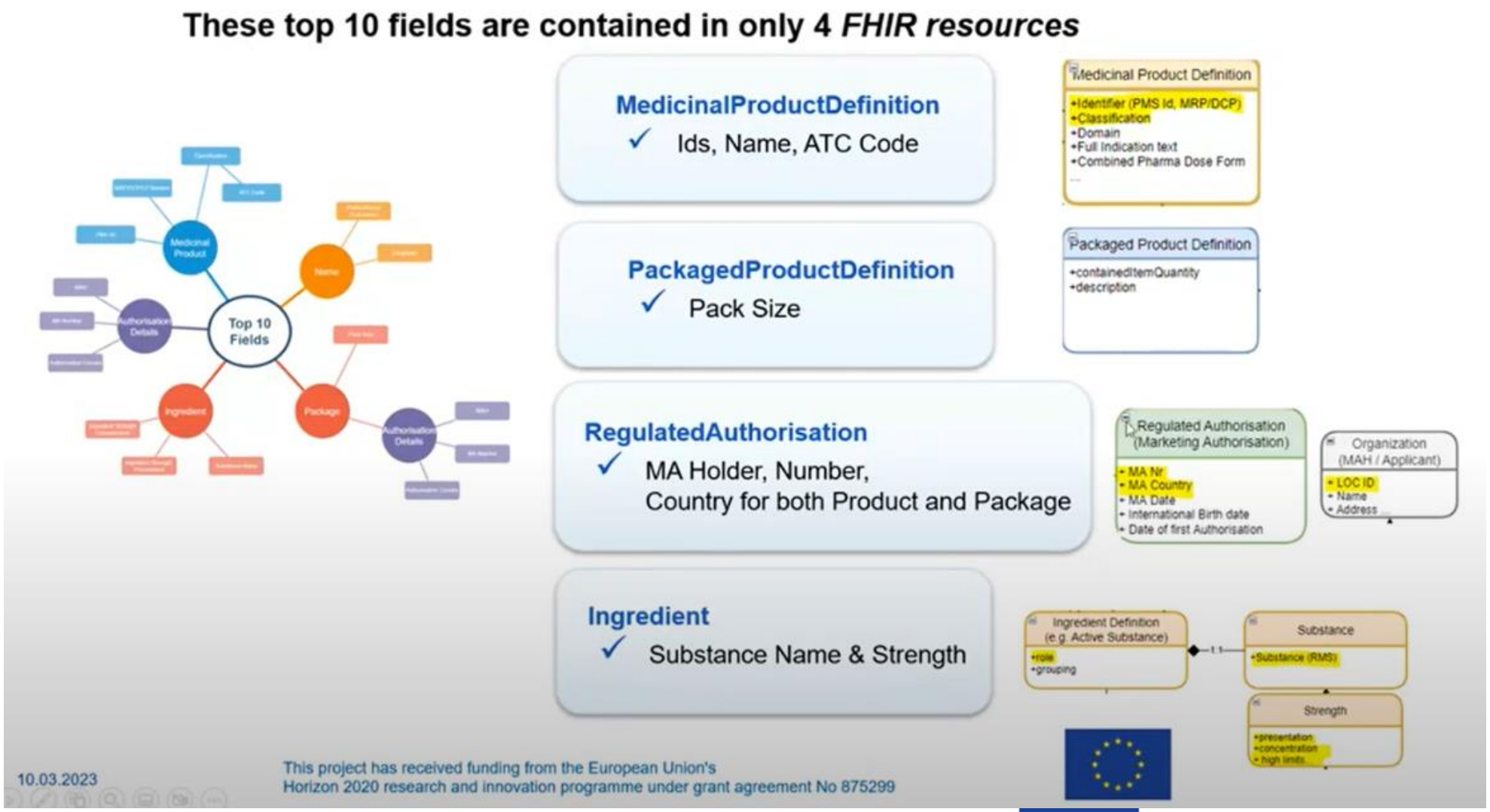
4 FHIR RESOURCES



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Delivery of selected ISO IDMP medicinal product data for cross-border pilots

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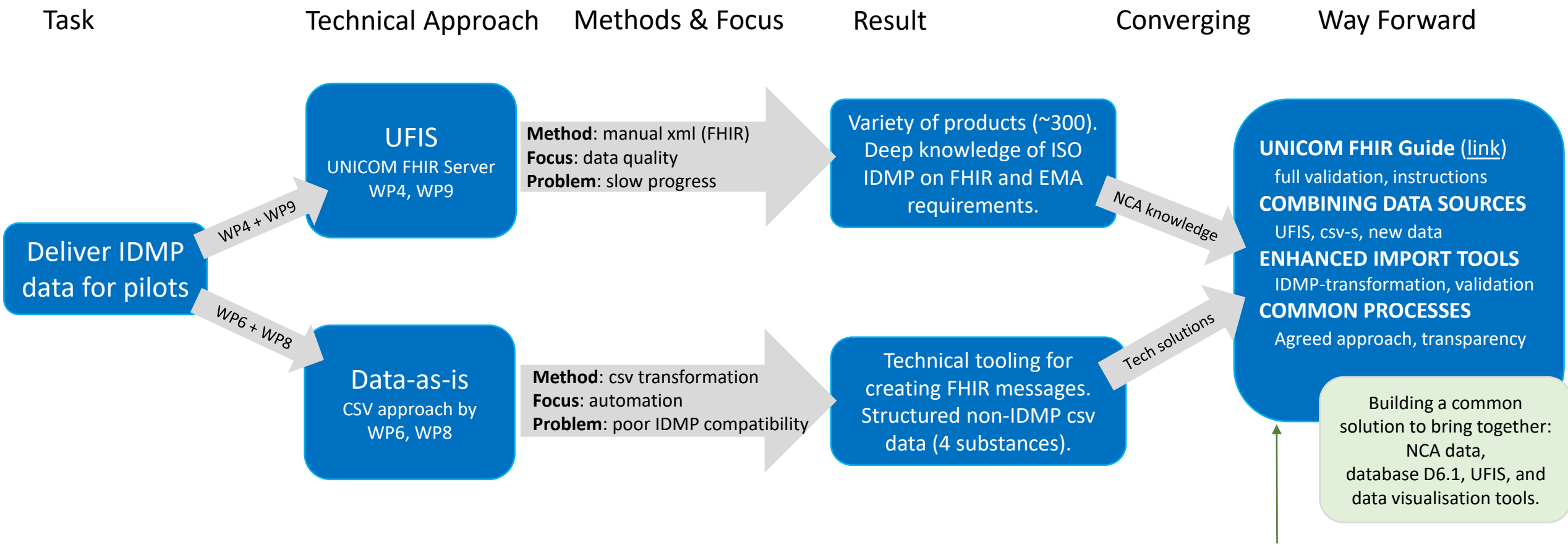
WP 4



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NCA readiness and implementation progress Matrix

1. Analysis and modelling											
GAP-analysis between current data model and IDMP											
Datamodelling based on GAP-analysis											
2. Mapping and transformation											
Data-mapping to RMS dictionary											
Data-mapping to OMS dictionary											
Data-mapping to SMS dictionary											
Data-transformation											
3. SPOR-connection											
Referentials RMS-connection											
Organisations OMS-connection											
Products PMS-connection											
Substances SMS-connection											
4. Prototype data feeds											
Prototyping and piloting of data feeds											

The Grand total will be filled out by the WP4 Lead based on the NCA reports

In progress according to plan or done	
Risk to be mitigated	
Progress in danger	
Not applicable	

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Burden of legacy conversion will be with the National Agencies

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There is no substitute for hard work in legacy conversion: 10.000 to 15.000 medicinal product packages per country

- Install an IDMP layer above their current systems

oR

- Re-engineer their current systems from scratch To a new IDMP compliant system of Drug Information

Strongly supported by central coordination (EU)

- Implementation Guide
- SPOR services
- Guidance
- Technical support

Validated by testing

- Internal and external validity checks
- Cross border Services
- Feedback from users

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Taking trusted IDMP data and delivers it to patients and clinicians, through MPD – the “last link in the chain”

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WP 9

MPD = Medicinal Product Dictionary* – the things that clinicians and patients use “in real life” within their systems (or apps) to describe medicines

A “**common approach and operating model” for best practice in using trusted IDMP data in patient care** in the different environments and with the different existing MPD that the member states have

* ISO: TS 19256 – MPD provide a “consistent representation of medication concepts (set of identifiers) at various levels of detail and with meaningful relationships between the concepts, in order to support parts of several processes in healthcare in which medication plays a role

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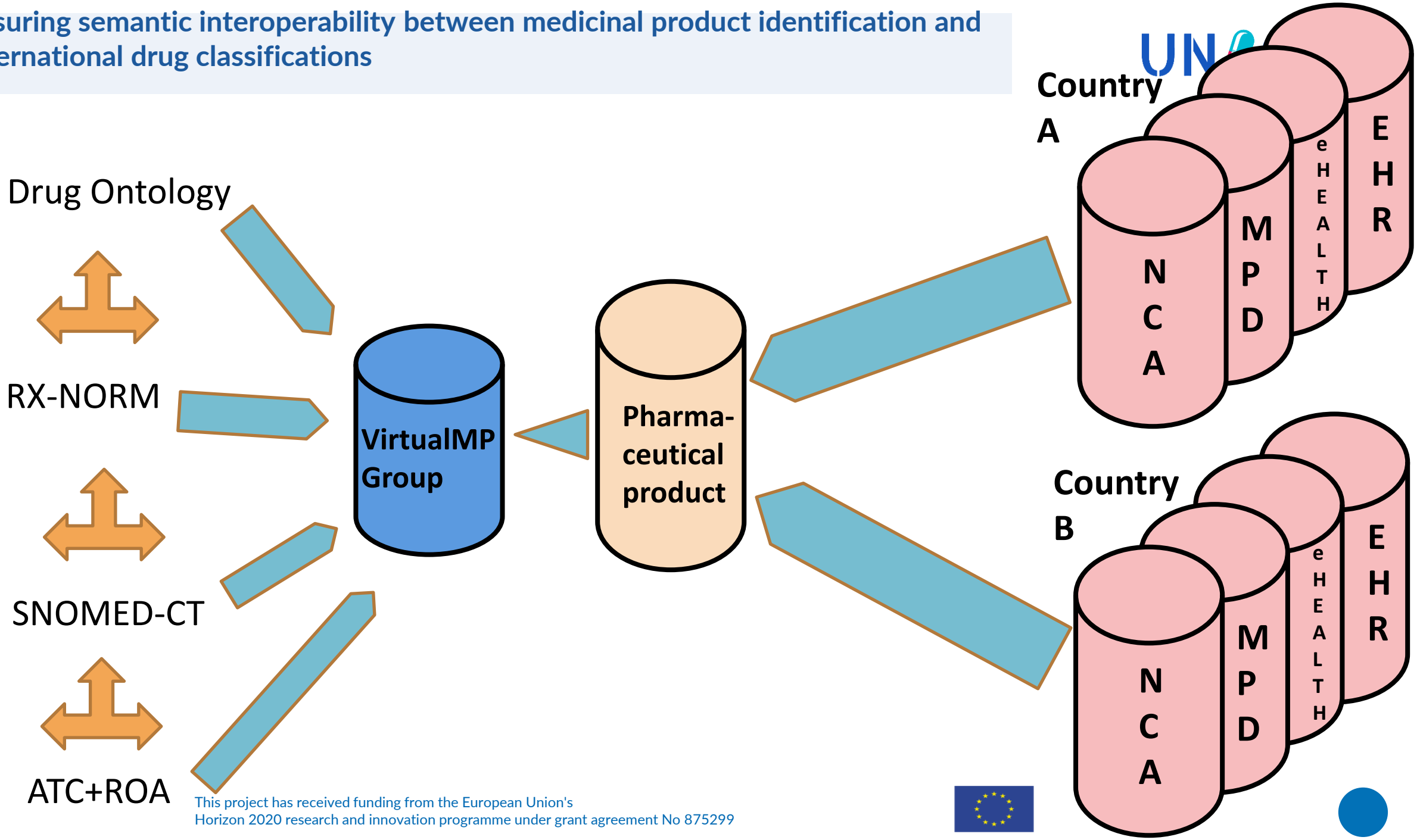
Assuring semantic interoperability between medicinal product identification and international drug classifications



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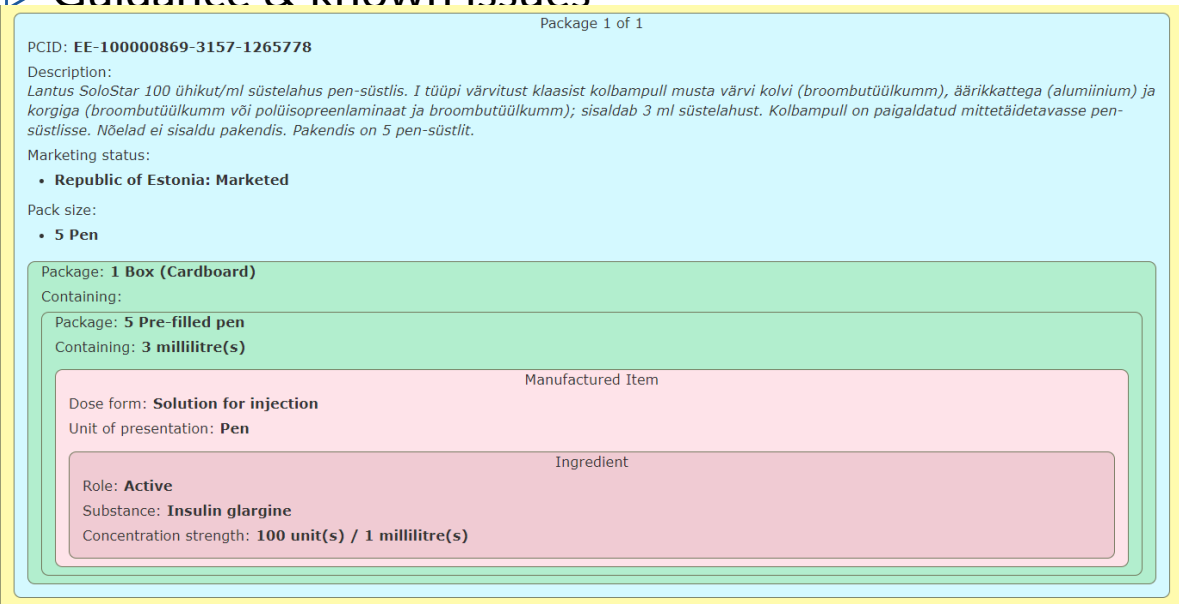
FHIR implementation guide contains

- Logical models
- FHIR profiles
- EMA SPOR & EDQM terminology
- Mappings
- **Example data with new visualiser**
- Custom search parameters
- Guidance & known issues



Name	Flags	Card.	Type	Description & Constraints
ManufacturedItemDefinition		0..*	ManufacturedItemDefinition	The definition and characteristics of a medicinal manufactured item, such as a tablet or capsule, as contained in a packaged medicinal product
implicitRules	?! Σ	0..1	uri	A set of rules under which this content was created
modifierExtension	?! Σ	0..*	Extension	Extensions that cannot be ignored
status	?! Σ	1..1	code	draft | active | retired | unknown **Binding:** PublicationStatus (required): The lifecycle status of an artifact.
manufacturedDoseForm	Σ	1..1	CodeableConcept	Dose form of the manufactured item (before preparing for administration) **Binding:** Pharmaceutical Dose Form (required)
unitOfPresentation	Σ	1..1	CodeableConcept	Unit of presentation of the manufactured item (before preparing for administration) **Binding:** Unit of Presentation EMA (required)

ManufacturedItemDefinition profile defines cardinalities and terminology bindings

UNICOM is the first to use such visualisation of example data inside FHIR IG

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CDA – New Identifiers for eHDSI Wave 6

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WP 6

Reference implementation supports the new identifiers *

Medicinal Product Identifier (MPID)

Medicinal Product Identifier	MPID_LantusSolostar

Pharmaceutical Product Identifier (PhPID)

Pharmaceutical Product Identifier	PhPID_LantusSolostar

Package identifier (PCID)

Package Identifier	PCID_LantusSolostar

Package Size	• Box
	  ◦ 5 unit(s) Pre-filled syringe
	  ▪ 3 milliliter Solution For injection in pre-filled syringe

* Even though the IDMP identifiers are not yet in existence, the CDA display tool has included them into its architecture to assure the presentation once they are.

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- **Usage: human view**
  - Specification & guidance
  - Data modelling help
  - Real-life examples
  - Bridge from regulatory domain to eHealth

- **Usage: machine-readable**
  - Automatic validation of data
  - Implementable specification for servers
  - Base template for new data
  - Custom search parameters
  - Mapping

Product Browser

ID	Name	Country	Viewer	Source
ABESYL-CAPS-10MG-CAP-204-GRC-MPD	**ABESYL CAPS 10MG/CAP**	Hellenic Republic	Viewer New Viewer	XML JSON
ABESYL-CAPS-5MG-CAP-203-GRC-MPD	**ABESYL CAPS 5MG/CAP**	Hellenic Republic	Viewer New Viewer	XML JSON
ADVIL-C-TAB-200MG-TAB-235-GRC-MPD	**ADVIL C.TAB 200MG/TAB**	Hellenic Republic	Viewer New Viewer	XML JSON
Agen-10mg-Tablet-EE-MPD	**AGEN 10 mg tabletid**	Republic of Estonia	Viewer New Viewer	XML JSON
Agen-5mg-Tablet-EE-MPD	**AGEN 5 mg tabletid**	Republic of Estonia	Viewer New Viewer	XML JSON

DataWizard's new product browser uses the IG as the base specification and for data migration tooling.

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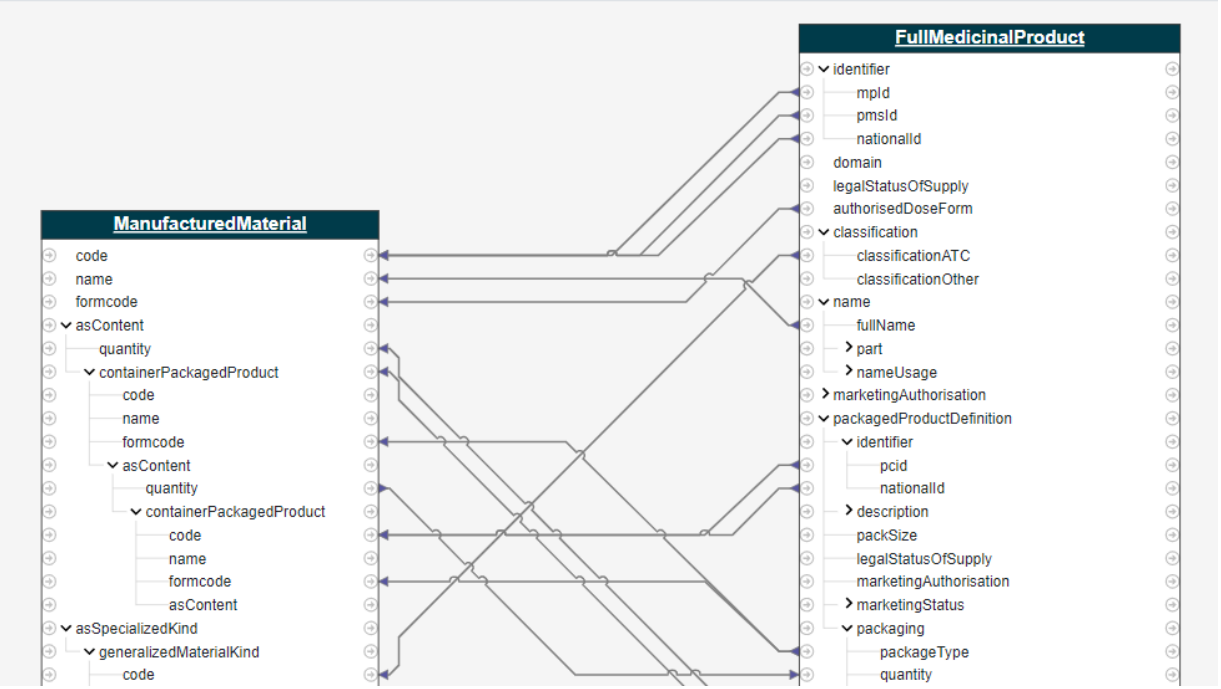
- **Next steps**
  - Finalise CDA-FHIR mapping in UNICOM context
  - Add all relevant terminology mappings
  - New dedicated sections for:
    - eHealth-regulatory bridge
    - Data migration
    - SNOMED bridge (?)
  - Report lessons learned



An exercise mapping between CDA medication template and PPL logical model

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Use Case ePrescription: IDMP Enhanced eP/eD & PS

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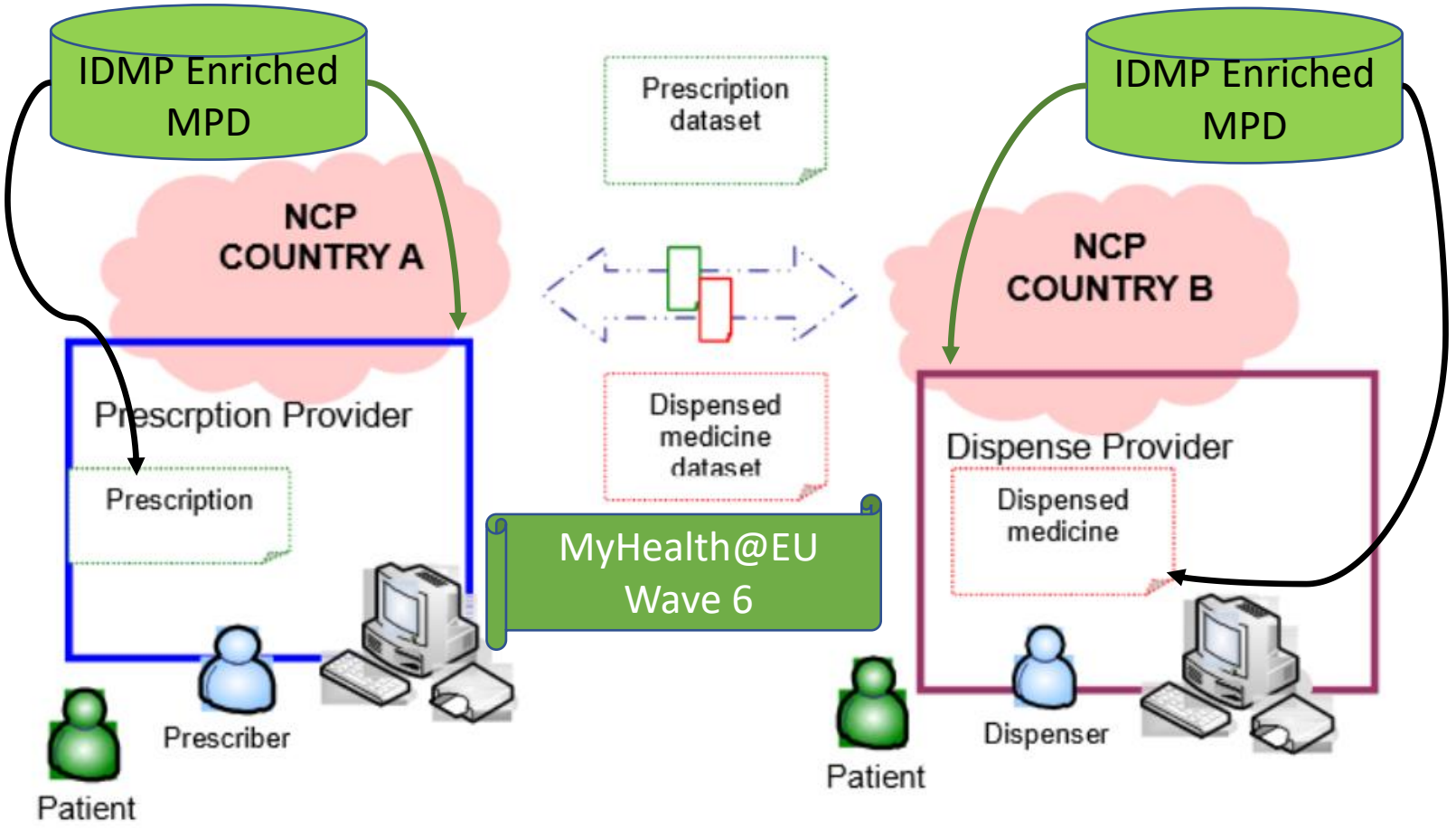
WP 7



- Member States would adopt in future in the National ePrescription Systems the IDMP Identifiers / Attributes

- ✓ MyHealth@EU Wave 6: IDMP Enhanced eP/eD & PS

- IDMP Attributes may be added when the eP/eD for cross-border use are generated before being transferred to the other Member State

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eHDSI Cross-Border Process: IDMP Identifiers - Operation

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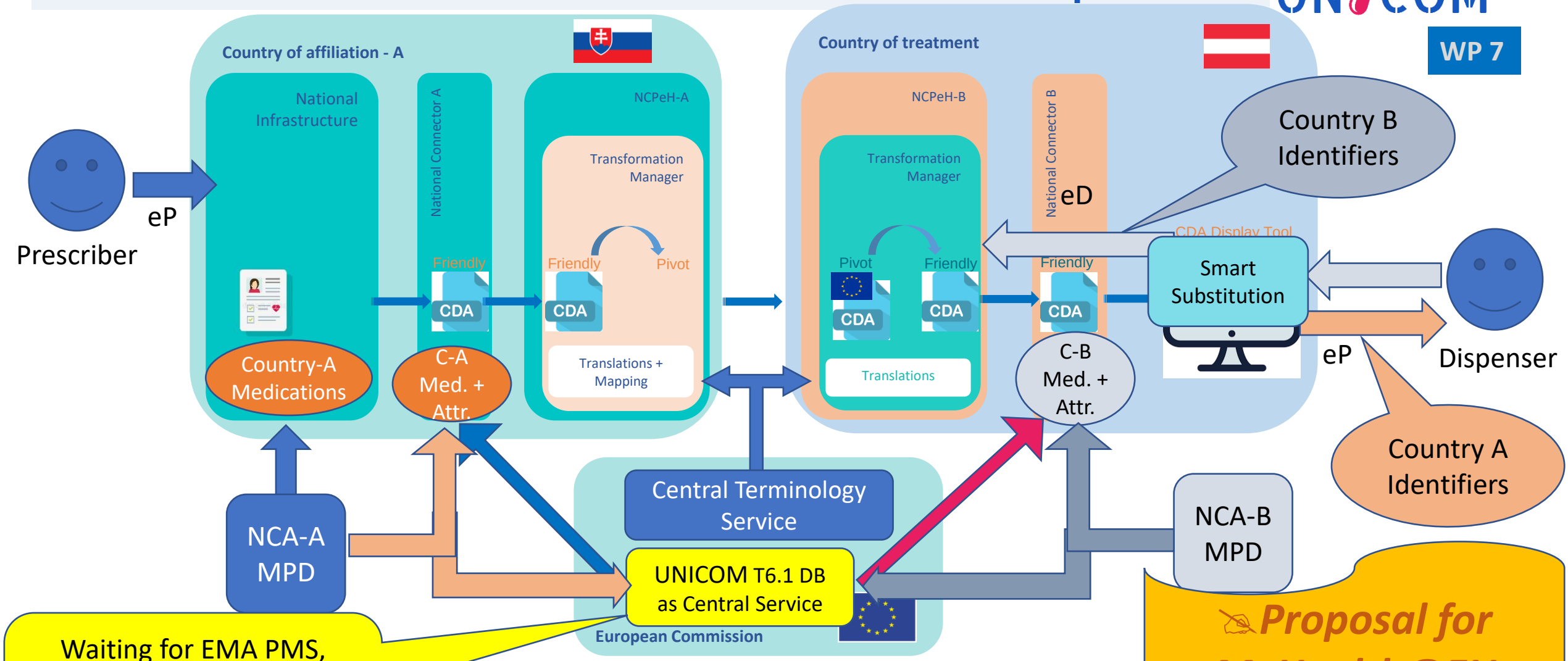
WP 7



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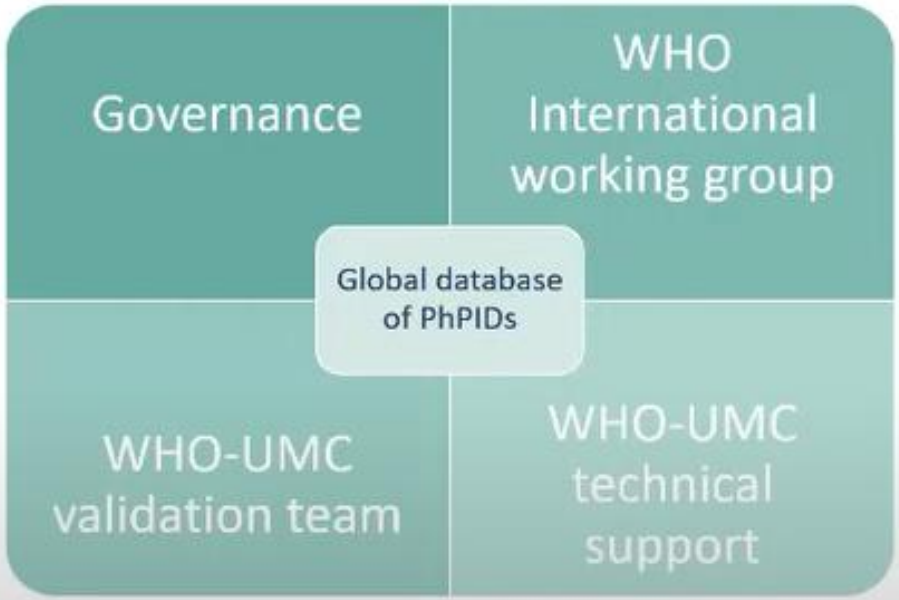
PhPID generation and governance

Proposed Global PhPID service responsibilities

- Setting the service offer, maintenance framework & validation process
- Regular reviews

- Validation according to agreed process
- Responding to questions and escalating issues
- Data updates including cross-references needed for pharmacovigilance



- Oversee assignments and solving issues
- Identify needs for updates of business rules
- Escalates to ISO for updates of the standard

- Ensure the availability of the service from a technical perspective
- User/API administration

Uppsala Monitoring Centre

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The UNICOM / GRAVITATE HEALTH Demonstrator

- Started with a personna based scenario: Elena's Journey
- Developed it into a technically testable scenario, with roles and interactions
- Developed the necessary **HL7 FHIR artefacts** to support the interactions during the September 2021 and Janary 2022 HL7 FHIR Connectathons
- **Collected test data, including the global PhPID for the relevant medications in different countries**
- Populated the UNICOM FHIR IDMP Server (UFIS) with the relevant test data
- Carried out tests during May 2022 HL7 FHIR Connectathon
  - Substitution at the hospital pharmacy in the country the patient is visiting
  - Retrieval of the electronic Product Information in the home language of the patient
- Used the scenario and the FHIR specifications to compile and submit a demonstrator presentation
- Presented the demonstrator during the Community of Expertise of August 2022
- Published a version of the demonstrator with a voice-over in January 2023 for broader communication

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The resulting demonstrator

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WP 1

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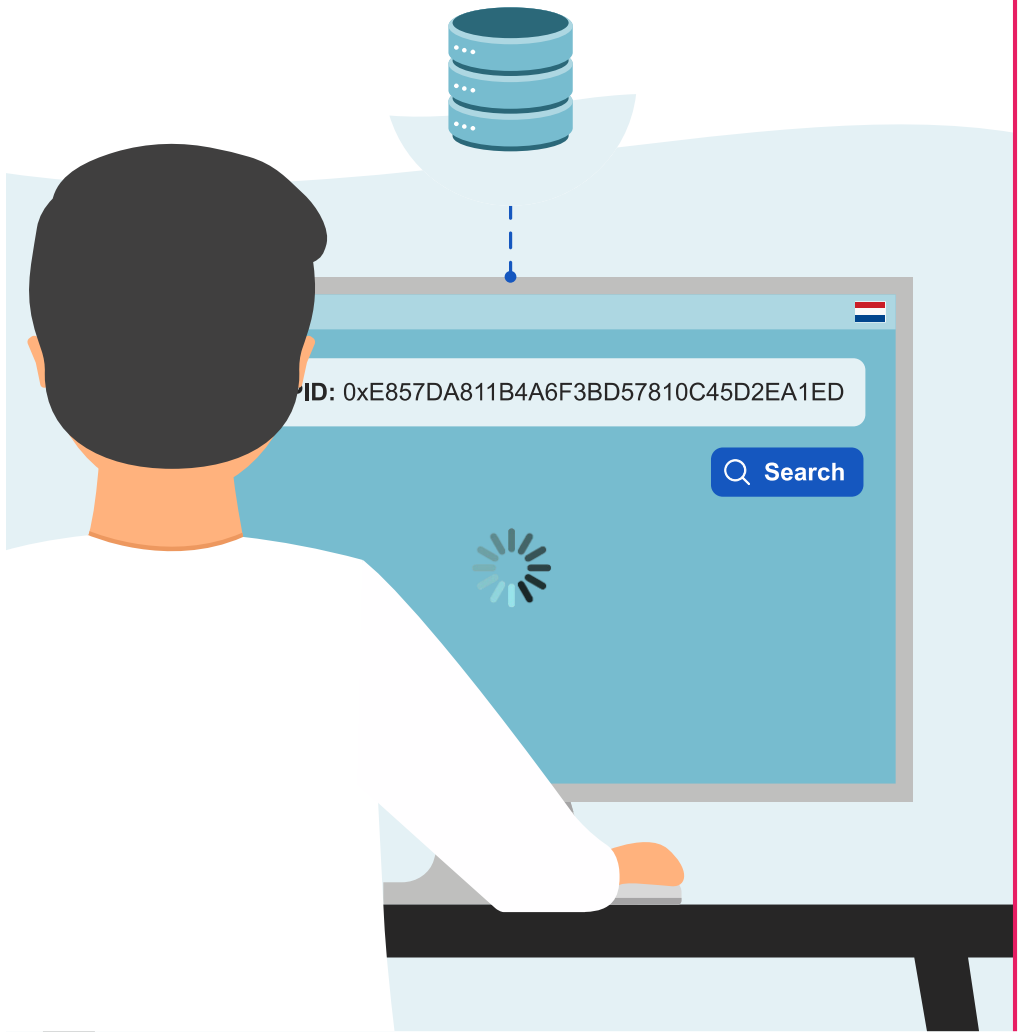
With actual interactions in HL7 FHIR format, using a global PhPID



Global PhPID: 0xE857DA811B4A6F3BD57810C45D2EA1ED

Pharmacy Information System

Global PhPID: 0xE857DA811B4A6F3BD57810C45D2EA1ED

Resources: AdministrableProductDefinition
MedicinalProductDefinition

MPD Product Look-up

NL MPD (UFIS)

Global PhPID: 0xE857DA811B4A6F3BD57810C45D2EA1ED

Search: [mpd fhir server]/AdministrableProductDefinition? identifier=https://www.who-umc.org/phpid|[PhPID]
&_include=AdministrableProductDefinition:form-of

FCAT May 2022, FHIR 4.6.0

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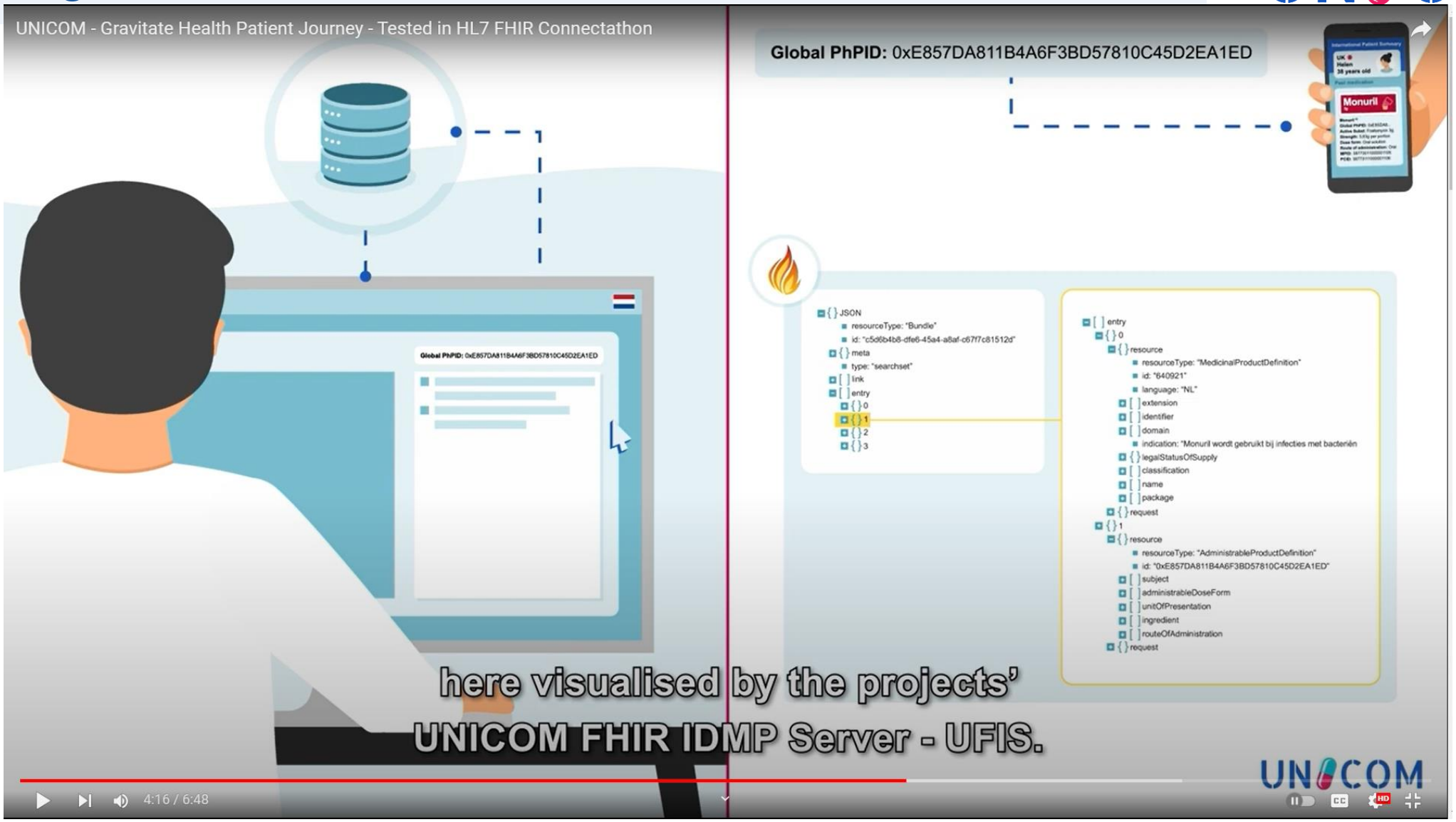
Connecting to the UNICOM FHIR IDMP



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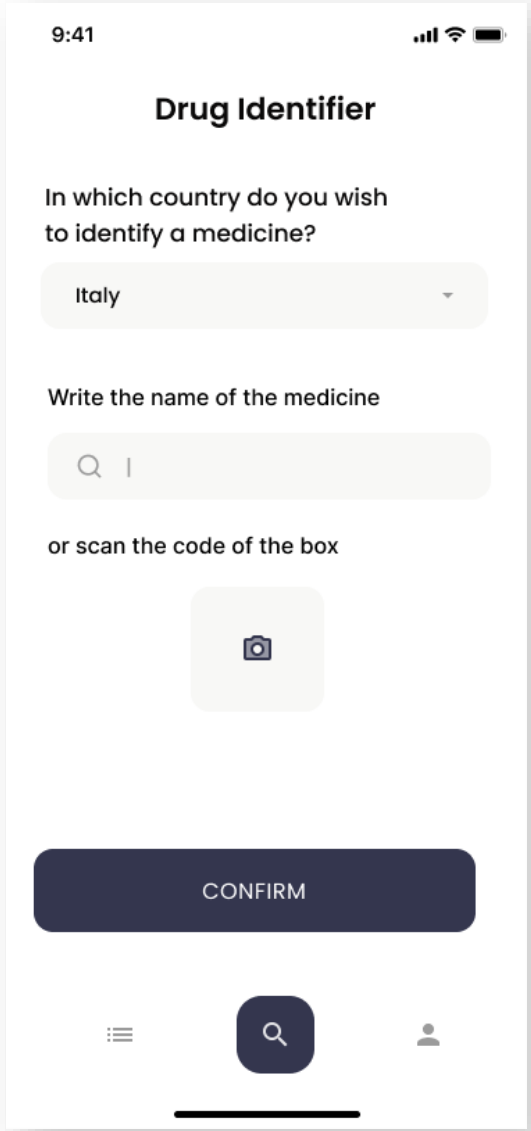
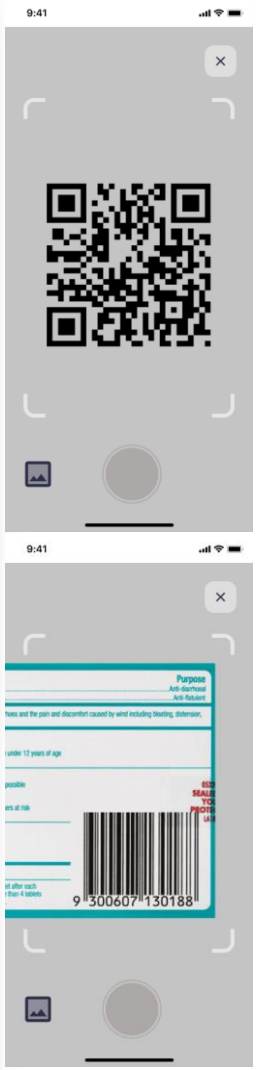
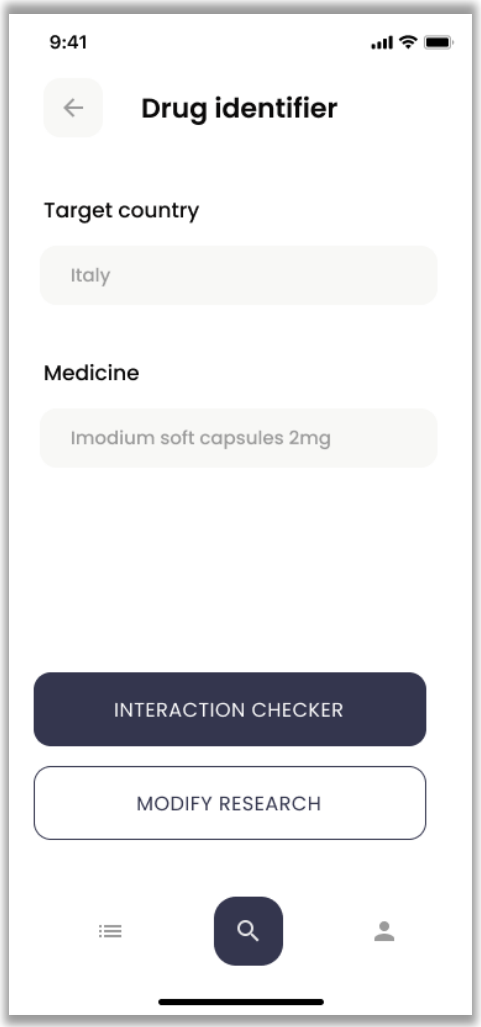
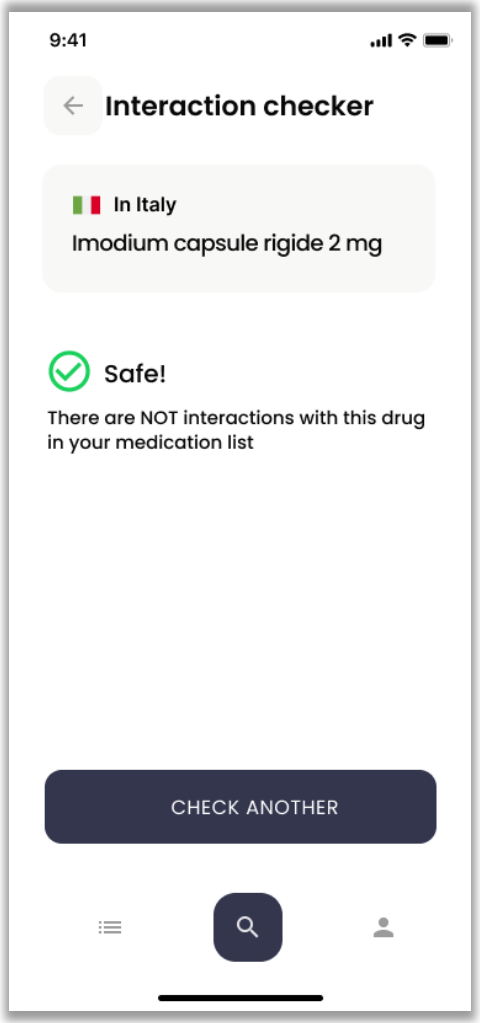
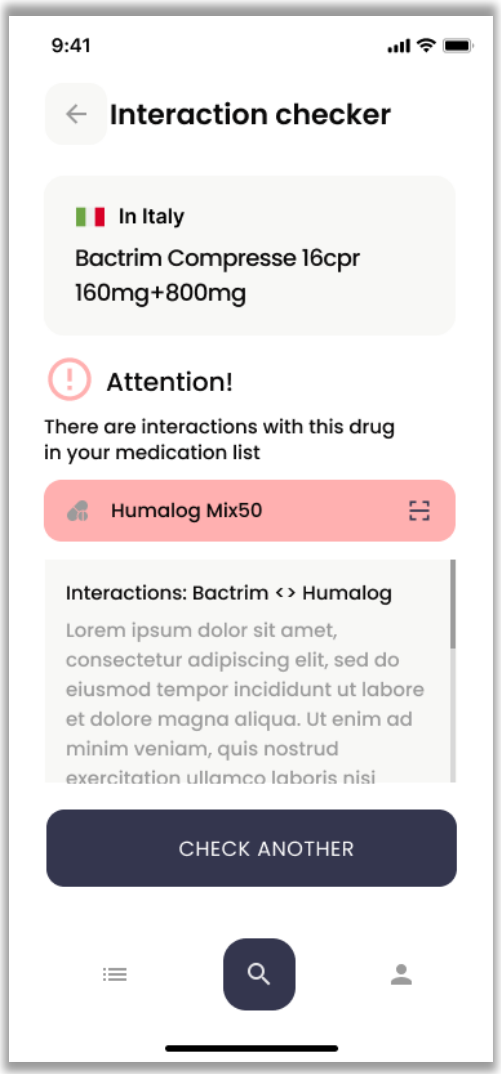
In an ideal world we will....











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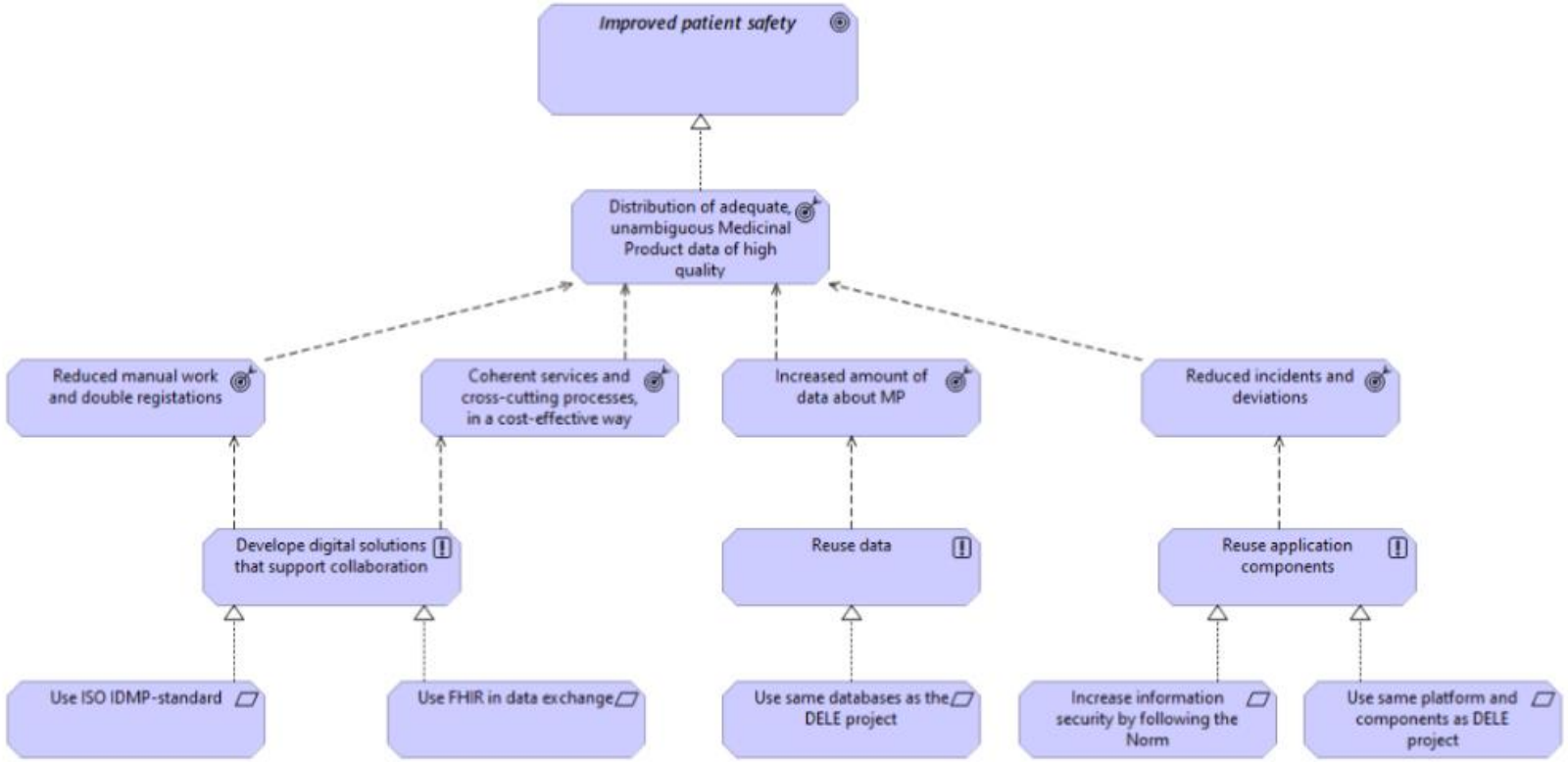
The vision is improved patient safety

by distribution of adequate, unambiguous, high-quality data about medicinal products



Norwegian Medicines Agency

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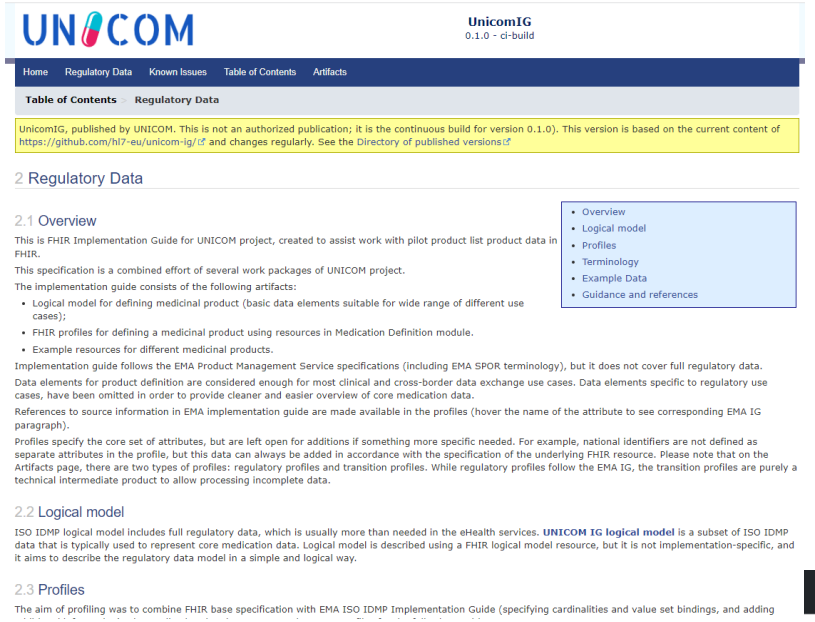
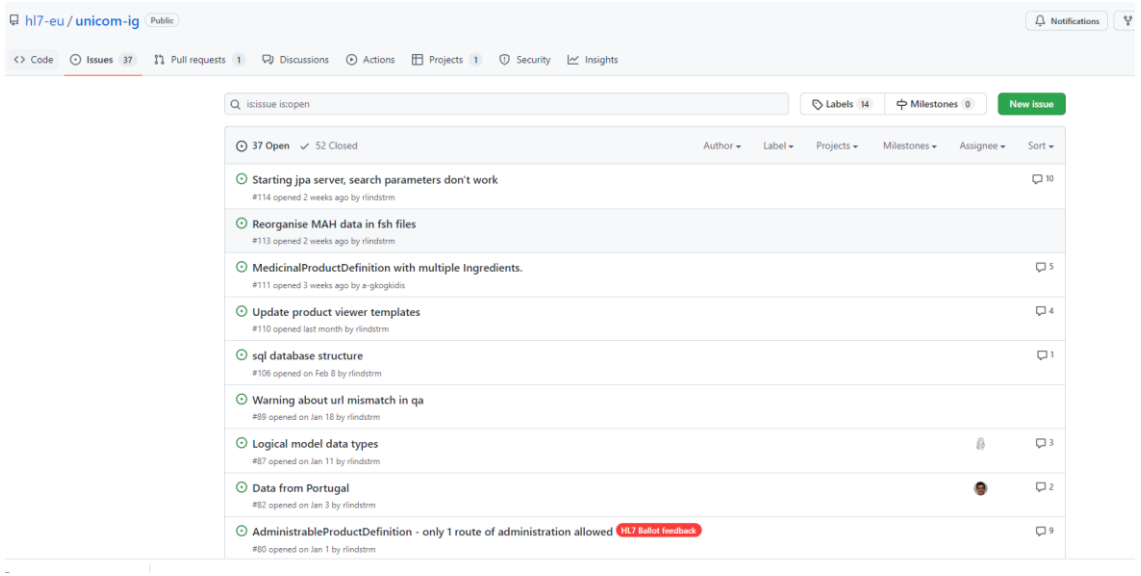
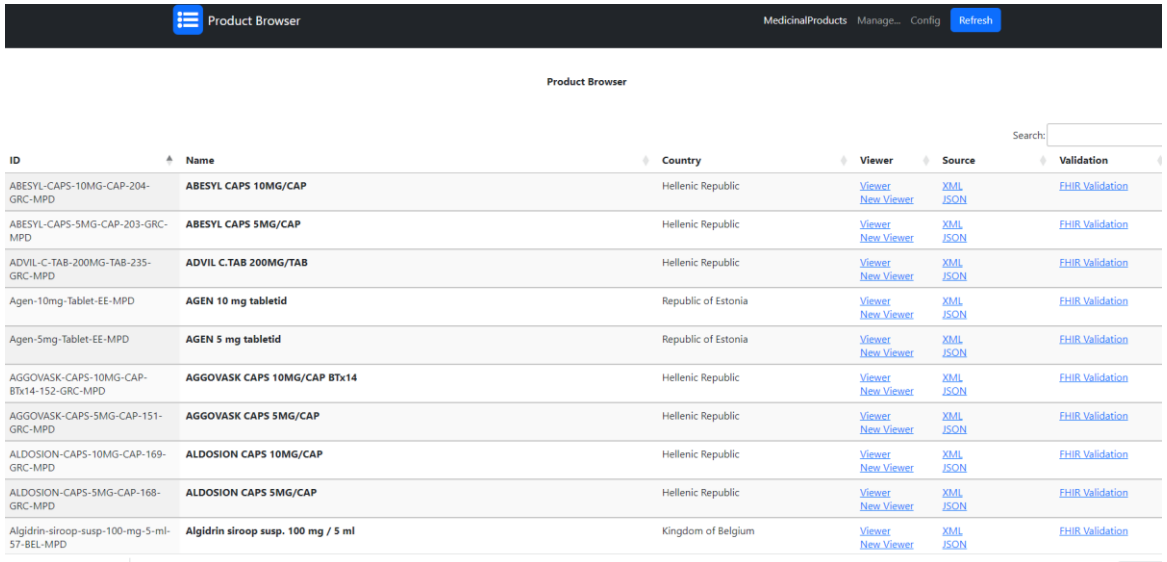
Access the key resources and be part of the adventure !







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THANK YOU

Our website
Our youtube channel

ISO IDMP Handbook "IDMP in a capsule" in English

With also French translation of "IDMP dans une capsule"

And even a Greek version: "IDMP σε κάψουλα »

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