

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

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



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 !



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.



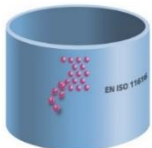
Substances (Substance ID/Specified Substance ID) - ISO 11238



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



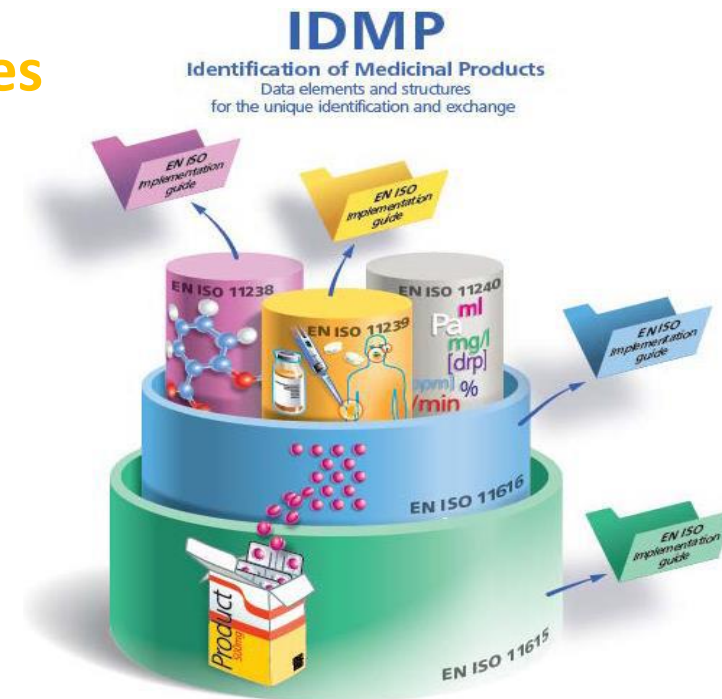
Units of measurement - ISO 11240



Pharmaceutical product (PhPID) - ISO 11616



Medicinal product (MPID/PCID) - ISO 11615



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*»

IDMP

Identification of Medicinal Products
Data elements and structures
for the unique identification and exchange



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

- ▶ 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

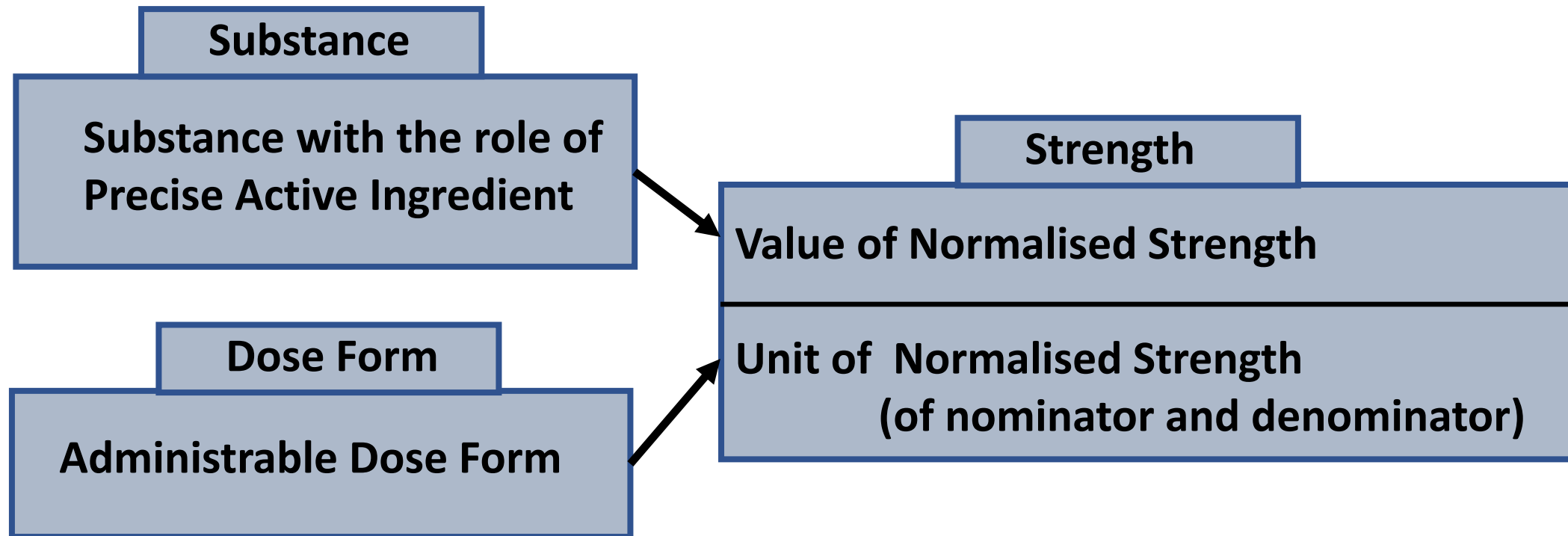


- ▶ Pharmacovigilance
 - ▷ Same medicinal product
 - Different name, expression of dosage, pharmaceutical dose form, route of administration
 - ▷ Same medicinal product?
 - What about substance(s)?
- ▶ Cross border prescriptions
 - ▷ How to identify medicinal products un-ambiguously?
 - ▷ How to decide 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?



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



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

- ❖ 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

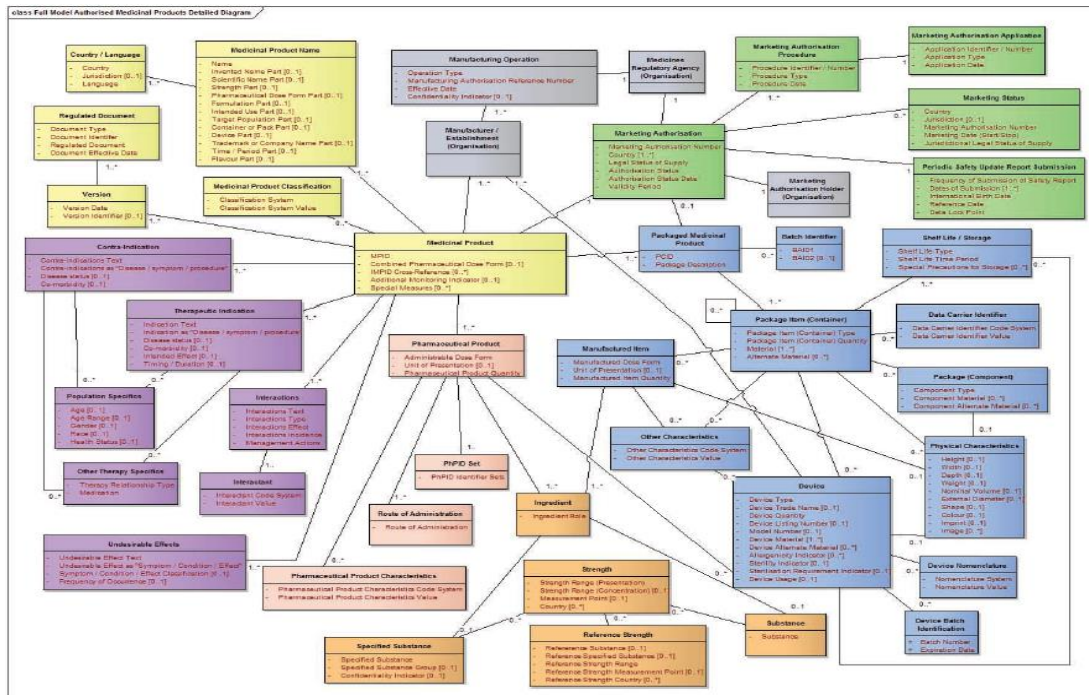


IDMP: from data models and terminologies to identifiers

5 ISO Standards containing ~250 data attributes

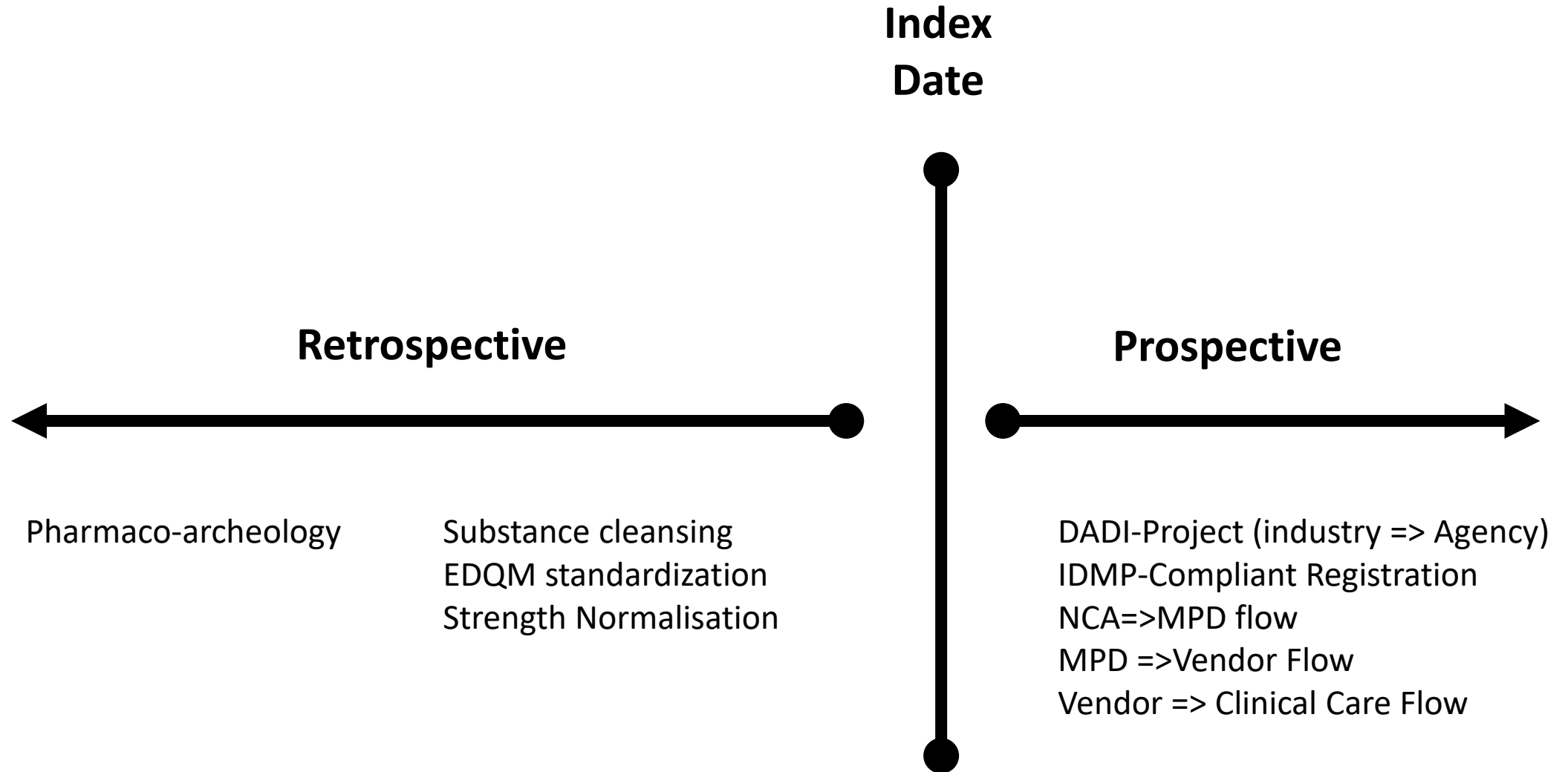


Unique Product Identifiers

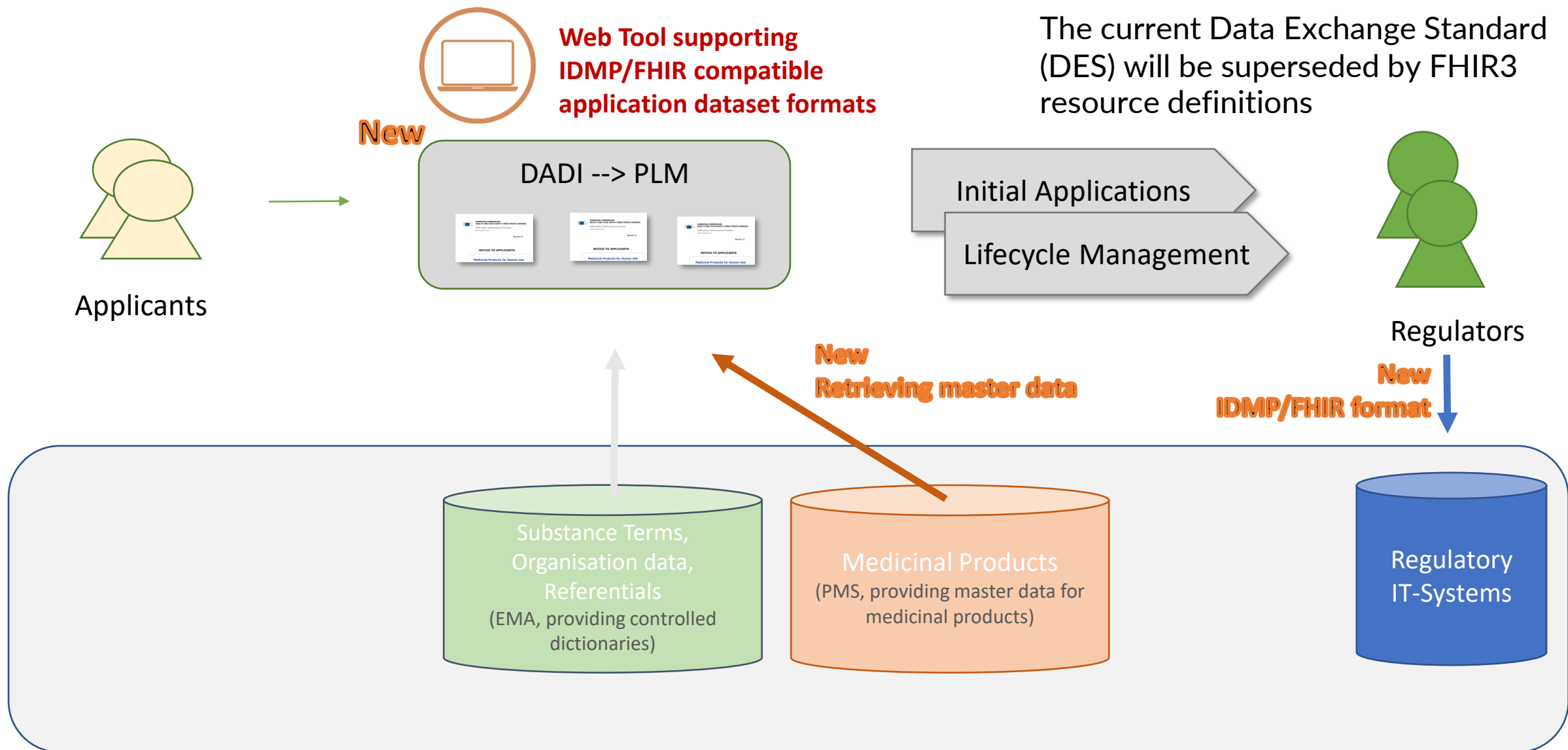


- PHPID** Pharmaceutical Product ID
- MPID** Medicinal Product ID
- SID** Substance ID
- PCID** Medicinal Product Package ID
- BAIDs** Medicinal Product Batch IDs





TO-BE: IDMP/FHIR compatible Electronic Application Forms



TO-BE: Status of development

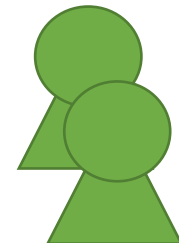
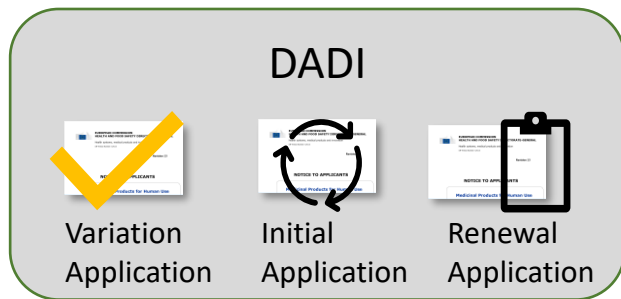
✓ UAT partly achieved, first Variation Application From release in production since 04/11/2022

↻ In progress

📄 pending

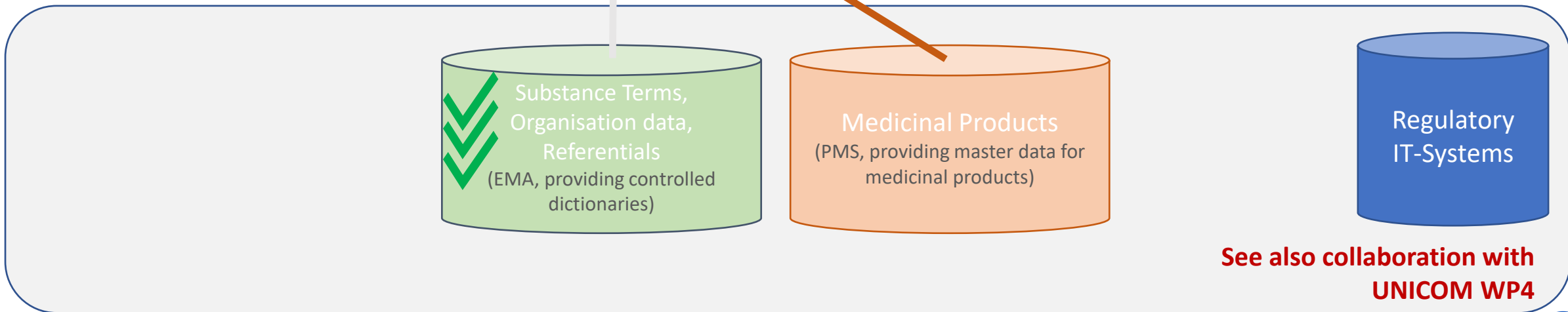


Web Tool supporting IDMP/FHIR compatible application dataset formats



Regulators

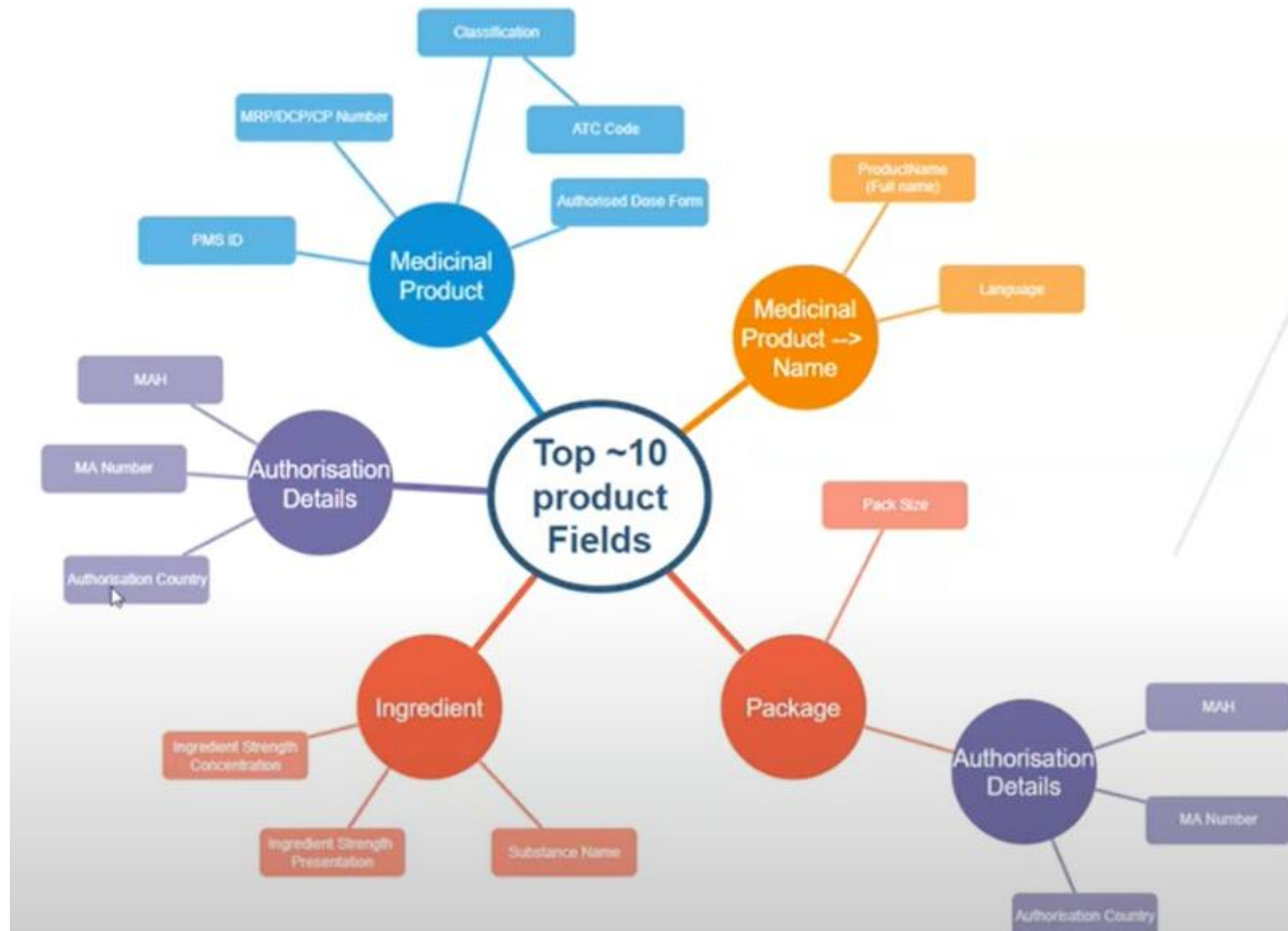
✓ New IDMP/FHIR format



See also collaboration with UNICOM WP4



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)



4 FHIR RESOURCES

These top 10 fields are contained in only 4 *FHIR* resources



MedicinalProductDefinition

- ✓ Ids, Name, ATC Code

Medicinal Product Definition

- Identifier (PMS Id, MRP/DCP)
- Classification
- Domain
- Full Indication text
- Combined Pharma Dose Form

PackagedProductDefinition

- ✓ Pack Size

Packaged Product Definition

- containedItemQuantity
- description

RegulatedAuthorisation

- ✓ MA Holder, Number, Country for both Product and Package

Regulated Authorisation (Marketing Authorisation)

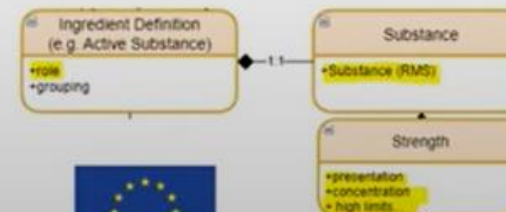
- MA Nr
- MA Country
- MA Date
- International Birth date
- Date of first Authorisation

Organization (MAH / Applicant)

- LOC ID
- Name
- Address

Ingredient

- ✓ Substance Name & Strength



10.03.2023

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



Task Technical Approach Methods & Focus Result Converging Way Forward

Deliver IDMP data for pilots

WP4 + WP9

UFIS
UNICOM FHIR Server
WP4, WP9

Method: manual xml (FHIR)
Focus: data quality
Problem: slow progress

Variety of products (~300).
Deep knowledge of ISO IDMP on FHIR and EMA requirements.

WP6 + WP8

Data-as-is
CSV approach by
WP6, WP8

Method: csv transformation
Focus: automation
Problem: poor IDMP compatibility

Technical tooling for creating FHIR messages.
Structured non-IDMP csv data (4 substances).

NCA knowledge

Tech solutions

UNICOM FHIR Guide ([link](#))
full validation, instructions
COMBINING DATA SOURCES
UFIS, csv-s, new data
ENHANCED IMPORT TOOLS
IDMP-transformation, validation
COMMON PROCESSES
Agreed approach, transparency

Building a common solution to bring together:
NCA data,
database D6.1, UFIS, and
data visualisation tools.



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											
<i>The Grand total will be filled out by the WP4 Lead based on the NCA reports</i>											
In progress according to plan or done											
Risk to be mitigated											
Progress in danger											
Not applicable											

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

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

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

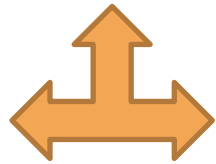


A “**common approach and operating model**” for best practice in using trusted IDMP data in patient **care** in the different environments and with the different existing MPD that the member states have

* 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

Assuring semantic interoperability between medicinal product identification and international drug classifications

Drug Ontology



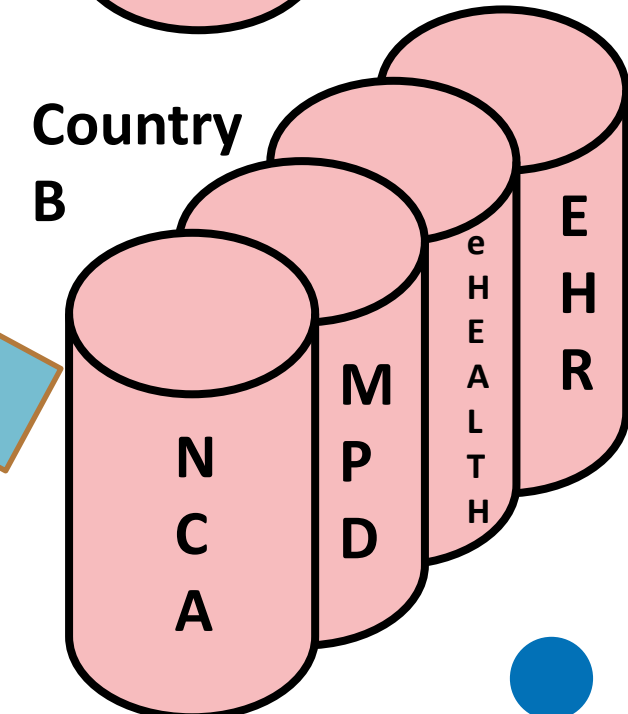
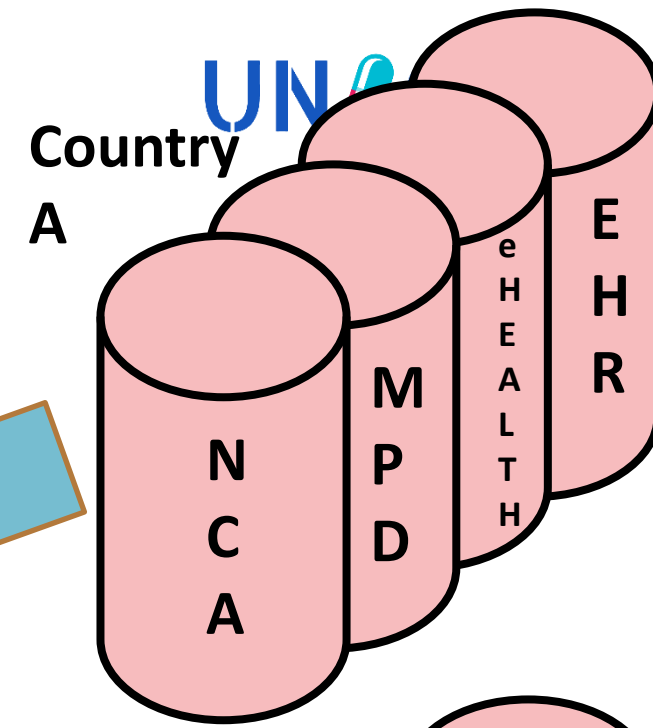
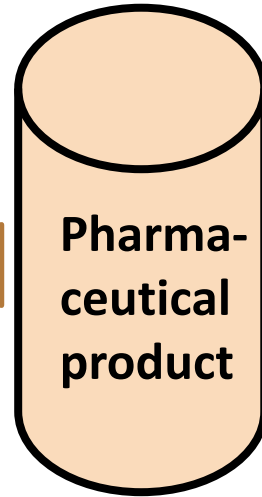
RX-NORM



SNOMED-CT



ATC+ROA



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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

Package 1 of 1

PCID: EE-100000869-3157-1265778

Description:
Lantus SoloStar 100 ühikut/ml süstelahus pen-süstlis. I tüüpi värvitust klaasist kolbampull musta värvi kolvi (broombutüülkumm), äärikkattega (alumiinium) ja korgiga (broombutüülkumm või polüisopreenlaminaat ja broombutüülkumm); sisaldab 3 ml süstelahust. Kolbampull on paigaldatud mittetäidetavasse pen-süstlisse. Nõelad ei sisaldu pakendis. Pakendis on 5 pen-süstlit.

Marketing status:

- Republic of Estonia: Marketed

Pack size:

- 5 Pen

Package: 1 Box (Cardboard)

Containing:

Package: 5 Pre-filled pen

Containing: 3 millilitre(s)

Manufactured Item

Dose form: **Solution for injection**

Unit of presentation: **Pen**

Ingredient

Role: **Active**

Substance: **Insulin glargine**

Concentration strength: **100 unit(s) / 1 millilitre(s)**

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

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.



► 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

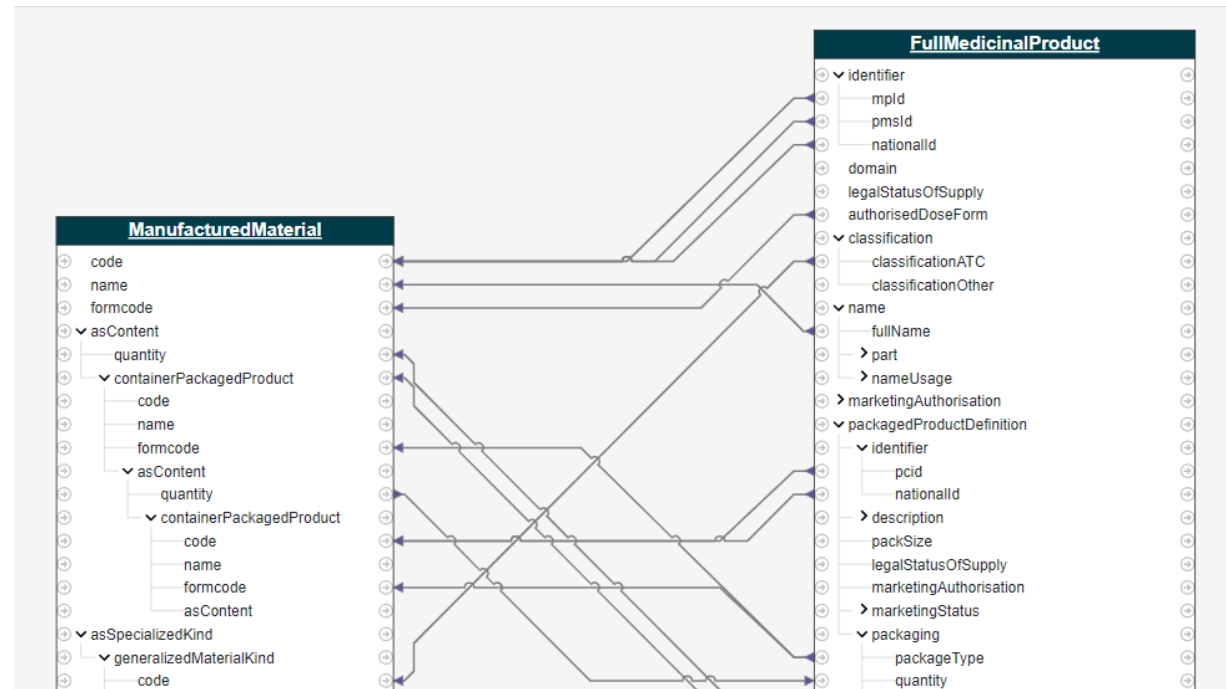
Product Browser

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

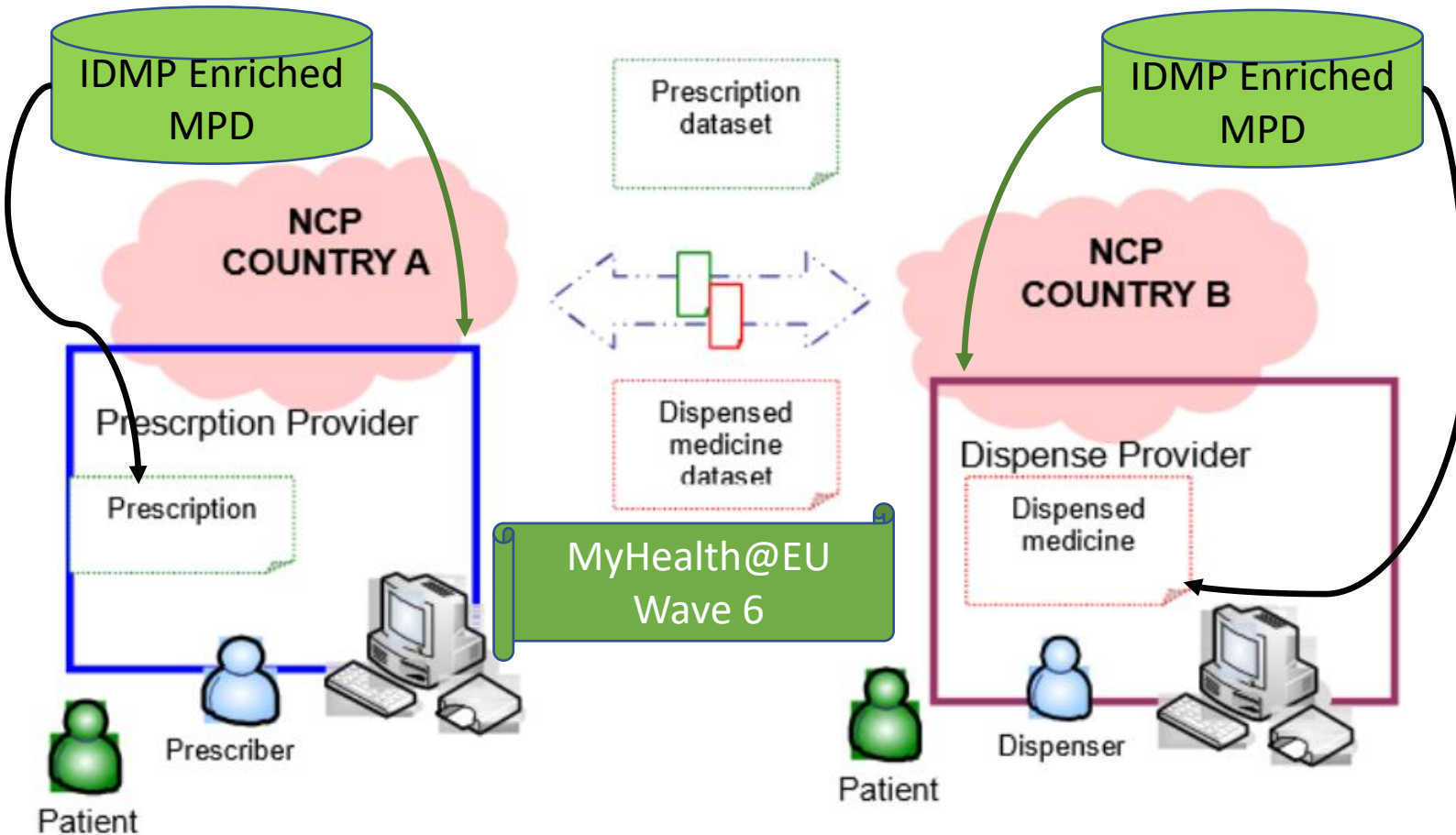
DataWizard's [new product browser](#) uses the IG as the base specification and for data migration tooling.

▶ 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

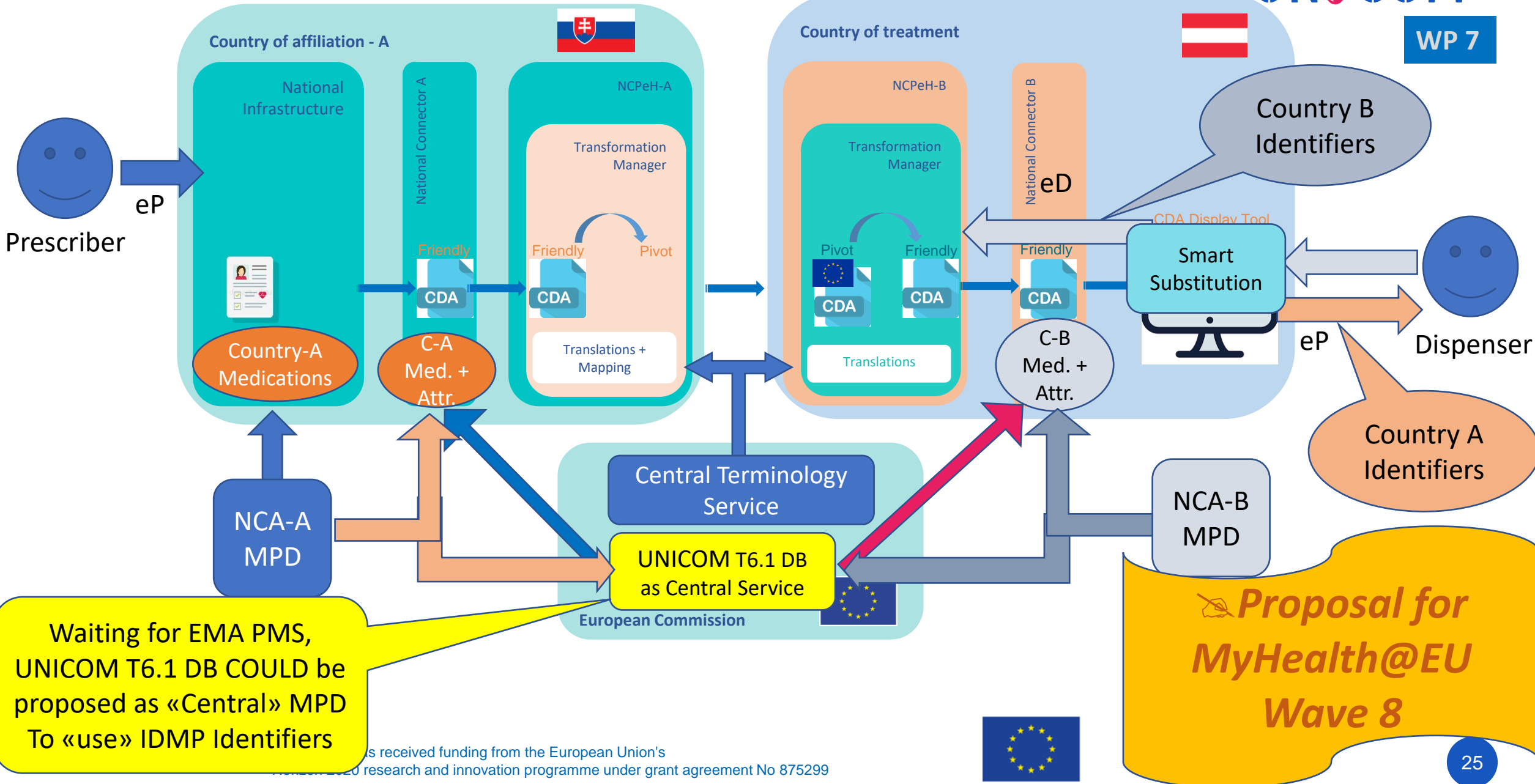


An exercise mapping between CDA medication template and PPL logical model



- 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

eHDSI Cross-Border Process: IDMP Identifiers - Operation



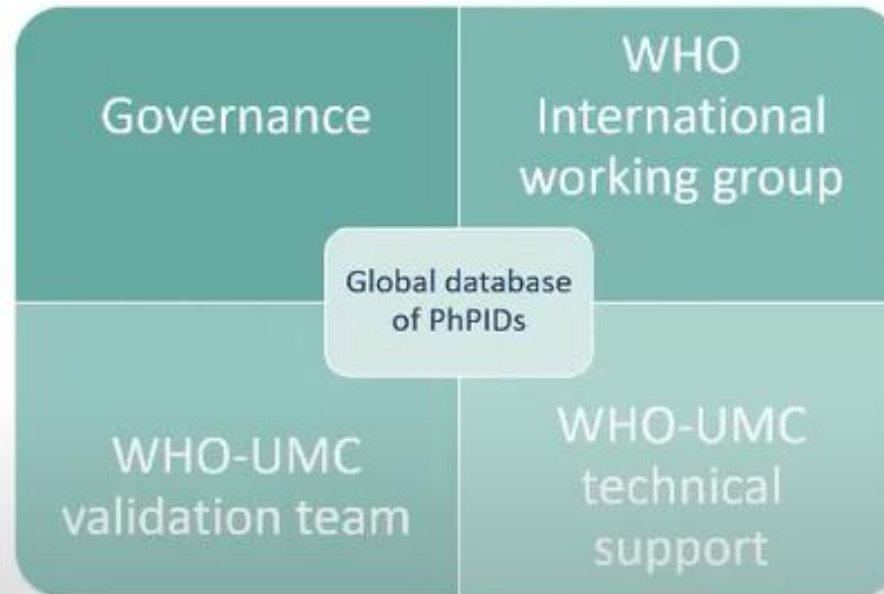
Waiting for EMA PMS, UNICOM T6.1 DB COULD be proposed as «Central» MPD To «use» IDMP Identifiers

Proposal for MyHealth@EU Wave 8



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

The UNICOM / GRAVITATE HEALTH Demonstrator

- ▶ Started with a persona 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 January 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



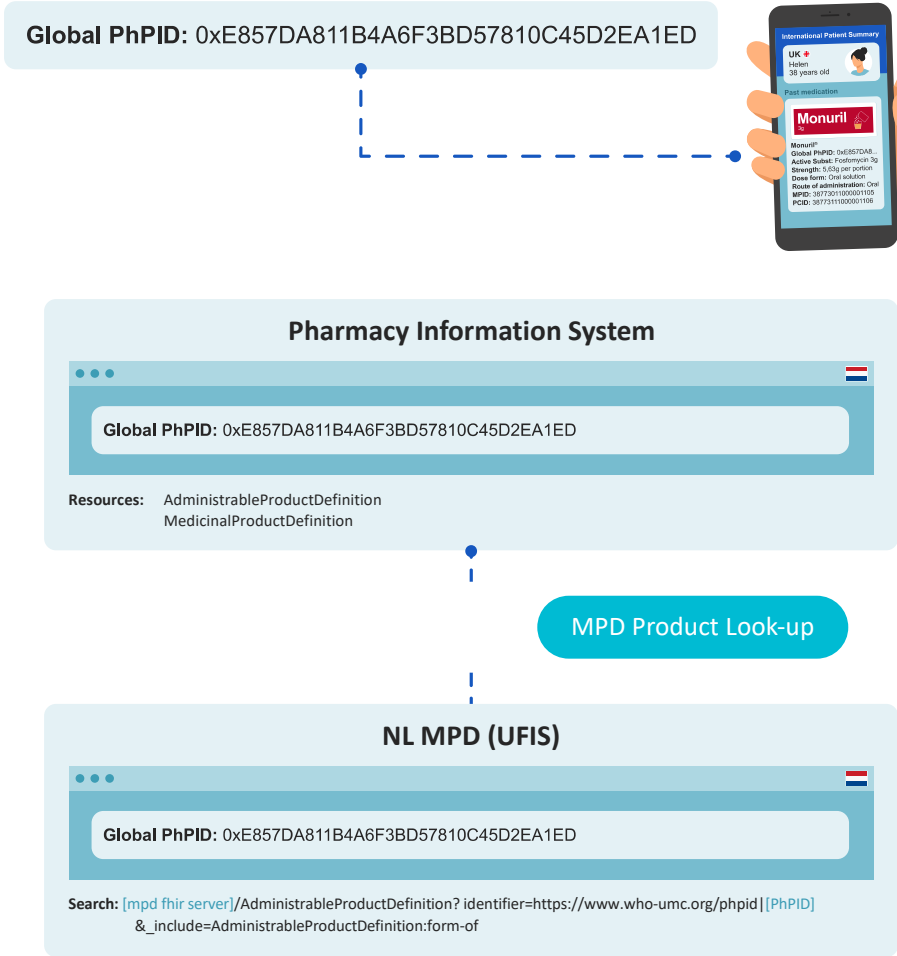
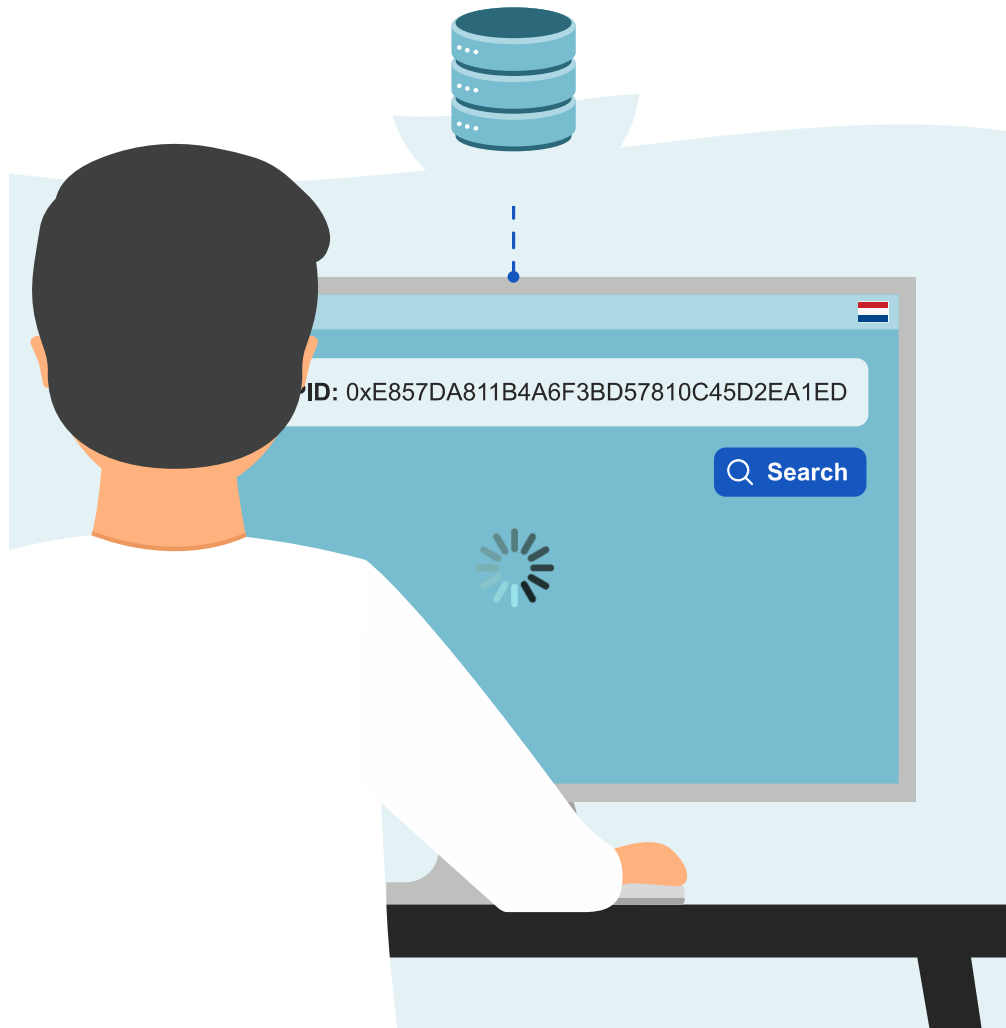
The resulting demonstrator



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



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



FCAT May 2022, FHIR 4.6.0



Connecting to the UNICOM FHIR IDMP

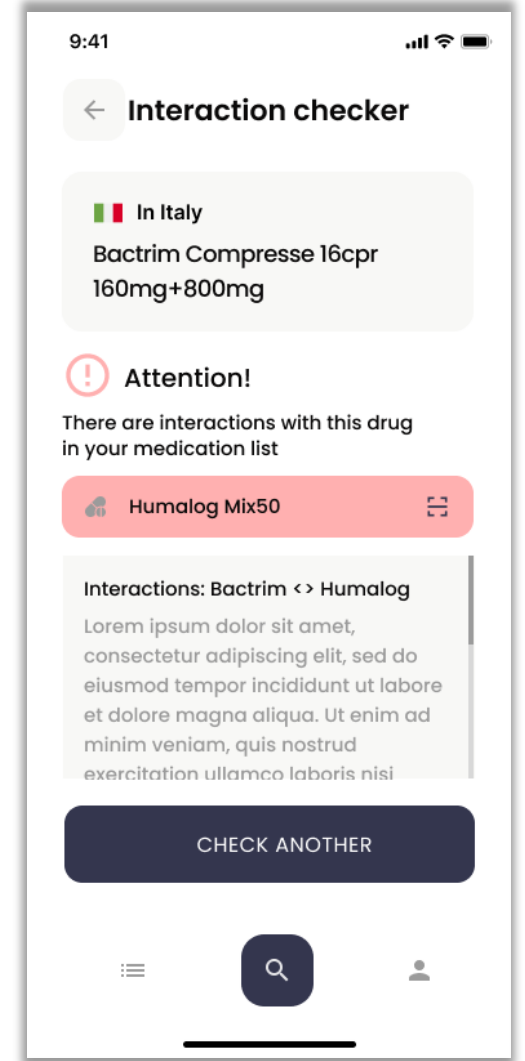
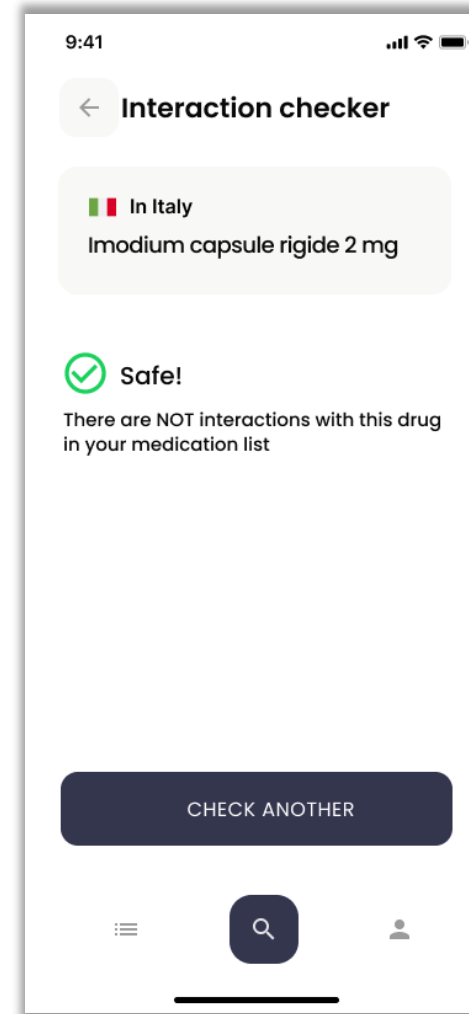
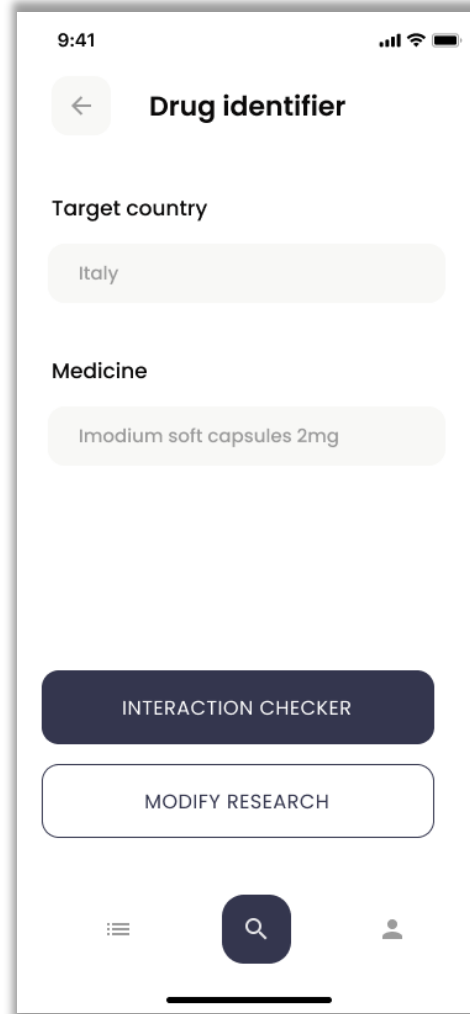
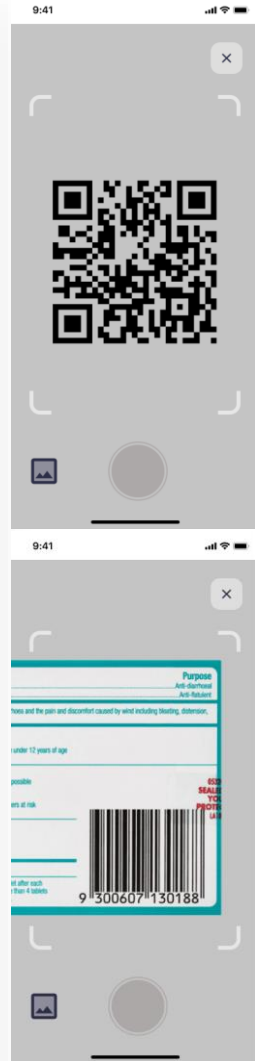
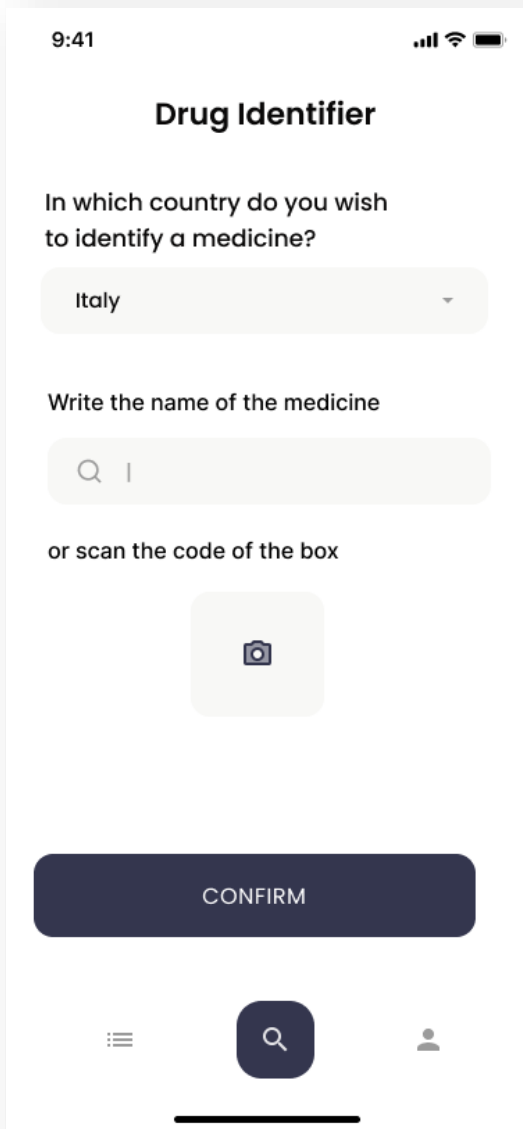
UNICOM - Gravitate Health Patient Journey - Tested in HL7 FHIR Connectathon

Global PhPID: 0xE857DA811B4A6F3BD57810C45D2EA1ED

```
{
  "resourceType": "Bundle",
  "id": "c506b4b8-dfe8-45a4-a8af-c6777c81512d",
  "meta": {
    "type": "searchset"
  },
  "link": {
    "entry": [
      {
        "id": 1
      },
      {
        "id": 2
      },
      {
        "id": 3
      }
    ]
  }
}
```

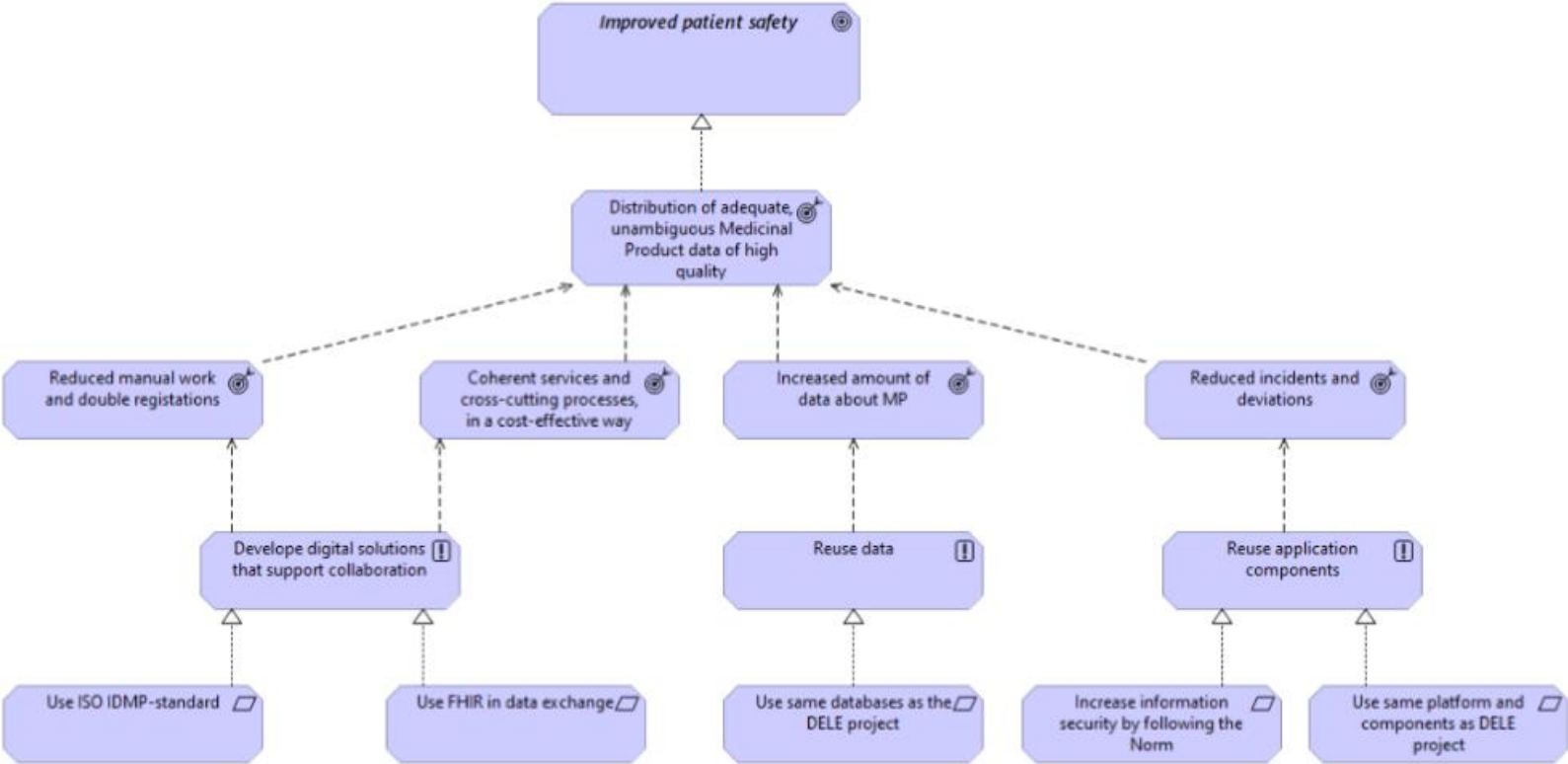
```
{
  "entry": [
    {
      "resource": {
        "resourceType": "MedicinalProductDefinition",
        "id": "640921",
        "language": "NL",
        "extension": {
          "identifier": {
            "domain": "indication",
            "value": "Monuril wordt gebruikt bij infecties met bacteriën"
          }
        },
        "legalStatusOfSupply": {
          "classification": {
            "name": "package"
          }
        },
        "request": {
          "resource": {
            "resourceType": "AdministrableProductDefinition",
            "id": "0xE857DA811B4A6F3BD57810C45D2EA1ED",
            "subject": "administrableDoseForm",
            "unitOfPresentation": "ingredient",
            "routeOfAdministration": "request"
          }
        }
      }
    }
  ]
}
```

here visualised by the projects'
UNICOM FHIR IDMP Server - UFIS.



The vision is improved patient safety

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



Access the key resources and be part of the adventure !



UnicomIG
0.1.0 - ci-build

Home
Regulatory Data
Known Issues
Table of Contents
Artifacts

Table of Contents
Regulatory Data

UnicomIG, published by UNICOM. This is not an authorized publication; it is the continuous build for version 0.1.0. This version is based on the current content of <https://github.com/h17-eu/unicom-ig/> and changes regularly. See the [Directory of published versions](#).

2 Regulatory Data

2.1 Overview

This is FHIR Implementation Guide for UNICOM project, created to assist work with pilot product list product data in FHIR.
This specification is a combined effort of several work packages of UNICOM project.
The implementation guide consists of the following artifacts:

- Logical model for defining medicinal product (basic data elements suitable for wide range of different use cases);
- FHIR profiles for defining a medicinal product using resources in Medication Definition module.
- Example resources for different medicinal products.

Implementation guide follows the EMA Product Management Service specifications (including EMA SPOR terminology), but it does not cover full regulatory data. Data elements for product definition are considered enough for most clinical and cross-border data exchange use cases. Data elements specific to regulatory use cases, have been omitted in order to provide cleaner and easier overview of core medication data.
References to source information in EMA implementation guide are made available in the profiles (hover the name of the attribute to see corresponding EMA IG paragraph).
Profiles specify the core set of attributes, but are left open for additions if something more specific needed. For example, national identifiers are not defined as separate attributes in the profile, but this data can always be added in accordance with the specification of the underlying FHIR resource. Please note that on the Artifacts page, there are two types of profiles: regulatory profiles and transition profiles. While regulatory profiles follow the EMA IG, the transition profiles are purely a technical intermediate product to allow processing incomplete data.

- Overview
- Logical model
- Profiles
- Terminology
- Example Data
- Guidance and references

2.2 Logical model

ISO IDMP logical model includes full regulatory data, which is usually more than needed in the eHealth services. **UNICOM IG logical model** is a subset of ISO IDMP data that is typically used to represent core medication data. Logical model is described using a FHIR logical model resource, but it is not implementation-specific, and it aims to describe the regulatory data model in a simple and logical way.

2.3 Profiles

The aim of profiling was to combine FHIR base specification with EMA ISO IDMP Implementation Guide (specifying cardinalities and value set bindings, and adding

h17-eu / unicom-ig Public
Notifications

<> Code
Issues 37
Pull requests 1
Discussions
Actions
Projects 1
Security
Insights

Labels 14
Milestones 0
New Issue

37 Open
52 Closed
Author
Label
Projects
Milestones
Assignee
Sort

- 🔍 **Starting jpa server, search parameters don't work**
🗨️ 10
- 🔍 **Reorganise MAH data in fsh files**
#113 opened 2 weeks ago by rindstrm
- 🔍 **MedicinalProductDefinition with multiple Ingredients.**
🗨️ 5
- 🔍 **Update product viewer templates**
🗨️ 4
- 🔍 **sql database structure**
🗨️ 1
- 🔍 **Warning about url mismatch in qa**
#89 opened on Jan 18 by rindstrm
- 🔍 **Logical model data types**
#87 opened on Jan 11 by rindstrm
- 🔍 **Data from Portugal**
#82 opened on Jan 3 by rindstrm
- 🔍 **AdministrableProductDefinition - only 1 route of administration allowed**
🗨️ 9

Product Browser
MedicinalProducts Manage... Config Refresh

Product Browser

Search:

ID	Name	Country	Viewer	Source	Validation
ABESYL-CAPS-10MG-CAP-204-GRC-MPD	ABESYL CAPS 10MG/CAP	Hellenic Republic	Viewer New Viewer	XML JSON	FHIR Validation
ABESYL-CAPS-5MG-CAP-203-GRC-MPD	ABESYL CAPS 5MG/CAP	Hellenic Republic	Viewer New Viewer	XML JSON	FHIR Validation
ADVIL-C-TAB-200MG-TAB-235-GRC-MPD	ADVIL C.TAB 200MG/TAB	Hellenic Republic	Viewer New Viewer	XML JSON	FHIR Validation
Agen-10mg-Tablet-EE-MPD	AGEN 10 mg tabletid	Republic of Estonia	Viewer New Viewer	XML JSON	FHIR Validation
Agen-5mg-Tablet-EE-MPD	AGEN 5 mg tabletid	Republic of Estonia	Viewer New Viewer	XML JSON	FHIR Validation
AGGOVASK-CAPS-10MG-CAP-BTx14-152-GRC-MPD	AGGOVASK CAPS 10MG/CAP BTx14	Hellenic Republic	Viewer New Viewer	XML JSON	FHIR Validation
AGGOVASK-CAPS-5MG-CAP-151-GRC-MPD	AGGOVASK CAPS 5MG/CAP	Hellenic Republic	Viewer New Viewer	XML JSON	FHIR Validation
ALDOSION-CAPS-10MG-CAP-169-GRC-MPD	ALDOSION CAPS 10MG/CAP	Hellenic Republic	Viewer New Viewer	XML JSON	FHIR Validation
ALDOSION-CAPS-5MG-CAP-168-GRC-MPD	ALDOSION CAPS 5MG/CAP	Hellenic Republic	Viewer New Viewer	XML JSON	FHIR Validation
Algirdin-siroop-susp-100-mg-5-ml-57-BEL-MPD	Algirdin siroop susp. 100 mg / 5 ml	Kingdom of Belgium	Viewer New Viewer	XML JSON	FHIR Validation

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