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WP6 - Software and extensions for CEF eHDSI
D6.1: UNICOM IDMP Data Base API

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Statement of originality
This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

2. Deliverable abstract

Task 6.1 involved developing an IDMP database and exposing APIs in order to be able to access the data it contains. Within this task, an IDMP database was therefore created, restricted to the MAL (Minimum Attributes List). As for the API, a FHIR (Fast Healthcare Interoperability Resources) server was created.

In this deliverable, after an introduction in which related Tasks are discussed, the approach that was used for the design and implementation of the IDMP Database and the FHIR Server will be described, also referring to the technologies that were used. After that, the system that was devised for importing data will also be discussed. Finally, it follows an explanation of the APIs, and an example of how the UI that was developed can be used.

In the absence of EMA's PMS, the T6.1 provides some minimal infrastructure in order to support the pilots of the UNICOM project, and to make eHDSI cross-border exchanges.

Keywords: IDMP, Database, MPD, Minimum Attribute List, FHIR

3. Disclaimer

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4. Executive summary

Task 6.1 involved the development of an IDMP database and the exposure of its API in order to access the data it contains. As part of this task, an IDMP database was therefore created, limited to the MAL (Minimum Attributes List). With regard to APIs, a FHIR (Fast Healthcare Interoperability Resources) server was created.

In this deliverable, after an introduction in which the relevant tasks are discussed, the approach used for the design and implementation of the IDMP database and the FHIR server will be described, also referring to the technologies used. Subsequently, the system designed for data import will also be discussed. Finally, an explanation of the API and an example of using the developed user interface will follow.

In the absence of the EMA PMS, T6.1 provides a minimum infrastructure to support UNICOM pilots and to perform cross-border eHDSI exchanges.

5. List of abbreviations

Abbreviation	Complete form
API	Application Programming Interface
ATC	Anatomical Therapeutic Chemical Classification
CDA	Clinical Document Architecture
CP	Change Proposal
D	Deliverable
DDD	Defined Daily Dose
eAF	Electronic Application Form
eD	Electronic Dispensation
eD	Electronic Dispensation
EDQM	European Directorate for the Quality of Medicines
eHDSI	eHealth Digital Service Infrastructure
eHOMB	eHealth Operational management Board
EMA	European Medicines Agency
EMA IG	European Medicines Agency - Implementation Guide
eP	Electronic Prescription
EU	European Union
FHIR	Fast Health Interoperability Resources
IDMP	Identification of Medicinal Products
IG	Implementation guide
ISO	International Organisation for Standardization
JPA	Java Persistence API

JSON	JavaScript Object Notation
MALeH	Minimum Attributes List for eHealth
MPD	Medicinal Product Database
MPID	Medicinal product identifier
MVC	Master Value Set Catalogue
NCA	National Competent Authority
NCPeH	National Contact Point eHealth
OID	standard Object Identifier
OMS	Organisation Management Services
ORM	Object Relation Mapping
PCID	Packaged Medicinal Product Identifier
PhPID	Pharmaceutical Product Identifier
PMS	Product Management Services
POJO	Plain Old Java Object
PPL	Pilot Product List
PPT	Pre-Production Test
PS	Patient Summary
REST	Representational state transfer
RMS	Referentials Management Services
RoA	Rout of Administration
SMS	Substance Management Services
SPOR	Substance, Product, Organisation and Referential
SQL	Structured Query Language
UCUM	Unified Code for Units of Measure
UFIS	UNICOM FHIR IDMP Server
UI	User Interface
UML	Unified Modelling Language
URL	Uniform Resource Locator
UX	User Exeperience
VMPP	Virtual Medicinal Packaged Product
WP	Work Package

Table 1. List of abbreviations

6. Introduction and Background

6.1 Aim and scope

This deliverable aims to describe the work carried out during the Task 6.1 "Implementation of the needed Pilot IDMP Database to be used for cross border piloting", among the Work Package 6 "Software and extensions for CEF eHDSI" of UNICOM Project.

The main scope of this task was to ensure proper connectivity via APIs to the UNICOM reference IDMP database. Depending on the needs of a specific pilot and eHDSI Cross border services, it may use the reference IDMP database or rely upon a nationally implemented database with IDMP support. The reference database was crucial for development and testing reasons, even if a pilot chooses to use a different database for actual operation.

This Task, as planned in the DoA, involved the following partners: DWIZ, ARIA, SPMS, GNOMON, KELA, IDIKA, IEDOH, INDRA. This task identified and implemented the needed IDMP database connectors so that Member State may use a common IDMP enabled database based on the EU SPOR concepts for IDMP piloting in eP/eD during the pilots of WP7/WP9. The following technical scenarios were foreseen taking into account the analysis done in WP5 and WP9 outputs: use an extract of the EMA SPOR database on a clean subset for testing with a predefined API to access the information, or use a validated subset on existing IDMP compliant databases at a Member State level, or create a fully independent reference IDMP database for pilot use ad eHDSI cross border services.

Therefore, the output of the Task is the IDMP Database of the UNICOM Project and its related API, depicted in the following chapters.

6.2 Why is this IDMP FHIR Server and Database important?

Unfortunately, the EMA PMS (Product Management System) is not currently available, and it is unknown when it will be. The T6.1 FHIR server and Database intends to serve as an interim substitute. It will be utilized by the pilots and for cross-border exchanges, while providing the bare minimum infrastructure required.

6.3 Related works and deliverables

The work carried out in Task 6.1 is part of a deep relationship between different Tasks of UNICOM, that collaborate directly and indirectly in order to enable the Task.

First, the Tasks among the Work Package 6 are strictly collaborating with each other, so Task 6.1 is in relation to Task 6.2 "Implement the smart substitution components" because the substitution components get Data from the IDMP Database. The T6.3 "Redesign and implementation of an enhanced IDMP compliant User Portal system and of an IDMP extended CDA display tool" are linked with Task 6.1. Actually, the scope of Task 6.3 is to expand the already existing user portal of eHDSI as used by several countries to enable smart substitution and IDMP usage in eDispensation scenarios of WP7. The portal and component implemented will also include an open API to allow direct connection with Medicinal Product Database and the IDMP Database, to enable the usage of IDMP for dispensation either in the point of care systems (Pharmacies) or other portal used by Member States.

Moreover, the WP6, Task 6.1 starting from the IDMP Handbook in WP1, Task 1.1 "IDMP data exchange" in particular; specifications of WP3, Task 3.1 in particular; Requirements of WP5, Task

5.1 in particular, plus additional requirements from WP8 and WP9. Task 1.1 is mainly concerned with the overall guidance on and maintenance of standards and materials for the data exchange in the regulatory cycles, from market authorization application through inclusion in European and national drug databases. So, it provides important assumptions to the IDMP Database of UNICOM. Task 3.1 performed a GAP-Analysis between the current application datasets and supporting tools and the IDMP standards. In T3.1 has evaluated the gaps between the current data structure of the application dataset and the new IDMP data structure, supporting the structure of the IDMP Data Base. Task 5.1 "Business requirements for the adoption of IDMP in eHealth Services", focusing on the description of the state of IDMP adoption in EU eHealth services. Actually, the Task includes specific Member States rules regarding the operation of eHealth services, and possible gaps in practical business and technical 'blueprints' for adoption that were useful for the Implementation of the IDMP Database and its API creation. Task 5.3 "Solution design and technical specifications to cross-border services", collected individual requirements and constraints from each country involved in the action to allow tailored definition of the eP and PS solutions. These technical specifications guaranteed compliance of the repositories with the ISO IDMP that are crucial for the Task 6.1 Specifications.

Finally, the Task 6.1 included a deep collaboration with WP4 "IDMP implementation at National Drug Agencies". Actually, some of the aims of the WP4 are strictly connected with the DISMP Database like the progression of legacy data migration towards ISO IDMP based on national migration plans, the progression of essential tasks on data connectivity to EMA's SPOR services based on national implementation plans, the provision of a prototype of an ISO IDMP compatible data feed to national eHealth providers according to national plans.

In the following paragraphs of this chapter, there are few tips of related works and deliverables, needed to introduce the reader into the understanding of the IDMP Database.

Tips on IDMP

The identification of medicinal products is a global problem - that is typically resolved by the use of medicinal product dictionaries (MPDs) and clinical decision support (CDS) system for medication. The MPD's and CDS's providers uses valuable resources to re-identify medicinal product information received from pharmaceutical companies, with the aim to provide some level of patient safety within hospital and ambulatory environments. There is a vast number of medicinal products in today's global market - prescription and over-the-counter products - that are dispensed in hospitals, pharmacies, and retail drug stores. Also, a medicinal product can be packaged in different ways, with different brand names and different strengths from country-to-country.

The need to have a common ground that can harmonize all the information can be addressed with the use of the Identification of Medicinal Products suite of standards IDMP. IDMP standards help provide complete and accurate data about a medicinal product throughout its life cycle - to all healthcare stakeholders across different jurisdictions and countries.

The medicinal product dictionary plays a central role in storing and disseminating information about medicinal products for prescription and dispensation in a country. The MPD is sourced with different types of information from the NCA's marketing authorization process, from regulated files and other (scientific) documentation, to include IDMP identifiers, authorised edication substitutions, pricing information and more. The MPD provides a structured repository of information from these sources and makes them available to multiple types of users such as clinicians (via supporting software and

systems), patients (via online queries), e-Health authorities and others. With IDMP identification standards in place in all countries' national MPDs, solution providers can develop an API to search for this information. This will give healthcare providers the tools needed to efficiently access the information and make informed decisions when prescribing and dispensing medicinal products.

Therefore, IDMP standards enable the aggregation and verification of medicinal product information to: Identify appropriate substitutions; Validate authenticity when falsification is suspected; analyse and prevent adverse drug events (ADEs); Recall a medicinal product; understand the impact of medicinal products on public health.

For more information on IDMP, please consult the report "IDMP in a capsule" written by the main authors: Christian Hay (Nictiz), Robert Stegwee (Nictiz) and other authors Maayke Klinkenberg (Nictiz) and Esther Peelen (Nictiz).

Gap and requirements analysis for IDMP compatible application forms (D3.1)

The content of application forms is defined by legal and regulatory needs. The EC group "Notice to applicants" (NtA)[3] is responsible for the content definition of the application forms. Changes triggered by NtA or by regulatory needs are organised in the eAF (electronic application form) Maintenance Group (eAF MG) 7 at EMA.

The IDMP standard together with the FHIR model will have an indirect impact on the content of the eAFs. The scope of the content will not be changed but the standards will have a major impact on the data representation and details in the future. Following the activities carried out in T3.1 "Perform a GAP-Analysis between the current application datasets and supporting tools and the IDMP standards" there is a significant change how the information is structured. These changes also introduce further improvements for e.g., "Name", "Substance", "Strength" content elements. These elements currently have to be entered in multiple sections of the PDF (e.g., in the declarations), causing potential discrepancies and inefficacy. As IDMP approaches data grouping as an "entity relation model data" this content will be linked rather than duplicated.

The goal of the new implementation is to keep it as close as possible to the NtA defined content scope, without sacrificing usability. This is due to the endeavour to make the transitions for users easier and avoid long NtA change processes. Therefore, even though the input of data might be structured differently, at the end of the process a PDF representation can be exported that will look the same as the PDF forms today.

Although the goal is to transform as little content as possible, amendments are necessary to become compatible with IDMP and FHIR and some changes in synergy with the general change process as they make sense in conjunction.

Package

Although the information about packages is the same, the new forms ensure a more structured data content which provides additional flexibility without the need to enter data in free text. The order of container and package elements have changed, and the package can now be entered in a recursive way – to say an (inner) package can be part of an (outer) package, that is part of a (primary) package, and so on. This has to be supported by the user interface and the FHIR resource structuring.

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[3] see https://ec.europa.eu/health/documents/eudralex/vol-2_en

The illustration below displays the current structure of packages in an eAF where the package describes the container involved and the different pack sizes available.
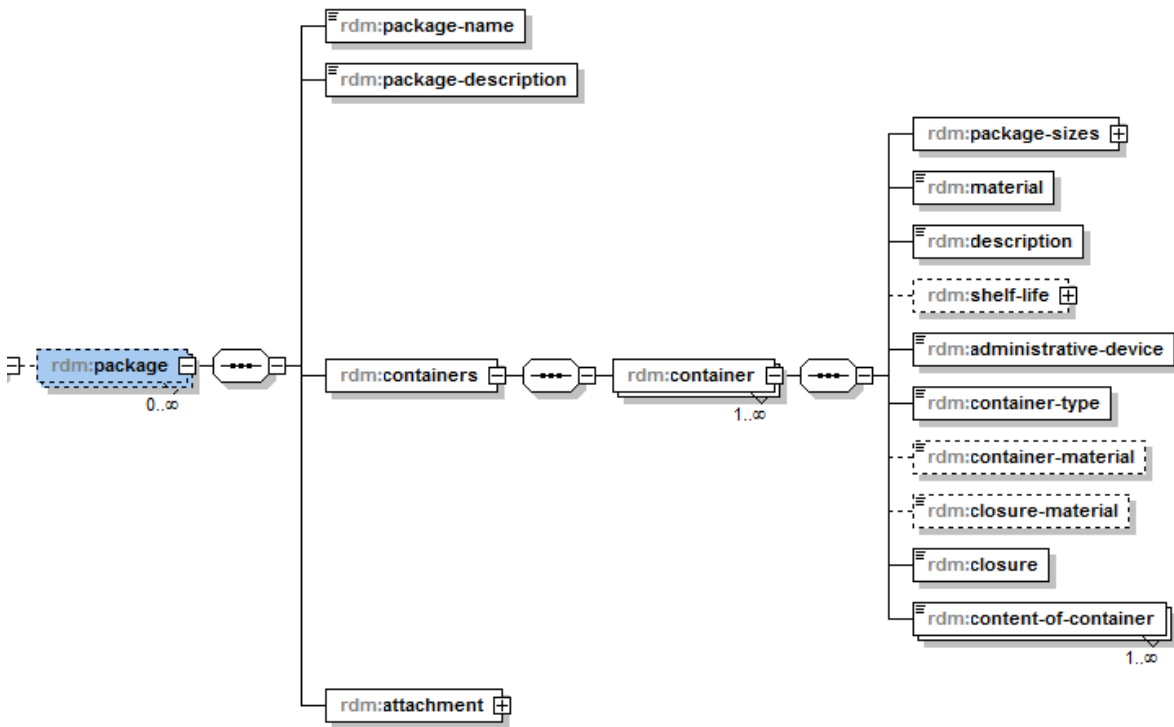

Figure 1. eAF AS-IS structure of a package

In contrast, the TO-BE structure in FHIR depicts a scenario where a "packaged product" contains a packaged item that has a type of package and a self-reference to allow for containers in container. In addition, the packaged item contains a reference to a number of manufactured items. This allows for needed hierarchies and linkage of manufactured items and packaged products.
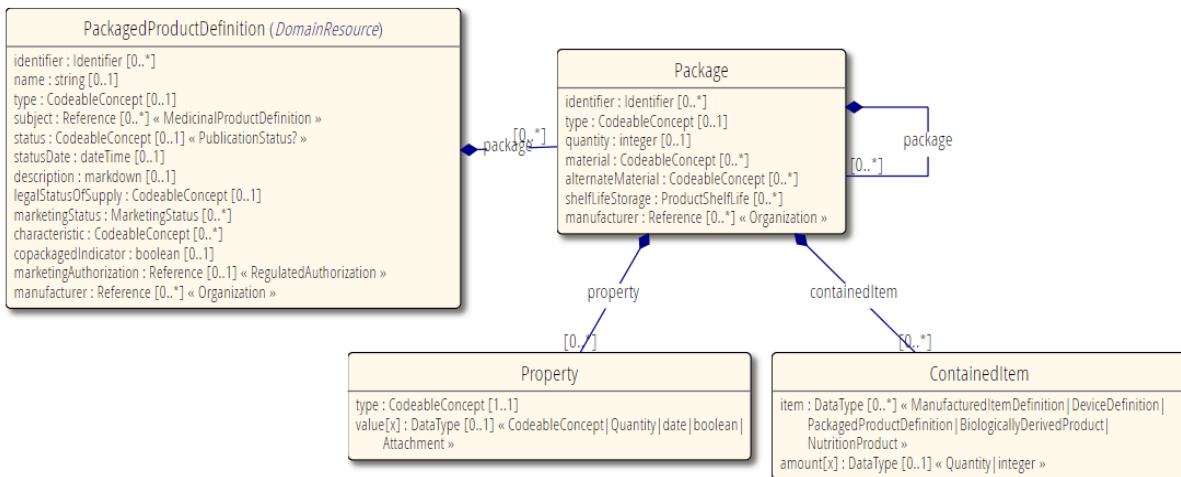

Figure 2. TO-BE FHIR structure of a package

Furthermore, the IDMP standards clearly define the semantics on how to describe a package data in a more defined way than the current eAF, e.g., rather than text

1. the package size is clearly defined as a number

2. material is a choice of controlled terms from RMS
3. the manufacturer is linked by a reference identification
4. characteristics/properties have separate fields and don't need to be all within "description"

Organisation and Contacts

Organisations and contacts in the current eAF are used in several sections e.g., to include a person for a manufacturer, MAH, responsible people for various obligations. The new tool will introduce improvements.

The detailed representation of an "Organisation" and its locations" will be described only once preferably based on mandatory selection from OMS. This will avoid administrative effort when entering data.

Contact persons will be mainly structured in a "Contact lists and attributed with their role rather than scattered throughout different sections of the form. To enable a list of different types of contacts RMS has created a contact type list and FHIR a section for medicinal product contacts.

Manufacturers

The list of fields used to describe a manufacturer will be standardised, so that all types of manufacturers have a similar level of information.

The only difference will be that some have a link to another resource in addition e.g.:

- substances – substance manufacturer
- package – package manufacturer
- device –device manufacturer

There will no longer be a different section for each manufacturer, but one consolidated section containing all manufacturer described by their details and manufacturing activities (or "Operation" as it is named in FHIR).

Ingredient

The concept of "ingredients" is defined by the IDMP standards. The list of ingredients can be compared to "qualitative and quantitative composition" in the current eAF.

IDMP standards enable a more specific description of the eAF content:

- A more specific strength definition for each ingredient, whereas the current eAF has limitations.
- It allows both a "low" and a "high value" to be specified, upper and lower range, as well as a comparator for each value, whereas in the eAF the comparator is used to depict only one of these options.
- Enables to specify a reference strength and an active moiety, whereas the eAF allows for either a base strength or an active moiety.
- There will now always be a presentation strength and in addition, a concentration strength can be specified as well
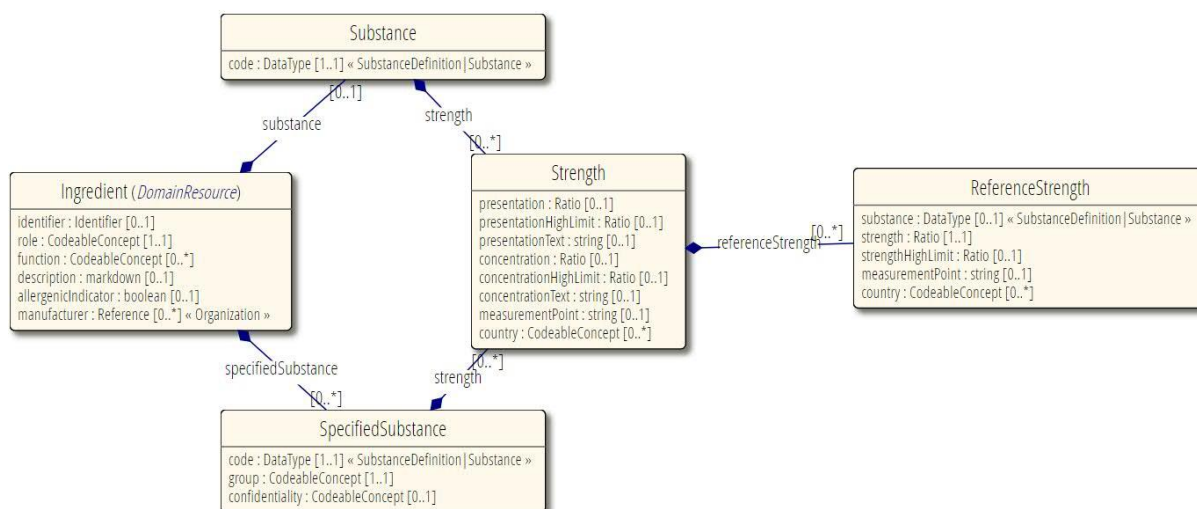
UML Diagram (Legend)

Figure 3. IDMP Ingredient represented in FHIR #R5

Manufactured item and Pharmaceutical product

Pharmaceutical products are administered to the patient in contrast to the manufactured item, which is the way it is produced and contained in a package.

The current application forms are not able to distinguish these two elements (manufactured item and pharmaceutical product) and usually only describe the manufactured item, although the header is called "pharmaceutical product"[4]

ISO IDMP standards introduce a more detailed concept to distinguish between the "pharmaceutical product" and "manufactured items". This required split could be considered as additional information in relation to the current NtA form, or as another way of representing current information.

In case the product is administered as it is manufactured, the ingredients (see chapter 4.1.1) will be linked and reused and the content is the same as for the manufactured item.

In other cases, there will be individual compositions defined.

What is missing in IDMP standards and the EU Implementation Guide[5] is a more refined grouping of ingredients into logical parts to depict e.g., capsule core, capsule shell, printing ink as a composition group, as it is used in the eAF today.

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[4] eAF MAA section 2.6 (LINK)

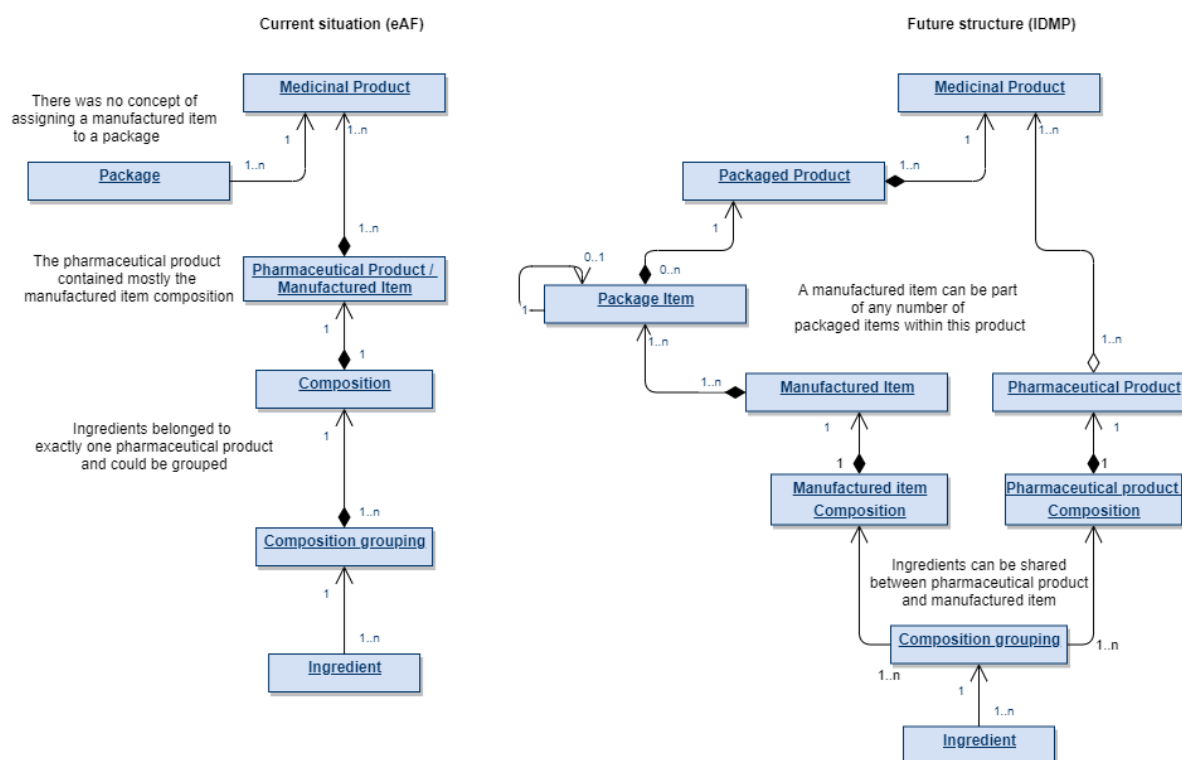[5] Implementation Guide of the IDMP Standard (LINK)

Figure 4. Composition comparison eAF / IDMP

For more details, please read the D3.1: Gap and requirements analysis document.

Common minimum dataset that needs to implement in the National NCA and eHealth solution

To further improve the implementation of IDMP, it was also necessary to define a minimum dataset to ensure the implementation of the ISO IDMP data for eHealth proposes, set the ground for a basic understanding of the data, and allow enrichment of the current clinical documents. This task is part of the WP5 of UNICOM.

The availability of a common minimum dataset recognised that each country or region may have a complex set of codes and attributes required to support local healthcare activities regarding the identification of medicinal products. By identification the 'minimum' dataset for cross-border exchange of healthcare information it is possible to provide a basic common set of information that will support the medicinal production data exchange for the different services associated with them.

The work previously completed on the WP5 deliverables has defined the guidelines and semantic specifications for the adoption of ISO IDMP in the eHealth services at national level, and their connections to the Medicinal Products databases both from National Competent Authorities (NCAs) and private providers. To further improve the implementation of IDMP, it is also necessary to define a minimum dataset to ensure the implementation of the ISO IDMP data for eHealth proposes, set the ground for a basic understanding of the data, and allow enrichment of the current clinical documents.

These datasets may be standardized through a national medicinal product dictionary, or they may be present across various drug files supporting local use cases. However, by identifying the 'minimum' dataset for cross-border exchange of healthcare information it is possible to provide a

basic common set of information that will support the medicinal production data exchange for the different services associated with them.

According to the UNICOM deliverable D5.7[6] (Common minimum data set that needs to be implemented in the national NCA and eHealth solution) we can read:

> The description of each medicinal product can be done by using attributes that represent all the essential features of the medicinal product for their respective identification. Such attributes can be found on the EMA Implementation Guide (EMA IG) Version V2.1.1[7]. This EMA IG guideline presents a list of approximately 200 items, which are fundamental to represent all the attributes necessary to cover the lifecycle of a medicinal product. However, it is important to highlight that only a small set of attributes relate to the ISO IDMP specifications are required to issue clinical documents (eP/eD & PS). In that sense, this document will focus on the key attributes required to issue the clinical documents (eP/eD & PS).
>
> In order to identify all attributes relevant to the ISO IDMP implementation from the EMA IG Version V2.1, the UNICOM FHIR IDMP Server (UFIS) working group has identified approx. 65 attributes. Based on the key elements for eP/eD and PS, this list of attributes was further reviewed and aligned to the current eHDSI data elements to achieve the critical minimum set of attributes necessary for the referred eHealth services at the cross-border level.
>
> The first version of the Minimum Attribute List for eHealth (MALeH) was analysed and presented within 'D5.3 - Guidelines for cross-border semantic interoperability', which was further refined and updated in 'D5.4 - Semantic Specifications'. This list was subject to multiple rounds of discussion and alignment with UNICOM partners and other stakeholders (e.g., eHealth Network – eHN and eHDSI). One key outcome of this process was the co-creation of the Change Proposal-066 – 'Prepare eHDSI Requirements Catalogue for ISO IDMP' (CP-066 - Annex 2) that will impact wave 6 of eHDSI. Therefore, the MALeH presents the minimum data that meets the expectations of the project and cross-border services.

(Table 1[8] presents the minimum dataset for eHealth services, their relationship with the eHDSI data elements, EMA IG and the recommended coding system to represent data when applicable. All the indicated preferred coding systems are international standards

Table 2: MALeH and their relationship with eHDSI data elements

EMA SPOR			eHDSI MVC 6.1.0		
#	Attributes from EMA IG V2.1	EMA-SPOR database	Preferred coding system	eHDSI Data Elements[22]	Value Set name
1.	**Medicinal Product**				
1.1	Product Management Service Identifier (PMS ID)			Medicinal Product Code	
1.2	Medicinal Product Identifier (MPID)				
1.5	**Authorised Pharmaceutical Form***	RMS	EDQM	Pharmaceutical Dose Form	eHDSIDoseForm
1.13	Product classification				
1.13.3	**ATC code(s)***	RMS	WHO - ATC	ATC code	eHDSIActiveIngredient

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[6] At the moment of writing this this document, the deliverable was not publicly accessible yet. When it will be available, it can be found on the UNICOM page: https://unicom-project.eu/

[7] See https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-organization-standardization-iso_en-0.pdf

[8] This table was extracted from the UNICOM D5.7 Common minimum data set that needs to be implemented in the national NCA and eHealth solution.
At the moment of writing this this document, the deliverable was not publicly accessible yet. When it will be available, it can be found on the UNICOM page: https://unicom-project.eu/

1.14	Medicinal Product Name				
1.14.1	Full name			Brand Name of the Medicinal Product	
2.	Marketing Authorisation Information				
2.8	Marketing Authorisation Holder	OMS (LOC-ID)	SPOR-OMS	Marketing Authorisation Holder of the prescribed medicinal product	
4.	Packaged Medicinal Product				
4.1	Packaged medicinal product Identifier (PCID)			Medicinal Product Code	
4.3	Pack size**		EDQM	Medicinal Product Package	eHDSIQuantityUnit
4.7	Package item (container)**				
4.7.1	**Package item (container) type***	RMS	EDQM	Medicinal Product Package	eHDSIPackage
4.7.5	Package item (container) quantity				
4.10	Manufactured Item				
4.10.1	Unit of Presentation	RMS	EDQM		eHDSIQuantityUnit
4.10.2	**Manufactured Item Quantity***	RMS	UCUM	Package size	eHDSIUnit
4.10.3	Manufactured Dose Form	RMS	EDQM	Pharmaceutical Dose Form	eHDSIDoseForm
5	Ingredient				
5.1	Ingredient role	RMS	SPOR-RMS		
5.5	Substance				
5.5.1	Substance	SMS	SPOR-SMS	Active Ingredient	eHDSISubstance
5.5.2	Strength (quantitative composition)				
5.5.2.2.2	Strength (Presentation single value or low limit)	RMS	UCUM	Strength of the Medicinal Product	eHDSIUnit
5.5.2.3.2	Strength (Concentration single value or low limit)	RMS	UCUM	Strength of the Medicinal Product	eHDSIUnit
5.5.3.	Reference Strength				
5.5.3.1	**Reference Substance***	SMS	SPOR-SMS	Active Ingredient	eHDSISubstance
5.5.3.3.2	**Reference Strength (Presentation single value or low limit)***	RMS	UCUM	Strength of the Medicinal Product	eHDSIUnit
5.5.3.4.2	**Reference Strength (Concentration single value or low limit)***	RMS	UCUM	Strength of the Medicinal Product	eHDSIUnit
6.	Pharmaceutical Product				
-	Pharmaceutical Product identifier (PhPID)[23]			Medicinal Product Code	
6.2	Administrable Dose Form	RMS	EDQM	Pharmaceutical Dose Form	eHDSIDoseForm
6.3	**Unit of Presentation***	RMS	EDQM	Foreseen to wave 6[24]	eHDSIQuantityUnit
6.6	**Route(s) of Administration***	RMS	EDQM	Route of Administration	eHDSIRouteof Administration

* The attributes marked in bold should be preferred over similar ones (e.g., dose forms and unit of presentation) and considered as highly recommended. The reader is advised to read the next section for further details.

**Pack size and Package item (container) should be considered optional for simple-type package medicines, but mandatory for complex packaging medicines (e.g., box containing 'tables + cream', or 'vial + syringe', etc.).

For more details, please read the D5.7: Common minimum data set for implementation in the national NCA and eHealth solutions

7. Source code

All source code of the software developed for this deliverable, can be found in the following GitHub repository (D6.1 branch):

- https://github.com/unicom-project-eu/wp6-db-api/tree/D6.1

8. The IDMP database

8.1 IDMP Database Data Model

The IDMP specifications define a data model for Authorized Medicinal Products.

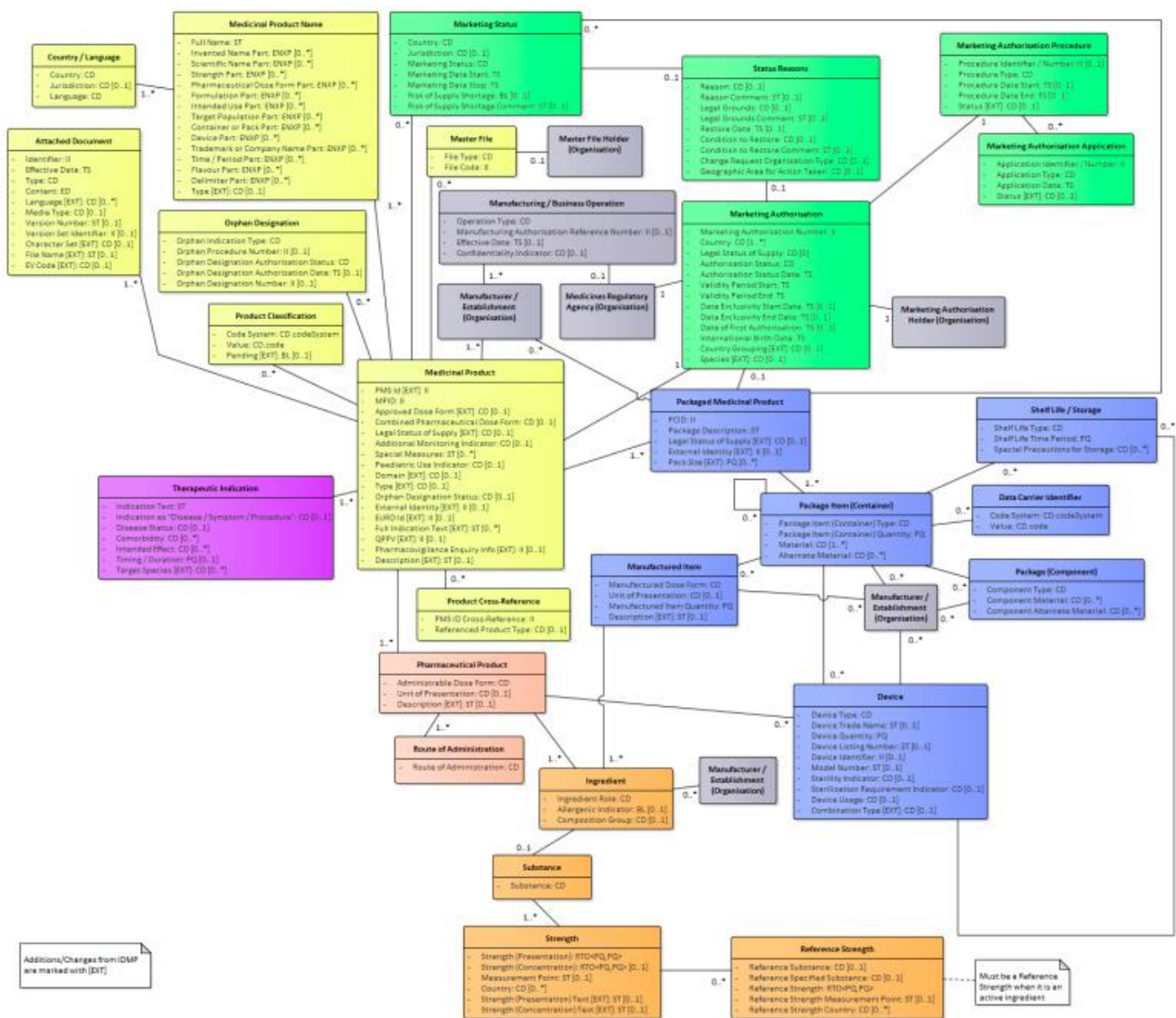*Figure 5. The IDMP Data Model*

For the creation of the data model of the T6.1 IDMP database, we started from the full IDMP data model and then we tried to "restrict" it to the MAL. We eliminated all entities that do not contain any of the attributes that are in the MAL and simplified some of the relationships. For example, we simplified the relationship between Ingredient and Strength.
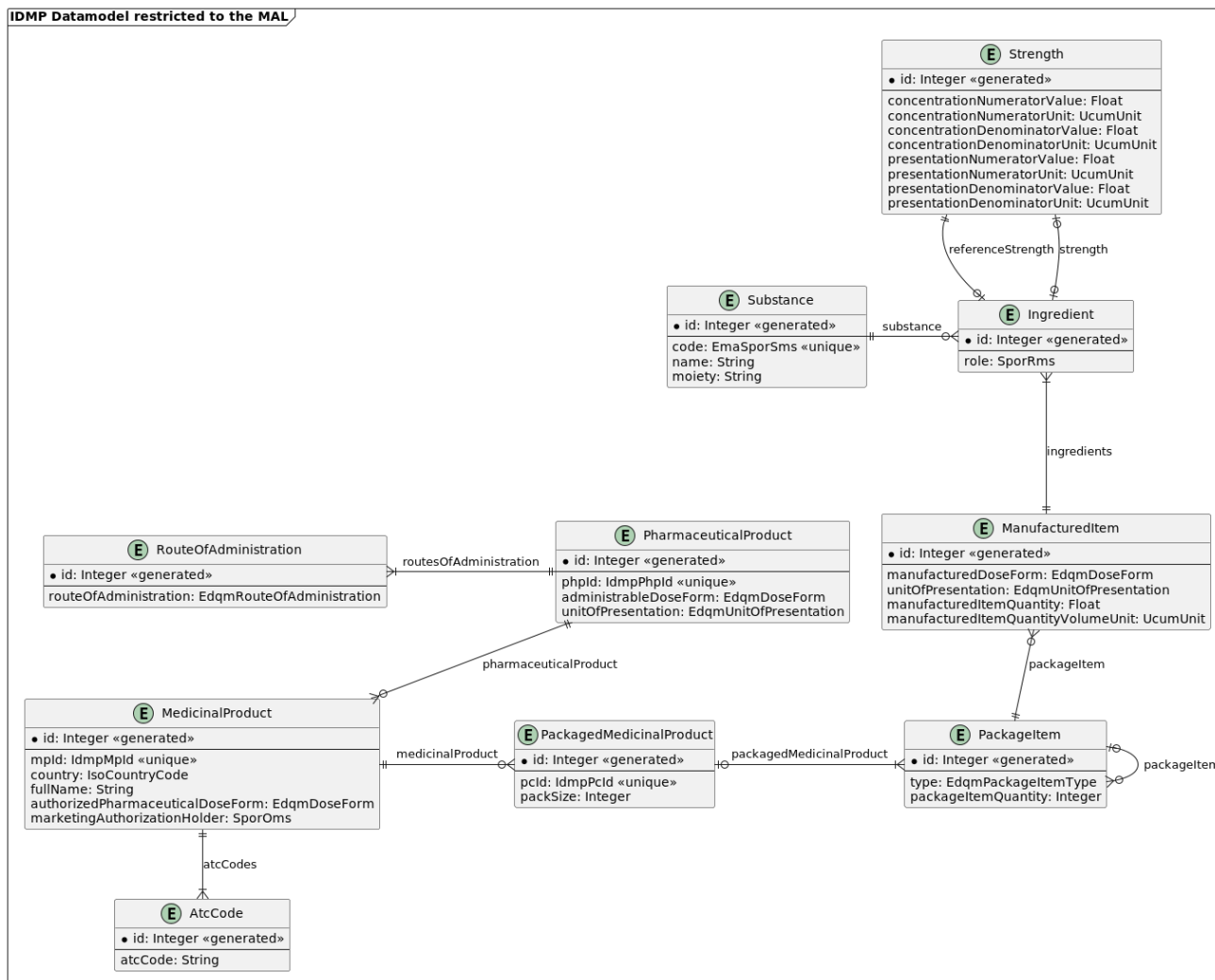
Figure 6. MAL . Minimum Attribute List

8.2 Implementation

DBMS and ORM

For the implementation of the T6.1 we relied on the PostgreSQL: a state-of-the-art relational DBMS. Since the FHIR Server is a Java 17 / Spring Boot project, for the management of the database we used the JPA (Java Persistence Api) through the Spring Data JPA module. This module provides an ORM (Object Relational Mapping) that allow us to define and use the database without writing SQL, but instead writing POJO classes decorated with the "@Entity" annotation.

Evolutionary Database Design

Evolutionary Database Design is a technique that allows a database to evolve. It involves defining incremental improvements, called migrations, that can also (not always) be reverted. This approach is analogous to version control, but for the database instead of the code, allowing for consistency among multiple instances of the database and the local environments of the developers. In order to achieve this, we decided to use Liquibase, a widely adopted and advanced solution. Each time the FHIR server is started, Liquibase will check the current database against a list of changesets and execute a migration for each of the ones that are not yet applied. With the Liquibase plugin for

Maven, it is also possible to generate Changesets automatically by comparing the current state of the Database and the JPA entities, facilitating by a great deal the process.

8.3 Data flow

Json Importer

All the data that we have received so far, is in a single-sheet Excel file format. While Excel is an excellent tool that is familiar for many people, it's not the best for describing structured data. The main problem is that in order to do complex relationships, a lot of repetition is required and this also very error-prone when these files are created manually. For this reason, we developed an importer that works with Json instead of Excel/csv files. Json is a markup language, it's simple, powerful, and is great for describing structured data like IDMP.

Since the data we have available is not in Json format, we created a Script that is able to convert data from Excel file, structured according to the import procedure of CSV file[9] into a Json file.

Currently, the only way to add data to the Database is to utilize this import module that we have developed. In the future, once the unicom-ig is ready, there will be other ways as well (for example FHIR POST request).

JsonSchema

In order to define the Structure of the Json to be imported, we created a JsonSchema specification[10]. A JsonSchema is a kind of Json that can be used to define the structure of other Jsons. The best thing about it, is that it can be used to validate Json, producing helpful error messages whenever something is wrong.

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[9] Import CSV fields procedures (LINK)
[10] accessible at: https://unicom.datawizard.it/schemas/import/v0.1.0/schema.json

9. Database API (FHIR)

9.1 Specifications

EMA Implementation Guide for PMS

To allow external access to data stored in the T6.1 Database we relied on FHIR. When developing the FHIR server, we based it on the EMA Implementation Guide for PMS (Product Management Service)[11]. As we found out during development, this IG has several issues:

- It's not computable. Sadly, this IG is distributed in a PDF format instead of FHIR resources. This means that it cannot be used to automatically validate the FHIR resources the server uses.
- It's not FHIR complaint. There are some mistakes in the IG that go against the FHIR specification, rendering it non FHIR compliant.
- It is based on an unstable version of FHIR R5 which is no longer supported by tools and libraries.
- It hasn't been updated in a while.

In order to make everything work, we followed the EMA IG as much as possible in our implementation, doing something differently when needed.

UNICOM-IG

We are collaborating in the development of the UNICOM Implementation Guide[12]. This new IG is based on the EMA IG, and it aims to solve, or at least address, its problems. At the moment of elaboration of this document, the UNICOM-IG is not ready yet, that's why we had to use EMA IG. Once the UNICOM-IG will be ready, it will be possible to use T6.6 to improve the FHIR server, and make it conform to this new IG.

9.2 Implementation

FHIR Library

For the implementation of the T6.1 FHIR server, we used Java 17 with the Spring Boot framework and HAPI FHIR, the most popular open-source FHIR library. This library fully supports all the major releases of FHIR, and has a lot of useful features.

Resource Providers

ResourceProviders are POJO classes that implement the IResourceProvider interface. They are used to implement the REST operations for each FHIR Resource. We used them in order to implement the encapsulation of data coming from the IDMP Database inside FHIR Resources, according to the EMA IG.

We created resource providers for:

- AdministrableProductDefinition
- Ingredient

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[11] EMA Implementation Guide for PMS (LINK)
[12] UNICOM Implementation Guide (LINK)

- ManufacturedItemMedicina
- lProductDefinition
- PackagedProductDefinition
- SubstanceDefinition
- Substance

We also created a ResourceProvider for the MedicationKnowledge resource, even if it's not part of the EMA IG, in order to better accommodate our GNOMON partner.

For each of those Resources, we implemented all terminology searches in order to be compliant with FHIR specification.

9.3 API usage

We deployed the FHIR server for the piloting environment, and its accessible at the following ULR:

- Web Interface: https://unicom.datawizard.it/fhir/swagger-ui/

In order to facilitate the querying of data from different countries, we used the Multitenancy approach, so we have defined a tenant for each of the countries that has data in the Database. In order to select a tenant, you need to specify the ISO 3166-1 alpha-3 country-code in the URL.

For example, if you want to get all the MedicinalProduct for Italy you can do a GET request like this (using the curl command line utility):

```
curl -X 'GET' \

'https://unicom.datawizard.it/fhir/ita/MedicinalProductDefinition' \

-H 'accept: application/fhir+json'
```

Alternatively, you can also use the web interface by clicking on MedicinalProduct on the top bar, select the Italian tenant using the drop-down control, go down to the section, click on try it out and then on execute and the server response will appear in the web page.

For performance reasons, when making a request which returns more than one resource, the FHIR server will divide the result set in bundles of maximum 50 resources. Each bundle except the last one will contain a "next" attribute, which inside has a URL to which you need to make a request in order to get the next bundle in the sequence.

9.4 OpenAPI documentation and swagger-ui

OpenAPI is a standard utilized to document and describe APIs with a JSON or YAML object. The FHIR server will automatically generate the OpenAPI documentation file, in YAML format, at the address: https://unicom.datawizard.it/fhir/api-docs .

In order to facilitate the use of the API, a web interface based on Swagger-ui is provided at:

https://unicom.datawizard.it/fhir/swagger-ui/

It will automatically fetch the OpenAPI documentation and generate forms and controls inside the page, in order to make requests.

Figure 7. Open API User Interface

The top section of the page is used to filter REST operations based on Resource type.

Just under that you will find a drop-down control that allows to select to which tenant you intend to make requests.

Figure 8. Open API User Interface

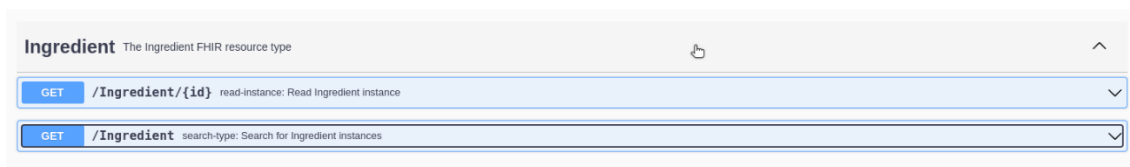The rest of the page contains sections with the possible REST operations:

Figure 9. Open API User Interface

By expanding one of these sections and click on the "Try it out" button, you will be able to set parameters for the request:
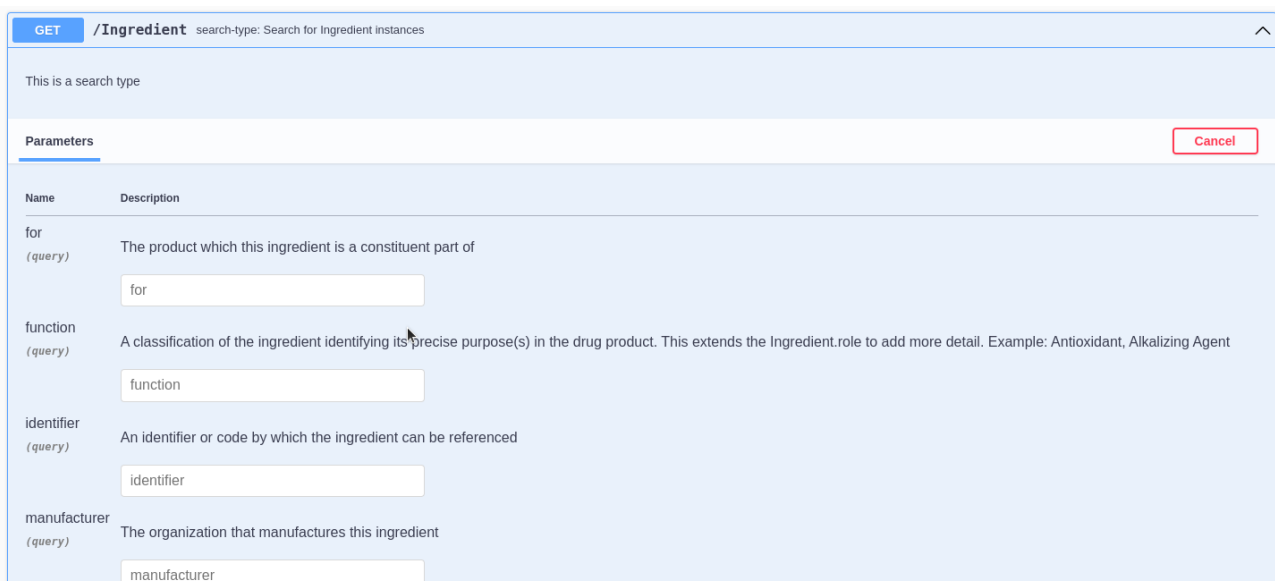

Figure 10. Open API User Interface

Finally, by clicking on the "Execute" button, you will perform the request and the server response will appear underneath.
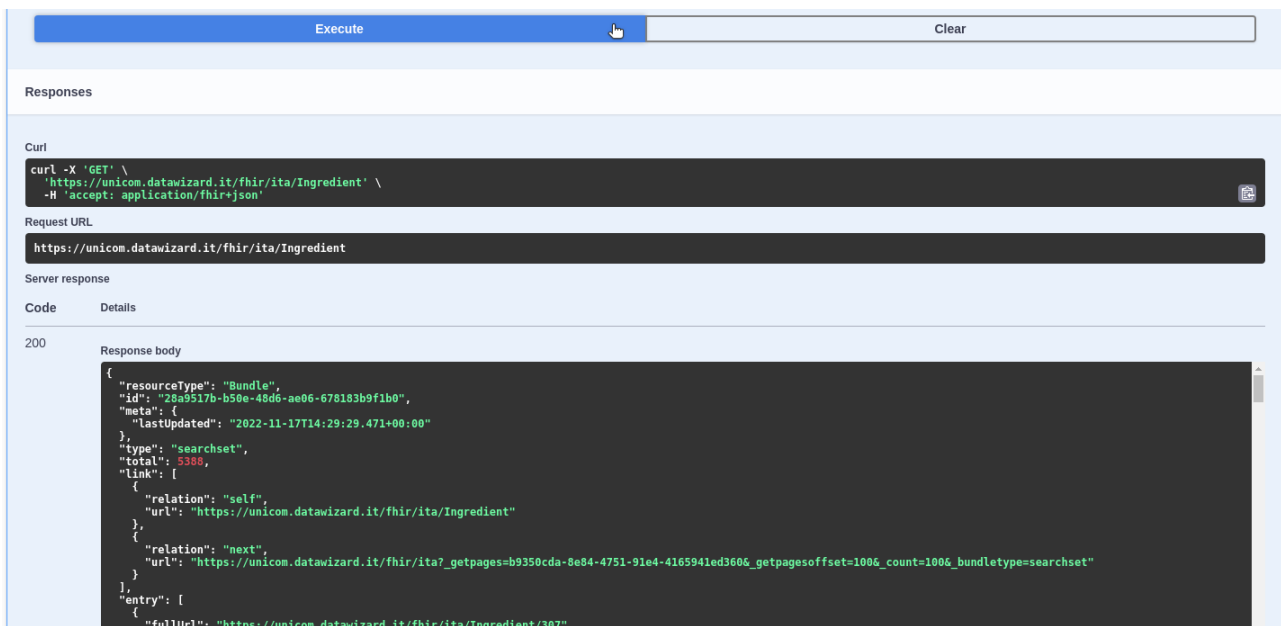
Figure 11. Open API User Interface

10. Database environments

10.1 The problem

The eHDSI Cross-Border Services need trusted and validated data from NCAs. Data that satisfies this requirement is not currently available, and won't probably be for some time.

At the same time, in order to develop, test and conduct User Facing Apps pilots, we need data. In this case we don't need trusted data

10.2 The solution

From the same codebase, we will create two instances of the T6.1 Database and FHIR Server, as depicted in Figure 12:

- **Production Environment**: used by the eHDSI Cross-Border Services. In this environment only trusted data that comes directly from the NCAs can flow in.
- **Piloting Environment**: used by the pilots of UNICOM Project, for eg. The Pilots that will be executed in Task 8.3 "IDMP and Patient Information Empowerment Apps". In order to accelerate the development process, in this environment data flows in from any source as long as it is IDMP compliant and useful for pilots. This includes data from NCAs that has been processed by third parties (like UFIS), and also exports from NCAs or MPDs. Once the Production environment has enough data, the pilots will be able to use that directly, and the Pilot environment will be dismantled.
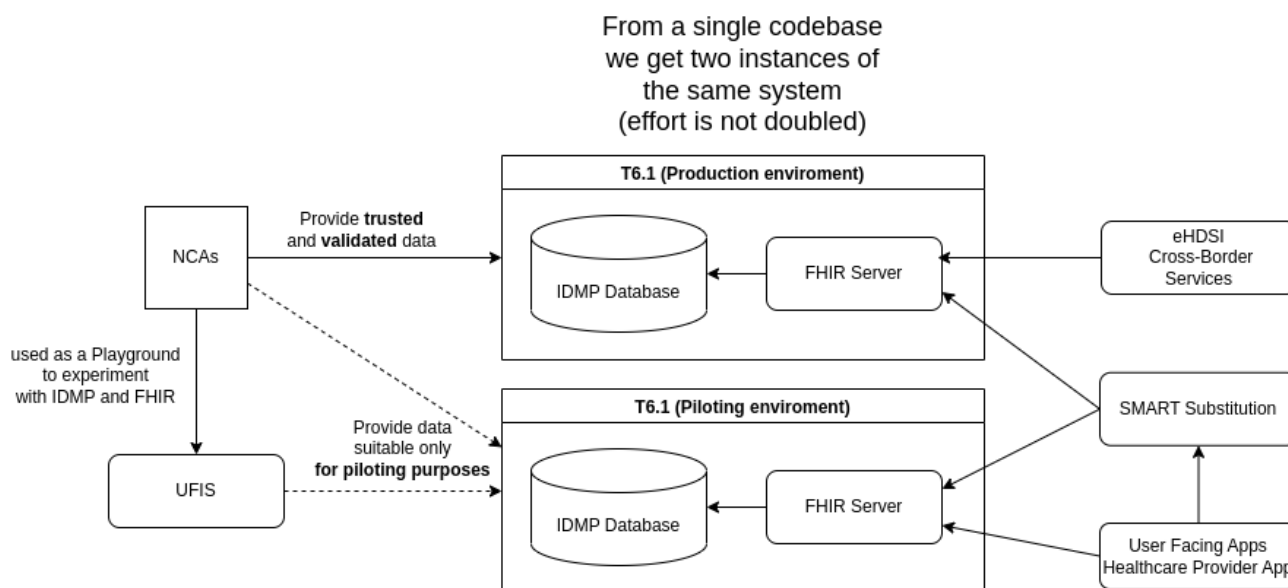
Figure 12. Database Environments

11. Lesson learned

The main difficulties that we encountered during the execution of this task are due to the fact that, while being a standard, IDMP has gaps and parts that are not clear. The result of this, and the lack of a technical coordination, is that different partners have different ideas about IDMP and the overall architecture of the project. Luckily, with the UNICOM-IG we are starting to converge on a single vision and understanding, using issue tracking tools in order to discuss technical matters. For these reasons, when the UNICOM-IG will be ready, T6.6 will be used in order to update the code of the FHIR server and IDMP database and conform to this new IG, instead of the flawed EMA one we used so far.

12. Annexes

- IDMP in a capsule: https://unicom-project.eu/wp-content/uploads/2021/10/UNICOM-handboek_A4_04.pdf
- EMA IG for PMS: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-organization-standardization-iso_en-0.pdf
- At the moment of writing this this document, the deliverables referenced in text were not publicly accessible. Eventually, they will be found on the UNICOM page: https://unicom-project.eu/