EDQM as a global terminology for Identification of Medicinal Products (IDMP) and UNICOM

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Acknowledgments and Disclosure

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▷ Chris Jarvis

▶ The help from UNICOM Work Package 1
   (IDMP and Standard Development Organisations)

▷ Christian Hay
▷ Robert Stegwee

No conflict of interest to declare

Overview

► Our Background

► UNICOM, IDMP, and EDQM

   ▷ Short presentation of The UNICOM Project

   ▷ Dose Form as a key variable for Pharmaceutical Product Identification in IDMP

► Analysis of EDQM as a global terminology

   ▷ Analysis of strengths and limitations of the information on dose form

   ▷ Proposals for improvement

   ▷ Request to review a new spreadsheet

► Proposal for an ontology of dose form

   ▷ Analysis of unique combinations of values of characteristics

   ▷ Development of an ontology of dose form

► Dilemma for doseform and PHPID production

► Recapitulation our request

Our Background

► Work Package WP8 (IDMP and Clinical Care)

► GP and Clinical Pharmacologist
  ▷ Practice and research experience
  ▷ Training experience in medicine and pharmacy

► Belgian Independent Drug Information Centre
  ▷ Web information for health professionals
  ▷ The Authentic source of medicines (SAM Database)
  ▷ The Belgian ICT-Implementation of INN Prescribing

► Drug Utilisation Research
  ▷ ESAC project (European Surveillance of Antibiotic Consumption)
  ▷ Guidelines for Cross National Comparison of Drug Exposure

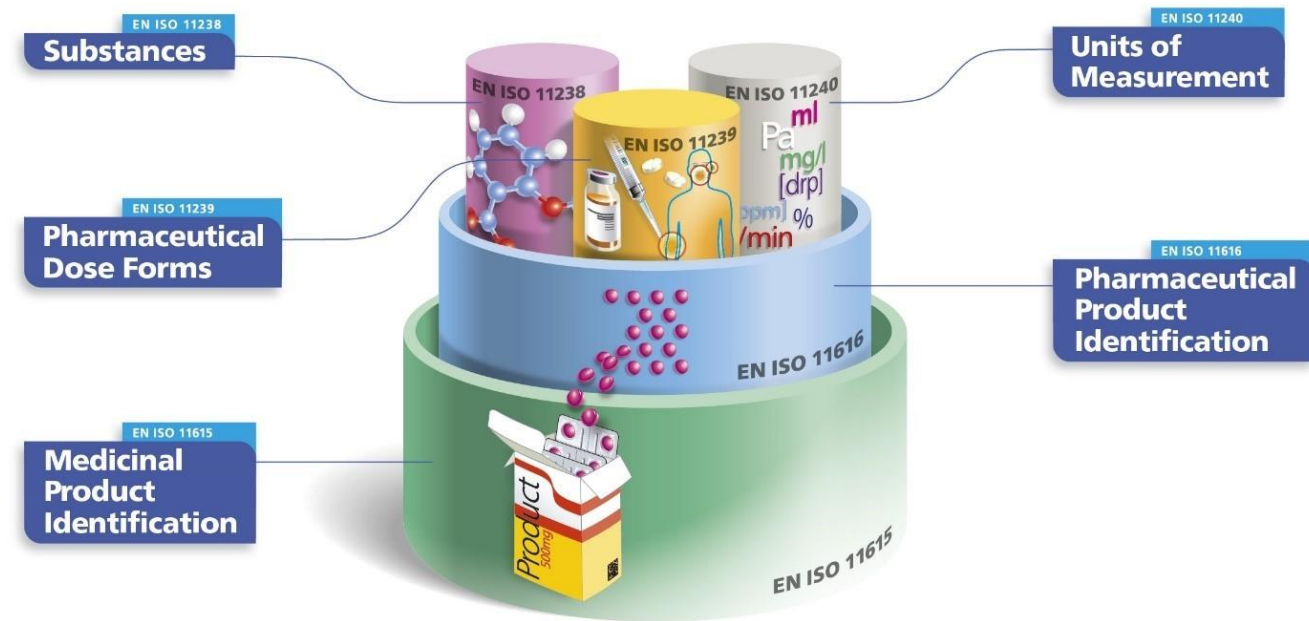► Doctoral Thesis on drug information for patients in package inserts

A few words about **UNICOM** and **IDMP**

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► **What if**

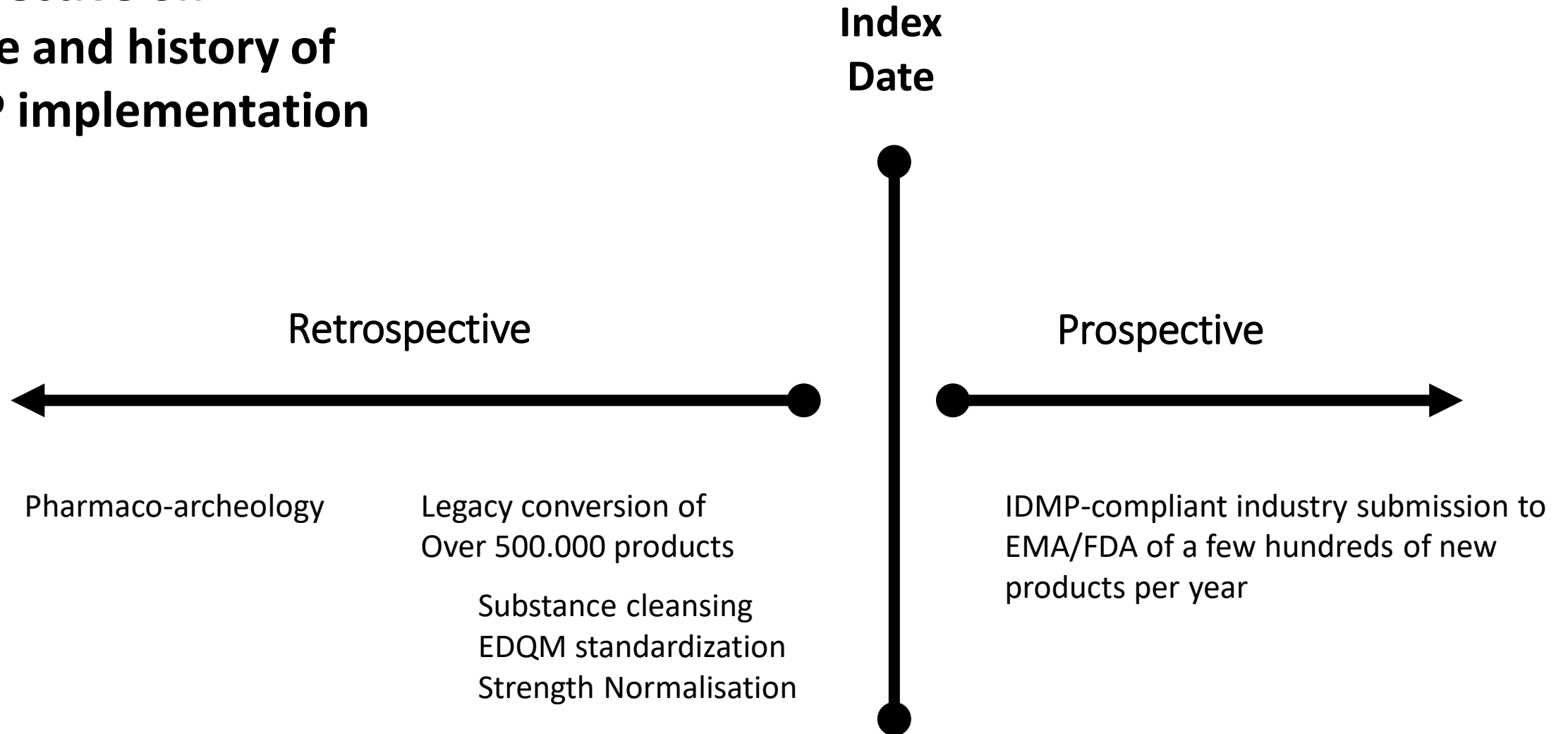We would be able to recognise any medicinal product from anywhere in the world anywhere in the world.

That is the ambition of the 5 SO/CEN Standards

UNICOM Project (2)

► A large action program, from the EU Horizon programme,
  ▷ with a 20 MEURO Budget,
  ▷ 44 participating organisations,
  ▷ among which 11 National Competent Agency for marketing authorization of Medicinal Products and a number of eHealth Insititutions
   • https://unicom-project.eu

► Testimony of large institutional support for IDMP implementation
  ▷ Supported by ICH (International Council of Harmonisation)
  ▷ Supported by EMA, FDA
  ▷ Supported by a global Working Group (bringing together FDA, EMA, WHO_Uppsala Monitoring Centre for Pharmacovigilance)
  ▷ Supported by Horizon 20/20 through UNICOM

Perspective on future and history of IDMP implementation

Index Date

Retrospective

Prospective

Pharmaco-archeology

Legacy conversion of
Over 500.000 products

Substance cleansing
EDQM standardization
Strength Normalisation

IDMP-compliant industry submission to
EMA/FDA of a few hundreds of new
products per year

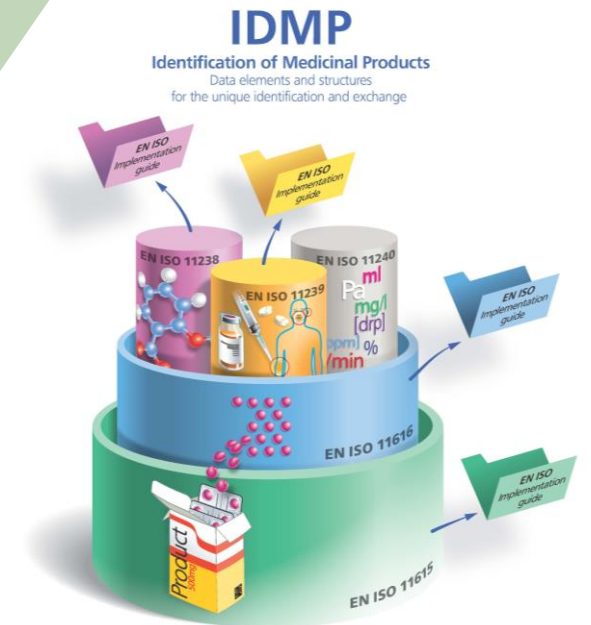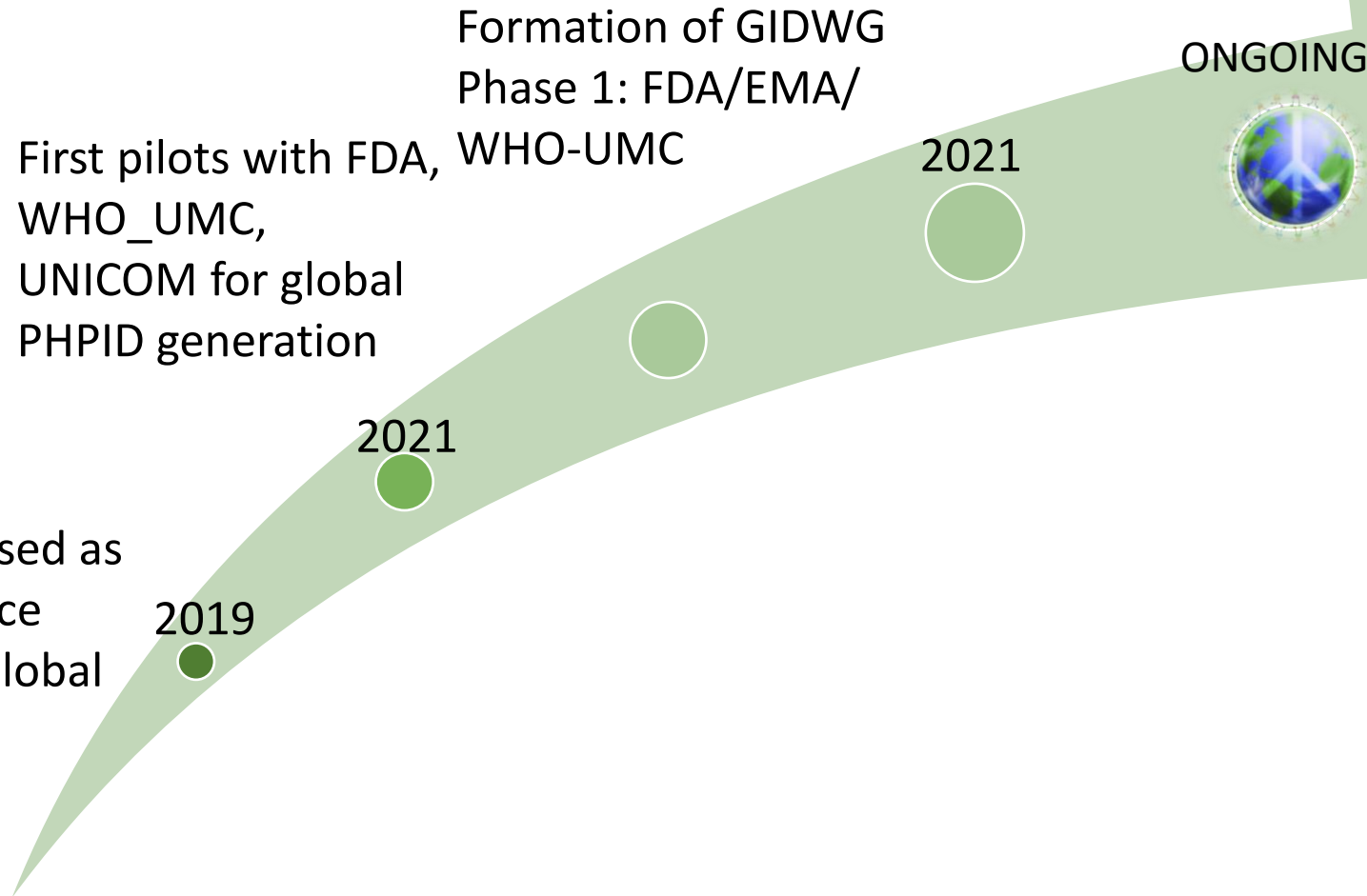# The role of Dose Form in IDMP identification of Products

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► Dose Form is a key element that determines the pharmaceutical product, together with substance and strength
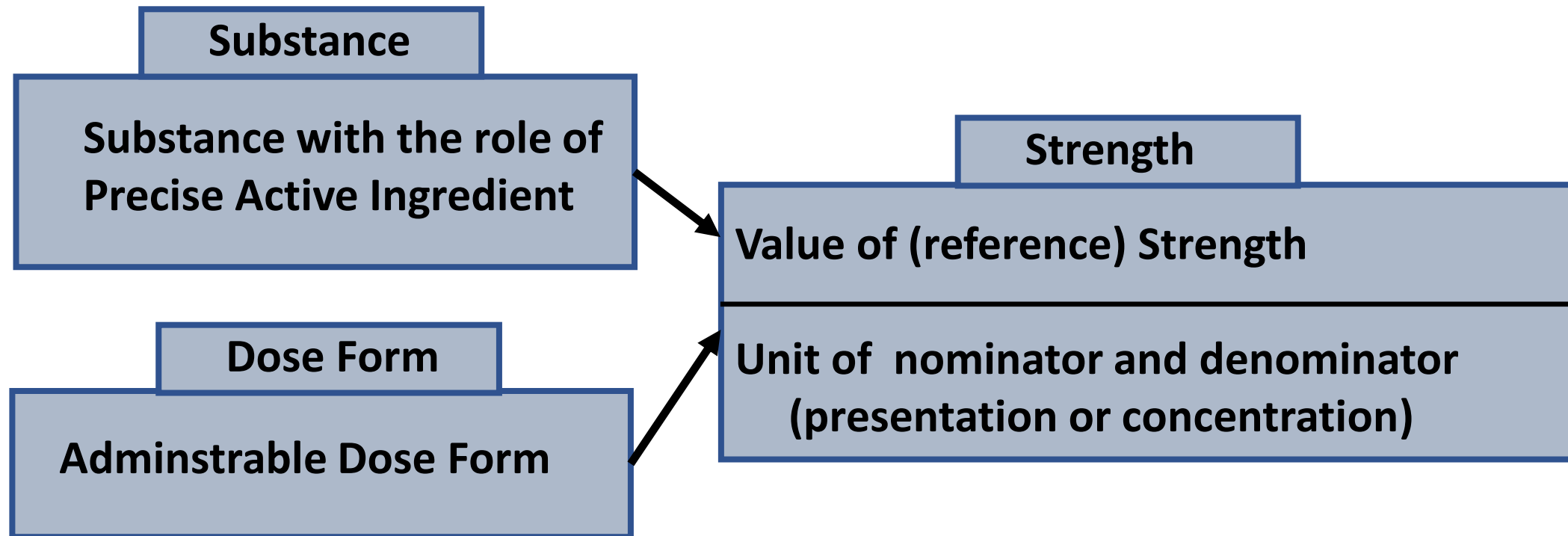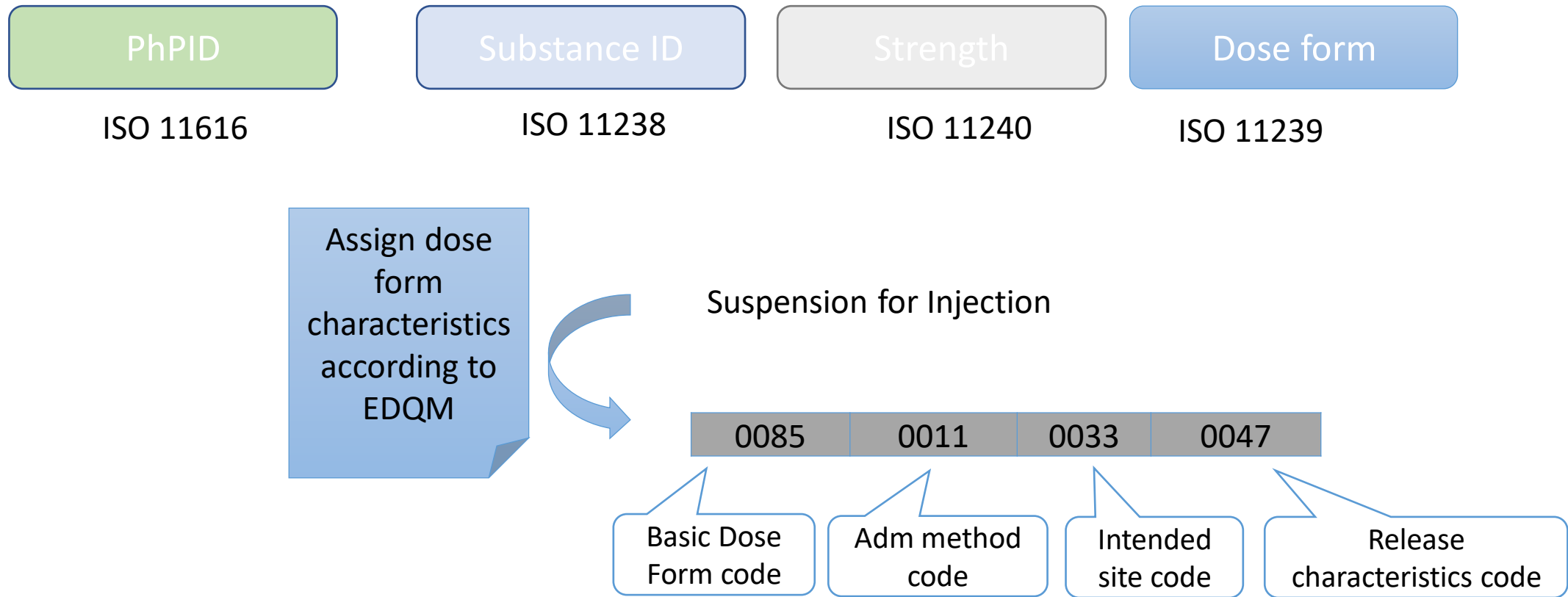

Note: Substance with dose form and strength determine the effect of the medication

Implementation of Global Pharmaceutical product (PhPID) : achievements & plans

Global PHPID available for all stakeholders

Formation of GIDWG
Phase 1: FDA/EMA/
WHO-UMC

ONGOING

2021

First pilots with FDA,
WHO_UMC,
UNICOM for global
PHPID generation

2021

WHO-UMC endorsed as
future maintenance
organization for Global
PhPID

2019

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

EN ISO
Implementation
guide

EN ISO
Implementation
guide

EN ISO 11238

EN ISO 11240

Pa ml
mg/l
[drp]
ppm] %
/min

EN ISO
Implementation
guide

EN ISO 11239

EN ISO 11616

EN ISO
Implementation
guide

Product

EN ISO 11615

Proposed process for expression of Dose form

PhPID	Substance ID	Strength	Dose form
ISO 11616	ISO 11238	ISO 11240	ISO 11239

Assign dose form characteristics according to EDQM

Suspension for Injection

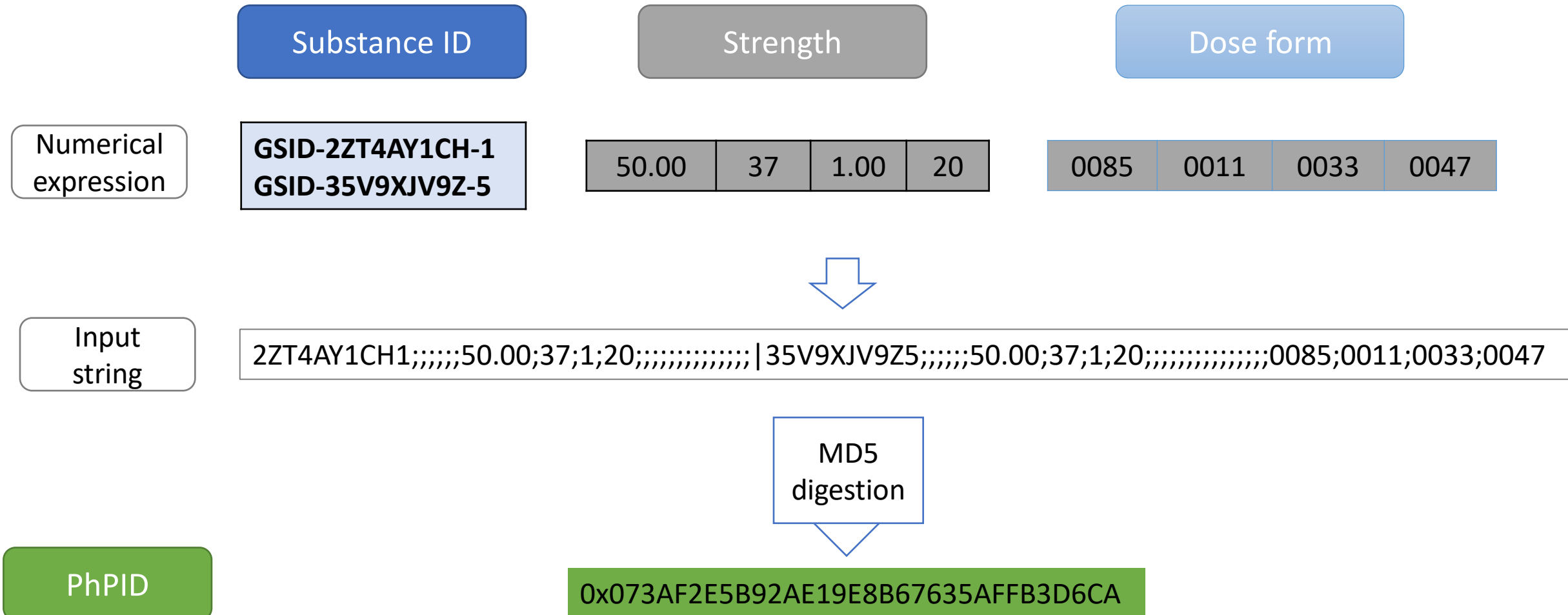| 0085	0011	0033	0047

Basic Dose Form code

Adm method code

Intended site code

Release characteristics code

PhPID generation for Humalog Mix50 KwikPen

50 mg/ml of Insulin lispro/Insulin lispro protamine suspension, solution for injection

Substance ID	Strength	Dose form

Numerical expression

Substance ID	Strength	Dose form
GSID-2ZT4AY1CH-1￼ GSID-35V9XJV9Z-5	50.00 | 37 | 1.00 | 20	0085 | 0011 | 0033 | 0047

Input string

2ZT4AY1CH1;;;;;;;50.00;37;1;20;;;;;;;;;;;;;;;|35V9XJV9Z5;;;;;;;50.00;37;1;20;;;;;;;;;;;;;;;;0085;0011;0033;0047

MD5 digestion

PhPID

0x073AF2E5B92AE19E8B67635AFFB3D6CA

Basis of Support for the crucial role of EDQM in IDMP

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► Endorsement by the International Council of Harmonisation (ICH)
of the Use of EDQM terminologies for Dose Forms and Routes of Administration for Individual Case Safety Reports in E2B(R3) message

► Endorsement of EDQM by EMA for SPOR

► Endorsement of EDQM by FDA, EMA, and WHO_UMC, the Global IDMP Implementation Working Group (GIDWG)
However, still discussion on how EDQM will be used for dose form identification.

Granular EDQM dose form versus

Combination of 4 basic characteristics

Dilemma for dose form identification in IDMP

▶ PHPID calculation based on :

Granularity

▷ 4 characteristics of EDQM Dose Form

179 unique combinations of 4 basic characteristics

or on

▷ the granular EDQM dose form

428 granular EDQM

With inherent information on characteristics

 **UNICOM Analysis of
EDQM Dose Form Terminology
(Standard Terms Database)**

Limitations of this presentation on EDQM Dose Form

For this presentation we will focus on simple dose forms

▷ Not on :

- **Combination pack**: "Single term to describe two or more medicinal products that are packaged together and marketed under a single licence, and which are intended to be administered independently, as separate pharmaceutical products." - example: Cream + pessary

- **Combined term:** "Single term to describe a pharmaceutical dose form (or combined pharmaceutical dose form) and an item of packaging, either for the purpose of distinguishing between marketed products that differ only in the container or administration device, or where the item of packaging has special characteristics that are relevant to the use of the medicinal product." - example: Solution for injection in pre-filled syringe

- **Combined pharmaceutical dose form**: "Single term to describe two or more manufactured items that are intended to be combined in a specific way to produce a single pharmaceutical product, and which includes information on the manufactured dose form of each manufactured item and the administrable dose form of the pharmaceutical product." - example: Powder and solvent for solution for injection

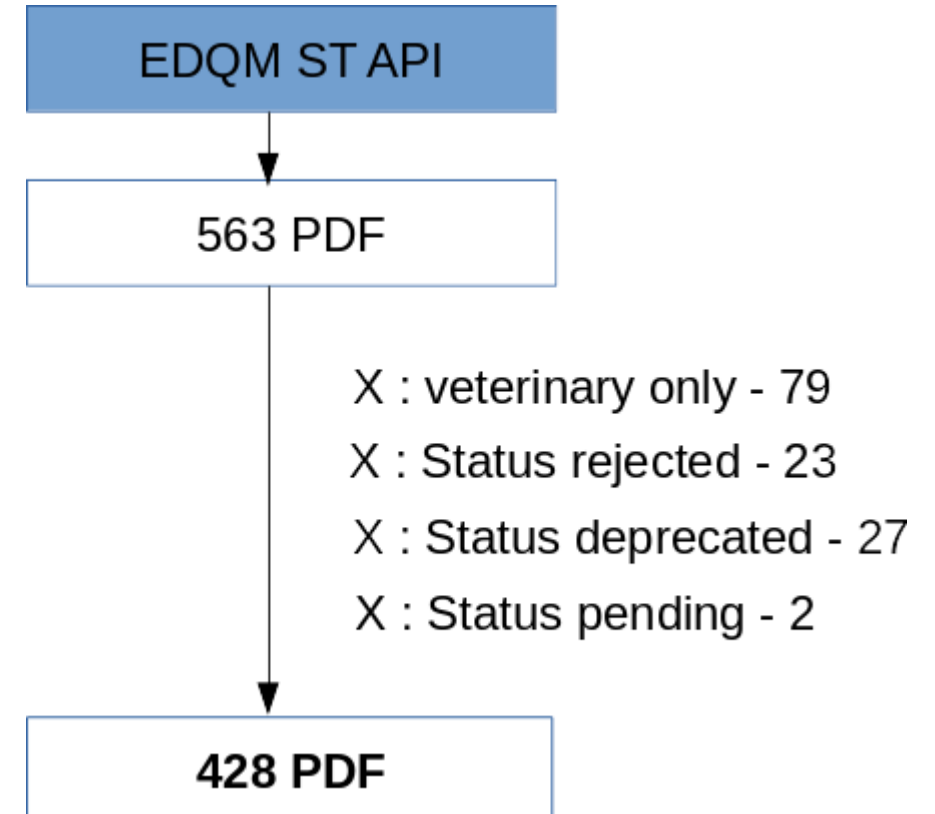# UNICOM analysis of EDQM as fit for purpose to become a global terminology

▶ The analysis was initiated within WP8 and WP1

▶ Then EDQM was the subject of UNICOM webinars in the Community of Expertise

▶ Many items were discussed in the revision of
the 2 ISO/CEN standards on Dose Form
ISO EN 11239 and ISO/TS 20440:2016

▶ Two scientific publications

   ▷ Vander Stichele, R.H.; Roumier, J.; van Nimwegen, D. How Granular Can a Dose Form Be Described? Considering EDQM Standard Terms for a Global Terminology. Appl. Sci. 2022, 12, 4337. https://doi.org/10.3390/ app12094337

   ▷ Karapetian N, Vander Stichele R, Quintana Y. Alignment of two standard terminologies for dosage form: RxNorm from the National Library of Medicine for the United States and EDQM from the European Directorate for the Quality in Medicines and Healthcare for Europe. Int J Med Inform. 2022. Sep;165:104826. doi: 10.1016/j.ijmedinf.2022.104826.

The analysis of EDQM Dose Form Terminology

► Objective

► Methodology

► Results

    ▷ Suggestions for improvements

    ▷ An ontology of dose forms

Objectives of the analysis

► Identify issues and propose small changes for EDQM and for the ISO/CEN revision

► Explore different combinations of characteristics of dose forms

▷ to test whether such combinations are definitional

▷ to create a simple ontology of dose forms

► Explore the use of such ontology of dose form in

▷ the linkage of PhPID to international classifications

▷ the global generation of Pharmaceutical Product Identifier PhPID

▷ in the alignment of other dose form terminologies

(Snomed-CT, RxNorm, CDISC, WHO Drug)

- Obtain the freely available data from

     the EDQM Standard Terms (ST) API

     on 2021-03-17 09:52:21

- Focus on the Human (and veterinary) PDFs

     that are "current"

- Focus on the simple dose forms

EDQM ST API

563 PDF

X : veterinary only - 79

X : Status rejected - 23

X : Status deprecated - 27

X : Status pending - 2

428 PDF

Suggestions for improvements

▷ Combined values in the value sets of the characteristics

▷ Multiplicity : Combinations of values for a characteristic in one product

▷ Systemic versus local

▷ PDF to ADF

  Resulting in a new extended spreadsheet of granular dose forms

Combined values in the existing value sets

► Combined values to be kept

- E.g. Injection/infusion

  There is a code for injection, one for infusion, one for injection/infusion, and these different values can be implemented product by product

► Combined values that might be split

- E.g. Cutaneous/transdermal

  There is no code for cutaneous and no code for transdermal, while for (almost) all products it is relatively easy to determine which of the two codes would be most appropriate.

Multiplicity : Combinations of values for a characteristic in one product

► For some Pharmaceutical products there can be more than one value for the characteristics of Transformation, Intended Site, or Administration Method

e.g.   50015450 cutaneous solution/concentrate for oromucosal solution
         TRA   dilution/no transformation

There is a code for each value, but no code for the unique combination of the values
         TRA   38   dilution

         TRA   42   no transformation

We introduced a temporary code for the combination, but it is not official
         TRA   99905040   dilution/no transformation

Systemic versus local

► For almost all Pharmaceutical Dose Forms it is possible to determine whether the dose form is intended for systemic use or for local use

► For some dermal, buccal, rectal, nasal, inhalation dose forms this is not inherently obvious.
However, when a concrete, single product is characterised, it becomes obvious
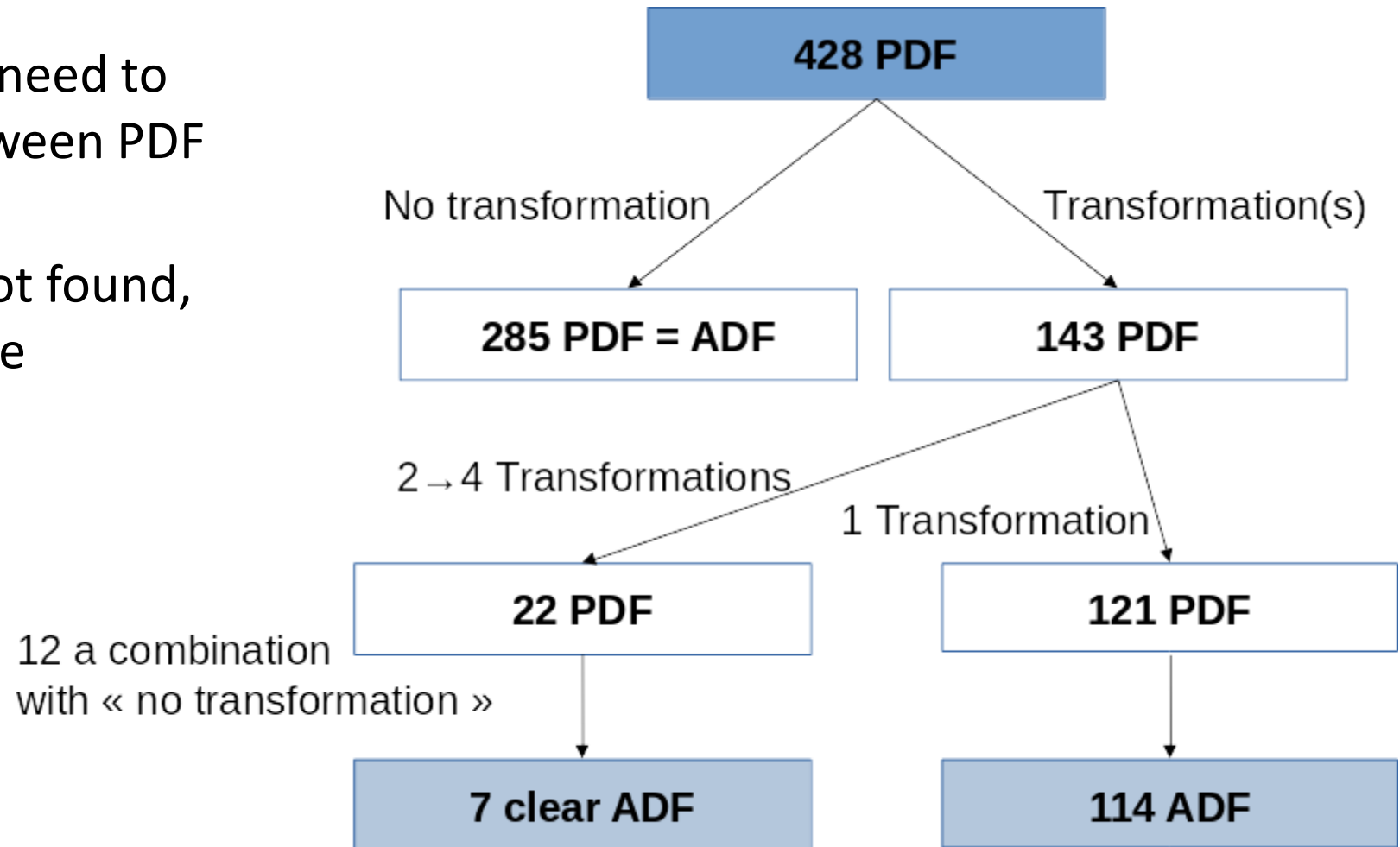
▷ Proposal to add a characteristic "systemic"

- Yes/No/systemic and local
- Would greatly facilitate the calculation of quality indicators for polypharmacy
  - (the use of 5 or more drugs with systemic action).

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Analysis of Pharmaceutical Dose form and Administrable Dose Form
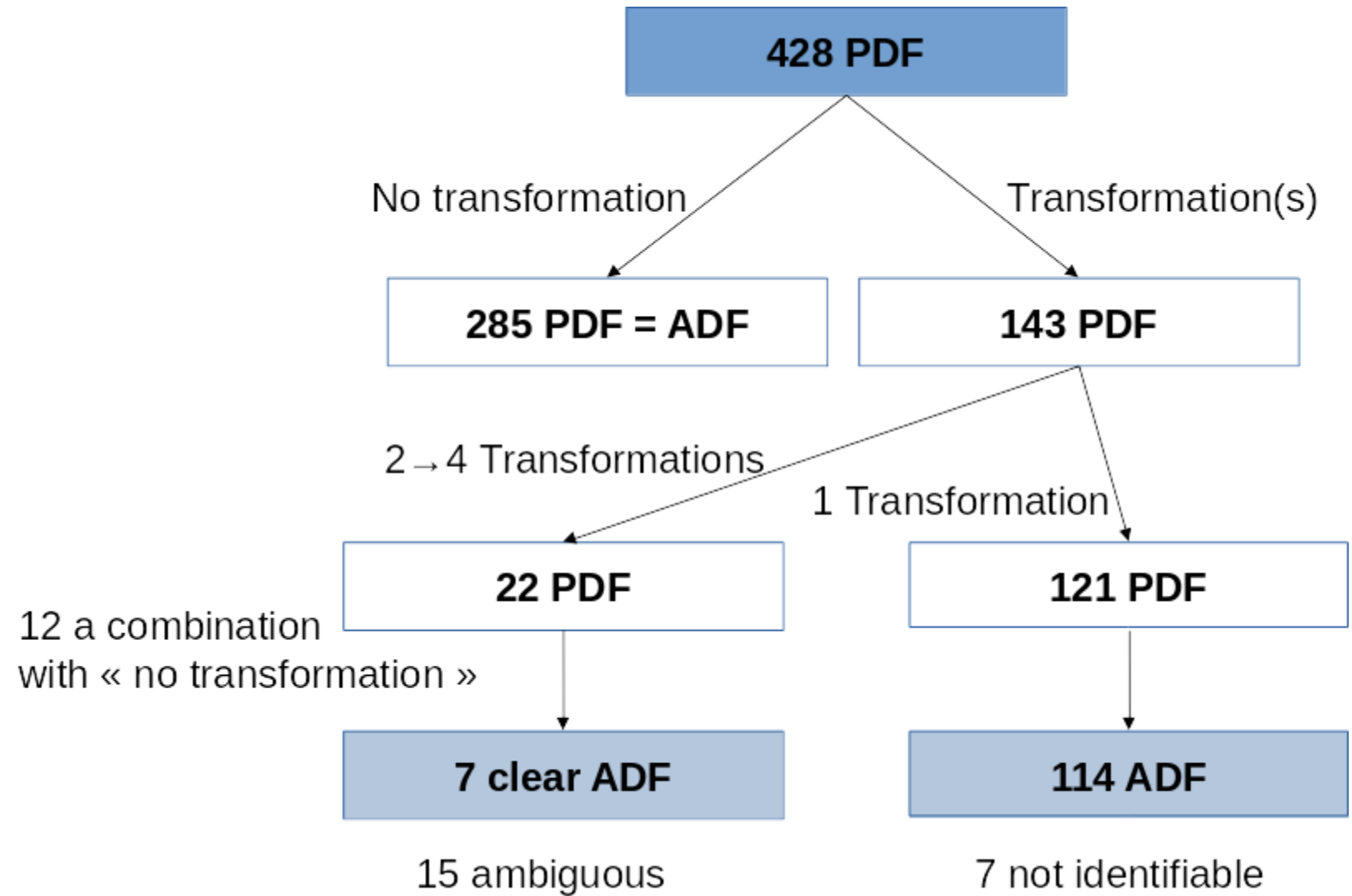
Analysis of Pharmaceutical Dose form and Administrable Dose Form

- Initial results confirm the need to make explicit the link between PDF and ADF

- Some resulting ADF are not found, or are ambiguous for some transformations

428 PDF

No transformation → **285 PDF = ADF**

Transformation(s) → **143 PDF**

2→4 Transformations → **22 PDF**

12 a combination with « no transformation »

7 clear ADF

1 Transformation → **121 PDF**

114 ADF

A closer look at : 15 ambiguous   7 not identifiable

pdf_code	english_pdf_and_md	adf_code	adf_term	bf	bf_term	so	som	som_definition
10118000	powder for syrup	10117000	syrup	66	powder	97	solid	solid preparation consisting of excipients to facilitate dissolut dissolved in water to obtain a s
10119000	granules for syrup	10117000	syrup	53	granules	97	solid	solid preparation consisting of dissolution and to obtain the c
10120000	soluble tablet	10104000	oral liquid				olid	solid single-dose preparation c specified liquid before being sv
10121000	dispersible tablet	10104000	oral liquid				olid	solid single-dose preparation c being swallowed.
10121500	dispersible tablets for dos	10104000	oral liquid				olid	solid preparation consisting of each tablet usually consisting and administered as a single d
10122000	herbal tea	10104000	oral liquid				olid	solid preparation consisting ex aqueous preparation by mean: bulk form or in bags. the tea is
10201000	oral powder	number tbc	oral solution/oral powder				olid	single-dose or multidose prepa fineness. oral powders are inte or another suitable liquid, but
10202000	instant herbal tea	10104000	oral liquid				olid	solid preparation consisting of use. instant herbal teas are su
10203000	Bu	10104000	oral liquid				olid	solid preparation consisting of substances and carbonates or carbon dioxide. effervescent p administration.
								solid single-dose or multidose p sufficiently resistant to withsta in the gastrointestinal fluids by

JARVIS Christopher:

JARVIS Christopher:
oral suspension

JARVIS Christopher:
oral suspension

JARVIS Christopher:
oral solution

JARVIS Christopher:
oral powder
oral solution
RVS: oral solution/oral powder (corrected for the

JARVIS Christopher:
oral solution
oral suspension
RVS: oral solution/oral suspension
Business rules to determine strength will be different from the rules for pre-prepared oral solutions

From PDF to ADF with Transformation

PDF term	concentrate for oral suspension
PDF code	10100500
BDF term	concentrate
BDF code	78
SOM term	liquid
SOM code	99
ADF term	oral suspension
ADF code	10106000
ADF BDF term	suspension
ADF BDF code	85
ADF SOM term	liquid
ADF SOM code	99

Further develop the file

- Implemented proposed changes :
  - Split of cutaneous/transdermal
    - ISIC_SPLIT
  - Introduction of new values in the value set for TRA, ISI, AME for unique combinations of multiple values
    - TRAC
    - AMEC
  - Systemic / Non Systemic
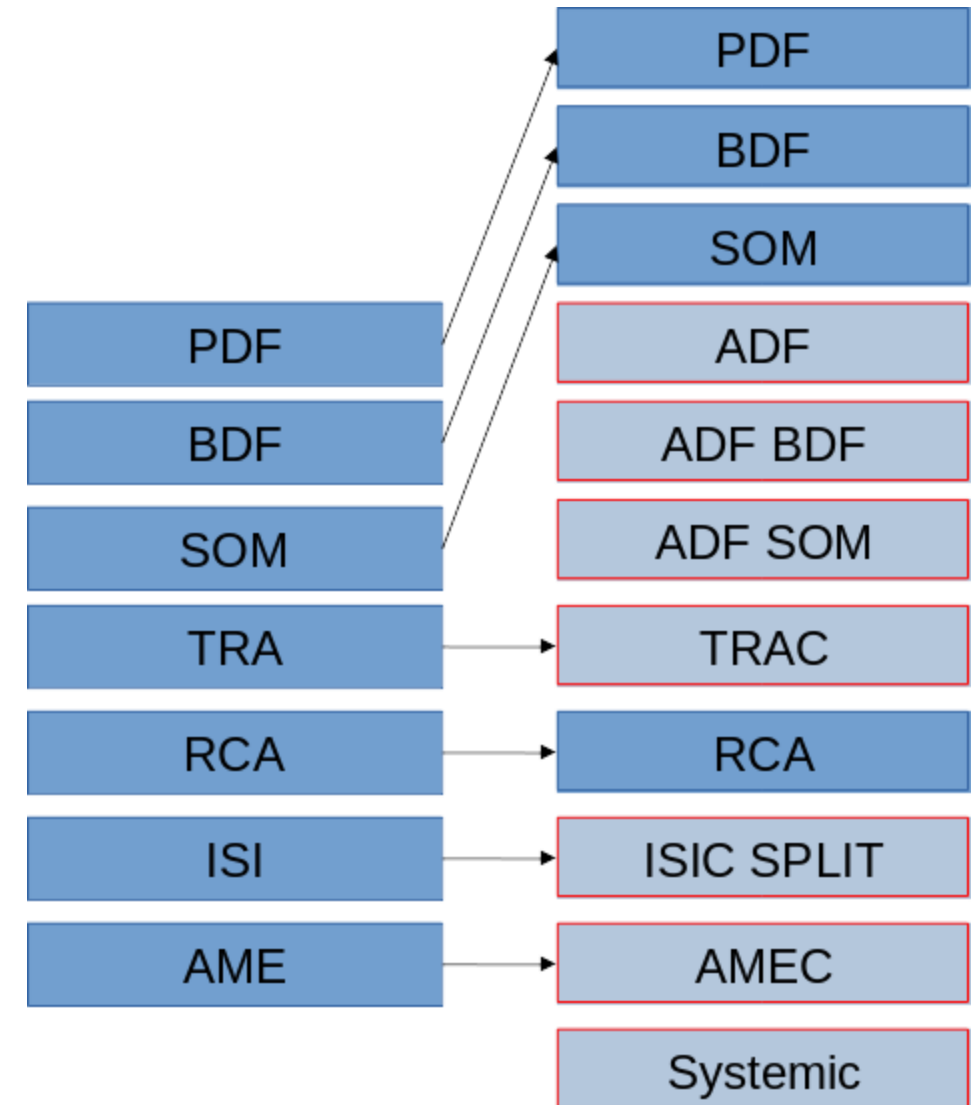
A new, more complex spreadsheet with 428 extended rows: to be verified

Analysis of Unique combinations of characteristics

List of items to be considered in the combination process :

BDF	Basic Dose Form of Pharmaceutical Dose Form
SOM	State of Matter of Pharmaceutical Dose Form
ADF_BDF	Basic Dose Form of Administrable Dose Form
ADF_SOM	State of Matter of Administrable Dose Form
TRAC	Transformation Combined
RCA	Release Characteristics
ISI_SPLIT	Intended site (with cutaneous and transdermal apart)
AMEC	Administration Method Combined
SYS	Systemic of local

Analysis of unique combinations in different sets of descriptors and characteristics of EDQM dose forms.

(a) Analysis Not Taking "Systemic/Local" into Account

Number of Analysis	Descriptors				Characteristics					Results				Check
	Basic Dose Form (PDF)	State of Matter (PDF)	Basic Dose Form (ADF)	State of Matter (ADF)	Transformation (TRAC)	Release Characteristics (RC)	Intended Site Split (ISI-s)	Administration Method (AMEC)	Systemic/Local	Total Number of Unique Combinations (UC)	Unique Combinations (UC) with 1 Occurence	Unique Combinations (UC) with 2+ Occurences	Sum of Occurences in Unique Combinations 2+	Sum of Occurences in UC2+ and in UC1
Analysis 1	x	x	x	x	x	x	x	x		377	340	37	88	428
Analysis 2			x	x	x	x	x	x		349	293	56	135	428
Analysis 3					x	x	x	x		192	113	79	315	428
Analysis 4			x			x	x	x		195	78	117	350	428

(b) Same Analysis but Now Taking "Systemic/Local" into Account

Number of Analysis	Basic Dose Form (PDF)	State of Matter (PDF)	Basic Dose Form (ADF)	State of Matter (ADF)	Transformation (TRAC)	Release Characteristics (RC)	Intended Site Split (ISI-s)	Administration Method (AMEC)	Systemic/Local	Total Number of Unique Combinations (UC)	Unique Combinations (UC) with 1 Occurence	Unique Combinations (UC) with 2+ Occurences	Sum of Occurences in Unique Combinations 2+	Sum of Occurences in UC2+ and in UC1
Analysis 1	x	x	x	x	x	x	x	x	x	383	350	33	78	428
Analysis 2			x	x	x	x	x	x	x	357	306	51	122	428
Analysis 3					x	x	x	x	x	206	128	78	300	428
Analysis 4			x			x	x	x	x	274	197	77	231	428

Descriptors: Basic Dose Form (BDF) and State of Matter (SOM) of Pharmaceutical Dose Form (PDF) and Administrable Dose Form (ADF)

Characteristics:

Transformation (TRAc): (6 values): dilution, dissolution, dispersion, mixing, no transformation, unknown.

Release Characteristics (RC): (4 values): conventional, prolonged, delayed, modified.

Intended Site (ISI-s): (25 values): example: auricular; ocular; oral (see Supplementary file for full list).

Administration Method (AMEc): (19 values): example: application; inhalation; injection. (see supplementary file for full list).

Systemic/local: (4 values): systemic, local, local/systemic, unknown

Analysis 1: Taking all descriptors and all characteristics into account

Analysis 2: Taking the descriptors of the administrable dose form and all characteristics into account

Analysis 3: Taking only all characteristics into account

Analysis 4: Taking the Basic Dose Form of the Administrable Dose Form, RC, ISI-s, and AMEc into account (mimicing the FDA/WHO_UMC pilot approach)

Unique combinations (UC) with 1 occurence: a specific combination of the values of descriptors and/or characteristics, represented by one PDF

Can be considered as a measure of granularity of the dose form terminology and an indicator of congruence with the textual definition

Unique combinations with 2 or more occurences (UC2+): a specific combination of the values, represented by two or more PDFs

Can be considered as a measure of aggregation for ontologic class creation

Sum of occurences in UC2+: the number of PDFs grouped in unique combinations of values with 2 or more occurences of dose forms

Can be considered as an additional measure of aggregation for ontological class creation

Total number of unique combinations: sum of UC and UC2+

Can be considered as an addtional measure of granularity of the dose form terminology

Check: the sum of UC and the sum of the occurences in UC2+ must always be 428 (grey cells)

Conclusion of the analysis of unique combinations

- Full use of all characteristics makes the unique combinations almost definitional

- Looking at different unique combinations helps to group similar PDFs

- This exercise is useful to create a small ontology of Dose Forms

Methodology to create the ontology of dose forms

Starting point

    We used the revised excel file with extended characteristics and PDF/ADF alignment

    We looked at the most aggregated unique combinations of characteristics

Ordening exercise

    We orderded them by Intented Site

    Within each group we listed first the PDFs with no transformation (hence ADFs)

Grouping exercice

    We splitted groups of PDFs when there was a clinical reason to do so

    We concatinated groups of PDFs when there was no clinical reason to keep them separated.

Naming exercise

    We named the resulting groups

Building of a simple Dose Form ontology in 3 levels

Level 1 : Granular Level of Aggregation :

428 EDQM PDFs

Level 2 : Intermediate Level of Aggregation

65 Dose form Groups

Level 3 : High level of aggregation

25 Intented Sites

01/09/2022

► Proposal for small ontology of dose form terminology

AURICULAR	ORAL, CONVENTIONAL-RELEASE
Auricular dose form	Oral solid dose form
Auricular/nasal dose form	Oral semi-solid dose form
Auricular/nasal/ocular dose form	Oral drops dose form
Auricular/ocular dose form	Oral liquid dose form
CUTANEOUS	Oral effervescent or dispersible dose form
Cutaneous dose form	Oral/rectal dose form
Cutaneous/transdermal dose form	ORAL, MODIFIED-RELEASE
Cutaneous/nasal dose form	Oral gastro-resistant dose form
Cutaneous/oromucosal dose form	Oral prolonged-release dose form
Cutaneous/parenteral dose form	Other oral modified-release dose form
DENTAL	OROMUCOSAL
Dental dose form	Oromucosal spray dose form
ENDOCERVICAL	Oromucosal solid dose form
Endocervical dose form	Oromucosal prolonged-release dose form
EXTRACORPOREAL	Oromucosal liquid dose form
	Oromucosal gargling/mouthwash dose form
Extracorporeal dose form	
EXTRACORPOREAL/PARENTERAL	Sublingual dose form
Dialysis dose form	PARENTERAL
GASTRIC	Implantation prolonged-release dose form
Gastric dose form	Injection prolonged-release dose form
GASTROENTERAL	Injection dose form
Gastroenteral dose form	Infusion dose form
INTRAPERITONEAL	Infusion/injection dose form
Intraperitoneal dose form	PULMONARY
INTRAUTERINE	Vapour dose form
Intrauterine dose form	Nebuliser dose form
Intrauterine device	Pressurised inhalation dose form
INTRAVESICAL	Inhalation dose form
Intravesical/intraurethral dose form	Medicinal gas dose form
	Endotracheopulmonary instillation dose form
OCULAR	
Ocular semi-solid dose form	RECTAL
Ocular drops dose form	Rectal systemic dose form
Ocular rinsing dose form	Rectal local dose form
Ocular intraocular dose form	TRANSDERMAL
Ocular prolonged-release dose form	Transdermal prolonged-release dose form
NASAL	Transdermal dose form
Nasal spray dose form	VAGINAL
Nasal solid or semi-solid dose form	Vaginal prolonged-release dose form
Nasal drops dose form	Vaginal dose form
Endosinusial dose form	Vaginal device
Nasal/ocular/pulmonary dose form	MISCELLANEOUS
	Radiopharmaceutical dose form
	Wound dressings prolonged-release dose form
	Ungrouped dose form

Visualising the ontology with WebProtégé

'Dose Form'

owl:Thing

'Oromucosal solid dose form'

'Nasal spray dose form'

'Endotracheopulmonary instilla...

'Gastric dose form'

'Infusion/injection dose form'

'Vaginal prolonged-relea...

'Ocular intraocular dos...

'Rectal local dose form'

'Oromucosal gargling/mouthw...

'Medicinal gas dose form'

'Ocular rinsing

'Oral effervescent or...

'Intrauterine

'Infusion dose form'

'Pressurised inhalation dose...

'Oral/rectal dose form'

'pressurised inhalation, emu...

'pressurised inhalation, sus...
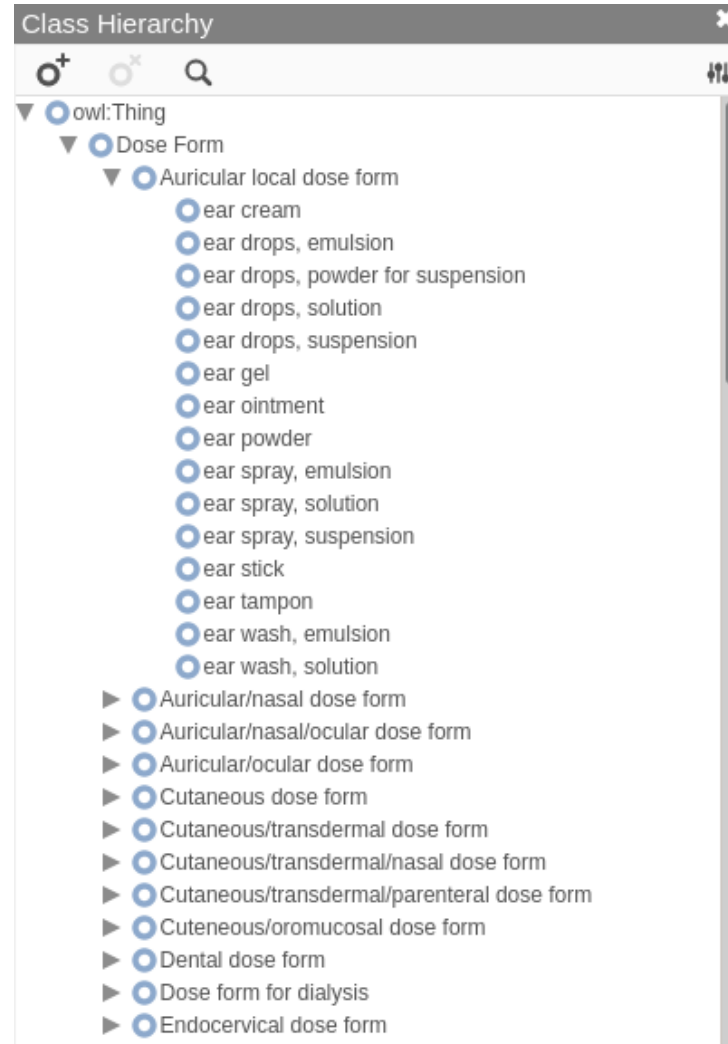
'pressurised inhalation, sol...
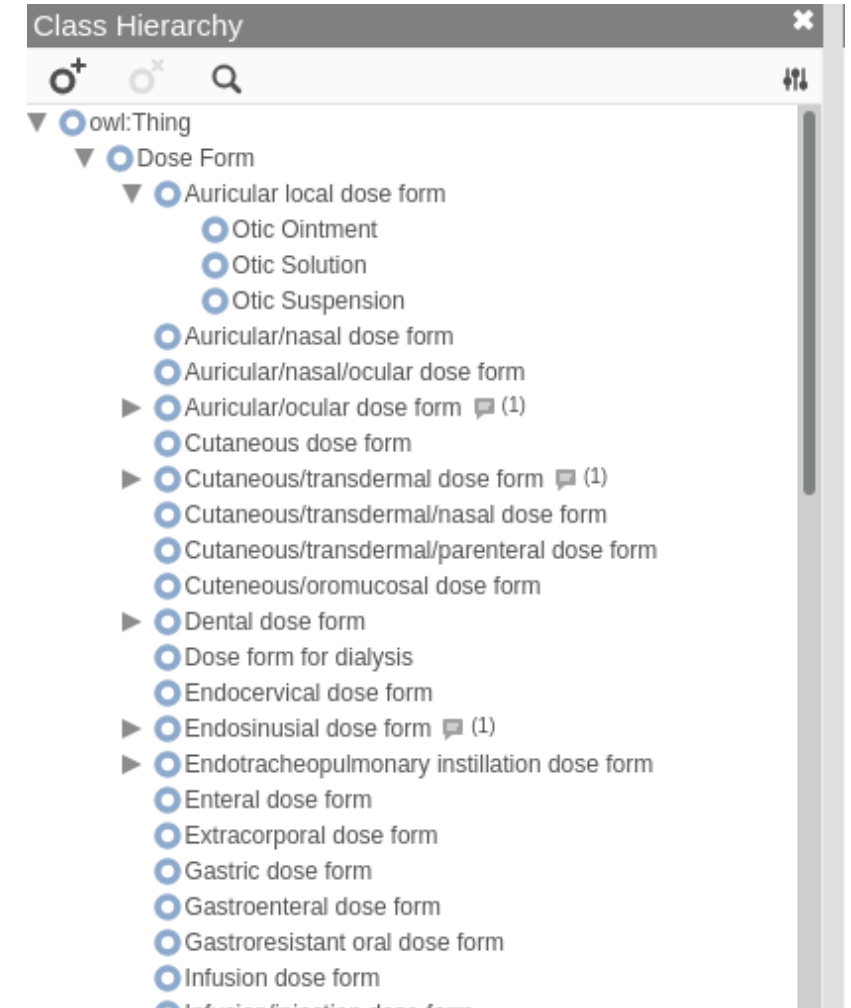
3 out of 428 PDFs

65 intermediary level dose form groupers

Connecting RxNorm to the ontology

- RxNorm has been connected to the small ontology by Natalie Karapetian (Harvard)

- Given the similarity between SNOMED-CT and EDQM, connecting SNOMED-CT should be easier
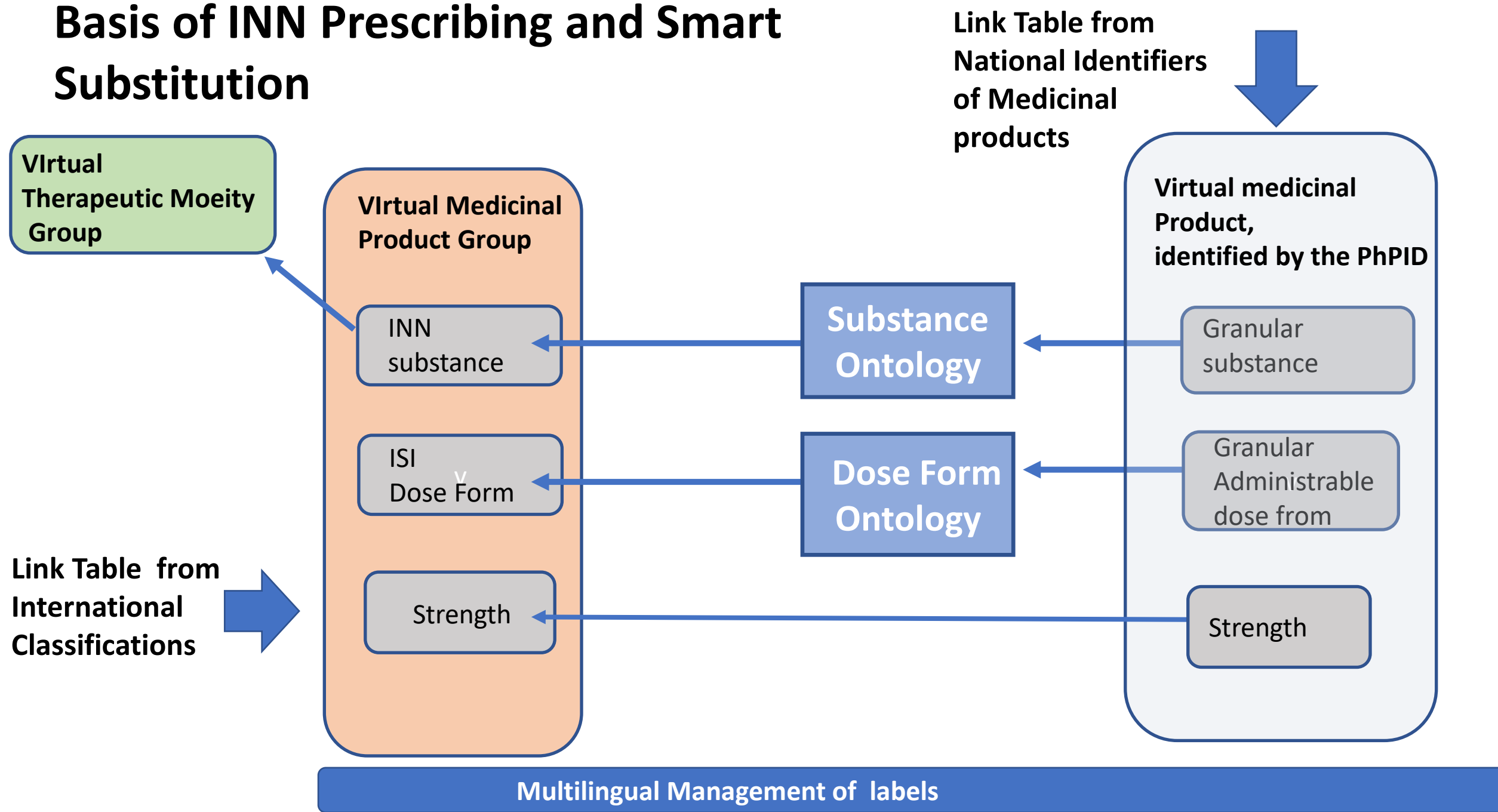

EDQM standard terms database

RxNorm dose forms

Basis of INN Prescribing and Smart Substitution

Link Table from National Identifiers of Medicinal products

VIrtual Therapeutic Moeity Group

VIrtual Medicinal Product Group

Virtual medicinal Product, identified by the PhPID

INN substance

Substance Ontology

Granular substance

ISI Dose Form

Dose Form Ontology

Granular Administrable dose from

Link Table from International Classifications

Strength

Strength

Multilingual Management of labels

Multilinguality and EDQM

For the 428 PDF labels,

    Lexical equivalents are available for 34 Languages

        The official EU languanes

        Albanian, Bosnian, …, Turkish and Ukrainian

For the value sets of the characteristics in English

    lexical equivalents are not avaible yet

        BDF, SOM

        TRA, RCE, ISI, AME

A real world example :
Will this be useful for cross-border exchange of prescriptions, medication lists and patient summaries ?

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What if

a Greek patient shows up on in a Belgian Pharmacy and requests a prescription for

αμλοδιπίνη

By identifying the IDMP data on the box, the pharmacist realizes that this about

amlodipine,
and more specifically
amlodipine oral 10 mg,
and even more specifically :
amlodipine besilate capsule, hard 10mg

In Belgium available as : Amlor 10 mg (Upjohn), and in generics by a number of companies but as tablets

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Example of aggregated representation of medicinal products at work

Grouper of Medicinal Products with the same active moiety of substance

C08CA01 amlodipine

Virtual Medicinal Product Group

amlodipine oral 10 mg

amlodipine oral 5 mg

Pharmaceutical Product

amlodipine besilate   capsule, hard   10 mg

amlodipine besilate   tablet   10 mg

(note : amlodipine maleate film-coated tablet 10 mg recently disappeared from the Belgian market)

amlodipine besilate   capsule, hard   5 mg

amlodipine besilate   tablet   5 mg

Medicinal Product (Belgium)

amlodipine besilate   capsule, hard   10 mg

Amlor harde caps. 10 mg   Upjohn

amlodipine besilate   tablet   10 mg

Amlodipine EG (PIP) tabl. (deelb.) Besilate 10 mg   PI-Pharma
Amlodipine EG tabl. (deelb.) Besilate 10 mg   EG
Amlodipine Mylan tabl. (deelb.) Besilate 10 mg   Mylan
Amlodipine Teva tabl. (deelb.) 10 mg   Teva
Amlodipin Sandoz (Impexeco) tabl. (deelb.) Besilaat 10 mg Impexeco
Amlodipin Sandoz tabl. (deelb.) Besilaat 10 mg   Sandoz
Amlobemed tabl. (deelb.) 10 mg   3DDD
Amlodipin AB tabl. 10 mg   Aurobindo

Amlodipin Sandoz tabl. (deelb.) Besilaat 10 mg   Sandoz

A question to EDQM Management :

What is the position on the right way to use EDQM in identifying dose form ?

UN COM

Dilemma for dose form identification in IDMP

▶ PHPID calculation based on :

Granularity

▷ 4 characteristics of EDQM Dose Form

179 unique combinations of 4 basic characteristics

or on

▷ the granular EDQM dose form

428 granular EDQM

With inherent information on characteristics

Recapitulation of our questions to the EDQM Standard Terms Working Party

UN COM

Recapitulation of our questions

1. Could you verify our extended Excel File of 428 PDFs ?
   ▷ Provide codes for combinations of values for characteristics
   ▷ Opinion on splitting "cutaneous/transdermal"
   ▷ Check of alignment of PDF to ADF
   ▷ Opinion on a new characteristic "systemic"

2. Would you cooperate in making the ontology of dose form better ?
   ▷ Participation in Alignment of RxNorm to the EDQM ontology
   ▷ Participation in experiments on Substitution rules in cross border prescription exchange
   ▷ Participation in experiments to find the best way to train legacy conversion experts in standardization of dose form to EDQM

3. Do you feel the need to reflect on the best way to represent Dose Form in IDMP implementation and PhPID creation ?

Thank you for your attention.
Time for questions ?

UN COM

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Virtual Drug Models

In

IDMPM
Snomed-Ct
RxNorm
Dm+D/SAM

Concepts in drug identification at the national level for concrete products

IDMP	SNOMED-CT	Dm+d/SAM	RxNorm
	Real Medicinal Product	Actual Therapeutic Moiety	Brand name
Medicinal Product	Real Clinical Drug	Actual Medicinal Product	Semantic Branded Drug
Packaged Medicinal Product	Real Packaged Clinical Drug	Actual Medicinal Product Package	Brand Name Pack

Concepts in drug identification for abstract but granular representation of medicinal products

IDMP	SNOMED-CT	Dm+d/SAM	RxNorm
PhPID Level 1 (precise active ingredient Group)	Medicinal Drug Precisely	Virtual Therapeutic Moeity	
PhPID Level 4 (Pharmaceutical Product Group)	Clinical Drug Precisely	Virtual Medicinal Product	Semantic Clinical Drug (not precise ingredient)
	Packaged Clinical Drug Precisely	Virtual Medicinal Product Package	Generic Pack

Concepts in drug identification for higher levels of abstraction in representation of medicinal products

IDMP	SNOMED-CT	Dm+d/SAM	RxNorm	UNICOM-PPL
	Medical Product Only			Virtual Therapeutic Moiety Group
	Medicinal Product Form Only + Strength	Virtual Medicinal Product Group	Semantic Clinical Drug Not high level dose form)	Virtual Medicinal Product Group
	Real Packaged Clinical Drug			

Medicinal Products

"Exact" abstract representation

Higher level aggregation

Haiku on what binds and seperates almost similar things

Cherry blossoms are cherry blossoms and not hedge bindweeds
They are pink, delicate and blossom in the spring
Yet, every cherry blossom is unique