WP-1 / community of expertise

22 April 2022

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

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

SOME RULES FOR THE VIRTUAL MEETINGS

UNICOM

Our interactive session:

UNICOM

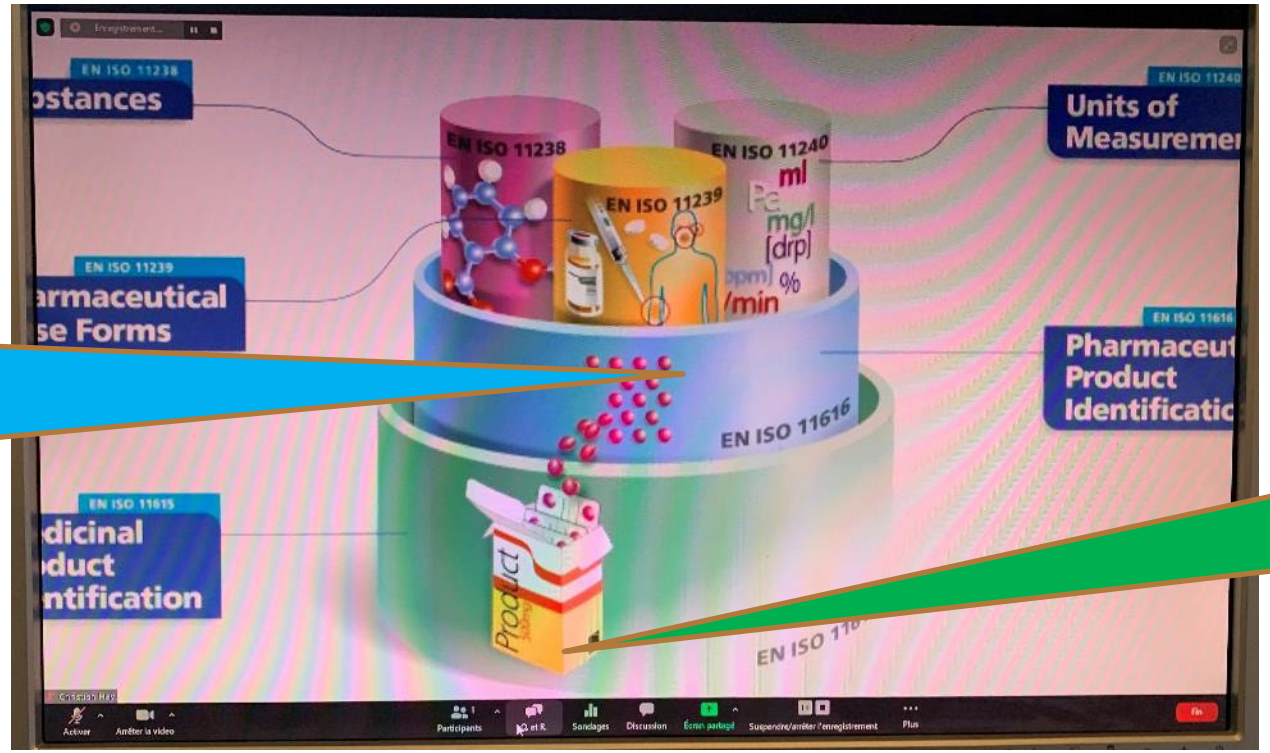
- ✓ **Everybody is on mute**
- ✓ **You post your question in the Q&A facility**
- ✓ **When you speak, please keep concise**
- ✓ **You may show your approval !**

After (and during) the introduction presentations, any UNICOM related question / comment may be shared with Q&A

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

Asking a question or making a comment: please use the Q&A facility

1. Move the mouse on the screen to have the options bar appearing



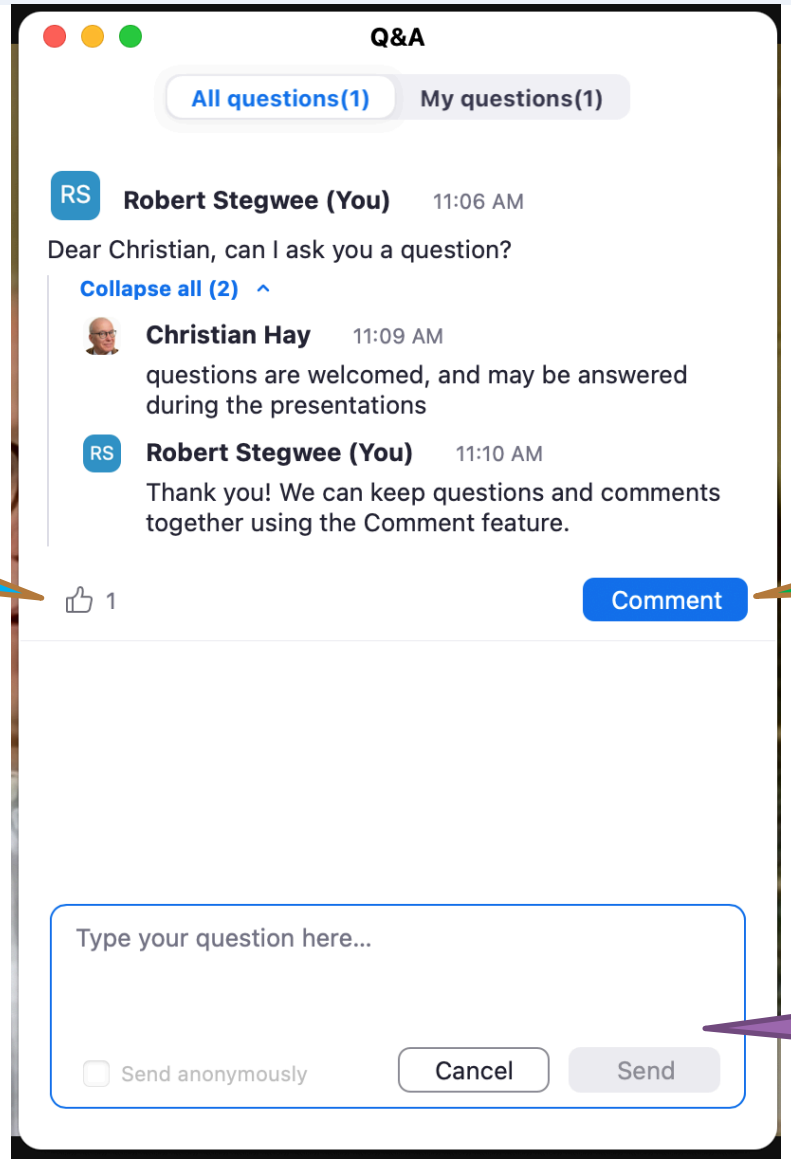
2. You then select «Q&A» and write your question

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

Showing support and providing a comment on a question or answer

UNICOM

You can support a question by clicking the «thumbs up» which moves it up on the list for the presenters



You can comment on a question or answer to engage in a conversation

Typing and sending a new question does not retain the context of your comment

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

Security

- Security is our priority
- This session is password protected

Recording of this session is made available on UNICOM's youtube channel
https://www.youtube.com/channel/UCBsNj4B33Q7-50XTXdqAGIg

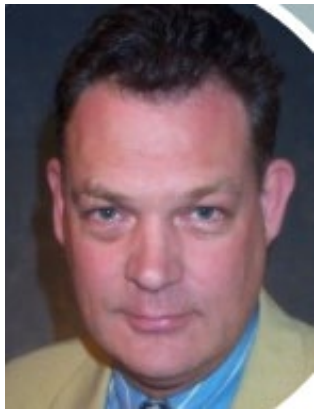
At the end of the virtual session, a questionnaire will be sent to the participants, to help us understand participant's reactions and needs

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

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

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

Questions in the Q & A facility, please
For feedback, please go to : https://forms.gle/76p2bNtRZzM6aY5r6

Thanks for your time

UNICOM

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

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

Introduction and Scope

Anderson Carmo

UNICOM

Why High-Quality Data?

Trust & Safety

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

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

What "was" the past? *Gaps between Regulatory & eHealth Worlds*

National dispensing

Cross-border dispensing

Not usable for ePrescription service

EMA Art. 57 DB

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

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

ISO IDMP towards the Semantic Interoperability

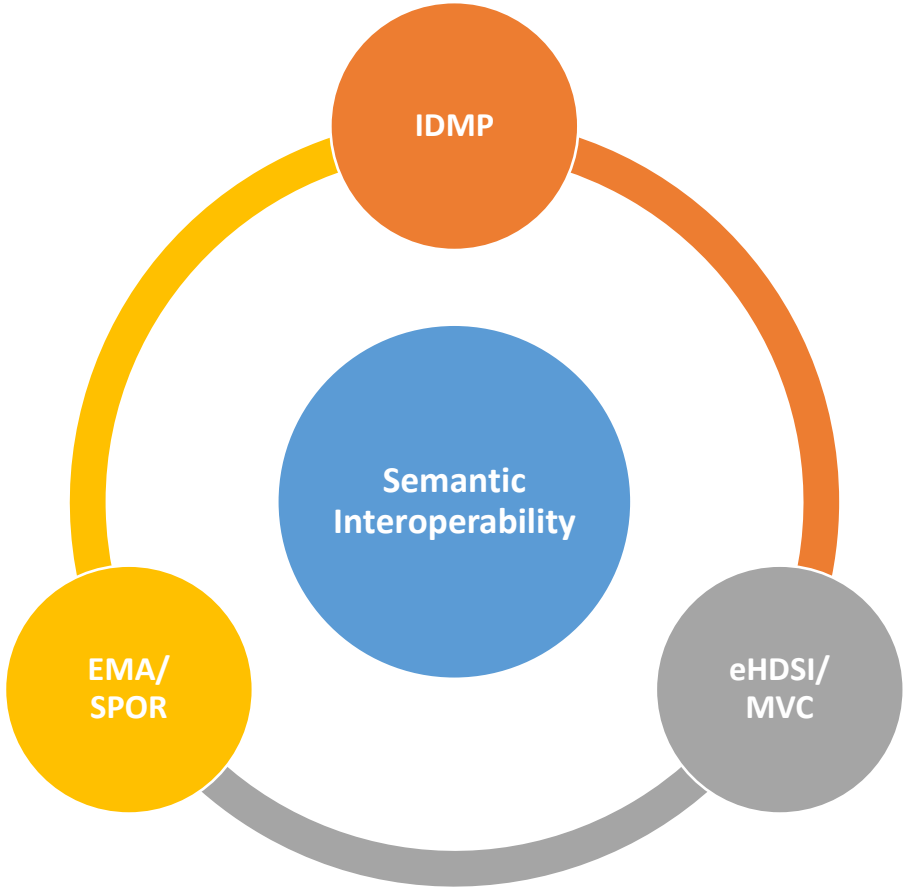
- The overarching objective of semantic interoperability is that data semantics (meaning) are consistent across specifications, and the following requirements are immediately evident:
  1. The meaning of data elements shall be clear, unambiguous, and shared between the parties.
  2. When data is coded,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

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

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

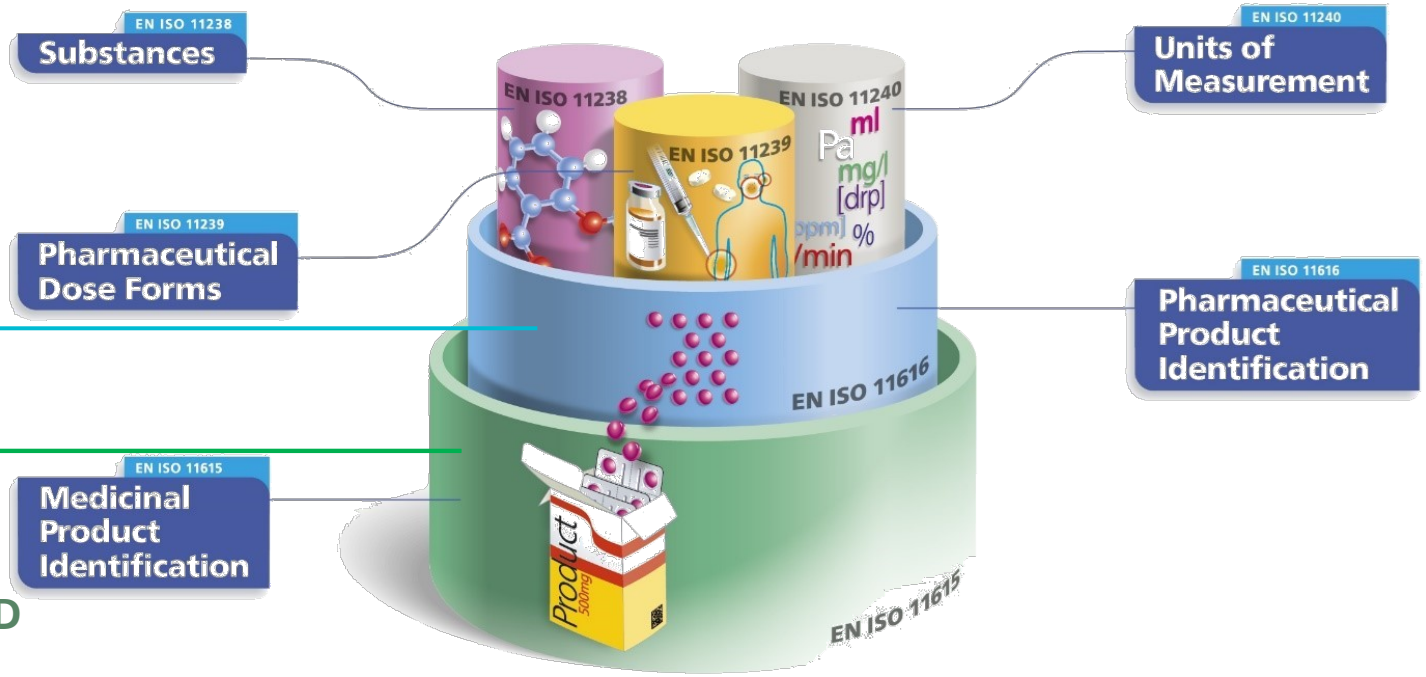


UNICOM has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299

IDMP concept

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



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

EMA/SPOR - Substances, Products, Organisations and Referentials

Substance Management Services (SMS)

Product Management Services (PMS)

Organisation Management Services (OMS)

Referentials Management Services (RMS)

The SPOR portal provides users with the following data management services:

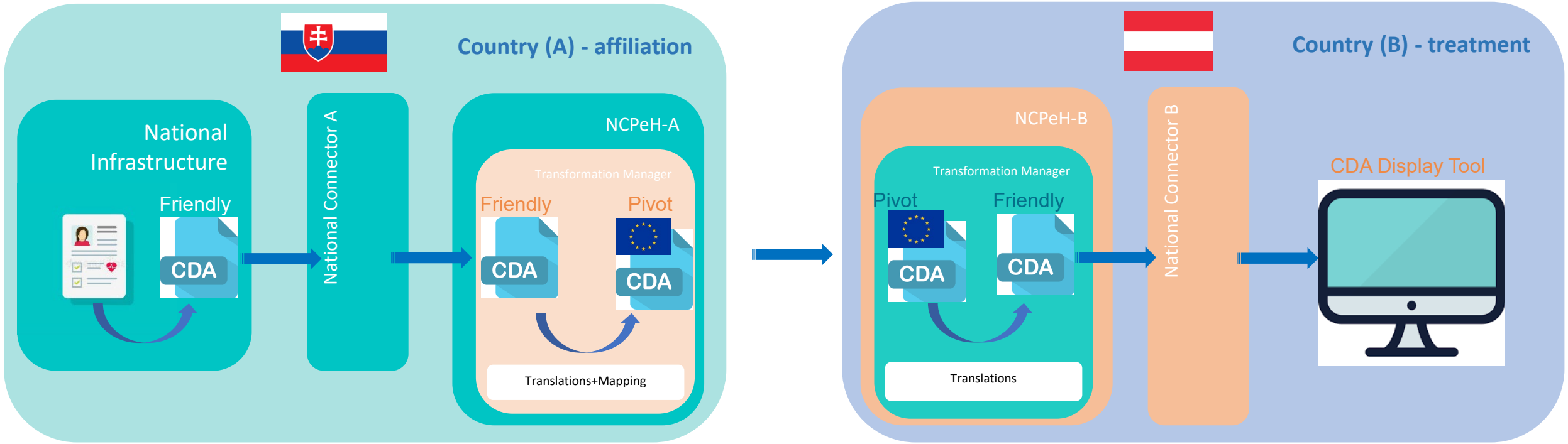
- view, search, export SPOR data;
- request new and updated SPOR data;
- translate SPOR data;
- browse relevant SPOR documentation.

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

Clinical document exchange via eHDSI

Transformation chain of the clinical documents through eHDSI

- NCPeH-A – eHDSI – NCPeH-B



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

Scope

Its 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.

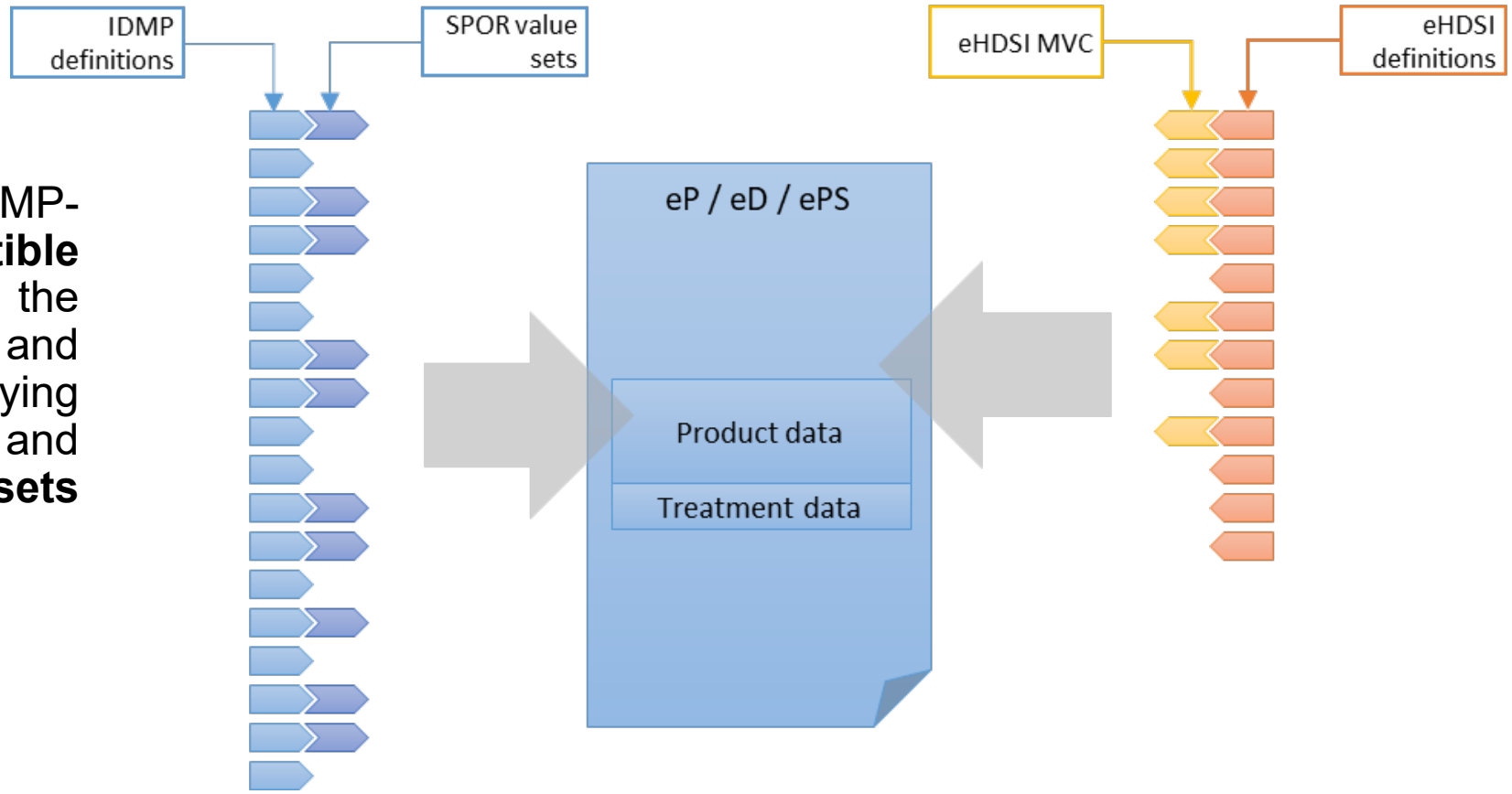
UNICOM supports semantic alignment with IDMP using:

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,

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

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**.



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

Semantic functional specifications for IDMP

José Teixeira

UNICOM

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

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

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.*

Semantic data specifications

- 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

Technical format specifications

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

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

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

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?

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

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

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

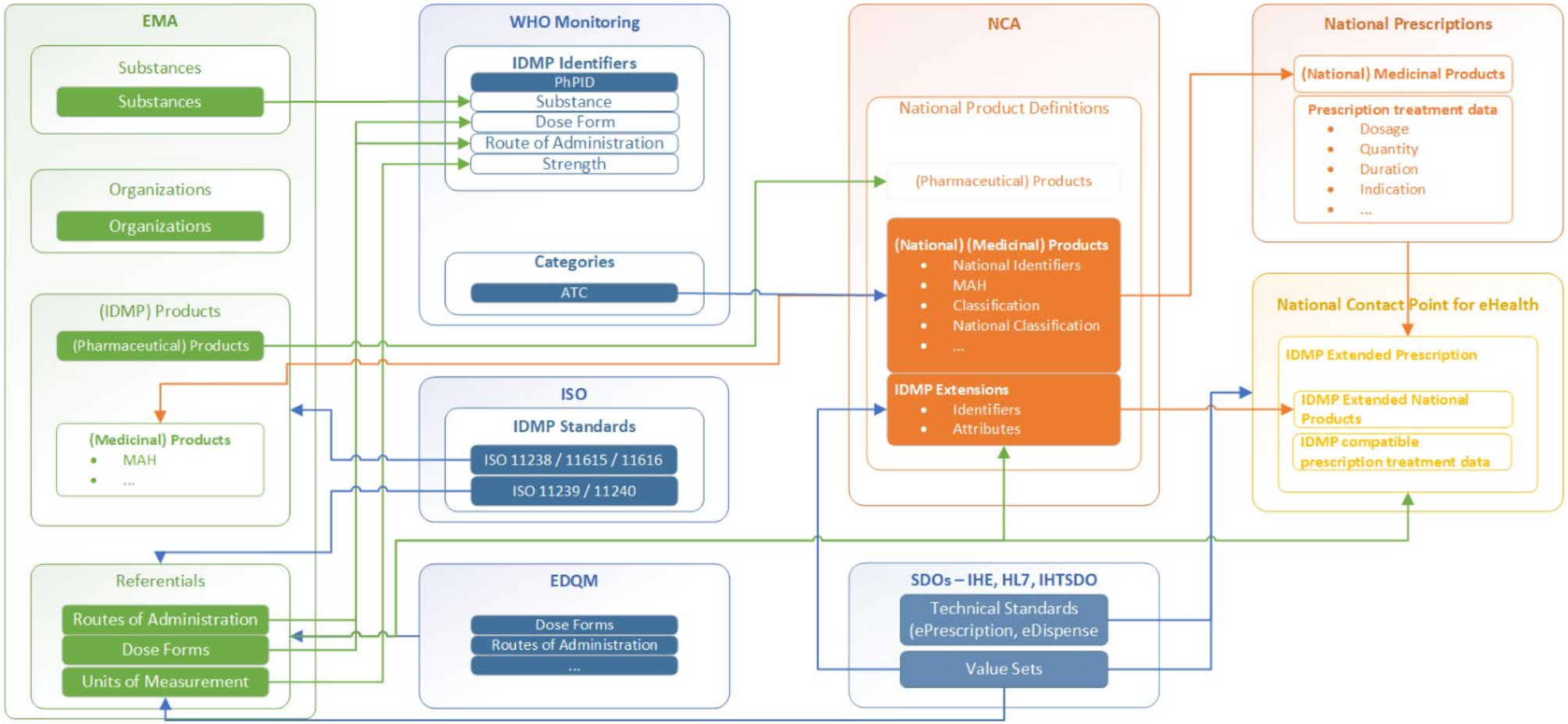
Defining semantic specifications

- 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

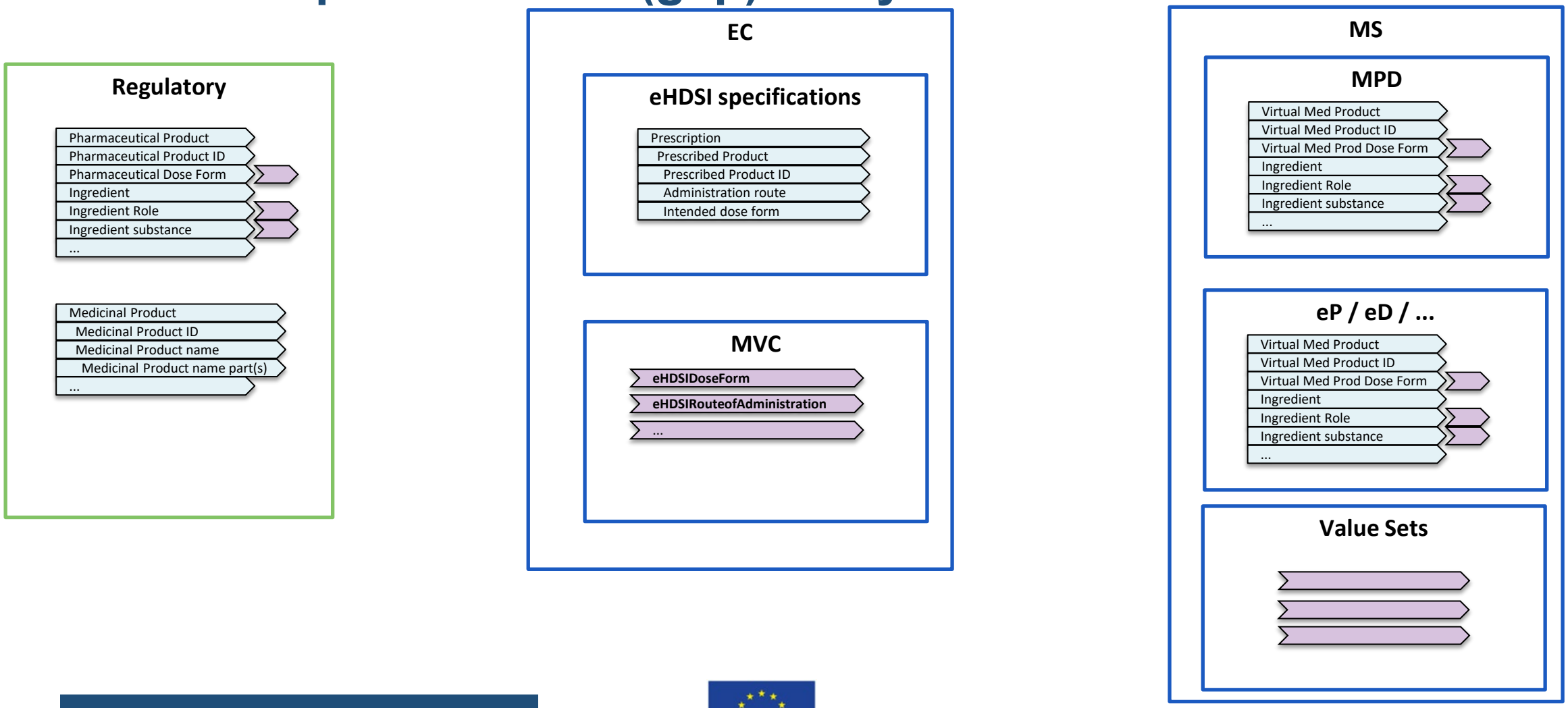
Contexts



Note: This is a conceptual representation. Some organizations are mentioned here but only to illustrate types of competences. This diagram does not presume or preclude any role assignment, commitment or delegation.

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



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

The approach

- Identify which elements are needed for interoperability in each context

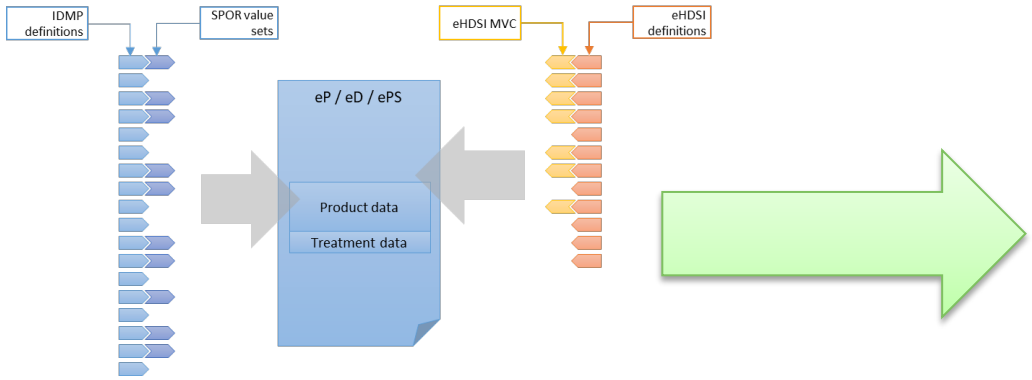
- Formally define the elements,
  - taking into consideration how IDMP can help in the gaps
  - Considering implied semantics and constraints of current implementation (e.g., CDA)

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

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

Results

- For ePrescription, eDispense – 17 attributes + gap analysis



UNICOM – D5.4: Semantic Specifications

Table 17: Minimal Attribute List[29]

Attributes from EMA IG Section V2.1 (2021-02)[28]			eHDSI data elements[30]	eHDSI MVC / Value set ID	Suggested specifications and enhancements
#	Class	Attribute			
6.4.	Medicinal Product	Ingredient	Active Ingredient / Active ingredient ID (code)	See footnote 10	When identifying a Substance, prepare the use of a new value set (SMS)
4.10.4.	Medicinal Product	Ingredient			
1.13.3.	Medicinal product	ATC Code(s)	ATC code	eHDSIActiveIngredient 1.3.6.1.4.1.12559.11.10.1.3.1.42.24	Add a new data element – Classification – and use the ATC value set
1.2.	Medicinal Product	Medicinal product identifier (MPID)	Medicinal Product Code	Not directly available in MVC – available via SPOR	SPOR to define the MPID name space for unambiguous use
4.1.	Medicinal Product	Packaged Medicinal Product Identifier (PCID)			SPOR to define the PCID name space for unambiguous use
2.8.	Medicinal Product	Marketing Authorisation Holder (Organisation)	Marketing Authorisation Holder of the prescribed medicinal product		SPOR to define the MAH name space for unambiguous use
1.14.1.	Medicinal Product	Full name	Brand Name of the Medicinal Product		SPOR to define the BrandName name space for unambiguous use
4.2.	Medicinal Product	Package description	Medicinal Product Package	eHDSIPackage 1.3.6.1.4.1.12559.11.10.1.3.1.42.3	Clarify that this is "PackageType"
4.3.	Medicinal Product	Pack size			Quantity – use eHDSIUnit
4.7.5.	Medicinal Product	Package item (container) quantity	Number of packages		Quantity – use eHDSIUnit
5.5.2.2.2.	Medicinal Product	Strength (Presentation single value or low limit)	Strength of the Medicinal Product	eHDSIUnit 1.3.6.1.4.1.12559.11.10.1.3.1.42.16	
5.5.2.3.2.	Medicinal Product	Strength (Concentration single value or low limit)*			
5.5.3.1.	Medicinal Product	Reference Substance			
5.5.3.3.2.	Medicinal Product	Reference strength (Presentation single value or low limit)*			
1.5.	Medicinal Product	(Authorised) pharmaceutical form	Pharmaceutical Dose Form	eHDSIDoseForm 1.3.6.1.4.1.12559.11.10.1.3.1.42.2	Consider creation of dedicated value set for pharmaceutical dose form
6.2.	Medicinal Product	Administrable Dose Form*			Consider creation of dedicated value set for administrable dose form
4.10.3.	Medicinal Product	Manufactured dose form			Consider creation of dedicated value set for manufactured dose form
6.6.	Medicinal Product	Route of Administration	Route of Administration	eHDSIRouteofAdministration 1.3.6.1.4.1.12559.11.10.1.3.1.42.12	

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

- Recommendations for "target" semantic specification

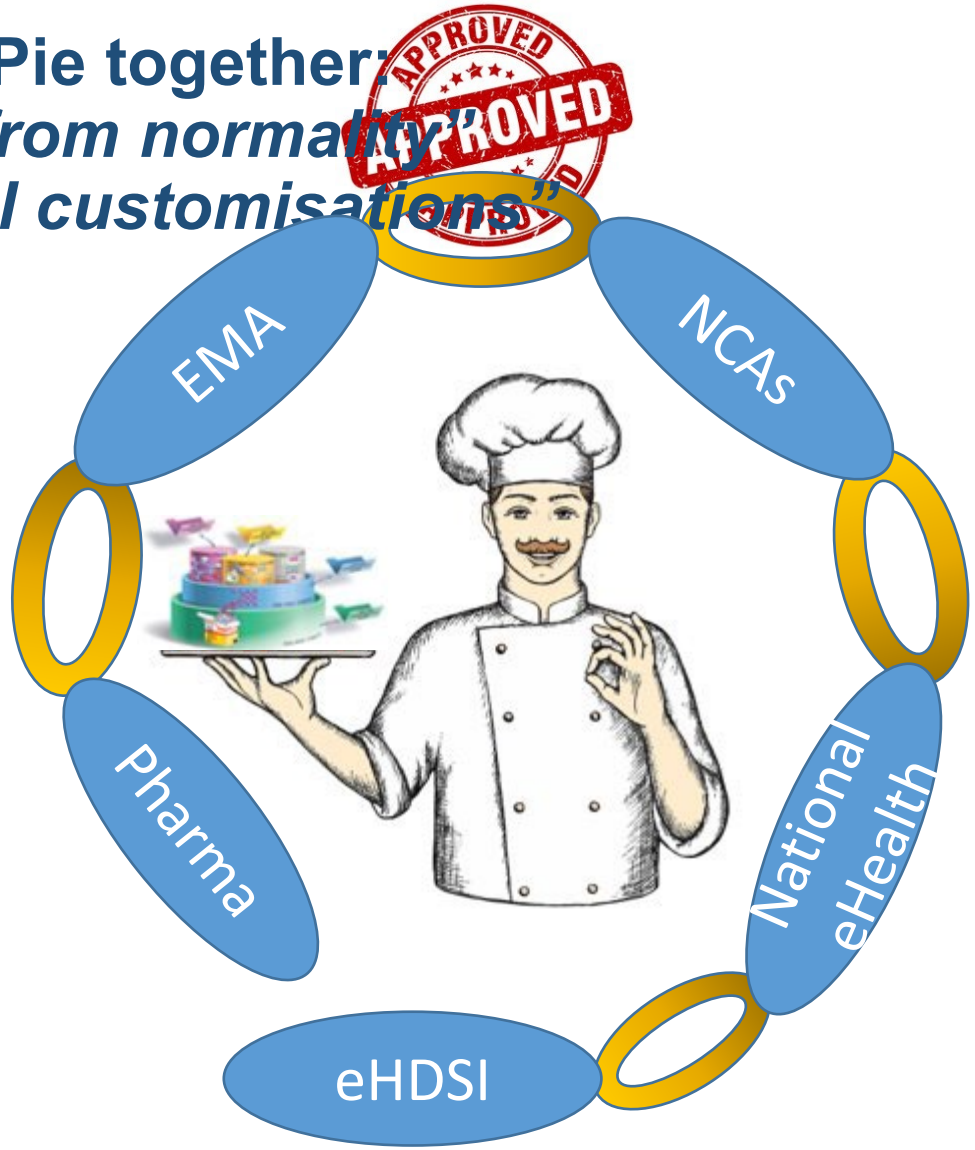
UNICOM has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299

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 attibutes as additional optional elements



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

Thank you!

Monviso, Po river head, as it is seen from Torino (Italy)

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

Thank you!

UNICOM

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

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

The position of the Medicinal Product Dictionary (MPD) as an intermediary in the IDMP landscape

UNICOM

A bridge between

The Regulatory World

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*)

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

The difference between MASTER DATA and REFERENCE DATA

UNICOM

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

Will be available soon from respected, existing sources (EU-SRS, EDQM, Regenstrief)

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)

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

An important distinction between procedures for new products and legacy conversion of older products

UNICOM

Index Date

Retrospective

Pharmaco-archeology

Substance cleansing
EDQM standardization
Strength Normalisation

Prospective

DADI-Project (industry => Agency)
IDMP-Compliant Registration
EMA =>NCA=>MPD
MPD =>Vendor
Vendor => Clinical Care

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

Crucial questions for IDMP standardisation at national level

UNICOM

- How soon will the REFERENCE DATA be avaialble 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 Compentent 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

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

Critical tasks for for IDMP standardisation at national level

UNICOM

- **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 moeity ?

    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 ?

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

What could be the motives for MPDs to engage in this ?

UNICOM

- 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

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

Mission of the Medicinal Product Dictionary

UNICOM

- 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,

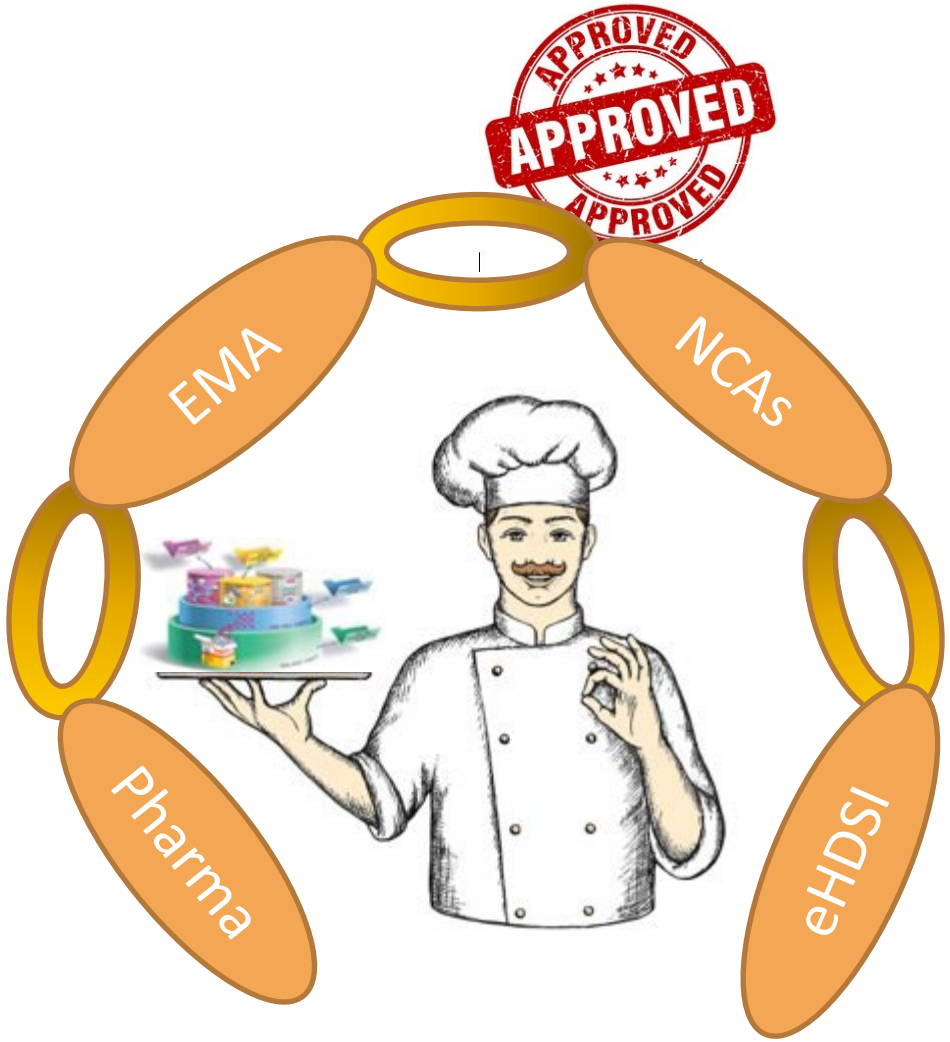
→ **The intra-national drug information providing eco-system**

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

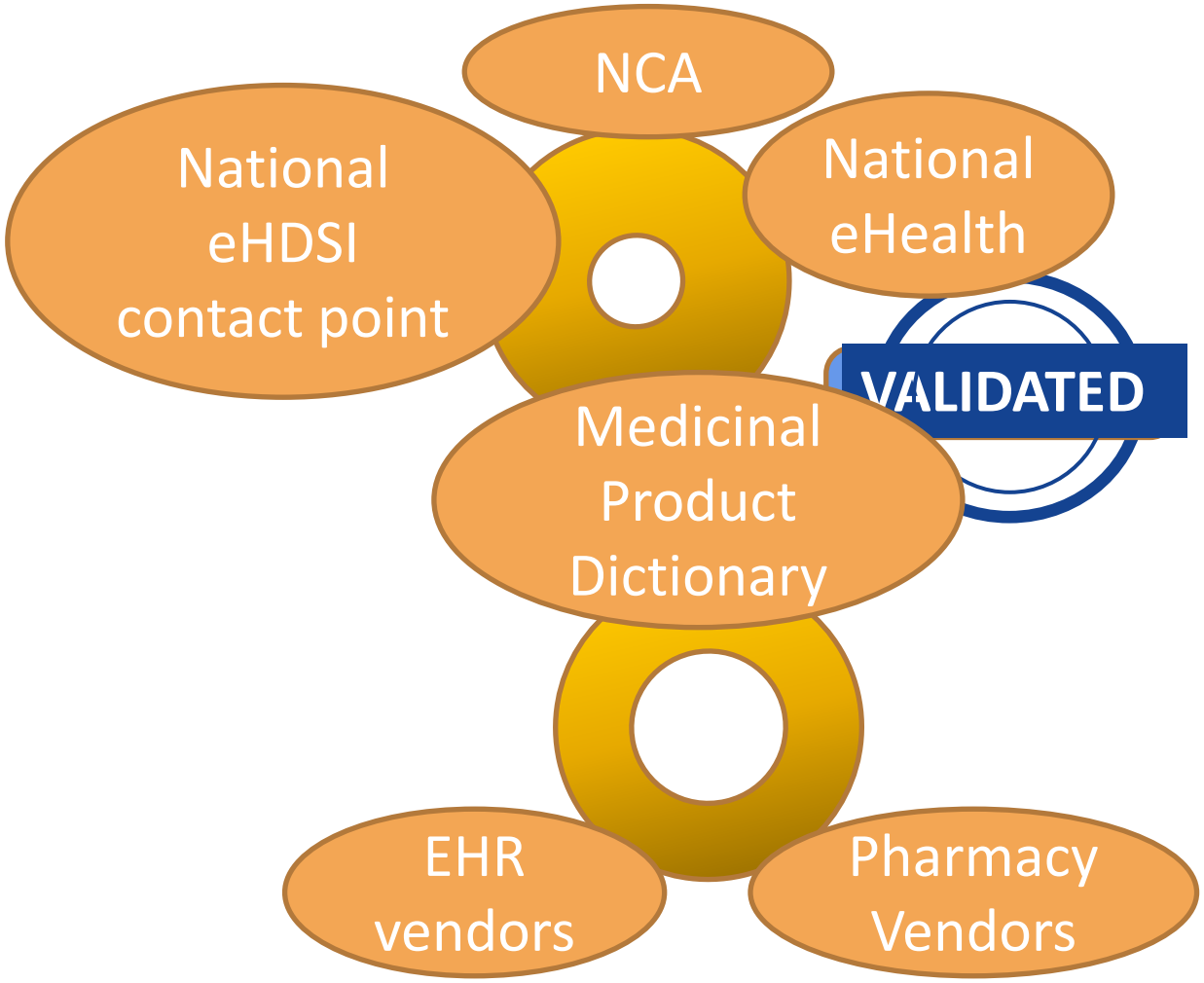
→ **The supra-national drug information providing eco-system**

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

Supra-national ecosystem



Intra-national ecosystem



(Courtesy from Marcello Melgara)

Conclusion

UNICOM

- Collaboration between the stakeholders

  at the supra-national eco-system

  and the intra-national eco-system

  is the key to succes in IDMP Implementation

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

European Commission

My Health in the EU

Digital exchange of ePrescriptions and Patient Summaries

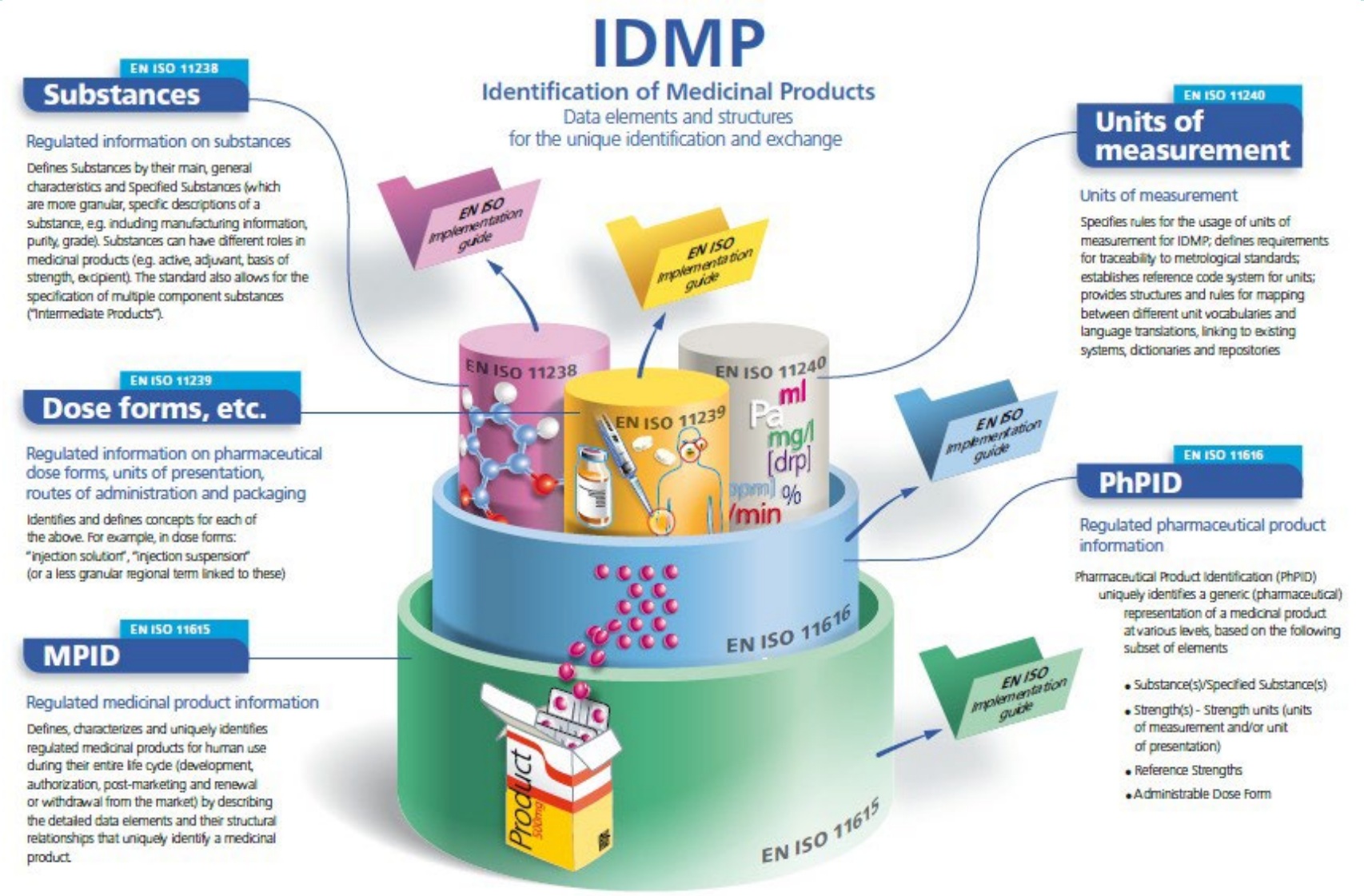
UNICOM – eHDSI perspective

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

eHDSI Requirements catalogue

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

MPID

A.1.4.2*	Identifier of the medicinal product	Identifier of a 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]	EMA PMS

PHPID

A.1.4.2.1	Identifier(s) of the pharmaceutical product	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]	EMA PMS

PCID

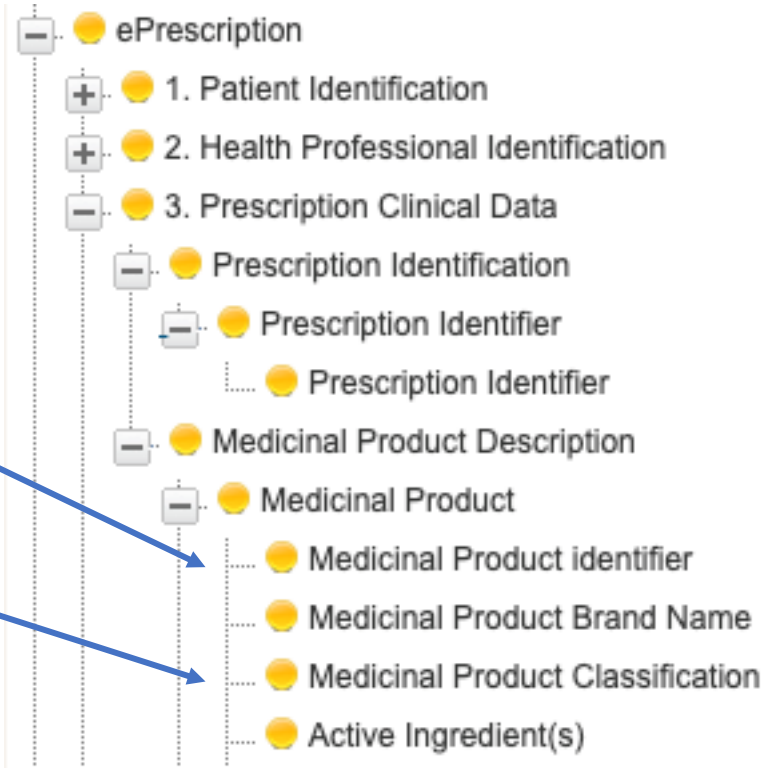
A.1.4.2.2	Identifier(s) of the packaged medicinal product	Identifier of a packaged medicinal product refers to a specific pack size of a specific product. It could be PCID according to ISO 11615 and/or its national equivalent. [not applicable for generic prescriptions]	EMA PMS

Dataset in CDA IGs

Requirements Catalogue

				3. PRESCRIPTION CLINICAL DATA (Identification of the prescribed medicine/medicinal product)	
22	**Prescription Identification**	**Prescription Identifier**	**BASIC**	**Prescription Identifier**	Identification of the prescription.
23	**Medicinal Product Description**	**Medicinal Product**	**BASIC**	**Medicinal Product identifier**	Identifier of a medicinal product refers to the product inside the package, not the packaged item as such. Example: EU100000396-00010000
24				**Medicinal Product Brand Name**	The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorization holder. Example: Termalgin.
25				**Medicinal Product Classification**	Standardized code corresponding to the product classification Example: PhPID Level 1 Substance: Acetaminophen
26				**Active Ingredient(s)**	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Country of treatment translates (does not change) the active ingredient from Country of affiliation to Country of treatment units (single concept), but it is the same active ingredient. Example: Paracetamolo.
27				**Active Ingredient Role(s)**	The role of the active ingredient in the strength calculation. Example: 1-S ACTI active ingredient

CDA IG (Art-Décor) Dataset



Dataset in CDA IGs

CDA IG (Art-Décor) Dataset

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

CDA Template Definitions

eHDSI eP/eD Manufactured Material –

Relationship: Generalization: template 2.16.840.1.113883.10.12.311 *CDA Material* (2005-09-07) ref ad1bbr-

Expand All | Collapse All | Search by name

Item	DT	Card	Conf	Description	Label
▼ hl7:manufacturedMaterial		0 ... *	R		eHDS-rial
@classCode	cs	1 ... 1	F	MMAT	
@determinerCode	cs	1 ... 1	F	KIND	
▼ hl7:templateId	II.EPSOS	1 ... 1	M		eHDS-rial
@root	uid	1 ... 1	F	1.3.6.1.4.1.12559.11.10.1.3.1.3.30	
▼ hl7:code	CE.EPSOS	0 ... 1	R	The element is used to convey a regional/national medicinal product code or MPID compliant with the IDMP system. The element MUST **NOT** be used to convey: • ATC code (see generalizedMaterialKind instead) • PCID code compliant with the IDMP system (see containerPackagedProduct.code instead) The <originalText> under the code MAY be included, but is not expected to be processed by the recipient of the document. If included, it SHALL contain a <reference> whose URI value points to the generic name and strength of the medication in the narrative, or just the generic name alone if strength is not relevant. If the code is not available, the whole field SHOULD be skipped.	eHDS-rial
	ehdsi-dataelement-207	Medicinal Product identifier		eHDSI Data Set	
	Example	Acceptable 1 `<code code="036772010" codeSystem="2.16.840.1.113883.2.9.6.1.5" codeSystemName="AIC" displayName="TIARTAN*28CPR RIV 600+12,5MG"/>`			
▼ pharm:asSpecializedKind		0 ... *	R	The Medicinal Product can be classified according to various classification systems, which may be jurisdictional or international. The classification system itself is specified using an appropriate identification system; the controlled term and the controlled term identifier shall be specified. When the IDMP Pharmaceutical Product Identifier(s) (PhPID Set) will become actually available for use, the PhPID will be represented by the generalizedMaterialKind/code element.	eHDS-rial
@classCode	cs	1 ... 1	F	GEN	

	Example	`<asSpecializedKind classCode="GEN">`
		`<generalizedMaterialKind classCode="MMAT">`
		`<code code="PhPID_Lvl1" codeSystem="1.999.999" displayName="Pharmaceutical Product Name" codeSystemName="PhPID Level 1"/>`
		`<name/>`
		`</generalizedMaterialKind>`
		`</asSpecializedKind>`			

▼ pharm:generalizedMedicineClass		1 ... 1	M		eHDS-rial
@classCode	cs	1 ... 1	F	MMAT	
▼ pharm:code	CD.EPSOS	1 ... 1	R	When the IDMP Pharmaceutical Product Identifier(s) (PhPID Set) will become actually available for use, this element will be used for representing the IDMP PhP Id. The level and the stratum of the PhPID will be distiguished by the OID of the code system.	eHDS-rial
	ehdsi-dataelement-205	Medicinal Product Classification		eHDSI Data Set	
pharm:name		0 ... *			eHDS-rial

XML example

```
<manufacturedMaterial classCode="MMAT" determinerCode="KIND">
  <code code="EU-100003791-00124567" codeSystem="<code system OID>" codeSystemName="<code system name>"/>
  <name>LANTUS</name>
  <pharm:desc>100 U/ml</pharm:desc>
  <pharm:formCode code="11201000" displayName="Solution for injection" codeSystem="0.4.0.127.0.16.1.1.2.1"/>
  <pharm:asContent classCode="CONT">
    <pharm:containerPackagedMedicine classCode="CONT" determinerCode="INSTANCE">
      <pharm:code code="PCID" codeSystem="PCID Code System OID"… />
      <pharm:name>LANTUS</pharm:name>
      <pharm:formCode code="11201000" displayName="Solution for injection" codeSystem="0.4.0.127.0.16.1.1.2.1"/>
      <pharm:capacityQuantity unit="mL" value="10" />
    </pharm:containerPackagedMedicine>
  </pharm:asContent>
  <pharm:asSpecializedKind classCode="GEN">
    <pharm:generalizedMedicineClass classCode="MMAT">
      <pharm:code code="A10AE04" displayName="insulin glargine" codeSystem="2.16.840.1.113883.6.73"/>
      <pharm:name>insulin glargine</pharm:name>
    </pharm:generalizedMedicineClass>
  </pharm:asSpecializedKind>
  <pharm:asSpecializedKind classCode="GEN">
    <pharm:generalizedMedicineClass classCode="MMAT">
      <pharm:code code="A10AE04" displayName="insulin glargine" codeSystem="2.16.840.1.113883.6.73"/>
      <pharm:name>insulin glargine</pharm:name>
    </pharm:generalizedMedicineClass>
  </pharm:asSpecializedKind>
  <pharm:asSpecializedKind classCode="GEN">
    <pharm:generalizedMedicineClass classCode="MMAT">
      <pharm:code code="PhPID" codeSystem="PhPID Code System OID" …/>
      <pharm:name/>
    </pharm:generalizedMedicineClass>
  </pharm:asSpecializedKind>
```

MPID

PCID

PHPID

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.

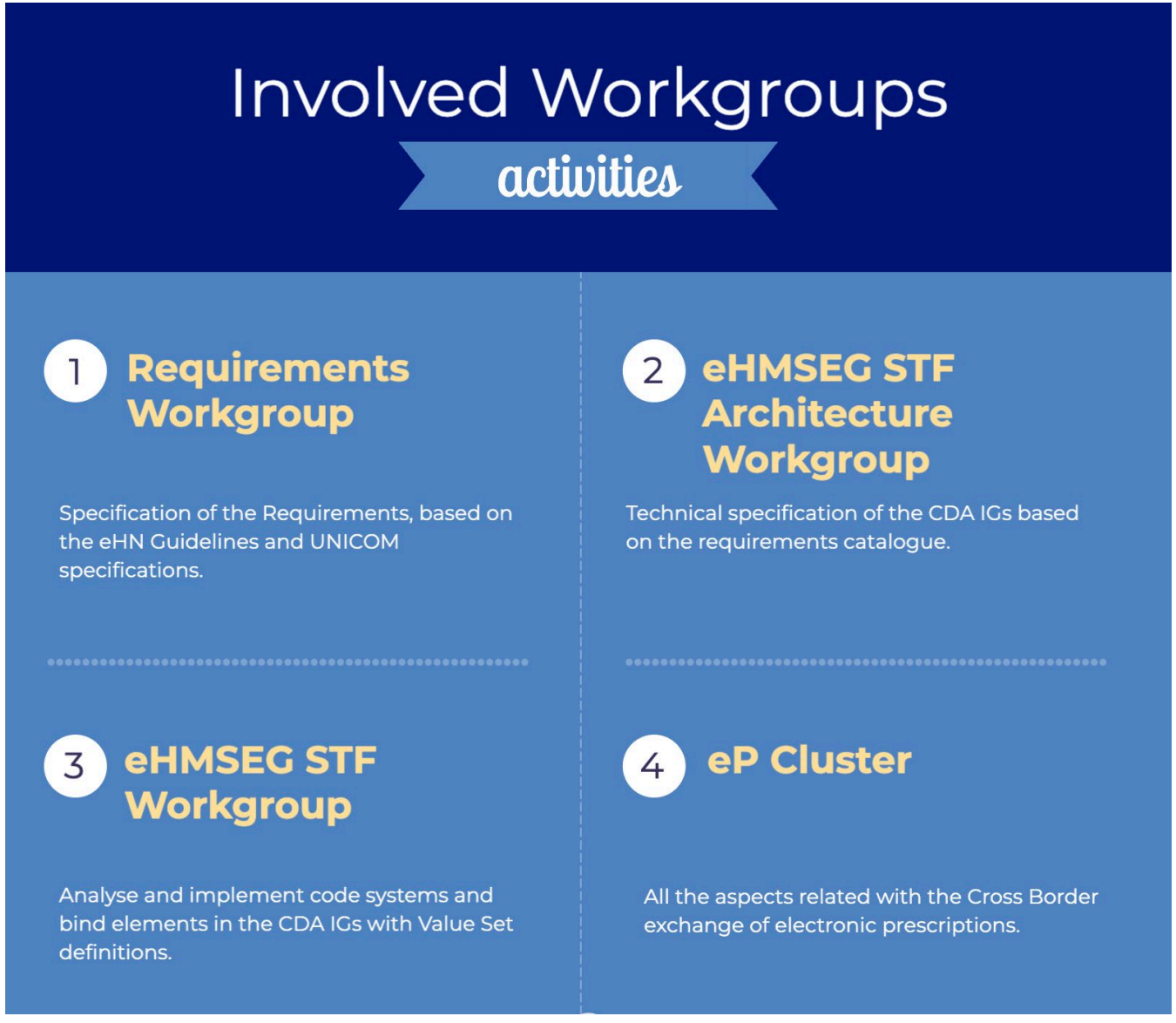
- **eHDSISubstance**

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

UNICOM

Questions, comments

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