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 medicinal product information across the globe

- detailed
- semantically coded
- interoperable

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

Substance

Substance with the role of Precise Active Ingredient

Dose Form

Administrable Dose Form

Strength

Value of Normalised Strength

Unit of Normalised Strength (of nominator and denominator)

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
- **MPI**: Medicinal Product ID
- **SID**: Substance ID
- **PCID**: Medicinal Product Package ID
- **BAIDs**: Medicinal Product Batch IDs
Perspective on Future and history of IDMP implementation

Retrospective
- Pharmaco-archeology
- Substance cleansing
- EDQM standardization
- Strength Normalisation

Prospective
- DADI-Project (industry => Agency)
- IDMP-Compliant Registration
- NCA=>MPD flow
- MPD =>Vendor Flow
- Vendor => Clinical Care Flow
TO-BE: IDMP/FHIR compatible Electronic Application Forms

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

Web Tool supporting IDMP/FHIR compatible application dataset formats

Applicants

DADI --> PLM

New

Initial Applications

Lifecycle Management

Regulators

The current Data Exchange Standard (DES) will be superseded by FHIR3 resource definitions

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

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

Regulatory IT-Systems

New

Retrieving master data

New

IDMP/FHIR format
TO-BE: Status of development

Web Tool supporting IDMP/FHIR compatible application dataset formats

DADI
- Variation Application
- Initial Application
- Renewal Application

Initial Applications

Lifecycle Management

Regulators

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

In progress

pending

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

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

New Retrieving master data

IDMP/FHIR format

New

Regulatory IT-Systems

See also collaboration with UNICOM WP4

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This is a collection of essential medicinal product data elements that are currently available in the PLM Portal (Variation form for CAPs) (Except Strength)
These top 10 fields are contained in only 4 FHIR resources:

- **MedicinalProductDefinition**
  - Ids, Name, ATC Code

- **PackagedProductDefinition**
  - Pack Size

- **RegulatedAuthorisation**
  - MA Holder, Number, Country for both Product and Package

- **Ingredient**
  - Substance Name & Strength
Delivery of selected ISO IDMP medicinal product data for cross-border pilots

<table>
<thead>
<tr>
<th>Task</th>
<th>Technical Approach</th>
<th>Methods &amp; Focus</th>
<th>Result</th>
<th>Converging</th>
<th>Way Forward</th>
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<tr>
<td></td>
<td></td>
<td>Focus: data quality</td>
<td></td>
<td></td>
<td>COMBINING DATA SOURCES UFIS, csv-s, new data</td>
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<td></td>
<td></td>
<td>Problem: slow progress</td>
<td></td>
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<td>ENHANCED IMPORT TOOLS IDMP-transformation, validation</td>
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<td></td>
<td>COMMON PROCESSES Agreed approach, transparency</td>
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<td></td>
<td>Data-as-is CSV approach by WP6, WP8</td>
<td>Method: csv transformation</td>
<td>Technical tooling for creating FHIR messages. Structured non-IDMP csv data (4 substances).</td>
<td></td>
<td>Building a common solution to bring together: NCA data, database D6.1, UFIS, and data visualisation tools.</td>
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<td></td>
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<td>Focus: automation</td>
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<tr>
<td></td>
<td></td>
<td>Problem: poor IDMP compatibility</td>
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</table>
## NCA readiness and implementation progress Matrix

<table>
<thead>
<tr>
<th>Category</th>
<th>Progress</th>
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<tbody>
<tr>
<td><strong>Analysis and modelling</strong></td>
<td></td>
</tr>
<tr>
<td>GAP-analysis between current data model and IDMP</td>
<td>Green (Complete)</td>
</tr>
<tr>
<td>Datamodelling based on GAP-analysis</td>
<td>Green (Complete)</td>
</tr>
<tr>
<td><strong>Mapping and transformation</strong></td>
<td></td>
</tr>
<tr>
<td>Data-mapping to RMS dictionary</td>
<td>Yellow (In progress)</td>
</tr>
<tr>
<td>Data-mapping to OMS dictionary</td>
<td>Yellow (In progress)</td>
</tr>
<tr>
<td>Data-mapping to SMS dictionary</td>
<td>Yellow (In progress)</td>
</tr>
<tr>
<td>Data-transformation</td>
<td></td>
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<tr>
<td><strong>SPOR-connection</strong></td>
<td></td>
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<tr>
<td>Referentials RMS-connection</td>
<td>Yellow (In progress)</td>
</tr>
<tr>
<td>Organisations OMS-connection</td>
<td>Green (Complete)</td>
</tr>
<tr>
<td>Products PMS-connection</td>
<td>Yellow (In progress)</td>
</tr>
<tr>
<td>Substances SMS-connection</td>
<td>Yellow (In progress)</td>
</tr>
<tr>
<td><strong>Prototype data feeds</strong></td>
<td></td>
</tr>
<tr>
<td>Prototyping and piloting of data feeds</td>
<td>Green (Complete)</td>
</tr>
</tbody>
</table>

*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
Burden of legacy conversion will be with the National Agencies

**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”

**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

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* 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

ManufacturedItemDefinition profile defines cardinalities and terminology bindings

UNICOM is the first to use such visualisation of example data inside FHIR IG
CDA – New Identifiers for eHDSI Wave 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 |

<table>
<thead>
<tr>
<th>Package Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Box</td>
</tr>
<tr>
<td>• 5 unit(s) Pre-filled syringe</td>
</tr>
<tr>
<td>• 3 milliliter Solution For injection in pre-filled syringe</td>
</tr>
</tbody>
</table>

* 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

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
Use Case ePrescription: IDMP Enhanced eP/eD & PS

- 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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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

Governance

WHO International working group

Global database of PhPIDs

WHO-UMC validation team

WHO-UMC technical support

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

Global PhPID: 0xE857DA811B4A6F3BD57810C45D2EA1ED

Pharmacy Information System

Resources: 
- AdministrableProductDefinition
- MedicinalProductDefinition

MPD Product Look-up

NL MPD (UFIS)

Global PhPID: 0xE857DA811B4A6F3BD57810C45D2EA1ED

Search: [mpf/for server]/[AdministrableProductDefinition]?identifier=https://www.who-umc.org/phpid/[PhPID] &_include=AdministrableProductDefinition.form-ef

FCAT May 2022, FHIR 4.6.0

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Connecting to the UNICOM FHIR IDMP

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

Global PhPID: 0xE857DA811B4A6F3BD57810C45D2EA1ED

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

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In an ideal world we will....

Drug Identifier

In which country do you wish to identify a medicine?

- Italy

Write the name of the medicine

- Imodium soft capsules 2mg

or scan the code of the box

- Confirm

Drug identifier

Target country

- Italy

Medicine

- Imodium soft capsules 2mg

Interaction checker

- In Italy

- Imodium capsule rigide 2 mg

Safe!

There are NOT Interactions with this drug in your medication list

Interaction checker

- In Italy

- Bactrim Compresse 16cpr 160mg+800mg

Attention!

There are interactions with this drug in your medication list

- Humalog Mix50

Interactions: Bactrim ↔ Humalog

Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi
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!
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”