IDMP Semantic Specifications for eHealth Services

Anderson Carmo
Jose Costa Teixeira
Robert Vander Stichele
Mathias Ghys
Frederic Bulckaen

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
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You may show your approval!

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2. You then select «Q&A» and write your question
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You can comment on a question or answer to engage in a conversation.

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At the end of the virtual session, a questionnaire will be sent to the participants, to help us understand participant's reactions and needs.
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Introductions to our esteemed colleagues and today’s speakers...

Anderson Carmo  Jose Teixeira  Robert Vander Stichele  Frederic Bulckaen  Mathias Ghys

...and our panellist

Marcello Melgara  Jean-Gonzague Fontaine
Questions in the Q & A facility, please
For feedback, please go to: https://forms.gle/76p2bNtRZzM6aY5r6

Thanks for your time
UNICOM
Up-scaling the global univocal identification of medicines

IDMP Semantic specifications for eHealth services

Anderson Carmo / José Teixeira
WP5 co-leader SPMS / WP1-5 I-HE
Date: 22 Apr. 2022

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Introduction and Scope

Anderson Carmo
Why High-Quality Data?

- National dispensing
- Cross-border dispensing
- Prescribing
- Pharmaco-vigilance
- Registration

Trust & Safety
What “was“ the past?  **Gaps between Regulatory & eHealth Worlds**

- National dispensing
- Cross-border dispensing

- Not usable for ePrescription service

- EMA Art. 57 DB

Community of Expertise 22/4/2022

UNICOM has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
ISO IDMP / EMA SPOR as the basis for future interoperability

- National dispensing
- Cross-border dispensing
- Prescribing
- Pharmaco-vigilance
- Registration
ISO IDMP towards the Semantic Interoperability

• The overarching objective of semantic interoperability is that data semantics (meaning) are consistent across specifications, and the following requirements are immediately evident:
  1. The meaning of data elements shall be clear, unambiguous, and shared between the parties.
  2. When data is coded, the values and their meaning shall also be shared between the parties.

• It supports a successful IDMP-based semantic interoperability and its implementation of the syntactical specifications (like CDA technical specifications).
Key enablers for Semantic Interoperability

• **IDMP** specifications define the meaning of the concepts and data elements required to identify and fully describe a medicinal product.

• **EMA/SPOR** specifications add to the IDMP specifications by providing some master value sets to be used in some of those data elements for a shared vocabulary.

• **eHDSI** specifications define the data elements and their meaning for ePrescription, eDispensation, and the Master Value Set Catalogue allowing the introduction of important concepts like compliance of attributes.
The ISO IDMP is a set of 5 ISO specifications to identify medicinal products

- Based on their structure and Attributes is possible to develop the IDMP identifiers
  - PhPID
    - Pharmaceutical Product ID
  - MPID
    - Medicinal Product ID
  - PCID
    - Package Medicinal Product ID
The SPOR portal provides users with the following data management services:

- view, search, export SPOR data;
- request new and updated SPOR data;
- translate SPOR data;
- browse relevant SPOR documentation.
Clinical document exchange via eHDSI

Transformation chain of the clinical documents through eHDSI

- NCPeH-A – eHDSI – NCPeH-B
Scope

It's present the semantic components that should be considered to adopt the ISO IDMP standards among the national and cross-border systems, and to ensure the semantic interoperability of eP/eD & PS in the different Member States.

UNICOM supports semantic alignment with IDMP using:

1. definition of a minimal (semantic) data set
2. determine the terminology systems and value sets for each element in the minimal data set, in line with eHDSI.
3. Mapping of national medicinal products to the IDMP codes of the minimal data set,
Common data attribute specifications

This work will result in an IDMP-based, CEF eHDSI-compatible data set, including the definitions and terminologies and the initial process is identifying the data elements in eHDSI and the corresponding value sets in the MVC.
Semantic functional specifications for IDMP

José Teixeira
What are semantic specifications?

• Semantic specification is the clear and unambiguous definition of what information is being exchanged, and what form it is expected to take.

• NOT the same as technical format.

• Examples:
  • Product → Prescribed product
  • Identifier → Product identifier → IDMP product identifier

• Including the vocabulary options where applicable
  • i.e., “dose form” → EDQM dose form / SPOR dose form
Semantic vs (Technical) Syntax specifications

• Technical specifications expose a syntax of how to present the data.

  • Example: "Patient has (optional) gender, which has possible values Male, Female, Unknown, Other.

• This may assume a meaning (technical specification does not define what "gender" is.
• May consolidate the semantic specification aspects (i.e., optionality, value sets)
• Introduces a lot of information
Context matters

• What is relevant and obvious in a context might not be in another context.
  • “product code”
  • “indication”

• What rules apply and codes are expected will also differ
  • Substance
Purpose & Impact of Semantic specifications

• Questions to answer with semantic specifications are formalized:
  • Can we share the data element across the data flow? - i.e., can data actually flow?
    • Most of the issues in UNICOM (and practically all projects)
  • Is the implementation semantically sound? How can we know?
  • Can we change format between specifications? Are they compatible?
Defining semantic specifications

- Defining the data structures for a given context, and include the formal definition of data elements:
  - Name
  - Definition
  - Rules

  - Optionality / Cardinality
  - Value sets
  - Other rules
Defining semantic specifications

• Identify the context(s) where the specification applies
• Identify what is really relevant in/across those context(s)
• Identify gaps, overlaps, misalignments

• Always formalizing the data definitions (not technical format)
UNICOM has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
Specifications (gap) analysis for UNICOM

**Regulatory**
- Pharmaceutical Product
  - Pharmaceutical Product ID
  - Pharmaceutical Dose Form
  - Ingredient
  - Ingredient Role
  - Ingredient substance
- Medicinal Product
  - Medicinal Product ID
  - Medicinal Product name
  - Medicinal Product name part(s)

**eHDSI specifications**
- eHDSIDoseForm
- eHDSIRouteofAdministration

**EC**
- Prescription
- Prescribed Product
- Prescribed Product ID
- Administration route
- Intended dose form

**MVC**
- Virtual Med Product
- Virtual Med Product ID
- Virtual Med Prod Dose Form
- Ingredient
- Ingredient Role
- Ingredient substance

**MS**
- Virtual Med Product
- Virtual Med Product ID
- Virtual Med Prod Dose Form
- Ingredient
- Ingredient Role
- Ingredient substance

**Value Sets**

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The approach

• Identify which elements are needed for interoperability in each context

• Formally define the elements,
  • taking into consideration how IDMP can help in the gaps
  • Considering implied semantics and constraints of current implementation (e.g., CDA)

• Check that semantic specifications map correctly to implementation(s)
  • Validate if the specs are semantically coherent.
Results

• For ePrescription, eDispense – 17 attributes + gap analysis

Table 17: Minimal Attribute List^{22}

<table>
<thead>
<tr>
<th>#</th>
<th>Class</th>
<th>Attribute</th>
<th>_ueHIS data elements</th>
<th>eHIS MVC / Value set ID</th>
<th>Suggested specifications and enhancements</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.4</td>
<td>Medicinal Product</td>
<td>Ingredient</td>
<td>Active Inactive ingredient</td>
<td>See footnote 10</td>
<td>When identifying a Substance, prepare the size of a new value set (IIS) Add a new data element – Classification – and use the ATC value set</td>
</tr>
<tr>
<td>6.10.4</td>
<td>Medicinal Product</td>
<td>Ingredient</td>
<td>Ingredient ID (code)</td>
<td>eHIS/MedicinalProduct 1.3.6.1.4.1.12588.11.10.1.3.1.42.24</td>
<td>SPOR to define the MPPD name space for unambiguous use</td>
</tr>
<tr>
<td>1.13.3</td>
<td>Medicinal Product</td>
<td>ATC Code(s)</td>
<td>ATC code</td>
<td>eHIS/MedicinalProduct 1.3.6.1.4.1.12588.11.10.1.3.1.42.24</td>
<td>SPOR to define the MPPD name space for unambiguous use</td>
</tr>
<tr>
<td>1.2</td>
<td>Medicinal Product</td>
<td>Medicinal product identifier (MPID)</td>
<td>Medical Product Code</td>
<td>Not directly available in MVC – available via SPOR</td>
<td>SPOR to define the MPPD name space for unambiguous use</td>
</tr>
<tr>
<td>4.1</td>
<td>Medicinal Product</td>
<td>Packaged Medicinal Product Identifier (P CID)</td>
<td>Marketing Authorisation Holder (Organisation)</td>
<td>For ePrescription, eDispense – 17 attributes + gap analysis</td>
<td></td>
</tr>
<tr>
<td>2.6</td>
<td>Medicinal Product</td>
<td>Marketing Authorisation Holder (Organisation)</td>
<td></td>
<td>Not directly available in MVC – available via SPOR</td>
<td>SPOR to define the BrandName name space for unambiguous use</td>
</tr>
<tr>
<td>1.16.1</td>
<td>Medicinal Product</td>
<td>Full name</td>
<td>Brand Name of the Medicinal Product</td>
<td>Not directly available in MVC – available via SPOR</td>
<td>SPOR to define the BrandName name space for unambiguous use</td>
</tr>
<tr>
<td>4.2</td>
<td>Medicinal Product</td>
<td>Package description</td>
<td>Medicinal Product Package</td>
<td>1.3.6.1.4.1.12588.11.10.1.3.1.42.3</td>
<td>Clarify that this is “PackageType”</td>
</tr>
<tr>
<td>4.3</td>
<td>Medicinal Product</td>
<td>Pack size</td>
<td>Quantity – use eHISUnit</td>
<td>Quantity – use eHISUnit</td>
<td></td>
</tr>
<tr>
<td>4.7.5</td>
<td>Medicinal Product</td>
<td>Package item (container) quantity</td>
<td>Number of packages</td>
<td>Number of packages</td>
<td></td>
</tr>
<tr>
<td>5.5.2.2.2</td>
<td>Medicinal Product</td>
<td>Strength (Presentation single value or low limit)</td>
<td></td>
<td>Quantity – use eHISUnit</td>
<td></td>
</tr>
<tr>
<td>5.5.3.3.2</td>
<td>Medicinal Product</td>
<td>Strength (Concentration single value or low limit)</td>
<td></td>
<td>Quantity – use eHISUnit</td>
<td></td>
</tr>
<tr>
<td>5.5.3.3.2</td>
<td>Medicinal Product</td>
<td>Reference Substance</td>
<td></td>
<td>Quantity – use eHISUnit</td>
<td></td>
</tr>
<tr>
<td>5.5.3.3.2</td>
<td>Medicinal Product</td>
<td>Reference strength (Presentation single value or low limit)</td>
<td></td>
<td>Quantity – use eHISUnit</td>
<td></td>
</tr>
<tr>
<td>1.5</td>
<td>Medicinal Product</td>
<td>(Authorised) pharmaceutical form</td>
<td></td>
<td>Quantity – use eHISUnit</td>
<td></td>
</tr>
<tr>
<td>1.5</td>
<td>Medicinal Product</td>
<td>Pharmaceutical Dose Form</td>
<td>eHIS/MedicinalProduct 1.3.6.1.4.1.12588.11.10.1.3.1.42.2</td>
<td>Consider creation of dedicated value set for pharmaceutical dose form</td>
<td></td>
</tr>
<tr>
<td>6.2</td>
<td>Medicinal Product</td>
<td>Administerable Dose Form</td>
<td>eHIS/MedicinalProduct 1.3.6.1.4.1.12588.11.10.1.3.1.42.2</td>
<td>Consider creation of dedicated value set for administrable dose form</td>
<td></td>
</tr>
<tr>
<td>4.10.3</td>
<td>Medicinal Product</td>
<td>Manufactured dose form</td>
<td>eHIS/MedicinalProduct 1.3.6.1.4.1.12588.11.10.1.3.1.42.2</td>
<td>Consider creation of dedicated value set for manufactured dose form</td>
<td></td>
</tr>
<tr>
<td>6.6</td>
<td>Medicinal Product</td>
<td>Route of Administration</td>
<td>eHIS/MedicinalProduct 1.3.6.1.4.1.12588.11.10.1.3.1.42.2</td>
<td>Consider creation of dedicated value set for manufactured dose form</td>
<td></td>
</tr>
</tbody>
</table>

*Required to generate the PI-PID – as such, it is important to define a well-bounded value set to avoid ambiguity when creating the PI-PID.

• Recommendations for "target" semantic specification
Cooking & eating the IDMP Pie together:
- “Quality comes from normality”
- “Don’t ask for additional special customisations”

• Take advantage of the EMA/SPOR formally defined, approved and implemented registration procedures and the data associated to IDMP Attributes

• Get from NCAs the official data of the IDMP attributes, defined as a limited sub-set of the global list of IDMP attributes,

• Inject in the ePrescription / eDispensation, the approved data of IDMP attributes as additional optional elements
Thank you!

Monviso, Po river head, as it is seen from Torino (Italy)
Thank you!
The perspective of the national Medicinal Product Dictionary on the production and availability of IDMP-compliant MASTER DATA and REFERENCE DATA in Europe

Community of Expertise, April 22, 2022

Robert Vander Stichele, MD, PhD, I-HD, WP8 leader in UNICOM
The position of the Medicinal Product Dictionary (MPD) as an intermediary in the IDMP landscape

A bridge between

The Regulatory World

Medicinal Product Dictionary

The Clinical World

1 to 4 (and more) MPDs in each country

Providing textual information and data on the
4,000 to 15,000 Medicinal Products Packs
in each of 27 member states of the EU
(27 times 8,000 MP packs)

A very valuable stakeholder at the national level

(see UNICOM D9.2)
The difference between **MASTER DATA and REFERENCE DATA**

**REFERENCE DATA on Terminologies**

- Held by S and R part of SPOR
- Held by the eHSDI Master Value Set
  - Substance (SMS code + label)
  - Dose Form (EDQM code + label)

  In 24 official EU languages

**MASTER DATA on actual Medicinal Products**

- Will be held by the P (Product) part of SPOR for Europe
- from 27 member states

  May not be available anytime soon.
  Will require cooperation at the national level

(see UNICOM deliverable D5.4)
An important distinction between procedures for new products and legacy conversion of older products

- **Index Date**
- **Retrospective**
  - Pharmaco-archaeology
  - Substance cleansing
  - EDQM standardization
  - Strength Normalisation
- **Prospective**
  - DADI-Project (industry => Agency)
  - IDMP-Compliant Registration
  - EMA =>NCA=>MPD
  - MPD =>Vendor
  - Vendor => Clinical Care
Crucial questions for IDMP standardisation at national level

► How soon will the REFERENCE DATA be available at the national level?
  ▶ Will the SPOR substance data and referentials (Dose Form) be available soon for NCAs and for other stakeholders at the national level?
  ▶ Will the eHSDI Master Value Set draw data from SPOR and make them available to National Contact Points? And other Stakeholders?

► Who will make the MASTER DATA for the medicinal products in legacy conversion?
  ▶ Will EMA be able to create master data for 27 times 8,000 products?
  ▶ Will EMA and National Competent authorities reach an agreement on division of work?
  ▶ Will NCAs cooperate with Medicinal Product Dictionaries and other national stakeholders to accomplish this massive task, country by country?

So that also in legacy conversion reliable IDMP data can flow from the NCA to EMA SPOR in a final stable solution
Critical tasks for for IDMP standardisation at national level

▶ Answers to be provided for each national medicinal product in legacy conversion for 27 times 8.000 Medicinal Products)

▶ Substance
  Does a modifier needs to be defined for the moiety?
  If yes, which modifier?
  What is the substance code for the substance with the role of Precise Active Ingredient

▶ Dose Form
  What is the EDQM term/code for the local dose form?

▶ Strength
  On what is the official authorized strength based?
  On the moiety? On the Moeity plus modifier? On a reference product?
What could be the motives for MPDs to engage in this?

► Willingness to improve the quality of internal data
► Interest in international cooperation
► Invest in good relationship with the National Competent Authority
► Desire to be an intermediary between NCA, eHealth, Vendors
► Ambition to produce minimal data sets for cross border pilots
Mission of the Medicinal Product Dictionary

Be a key player between the stakeholders at the national level
- The National Competent Authority: Drug Agency
- The eHealth system
- The Electronic Health Record Vendors, the Pharmacy dispensing systems
- The National Contact Point for Cross border prescribing and dispensing,

The intra-national drug information providing eco-system

In such a way that it profits from and to the supra-national eco-system
- Pharma Headquarters
- EMA
- Heads of Medicines Agencies
- eHDSI

The supra-national drug information providing eco-system
Supra-national ecosystem

Intra-national ecosystem

(E Courtesy from Marcello Melgara)
Conclusion

► Collaboration between the stakeholders

at the supra-national eco-system

and the intra-national eco-system

is the key to success in IDMP Implementation
UNICOM – eHDSI perspective

April 22, 2022

UNICOM - Community of Expertise

eHDSI Solution Provider
IDMP – Identification of Medicinal Products
eHDSI Change Proposals – CP-063 & CP-066

• **CP-063: Improve Medication Information Representation**
  • Proposed by the STF Architecture Workgroup
  • 6 positive assessments from Member States

• **CP-066: Prepare eHDSI Requirements Catalogue for ISO IDMP**
  • Proposed by the eP Cluster, STF and STF Architecture Workgroup
  • 7 positive assessments from Member States

• Implementation target for Wave 6 (Requirements Catalogue delivered for April 2022 – Technical specifications delivered for May 2022)

• Will be tested in eHDSI test events:
  • Preliminary test event -> October 2022
  • Formal and upgrade test event -> Mars 2023
2 points open for discussion on the Requirements Workgroup and Semantic Workgroup:

- Use of the Reference Strength:
  - Allows to define the strength of a substance based on a referential substance.
  - Is part of the ISO IDMP standards and used in the EMA data structure
  - Already used by Sweden at national level, planned to be used by Finland

- Units of presentation:
  - Allows the use of advanced units for package size representation
    Example: number of tablets, number of syringes, ml, mg, etc
### In parallel, eHN Guidelines – ePrescription v3

- **Definition of the identifiers by eHN – Planned release for June 2022**

<table>
<thead>
<tr>
<th>Identifier Type</th>
<th>Description</th>
<th>Example</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MPID</strong></td>
<td>Identifier of the medicinal product refers to the product inside the package, not the packaged item as such. It could be MPID according to ISO 11615, EMA PMS ID and/or a national identifier. [not applicable for generic prescriptions]</td>
<td>EMA PMS ID, EMA PMS ID, National Identifier</td>
<td>EMA PMS</td>
</tr>
<tr>
<td><strong>PHPID</strong></td>
<td>Identifier of a pharmaceutical product refers to unique PhPID according to ISO 11616. This could be a part of a description of a specific medicinal product or an attribute of a generic prescription. [not applicable for generic prescriptions]</td>
<td>EMA PMS ID</td>
<td>EMA PMS</td>
</tr>
<tr>
<td><strong>PCID</strong></td>
<td>Identifier of a packaged medicinal product refers to a specific pack size of a specific product. It could be PCID according to ISO 11615 and/or its national equivalent. [not applicable for generic prescriptions]</td>
<td>EMA PMS ID</td>
<td>EMA PMS</td>
</tr>
</tbody>
</table>
### Dataset in CDA IGs

#### Requirements Catalogue

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>22</td>
<td>Prescription Identification</td>
<td>Prescription Identifier</td>
</tr>
<tr>
<td>23</td>
<td>Medicinal Product Description</td>
<td>Medicinal Product</td>
</tr>
<tr>
<td>24</td>
<td>Medicinal Product Brand Name</td>
<td>Medicinal Product</td>
</tr>
<tr>
<td>25</td>
<td>Medicinal Product Classification</td>
<td>Medicinal Product</td>
</tr>
<tr>
<td>26</td>
<td>Active Ingredient(s)</td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>Active Ingredient Role(s)</td>
<td></td>
</tr>
</tbody>
</table>
# Dataset in CDA IGs

## CDA IG (Art-Décor) Dataset

### CDA Template Definitions

#### eHDI ePvD Manufactured Material

<table>
<thead>
<tr>
<th>Item</th>
<th>DT</th>
<th>Card</th>
<th>Conf</th>
<th>Description</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>hld:manufacturedMaterial</td>
<td>cs</td>
<td>0-1</td>
<td>F</td>
<td></td>
<td>eHDSI-rel</td>
</tr>
</tbody>
</table>

- **ePrescription**
- **1. Patient Identification**
- **2. Health Professional Identification**
- **3. Prescription Clinical Data**
- **Prescription Identification**
  - Prescription Identifier
  - Medicinal Product Description
- **Medicinal Product**
  - Medicinal Product identifier
  - Medicinal Product Brand Name
  - Medicinal Product Classification
  - Active Ingredient(s)

#### Medical Product Identifier

**Example**

```xml
<code code="2.16.840.1.113883.10.12.311" codeSystem="urn:oid:2.16.840.1.113883.10.12.311" codeSystemName="LOINC" display="Drug Identification Number (HIS)"/>
```

#### Medicinal Product Data Set

**Example**

```xml
<code code="1.3.6.1.4.1.19373.1.8.3.1.12.600" codeSystem="urn:oid:1.3.6.1.4.1.19373.1.8.3.1.12.600" codeSystemName="SCT" display="Drug Identification Number (HIS)"/>
```

#### Medicinal Product Classification

**Example**

```xml
<code code="2.16.840.1.113883.10.12.311" codeSystem="urn:oid:2.16.840.1.113883.10.12.311" codeSystemName="LOINC" display="Drug Identification Number (HIS)"/>
```
Value Sets on eHDSI related to ISO IDMP

• **eHDSIDoseForm**
  Value Set contains concepts from EDQM’s Code System and it is used to present physical manifestation of a product that contains the active ingredient(s).

• **eHDSIRouteOfAdministration**
  Value Set contains concepts from EDQM’s Code System and it is used to indicate the part of the body on which, through which, or into which the medicinal product is to be administered.

• **eHDSIPackage**
  Value Set contains concepts from EDQM’s Code System and it is used to represent the administration device, closure, or container of manufactured item.

• **eHDSIQuantityUnit**
  Value Set contains concepts from EDQM’s Code System and it will be used to present unit of presentation, which is describing the discrete countable entity in which a pharmaceutical product or manufactured item is presented.

• **eHDSISubstance**
  Value Set contains concepts from EMA SMS list of Substances and it will be used to indicate active ingredient of medical product.
Work to be done

CDA Display Tool

- Display the different identifiers:
  - MPID
  - PCID
  - PhPID
Questions in the Q & A facility, please
For feedback, please go to: https://forms.gle/76p2bNtRZzM6aY5r6

Thanks for your time