Global IDMP Working Group

Day 1

16 October 2023

3d Global IDMP Working Group (GIDWG) Stakeholders Meeting

AGENDA
Global IDMP Working Group (GIDWG) Stakeholders Meeting

Day 1 9:00-17:00 EDT

9:00	Welcome and Introduction	Isabel Chicharo (EMA) / Malin Fladvad (UMC)/Ron Fitzmartin (FDA)
9:30	Opening remarks	Hilmar Hamann (EMA) / Ron Fitzmartin (FDA) / Shanthi Pal (WHO)
10:15	GIDWG executive summary	Malin Fladvad (UMC)/Ron Fitzmartin (FDA)
11:00	Break	
11:15	Review and Consensus on Global substance ID	Olof Lagerlund (UMC)
12:00	Review and Consensus on Global Dose form ID	Julia Nyman (UMC)
12:30	Lunch	
13:30	Review and Consensus on Global Strength	Norman Schmuff (FDA)
14:00	Review and Consensus on global PhPID Operating Model	Malin Fladvad (UMC)
14:45	Status report on HL7 FHIR for IDMP	Panagiotis Telonis (EMA)
15:15	Break	
15:45	GIDWG Communication Plan	Ron Fitzmartin (FDA)
16:30	Wrap up and Review of actions	Isabel Chicharo (EMA)/Malin Fladvad (UMC)/Ron Fitzmartin (FDA)/All

3rd Global IDMP Working Group Stakeholders Meeting

Opening Remarks

Hilmar Hamann(EMA)/

Ron Fitzmartin (FDA)/

Shanthi Pal (WHO)

16 October 2023

Disclaimer

The views presented are those of the presenter, and do not necessarily reflect the views and/or policies of the U.S. Food and Drug Administration.

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- FDA strives to be on the forefront of adopting/ supporting innovative technologies and supporting the use of consensus-based international data standards for use in regulatory submissions.

- In the 80s, sponsors prided themselves on the development of their own data standards, formats and submission structures.
  - *However, it became clear that reg authorities could not handle submissions in multiple different technologies, data standards, formats and hardware.*

- In the 90s, ICH was founded to harmonize processes and practices in drug development. This coincided with founding of CDISC and introduction study data standards. Two Game Changers.

- Global adoption of multiple data standards for various content areas is critical now for submissions and regulatory review.

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- Fast forward to 2012 and the release of the initial versions of ISO IDMP standards.
  - *Only in the last 5 years have we seen that they could not be implemented for global use without revision, testing, and much more.*

- FDA supports the GIDWG and its mission to fill the gap to ensure that IDMP is fit for global implementation and use.

- FDA must align, harmonize, collaborate with other regulatory agencies / stakeholders on global IDMP identifiers, using international collaborations / international organizations, e.g., ICH and ICMRA.

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Let’s have a great meeting

Thank You

GIDWG Executive Summary: Accomplishments and Planned Activities

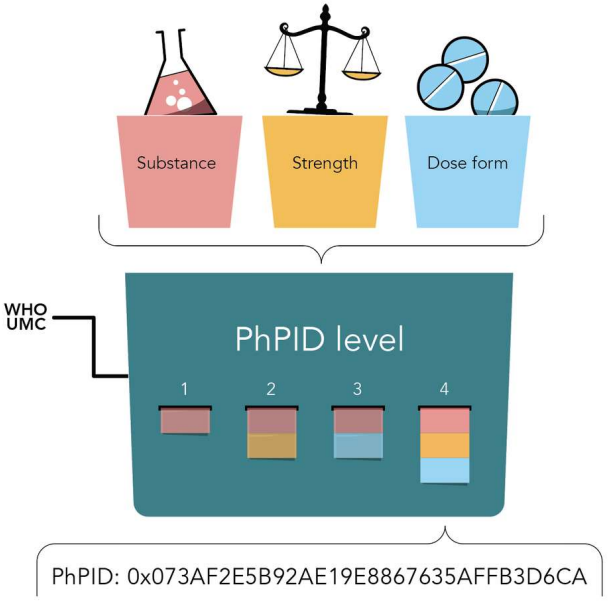
Malin Fladvad, UMC
Ron Fitzmartin, U.S. FDA

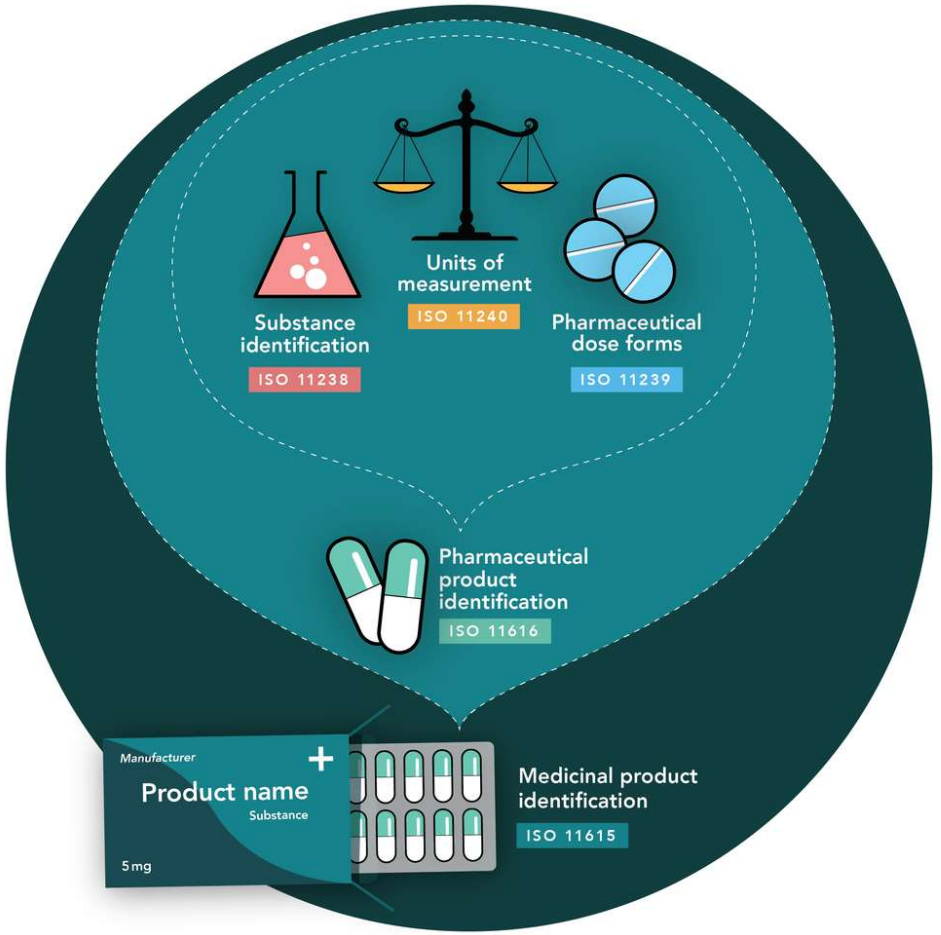
October 16, 2023

Why GIDWG?

- GIDWG was chartered in 2021 as an outcome of a 2019 WHO IDMP Workshop in Geneva, September 2019.
  - Why was GIDWG established?
    - There was no organization focused on demonstrating that the standards can be implemented globally.
  - Membership
    - Founding members include EU EMA, U.S. FDA, and WHO-UMC. IFPMA has joined as an industry member, as well as other regulators, e.g., Health Canada and Brazil ANVISA.
  - What is its focus?
    - Develop and execute projects to demonstrate that the IDMP standards are “fit” for global implementation.
    - Develop a framework, including business rules, best practices and operating model, for the global IDMP implementation and maintenance of global identifiers for marketed products.

What is IDMP?





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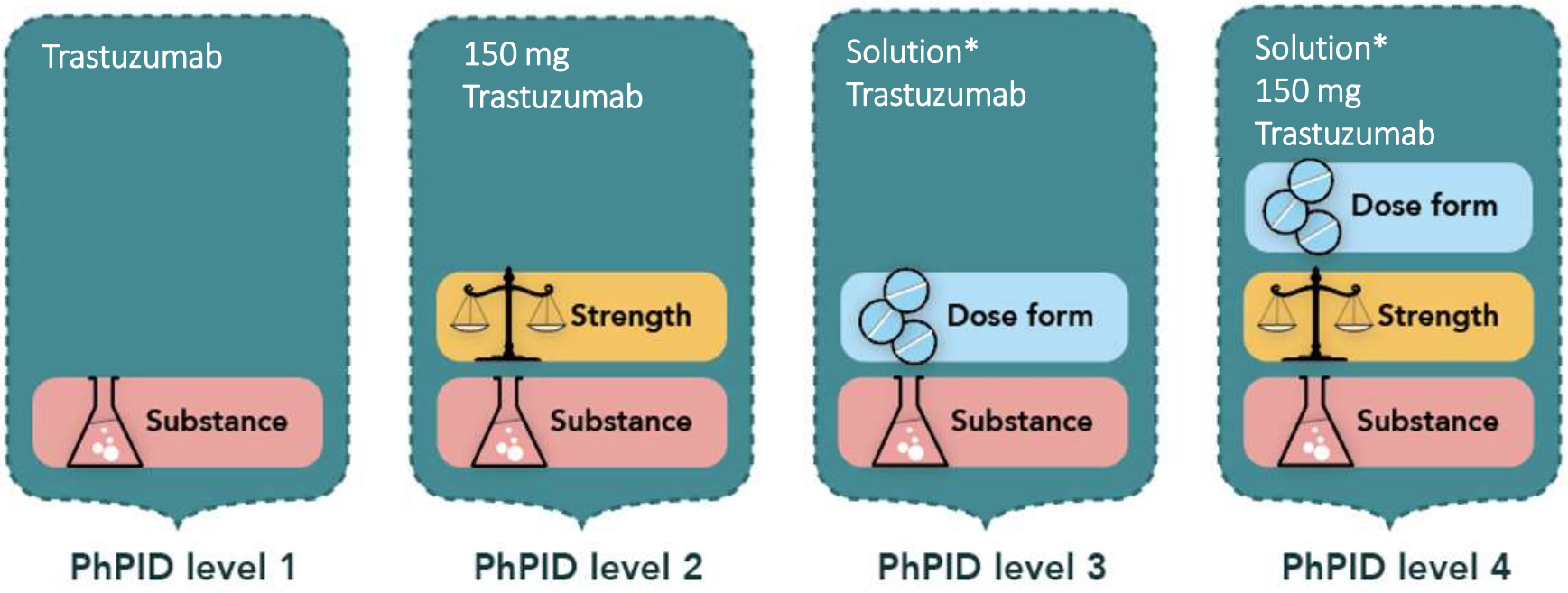
The PhPID and its levels



*Dose form characteristics: Solution, Injection, Parenteral, Conventional

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Global PhPID connecting the dots

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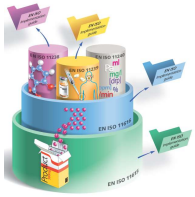
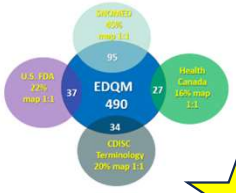
GIDWG's Journey so far…

ISO IDMP



2012

ISO 11239 – Dose Form for Global implementation



2018

WHO Workshop

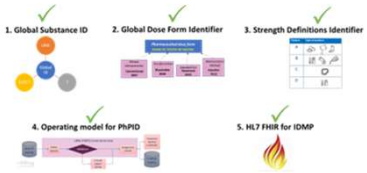
2019

GIDWG

Global IDMP Working Group

2021

GIDWG Projects



2022

Use Cases

Q4 2023

End to End Testing

2024

Start of onboading

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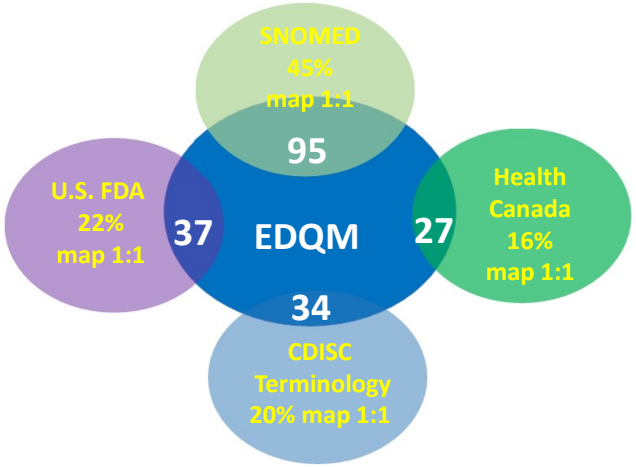
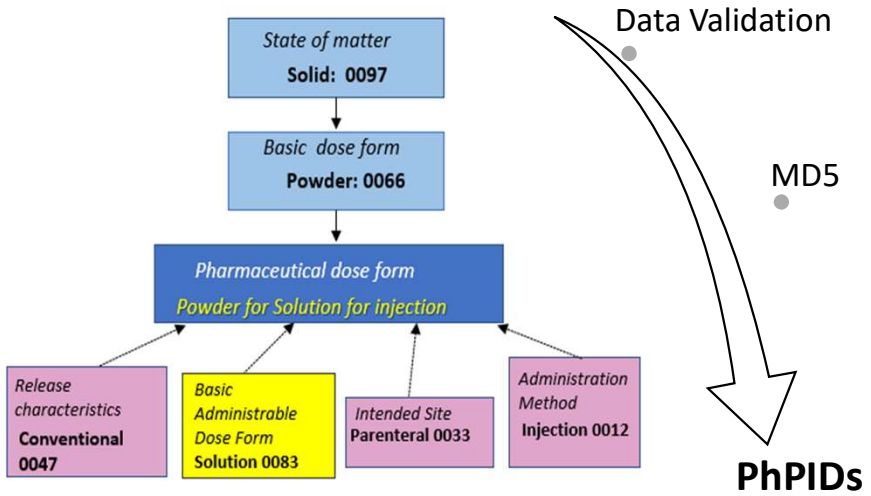
FDA/UMC pilot for Global PHPIDs

Feasibility of using dose form characteristics for mapping to regional terminologies



Mapping of regional terminologies to EDQM PDF



The pilot validated 1,289 US marketed medicinal products corresponding to 37 selected substances identified in the UNICOM pilot product list

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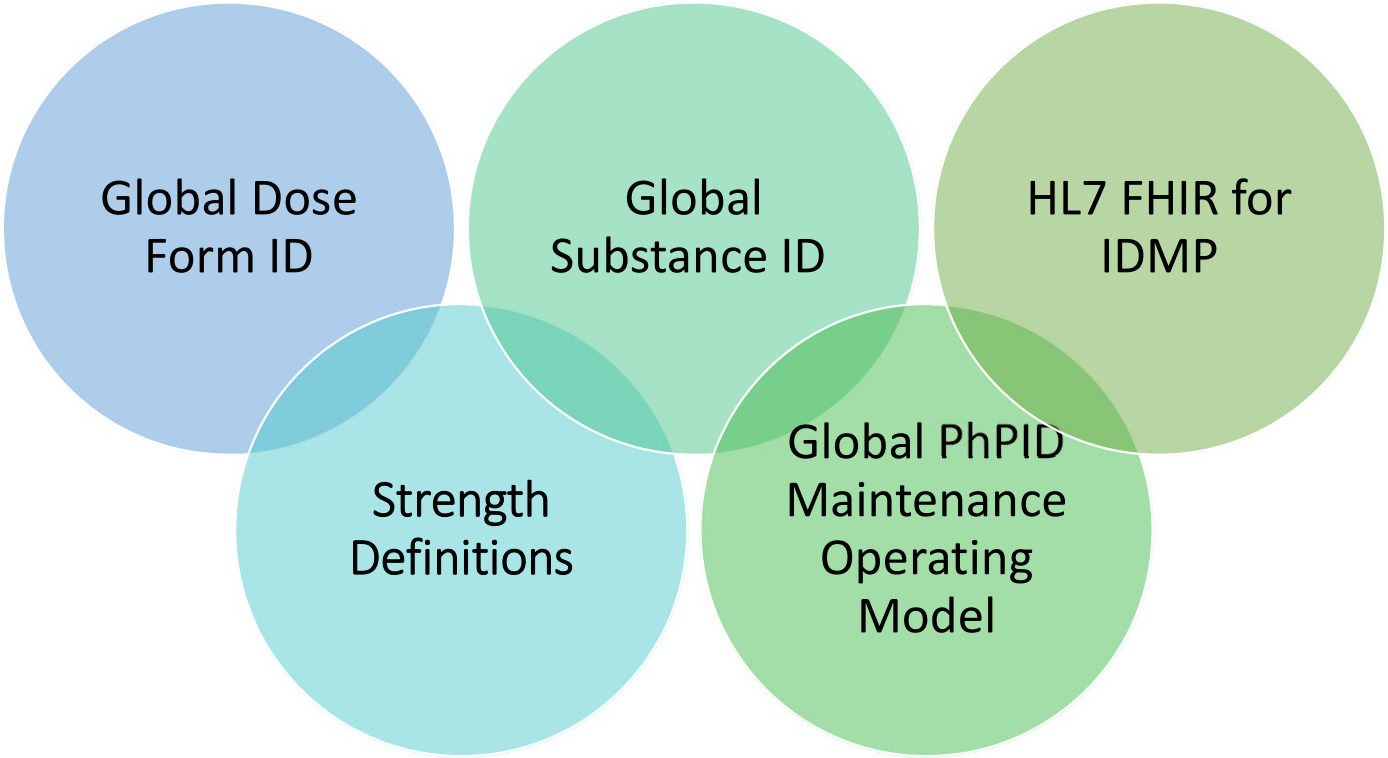
GIDWG projects

Aim to define and reach consensus on processes, best practices and an operating model for maintenance of global identifiers for marketed medicinal products



SME from US FDA, EMA, ANVISA, Health Canada, Swissmedic, WHO-UMC, WHO, EDQM, INN, USP, HL7, HMA-SVG, US-NIH, IFPMA, ISO/CEN, USP

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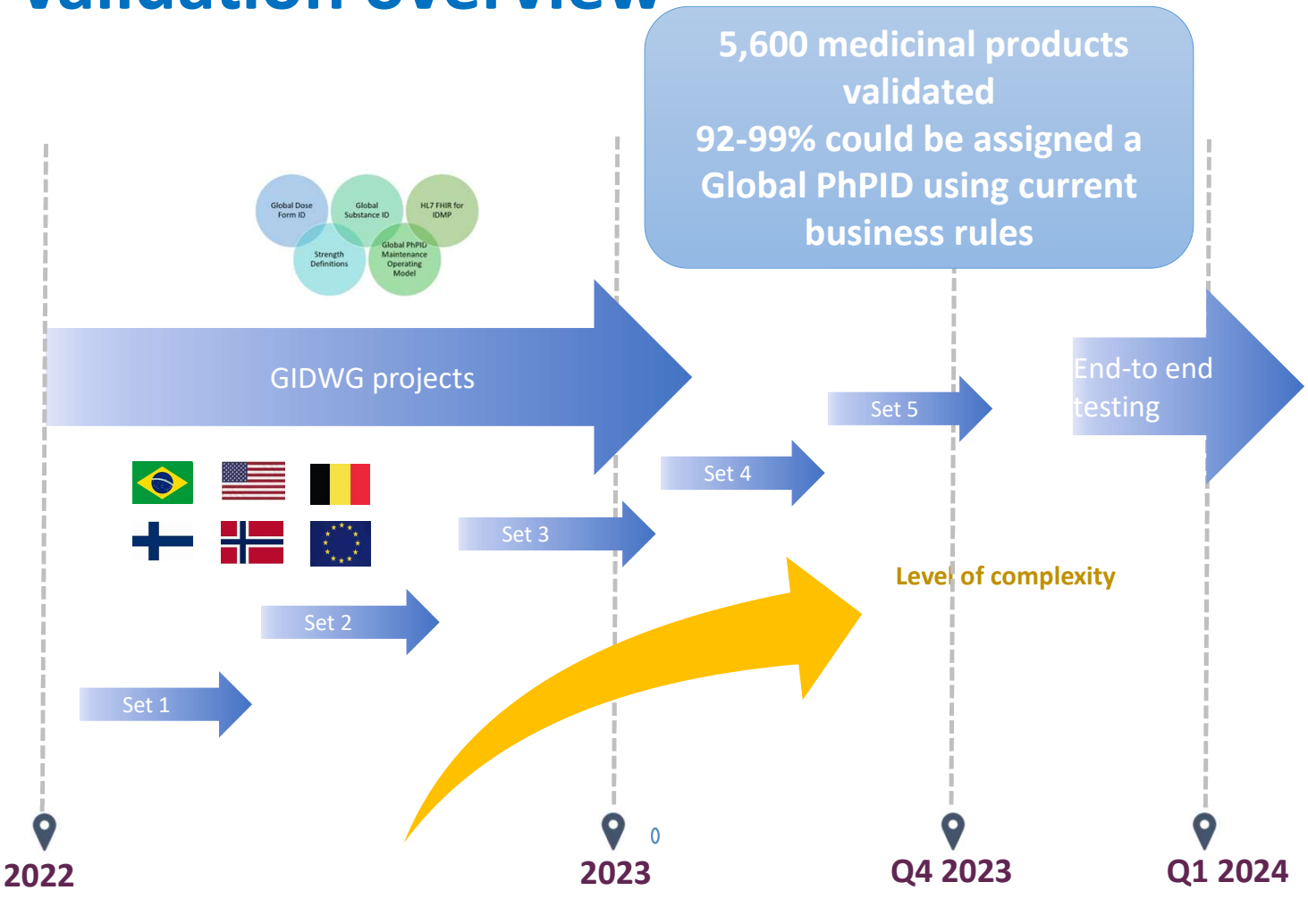
GIDWG validation overview



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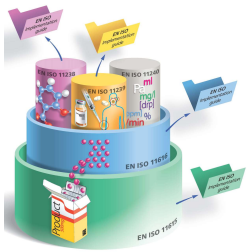
Data validation working process

Medicinal product data

Selected data set of chemicals, proteins and vaccines

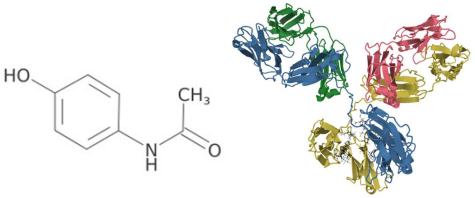


Substance

Dose form

Strength

PhPID



Administration method

Intended site

Basic dose Form

Release characteristics

Pattern	Type of product
A	
B	
C	

0x073AF2E5B92AE19E8B67635AFFB3D6CA

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IDMP

End-to-End Demonstration Q4 2023

Testing to demonstrate the use cases for GSID/PhPID operating model

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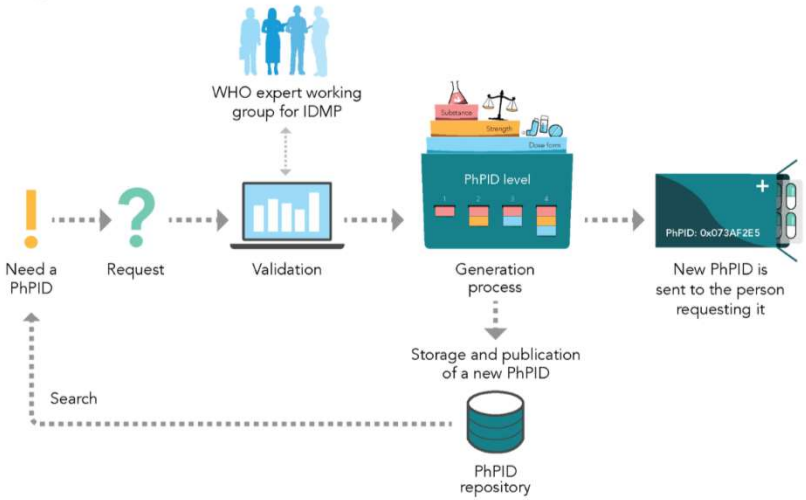
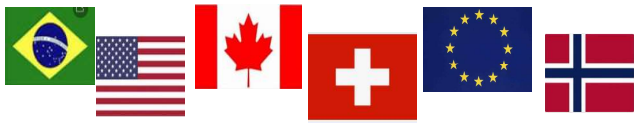
SCOPE:

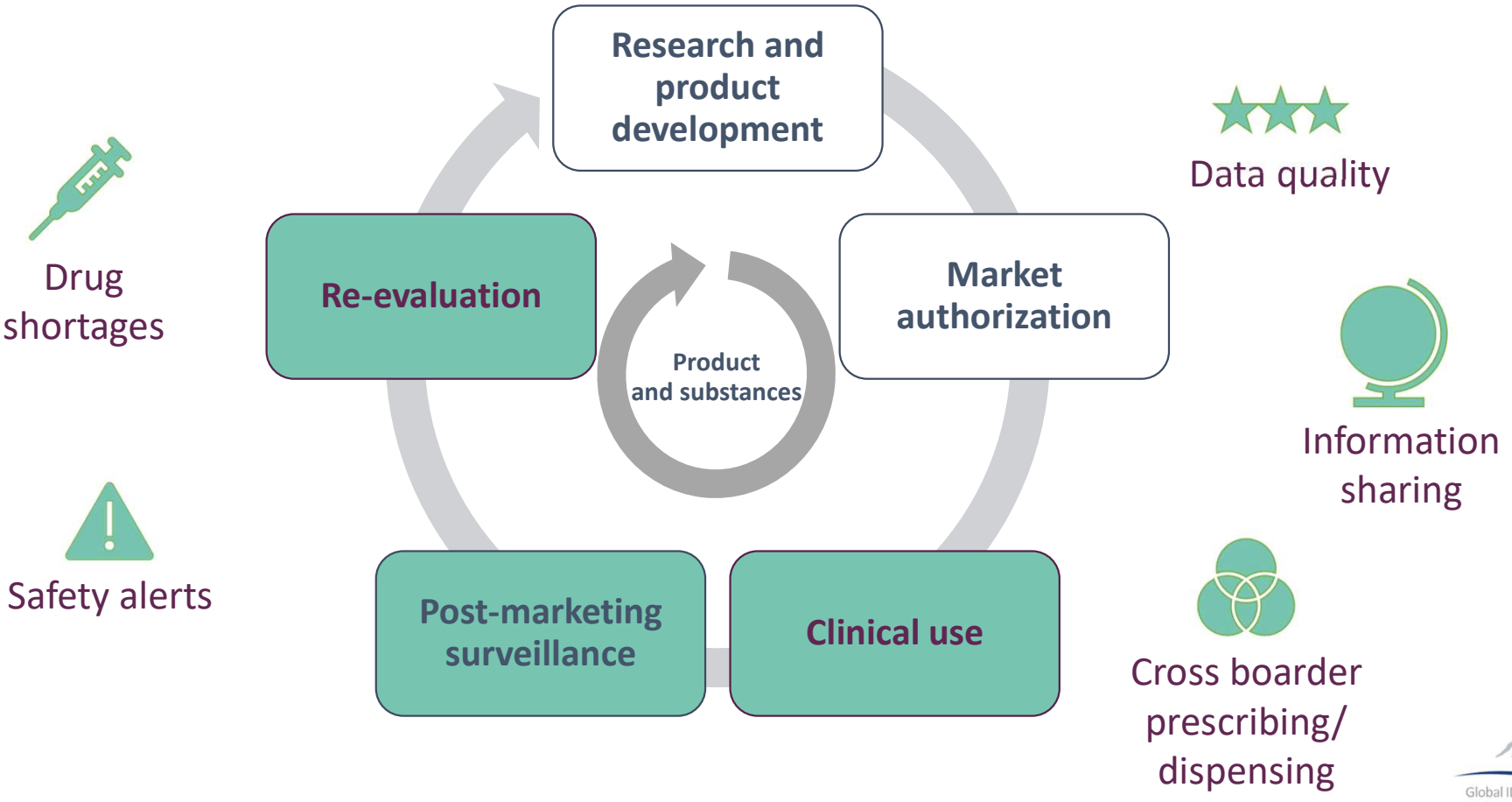
- Validate and generate PhPIDs for products based on the GIDWG/EWG business rules
- EDQM + non-EDQM countries
- Similar products from different countries
- Larger batches & smaller data sets for regulators
- Validated Data Sets based on **150 substances** including Chemicals, Biosimilars, Polymers, Nucleic Acids, Structure Divers, 'Mixtures'



Proposed candidate countries:

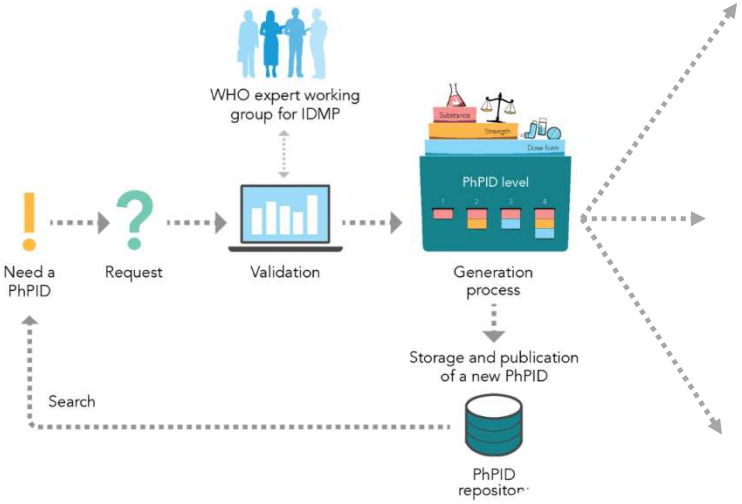


Use cases for global PhPID



End-to-End demonstration Q4 2023

Testing to demonstrate the use cases for GSID/PhPID operating model



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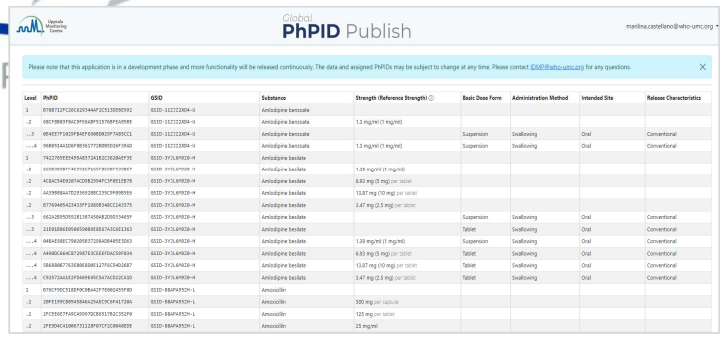
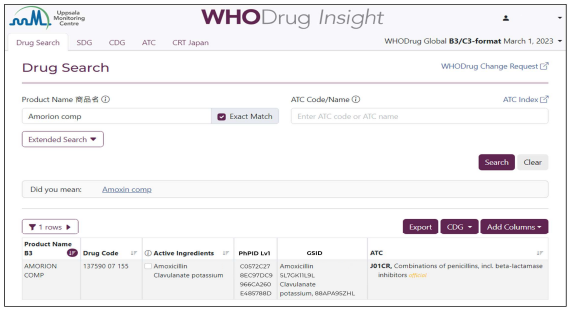


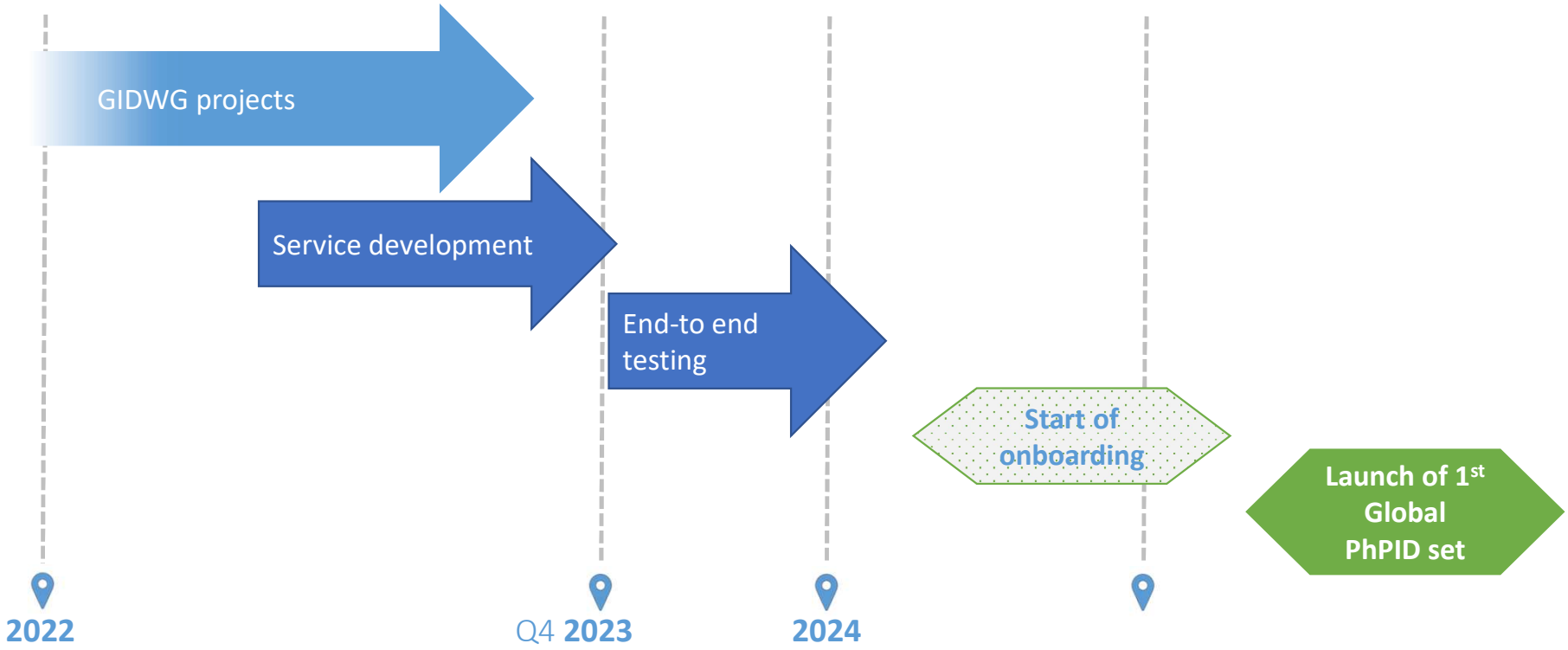
Daily updates

FHIR in pilot



Daily updates

Future plans – Global PhPID



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GSID for PhPID assignment in the GIDWG pilots

Olof Lagerlund, October 16th

Agenda

Introduction

GSID for PhPID assignment in the GIDWG pilots

Results from GIDWG pilots

GSID now and future perspective

Why a Global substance identifier (GSID)?

GSID is an identifier and not a name

International naming organizations

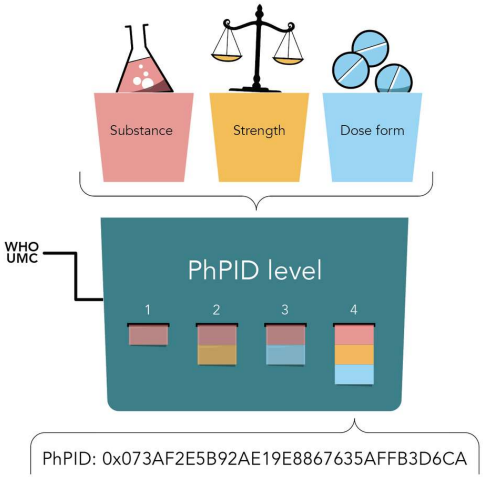
- INN, USAN, JAN…

Pharmacopeias

- Ph Eur, Korea, Brazil…

Regional/national identifiers/codes

- UNII, SMS-ID, Ijoken…



To have consistent generation of global PhPIDs, a single controlled GSID is needed.

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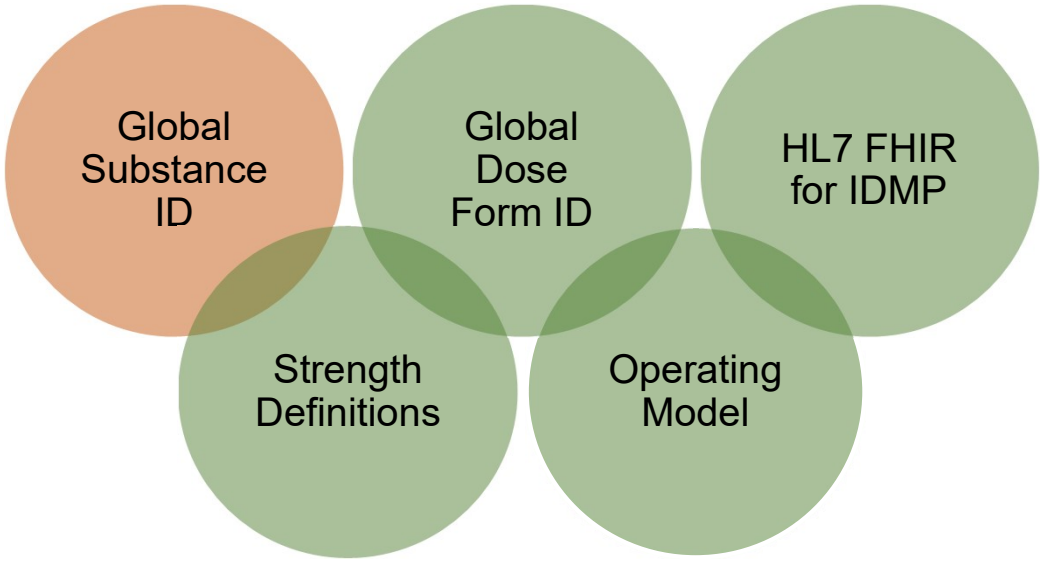
GIDWG GSID project, Project Scope and Deliverables

Goal: Globally harmonize and define capture of standardized information for global Substance identification and hereby ensure consistent PhPID construction through/by:

- Identifying the core information set via the ISO TC215 WG6 signature field sub-group.
- Adopting a Global substance ID, i.e., GSID
- Establishing business rules regarding which standardized substance data (GSID) to use in the PhPID generation.
- Establishing a mechanism for the use of confidential data in GSID assignment.



www.gidwg.org

WHO, WHO-UMC, INN, FDA, EMA, HMA-SVG, Health Canada, SwissMedic

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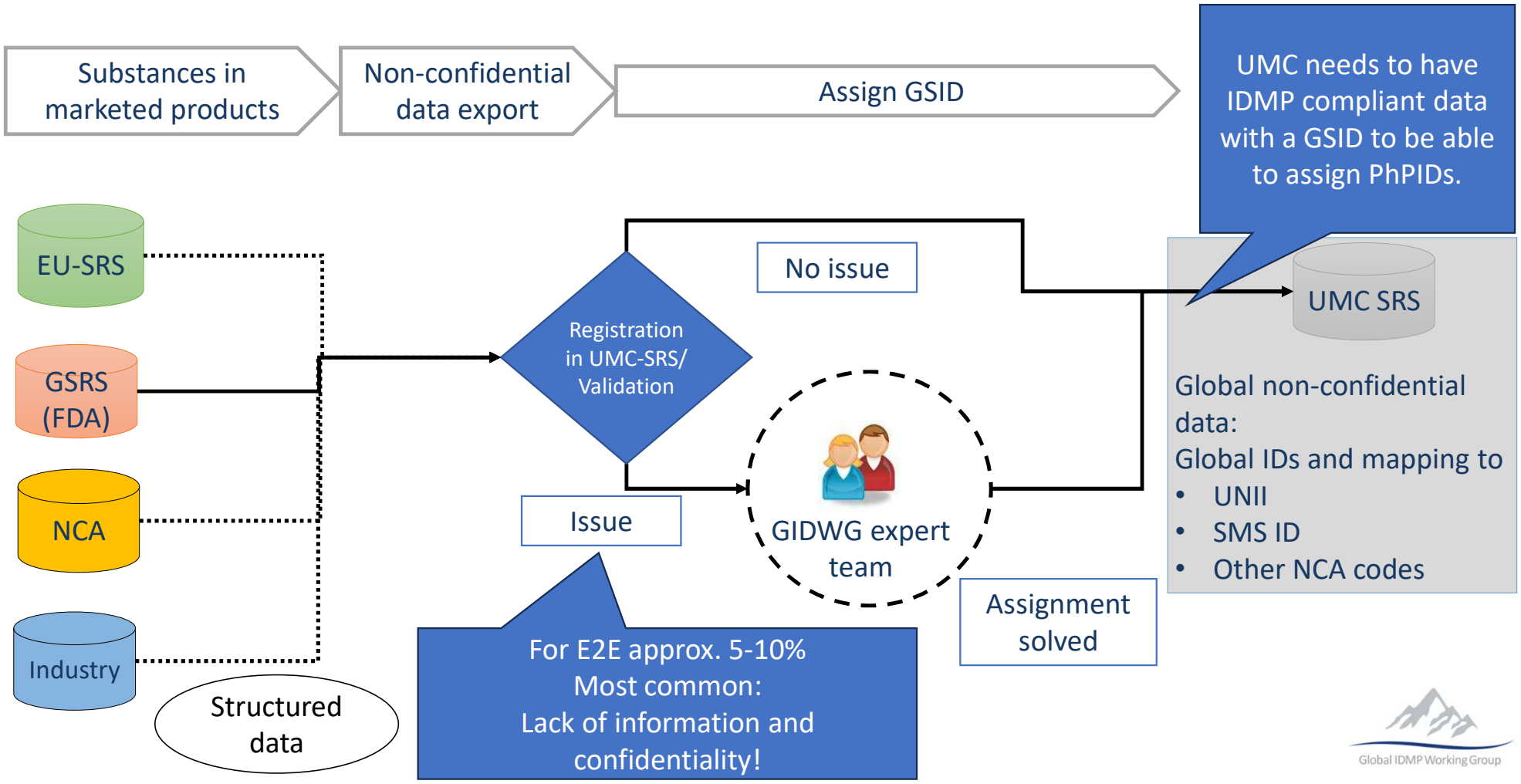
Global substance process in the GIDWG pilots



Construction of GSID used in the GIDWG pilots

- A unique and consistent code following the ISO/IEC 15459 - Part 3 (Ref ISO/IEC 15459). The code consists of 17 characters long text buildup of a Qualifier, Unique text, and Check character.

GSID9ST5UC24F36TN

- The first 4 characters is the qualifier and will always be the text GSID.
- The middle 12 characters are a unique text buildup of random digits and letters.
- The last character is a check character which is used as a redundancy check used for error detection on identification numbers
- The order for how substance combination are expressed in PhPID algorithm is: Order by GSID (not by substance name) where numbers precedes letters i.e. 9 before A.

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Business rules for GIDWG pilots

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Business rules for GSID

- The GSID assignment is based on the ISO 11238 and TS 19844. The Business rules should clarify the standards when needed.
- A GSID is a requirement for PhPID assignment.
- To assign a GISD to a substance, the information defining the substance, needs to be publicly available.
- All active ingredients (GSIDs) will be used in the PhPID assignment.
- Process for using the appropriate GSID when generating a PhPID in a consistent manner.

Note: UMC works with harmonisation of data, but is not a regulatory agency

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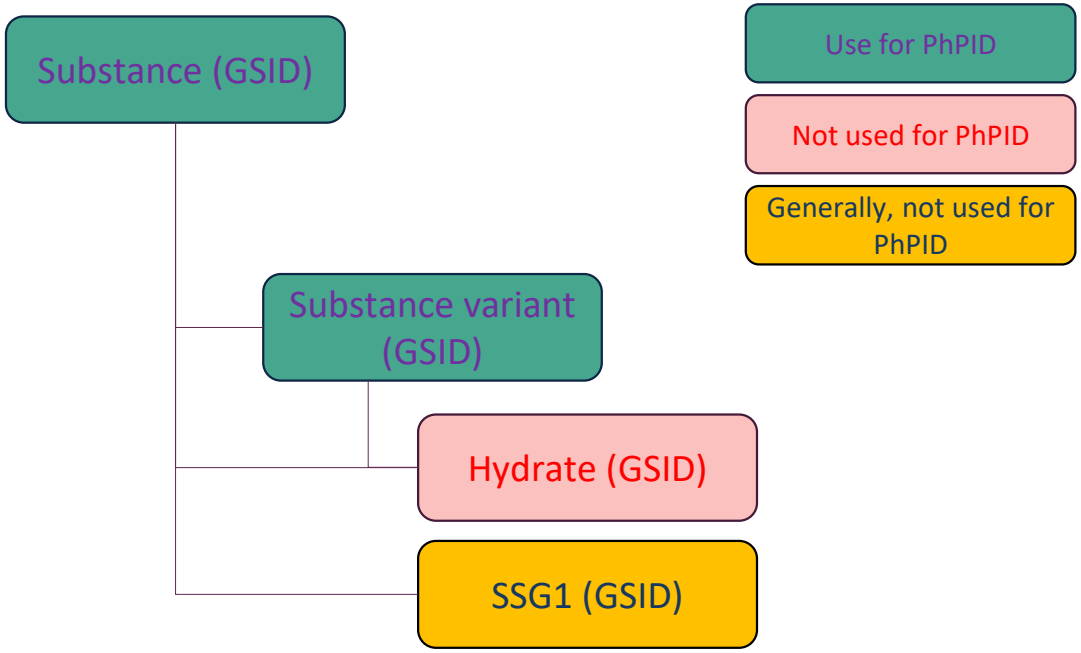
GSID selection for PhPID assignment



GSID can be assigned either on the substance and SSG1 level.

The active ingredient, disregarding hydrates (replace with the non-hydrated substance), is used.

The SSG1-level is only used for certain cases where SSG1 is important for distinction in-between different PhPID.

Input string: GSID; strength; dose form

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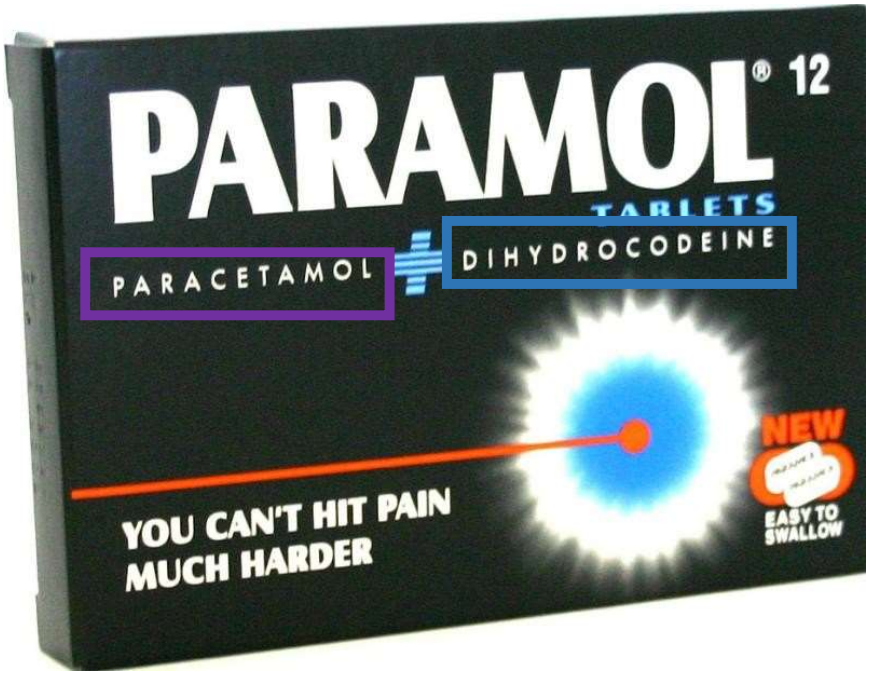
GSID for PhPID, Combination products



GSID1: Paracetamol
GSID2: Codeine anhydrous

Combination products will be assigned one GSID for each active ingredient. All active ingredients will have a corresponding strength in to be assigned a PhPID.

Input string: GSID1; strength1;; GSID2; strength2; dose form

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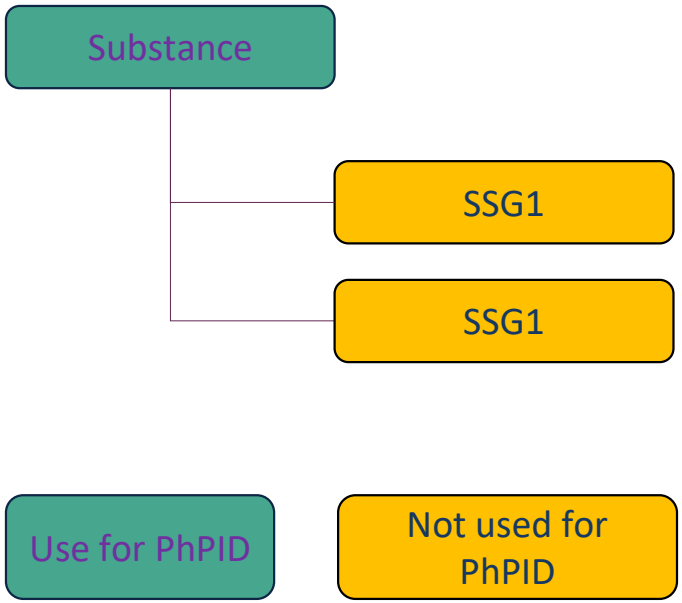
GSID for PhPID, Proteins



GSID can be assigned on the substance and SSG1 level.

The substance level GSID will be used for PhPID for all proteins, except insulins where both can be used.

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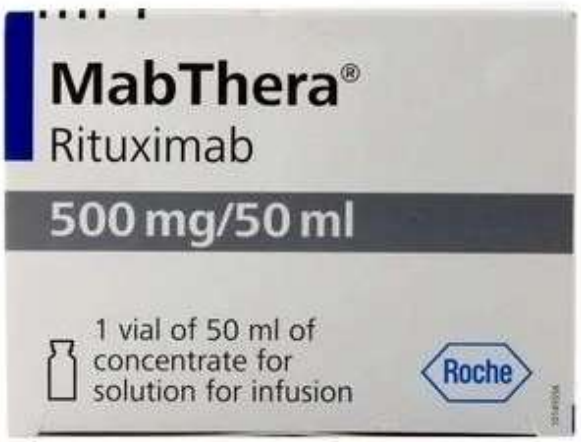
GSID for PhPID, Proteins

Q: Should the GSID of the substance level or SSG1 level be used for PhPID generation?



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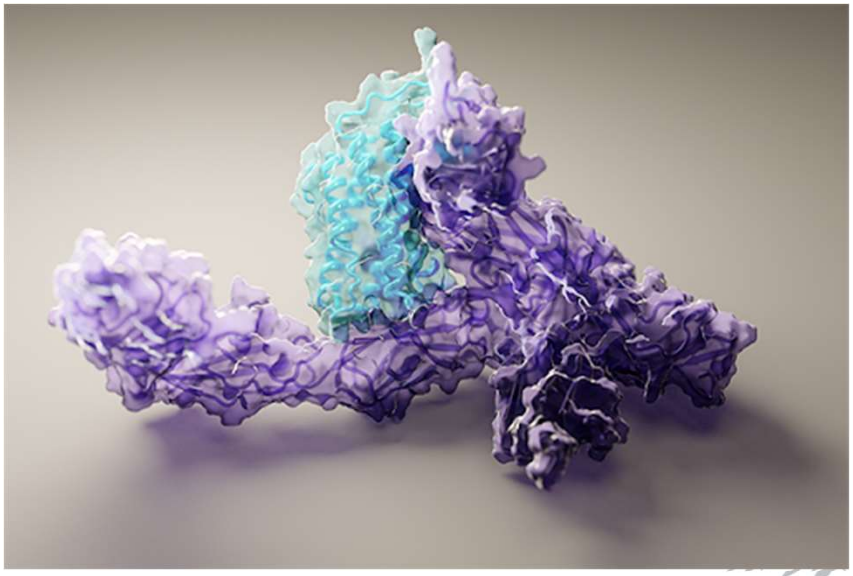
GSID for PhPID, Proteins

Protein property	Substance level	SSG1
Amino acid sequence	**Mandatory**	
Glycosylation site	**Conditional**	
Glycosylation type	**Conditional**	
Disulfide linkage	**Conditional**	
Detailed glycosylation info**		Conditional

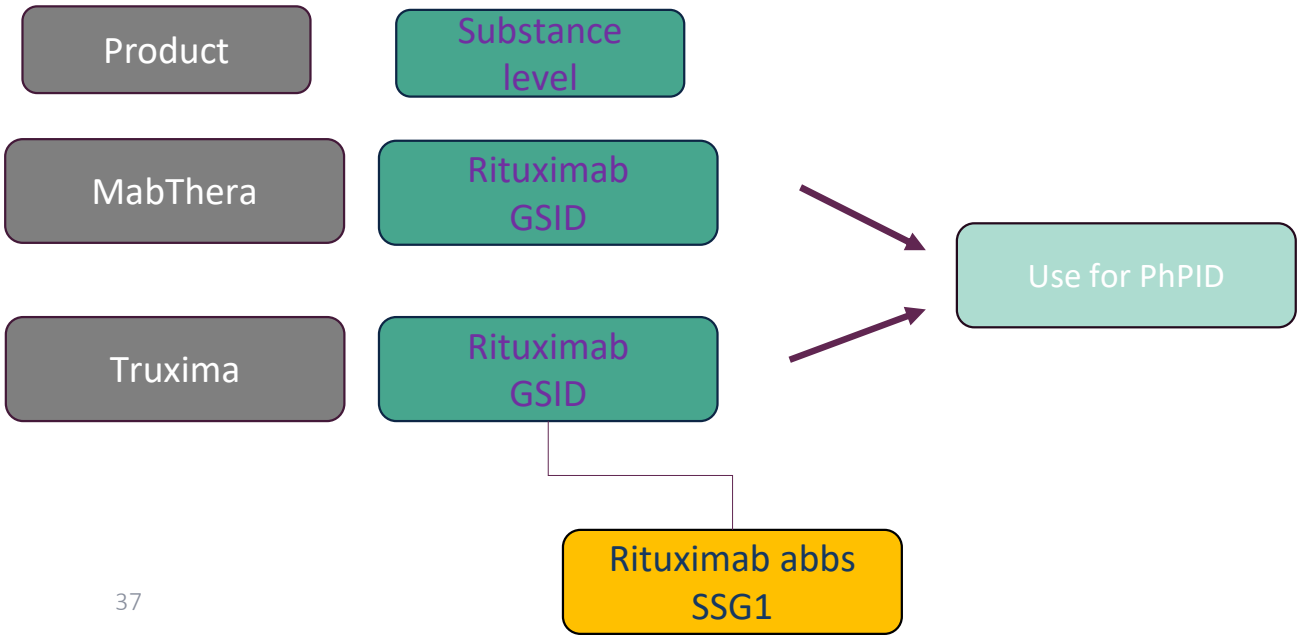
If any Protein property on substance level is different, it results in a different GSID.



https://biosciences.lbl.gov/2021/09/07/ai-fueled-software-reveals-accurate-protein-structure-prediction/

*According to ISO/TS 19844:2018
**Generally, not available in the public domain for marketed products.

GSID for PhPID, Proteins



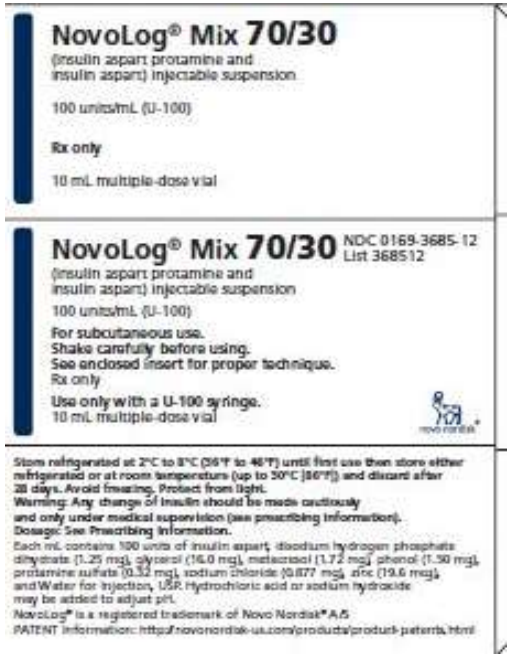
A: The GSID of the substance level will be used for PhPID generation.

Note: UMC works with harmonisation of data, but is not a regulatory agency

GSID for PhPID, Insulins

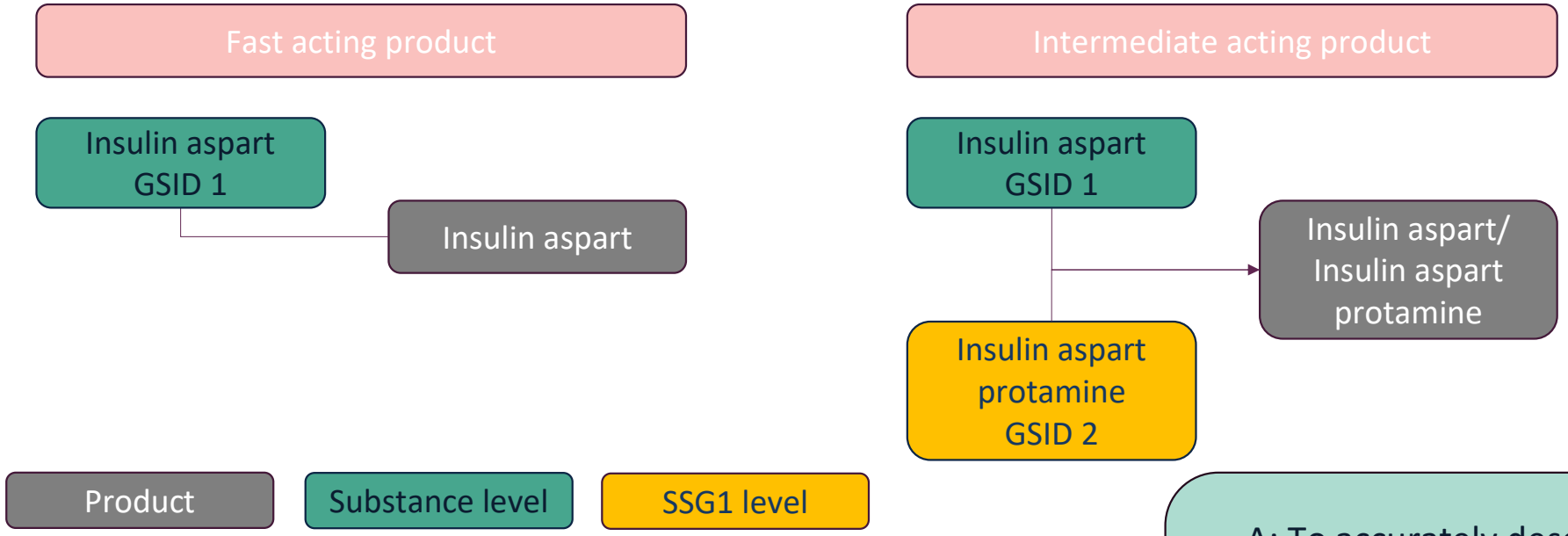
Fast acting product

Intermediate acting product



Q: How to describe the difference between fast- and intermediate acting insulin products?

GSID for PhPID, Insulins



A: To accurately describe the difference between the two products, the GSID for both Substance level and SSG1 level will for PhPID generation.

Note: UMC works with harmonisation of data, but is not a regulatory agency

GSID for PhPID when products are described differently; Active ingredient variant or active ingredient and excipient, for solids

Q: Is the active ingredient the Substance base and excipient, or the Substance variant?

Substance and excipient

Substance variant

GSID for PhPID when products are described differently; Active ingredient variant or active ingredient and excipient, for solids

Substance and excipient

Substance variant

Q: Is the active ingredient the substance or the substance variant?

Fiche info | Résumé des caractéristiques du produit | Notice

SPEDIFEN 400 mg, film-coated tablet - Summary of product characteristics

ANSM - Updated on: 12/27/2022

1. NAME OF THE MEDICINAL PRODUCT

SPEDIFEN 400 mg, film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen..... 400 mg

For one film-coated tablet.

6. PHARMACEUTICAL DATA

6.1. List of excipients

Arginine, sodium bicarbonate, crospovidone, magnesium stearate.

Coating: hypromellose, sucrose, titanium dioxide (E171), macrogol 4000.

1906

I- IDENTIFICAÇÃO DO MEDICAMENTO

Spidufen®
ibuprofeno arginina

APRESENTAÇÕES
Comprimido revestido 770 mg (equivalente a 400 mg de ibuprofeno e 370 mg de arginina): Embalagens com 6, 10, 90 comprimidos.

USO ORAL
USO ADULTO E PEDIÁTRICO ACIMA DE 12 ANOS

Cada comprimido revestido contém:
ibuprofeno arginina.....770 mg*
Excipientes..... q.s.p 1 comprimido revestido.

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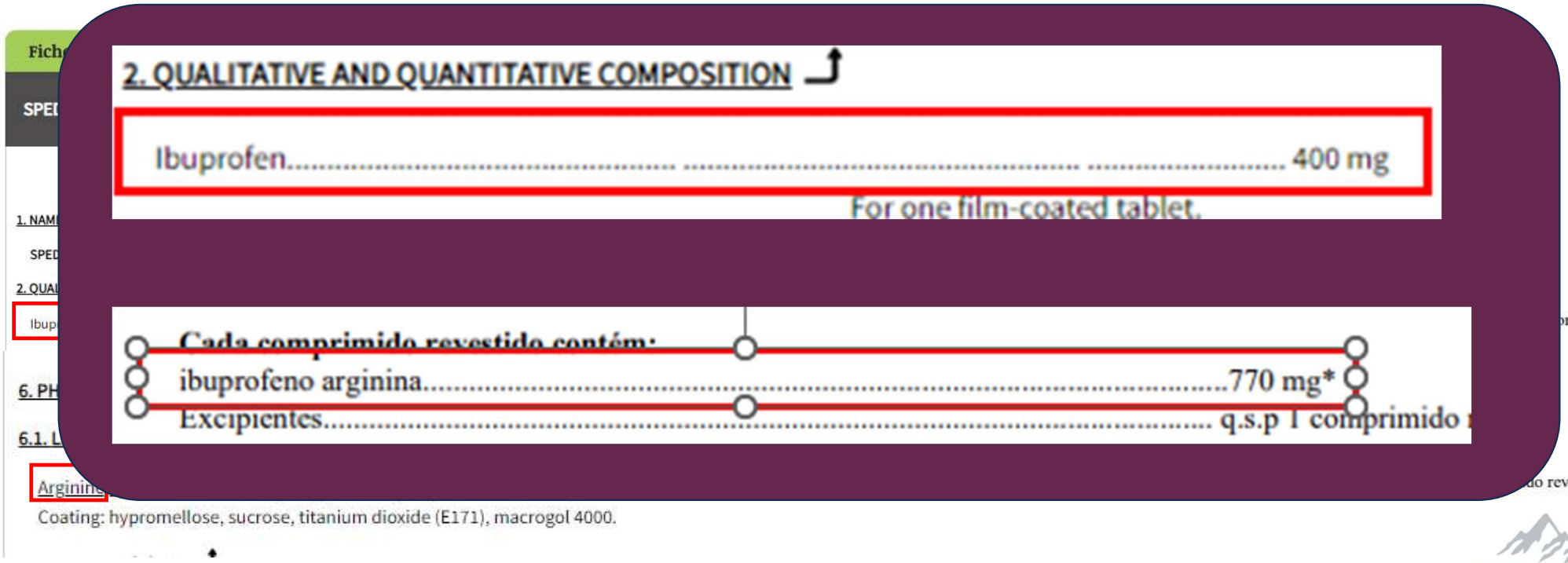
GSID for PhPID when products are described differently;
Active ingredient variant or active ingredient and excipient, for solids

Substance and excipient

Substance variant



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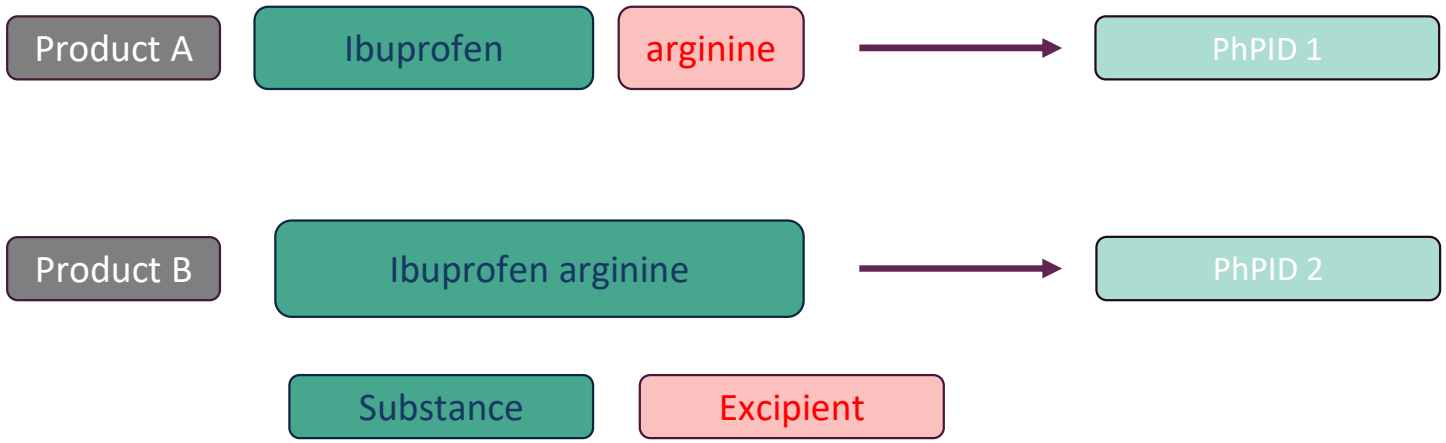
GSID for PhPID when products are described differently; Active ingredient variant or active ingredient and excipient, solid dose forms

If the description of a solid dose form product differs between countries i.e. Product A contains one active ingredient and one excipient, and Product B contains the **substance variant** of the ingredient and the excipient, two PhPIDs, one for Product A and one for Product B will be assigned based on the SmPCs.



A: For solid dose forms UMC follow the SmPC and assign different PhPIDs.

Note: UMC works with harmonisation of data, but is not a regulatory agency

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GSID for PhPID for products combination products

Amoxicillin and clavulanic acid

Q: Should these product be viewed as a Combination product or single active ingredient product?

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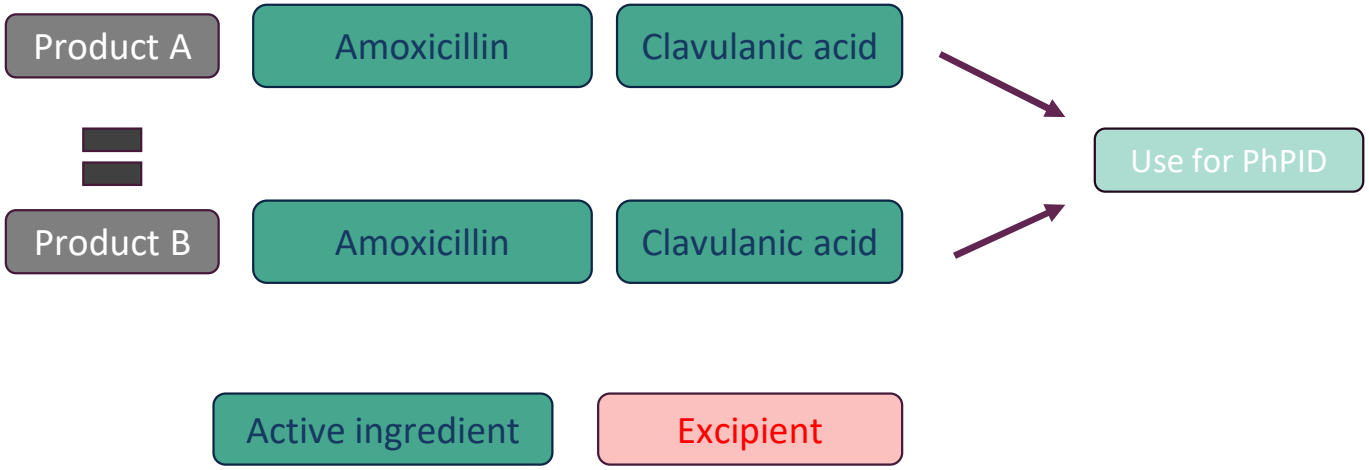
GSID for PhPID for products combination products
Amoxicillin and clavulanic acid

The investigated products have all been described as combination products.



A: These products are described as combination products and will be assigned the same PhPID.

Note: UMC works with harmonisation of data, but is not a regulatory agency

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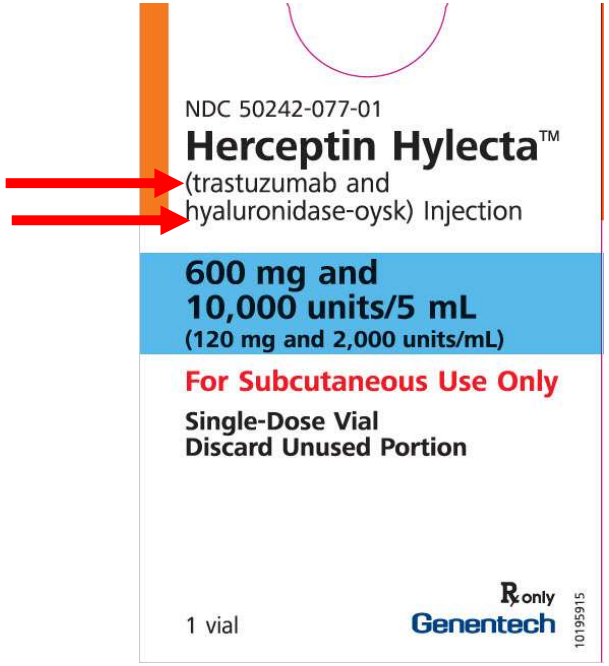
GSID for PhPID when products are described differently; Two active ingredients or one active ingredient and one excipient, injectable

Two active ingredients



One active ingredient

Q: Should this product be viewed as a Combination product or single active ingredient product? And should the PhPID for these Trade names be harmonized?

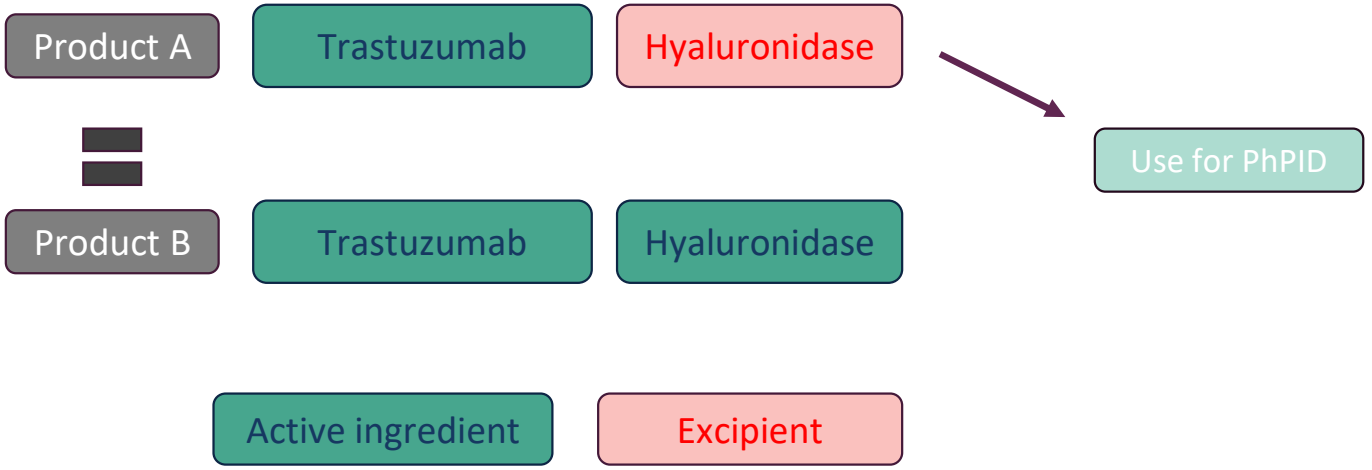
Note: The products are from the same MAH!

GSID for PhPID when products are described differently; Two active ingredients or one active ingredient and one excipient, injectable

Example Trastuzumab subcutaneous injection.		
Product name	Active ingredient	Excipient*
Herceptin hylecta[USA]	Trastuzumab and hyaluronidase-oysk**	NA
Herceptin SC[EMA]	Trastuzumab	Vorhyaluronidase alfa**
Herceptin (SC)[New Zealand]	Trastuzumab	Recombinant human hyaluronidase (rHuPH20)**

Note: UMC works with harmonisation of data, but is not a regulatory agency

GSID for PhPID when products are described differently; Two active ingredients or one active ingredient and one excipient, injectable



A: When regulators don't agree concerning the number of active ingredients the view of the majority of the regulators takes precedents. In this case the PhPID will be harmonized based on one active ingredient.

Note: UMC works with harmonisation of data, but is not a regulatory agency

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GSID now and future perspective

Where are we now?

- Business rules for assigning GSID and use in PhPID developed for:
  - Chemicals
  - Proteins
  - Nucleic acids
  - Polymers
- Structurally diverse
  - Basic hierarchy suggested for Herbals
  - Basic hierarchy suggested for vaccines and preliminary PhPIDs for COVID-19 vaccines
- Business rules proposed for Radiopharmaceuticals
- Limitations due to confidentiality and lack of information

Future perspective

- Explore how to solve the limitations and challenges with GSID assignment and use in PhPID generation
- Structurally diverse
  - Vaccines
  - Herbals
- Radiopharmaceuticals continued
  (in collaboration with GIDWG strength)
- Global harmonization of entering data in the different SRS systems
  - Guides, controlled vocabulary etc.
- Exchange of substance data between stakeholders

GIDWG
Global Dose Form ID Project

Julia Nyman

3d Global IDMP Working Group (GIDWG) Stakeholders Meeting
October 16, 2023

Outline

- Background
- GIDWG Dose Form Identifier project
  - Project Overview
  - Validation Process
  - Business Rules and examples
- Limitations
- Q&A

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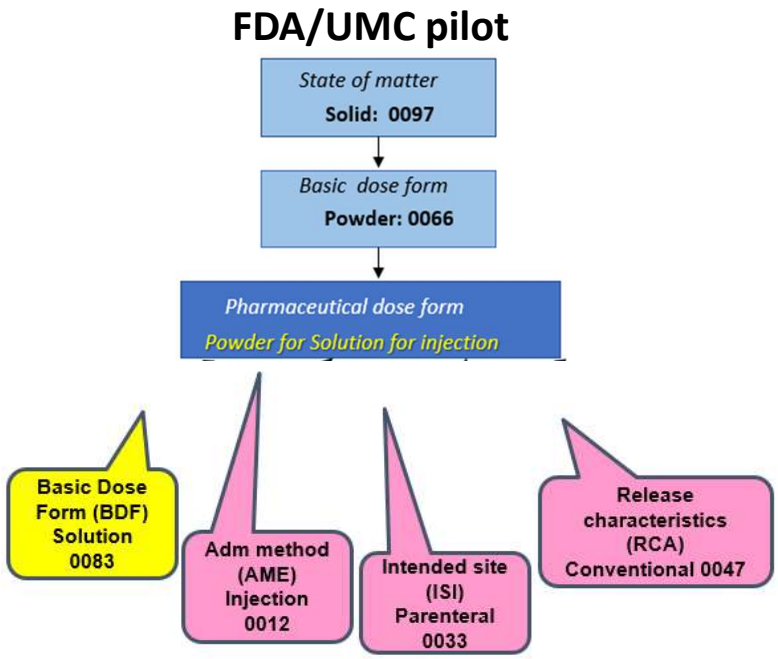
Background

Findings from dose form pilots

- A centrally-maintained dose form terminology for global IDMP is not available.
- Regulatory authorities can continue to use their regional dose form terminology
- Centrally maintained set of dose form characteristics is viable solution for global IDMP
- Cases when dose forms are expressed differently within different jurisdictions
- Cases where certain dose form characteristics have multiple values
- Cases when the medicinal product dose form description is twofold in SmPC



edqm European Directorate for the Quality of Medicines & HealthCare

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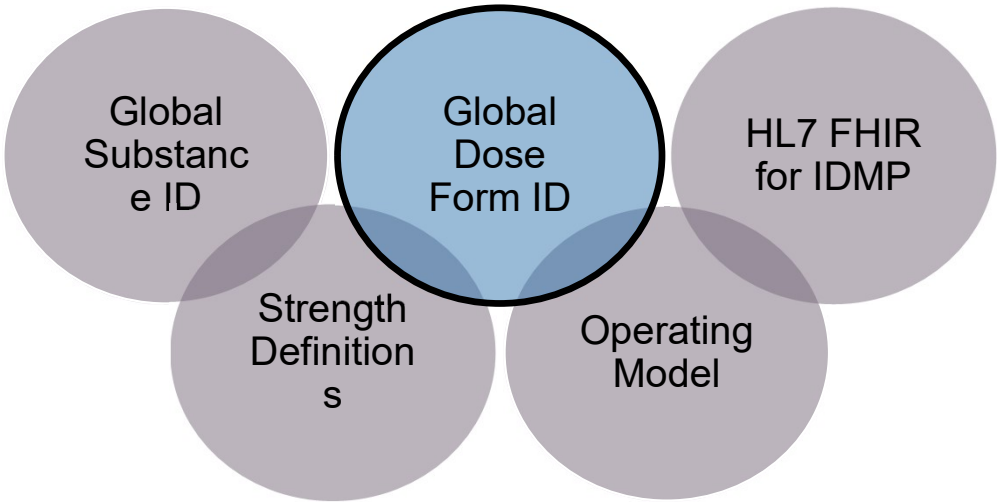
GIDWG Dose Form Identifier project

Project Scope and Deliverables

- Further investigate 4 dose form characteristic approach on larger datasets for at least one another region
- Assert the scalability and automation of the process
- Develop and Formalize Business Rules



www.gidwg.org

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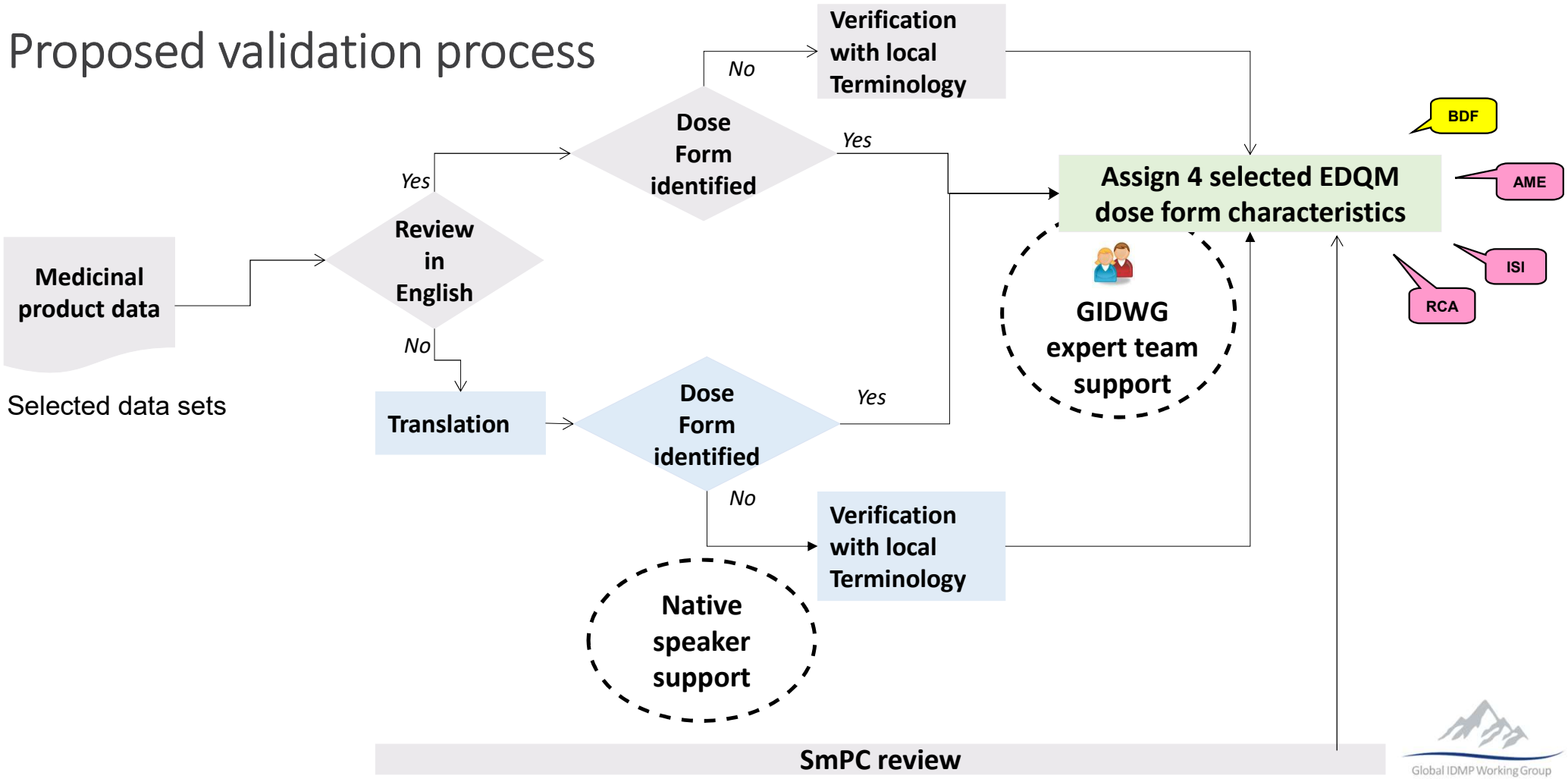
GIDWG Dose Form Identifier project

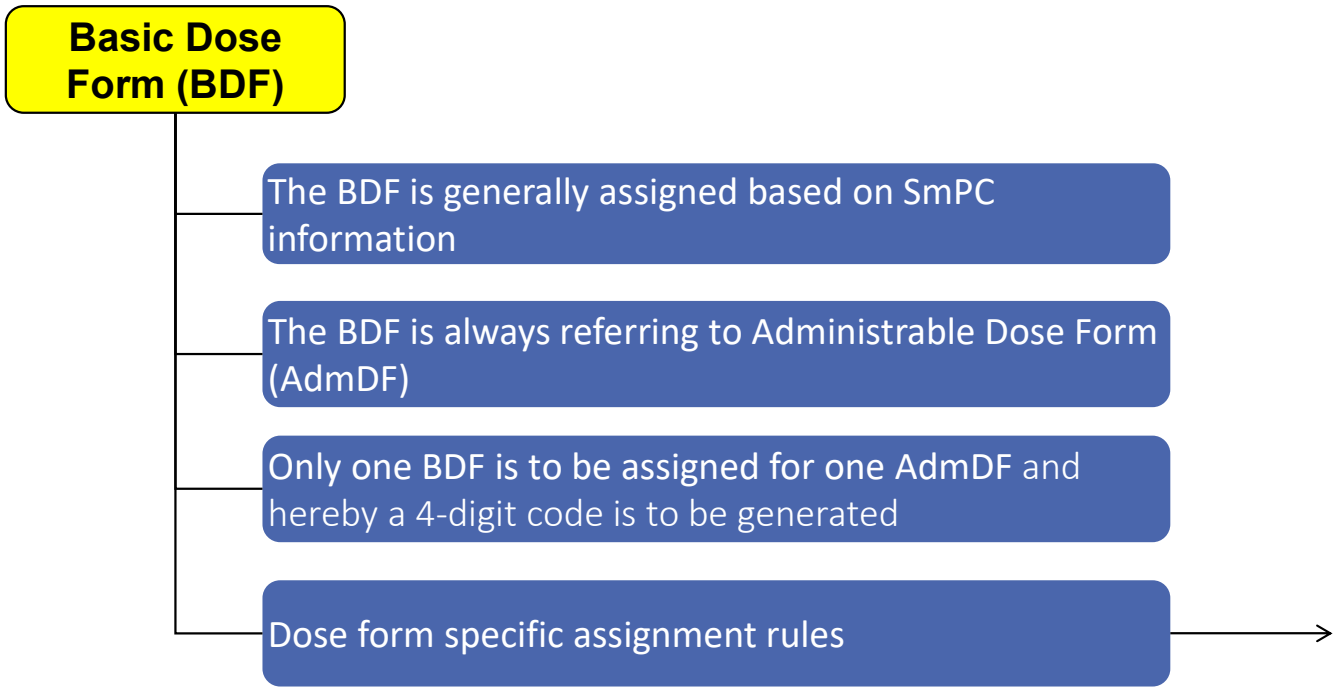
Proposed validation process



GIDWG Dose Form Identifier project

High-level Business Rules

Basic Dose Form (BDF)



e.g.

BR: Where a medicinal product is described as 'Syrup', the term 'Solution' or 'Suspension' will be assigned. The basic dose "syrup" should never be used since syrup is either a solution or a suspension

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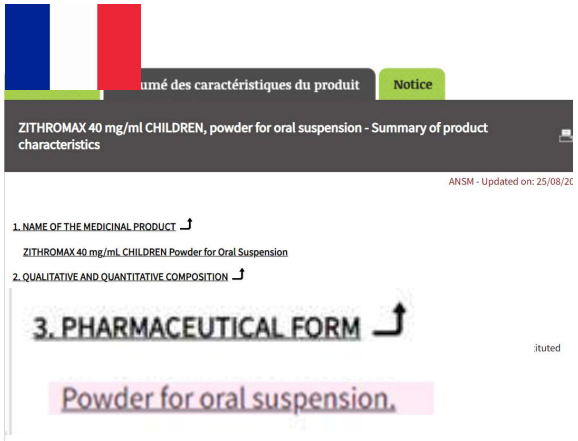
GIDWG Dose Form Identifier project

Basic Dose Form (BDF)

Challenges

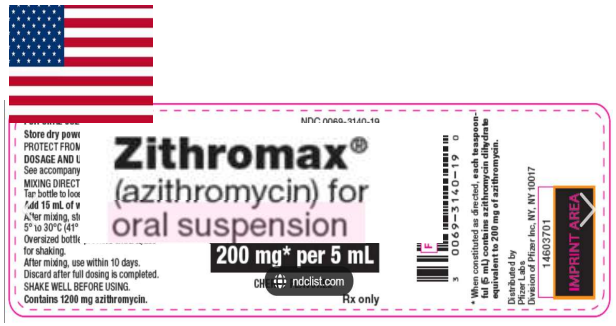
French SmPC indicates
´powder for oral suspension´
Korean SmPC - ´Dry Syrup´
USA SmPC - ´For suspension´

Different dose forms depending on the Manufactured and Administrable item



Korean product name	Jithromax®Dry Syrup
English product name	Zithromax®
Korean ingredient name	azithromycin hydrate
English ingredient name	Azithromycin Hydrate
Efficacy classification	Antifungals/antibiotics

Zithromax® 지스로맥스®건조시럽 | 한국화이자 | 한국화이자



www.accessdata.**fda**.gov/drugsatfda docs/label

ZITHROMAX for oral suspension is supplied in bottles containing azithromycin dihydrate powder equivalent to 300 mg, 600 mg, 900 mg, or 1200 mg azithromycin per bottle and the

Summary of Product Characteristics - ZITHROMAX 40 mg/mL CHILDREN Powder for Oral Suspension - Public Drug Database (medicaments.gouv.fr)

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GIDWG Dose Form Identifier project

Basic Dose Form (BDF)

Harmonization

Medicinal Product	Country	SmPC Dose form	SmPC ManBDF	SmPC AdmBDF	Harmonized BDF
Zithromax® 200mg/5mL (azithromycin)	France	Powder for Oral Suspension	Powder	Suspension	Suspension
	USA	For oral suspension	Powder	Suspension	
	Korea	드라이 시럽 Dry syrup	Powder	Syrup	

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GIDWG Dose Form Identifier project

Administration Method (AME)

High-level Business Rules

Administration Method (AME)

- AME is generally assigned based on SmPC information.
- AME is generally assigned based on primary use.
- One AME or multiple AMEs can be assigned to a medicinal product. When multiple AMEs can be assigned, multiple-value code is generated per AME.
- Dose form specific assignment rules

e.g. *BR: Where a medicinal product can be administered as 'Injection' and/or 'Infusion', only AME 'Injection' is assigned*

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Administration Method (AME)

Challenges

USA label says ´For injection´
In Norway ´Infusion´ only.
In Brazil ´Injectable solution´ and ´Intravenous infusion´

We review Brazilian SmPC with our Portuguese speaking colleagues

LABEL (fda.gov)

Herceptin

Roche (Roche Norway AS)

Herceptin «Roche» - Felleskatalogen

POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION 150 mg: *Each via*
trastuzumab ***150 mg***, L-histidine hydrochloride, L-histidine, α,α-trehalose dihyd
Without preservative.

Herceptin®

(trastuzumabe)

Lyophilized Powder for Injectable Solution

Produtos Roche Químicos e Farmacêuticos S.A.
Pó liofilizado para solução injetável
150 mg

INTRAVENOUS INFUSION
ADULT USE
COMPOSITION
Active ingredient: each single-dose vial contains 150 mg of trastuzumab lyophilized powder for solution injectable for intravenous infusion. Reconstituted Herceptin concentrate contains 21 mg/mL trastuzumab.

Herceptin - Bula de Profissionais de Saúde (dialogoroche.com.br)

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GIDWG Dose Form Identifier project

Administration Method (AME)

Harmonization

Medicinal Product	Country	Dose form (SmPC)	Administration method according to SmPC	Harmonized AME
Herceptin (Trastuzumabe)	Brazil	Lyophilized Powder for Injectable Solution	Injection	Injection
Herceptin (Trastuzumab)	Norway	Powder for concentrate for solution for infusion	Infusion	
Trazimera for injection (Trastuzuma-gyyp)	USA	For injection (lyophilized powder)	Injection	

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GIDWG Dose Form Identifier project

Intended site (ISI)

High-level Business Rules

Intended site (ISI)

- ISI is often indicated in SmPC.
- One ISI or multiple ISIs can be assigned to a medicinal product. When multiple ISIs can be assigned, multiple-value code is generated per ISI.
- Where a medicinal product can be used in more than one way, the focus should be on what is considered to be the **primary use** or the term with **the strictest microbiological requirements**
- Dose form specific assignment rules

e.g. *Gel, ointments, and creams for cutaneous use that also can be used rectally, oromucosal and other sites are assigned ISI 'Cutaneous'*

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GIDWG Dose Form Identifier project

Intended site (ISI)

Challenges

What is primary use? Nasal, oromucosal, dental? Pulmonary? Vaginal and/or Cutaneous?

Primary use is not specified. However, obstetrics is associated with skin damage, referring to strictest microbiological requirements

Xylocaine®

Aspen Nordic

Cutaneous spray, solution 100 mg/ml

(Clear to almost clear, slightly pinkish or yellow liquid with the smell of ethanol and menthol and banana flavor.)

4.1 Therapeutic indications

Surface anesthesia on mucous membranes

- *Odontology:* Surface anesthetics, for example, before injections during injection anaesthesia.
- *Oto-rhino-laryngology:* Surface anesthesia for maxillary sinus puncture and for procedures in the nose, pharynx and epipharynx
- *Obstetrics:* During childbirth, in the final stages and when suturing birth injuries
- *Closure of instruments, tubes and catheters in the respiratory tract and gastrointestinal tract*

https://www.fass.se/LIF/product?userType=0&nplId=19901126000029

4. Clinical particulars

4.1 Therapeutic indications

General

This product is **non-sterile** and therefore not recommended for use prior to procedures that require aseptic techniques.

For the prevention of pain associated with the following procedures:

Otorhinolaryngology

Anaesthesia prior to minor non-invasive procedures in the nasal cavity, pharynx and epipharynx including rhinoscopy and laryngoscopy.

Obstetrics

As supplementary pain control for procedures not requiring aseptic technique.

Insertion of instruments and catheters into the respiratory and digestive tract

Provides surface anaesthesia for the oropharyngeal and tracheal areas to reduce reflex activity, attenuate haemodynamic response and to facilitate insertion of the catheter or the passage of instruments during endotracheal intubation, laryngoscopy, bronchoscopy, oesophagoscopy and gastroscopy.

Dental practice

Before minor dental procedures where local anaesthesia is desired.

https://www.medicines.org.uk/emc/product/882/smpc/print

INFORMAÇÕES AO PROFISSIONAL DA SAÚDE

1. INDICAÇÕES

A lidocaína 10% é indicado como anestésico tópico na prev

Otorrinolaringologia

- Punções dos seios maxilares

-Anestesia da orofaringe para prevenir náuseas e vômitos d

Obstetrícia

Durante o estágio final do parto e antes da episiotomia e sut

Odontologia

Antes de injeções, impressões dentárias, radiografias, remo

https://consultas.anvisa.gov.br/#/bulario/q/?numeroRegistro=113430175

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Intended site (ISI)

Harmonization

Medicinal Product	Country	ISI in SmPC	Possible EDQM ISI	Harmonized ISI
Xylocain Cutaneous spray 100 mg/mL (lidokain)	Sweden	• Odontology • Oto-rhino-Laryngology • **Obstetrics** • Closure of instruments, tubes and catheters in the respiratory tract and gastrointestinal tract	• Nasal • Oromucosal (also reflects laryngopharyngeal use) • Dental • Pulmonary • Vaginal and/or **Cutaneous**	Cutaneous
Xylocaine 10mg Spray (Lidocaine)	UK	• Otorhinolaryngology • Dental practice • **Obstetrics** • Insertion of instruments and catheters into the respiratory and digestive tract	• Nasal • Oromucosal (also reflects laryngopharyngeal use) • Dental • Pulmonary • Vaginal and/or **Cutaneous**	
Lidocaína 10% (Lidocaine)	Brazil	• Odontology • Oto-rhino-Laryngology • **Obstetrics**	• Nasal • Oromucosal (also reflects laryngopharyngeal use) • Dental • Vaginal and/or **Cutaneous**	

GIDWG Dose Form Identifier project

Release characteristics (RCA)

High-level Business Rules

RCA is to be assigned based on the following principles:

Release characteristics (RCA)

- RCA is often indicated in SmPC.
- RCA is sometimes included in the product name or dose form. In some cases, the information can be found in different sections in the SmPC, e.g., pharmacokinetics. When no information about prolonged/modified/delayed release is found in the label, the 'Conventional' term is assigned.
- Dose form specific assignment rules

e.g. *BR: If more than one RCA applies to 'oral capsules' and 'tablets', only one RCA shall be assigned*

GIDWG Dose Form Identifier project

Release characteristics (RCA)

Challenges RCA

Both SmPCs indicate DUAL DELAYED release technology. Irish SmPC describes dose form as modified-release capsule

We examine carefully pharmacokinetics

Gladexa in Ireland
The formulation of Gladexa utilising **dual delayed release** technology results in a dexlansoprazole plasma concentration-time profile with two distinct peaks; the first peak occurs 1 to 2 hours after administration, followed by a second peak within 4 to 5 hours

Dexilant in US
The **dual delayed release** formulation of DEXILANT results in a dexlansoprazole plasma concentration-time profile with two distinct peaks; the first peak occurs 1 to 2 hours after administration, followed by a second peak within 4 to 5 hours

3 PHARMACEUTICAL FORM

Modified-release capsule, hard

License (hpra.ie)

DOSAGE FORMS AND STRENGTHS

- Delayed-Release Capsules: 30 mg and 60 mg. (3)

DEXILANT (dexlansoprazole) Label (fda.gov)

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Release characteristics (RCA)

Harmonization

Medicinal Product	Country	RCA in SmPC	EDQM RCA	Harmonized RCA
Gladexa (Dexlansoprazole)	Ireland	Modified-release capsules	Modified	Delayed
Dexilant (Dexlansoprazole)	USA	Delayed-release capsules	Delayed	

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Limitations

- Automation of the whole assignment process
- Risk of inconsistencies

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Q&A

Global IDMP Working Group

GIDWG
Global Strength Definitions
ID Project

Norman Schmuff

3d Global IDMP Working Group (GIDWG) Stakeholders Meeting
October 16, 2023

Outline

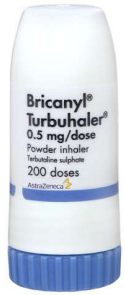
- Background
- GIDWG Strength Definitions project
  - Project Overview
  - Validation Process
  - Business Rules and examples
- Limitations
- Q&A

Global IDMP Working Group

Background

Identified challenges

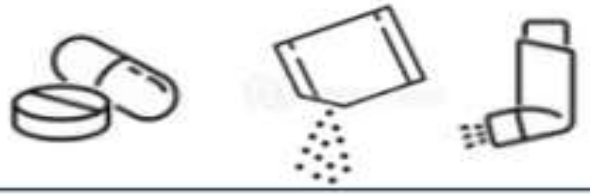
- Presentation strength versus concentration strength application on strength expression
- How to express strength for products requiring dilutions
  - Concentrates which shall be diluted with an unknown amount of
  - Products where different amounts of diluent is to be added, resu one presentation strength and two or more different concentrati strengths
- Variation in use of units for strength expression for similar products
- The given strength may need to be recalculated based the molecular weight



Background

Findings: proposed strength pattern framework

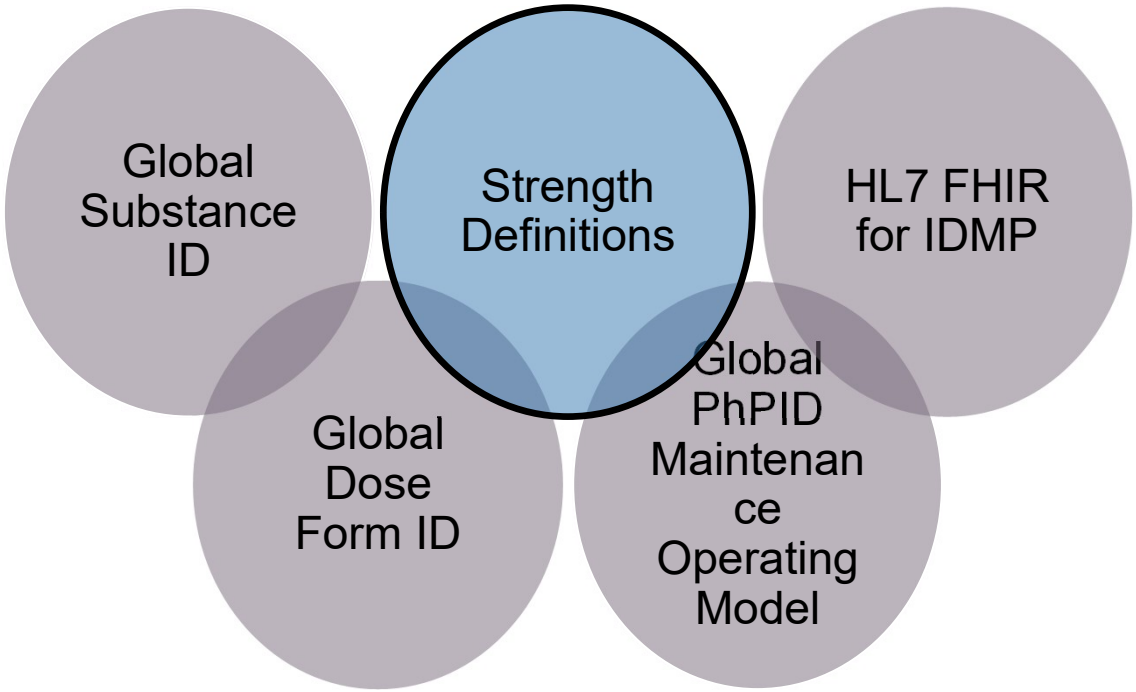
The pattern framework determines how the strength of a Pharmaceutical Product (PhP) should be expressed for a certain type of product, using presentation strength or concentration strength.

Pattern	Type of product
A	
B	
C	

GIDWG Global Strength Definitions ID project

Project Scope and Deliverables

- Identify and address different representation of strength for products in different regions
- Clarify the use of presentation strength and concentration strength
- Explore the Pattern Framework further to ensure prioritized dose forms in EDQM and additional product data set are covered
- Assert the scalability and automation of the process
- Formalize Business Rules for each pattern and investigated dose forms



SME from EMA, US-FDA, Swissmedic, Health Canada, ANVISA, PMDA, WHO-UMC, WHO, EDQM, INN, USP

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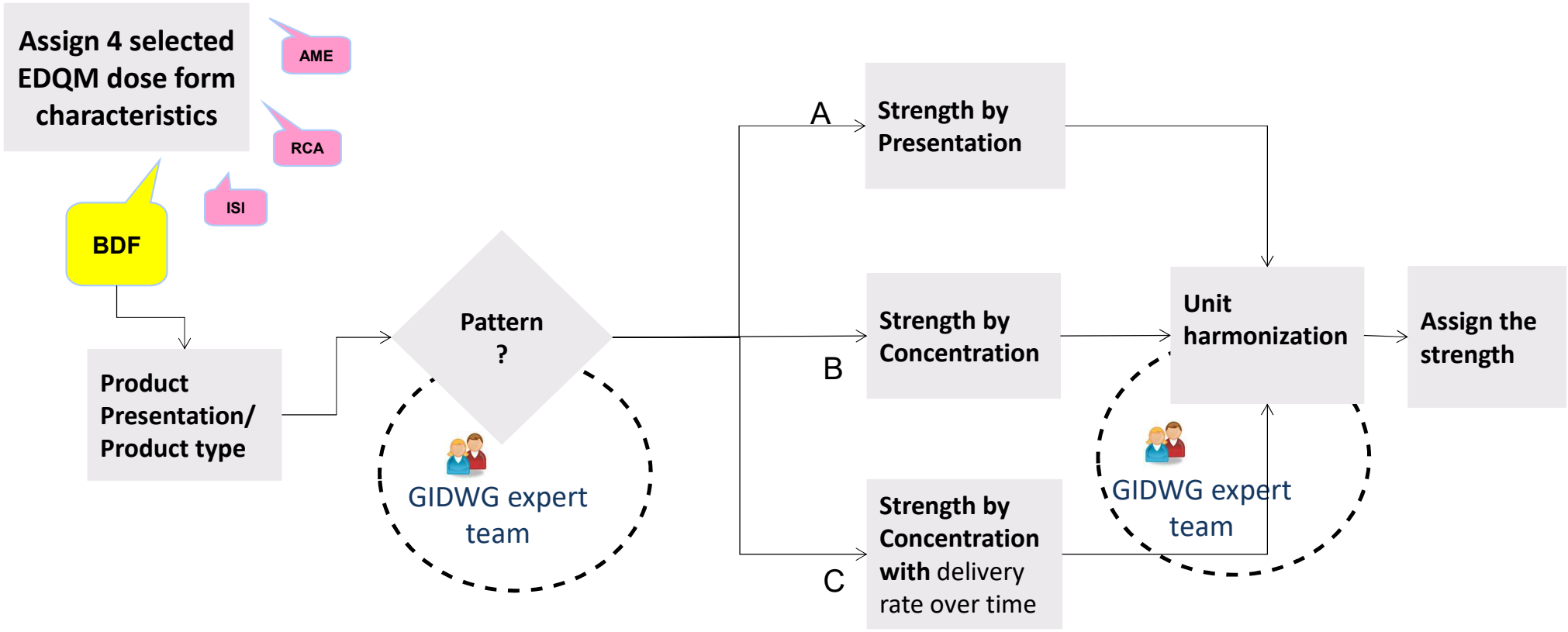
GIDWG Global Strength Definitions ID project

Proposed validation process



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Business Rules Overview - numerical values

Value	Business Rule applied
Reference Strength	No longer is part of PhPID generation
Value range	Strength should be expressed in the value range of 1-999 with two decimals: O,1 g or 100 mg, select 100 mg 1000 mg or 1 g, select 1 g Per day, a number of hours are selected (e.g., 24h).
Value number	The value number should always be 1. e.g., mg/mL. If the strength is given as 100 mg/ 5 mL it should be converted to 20 mg/ 1 mL
Liquid preparations (e.g., Cutaneous solution)	The value number should always be mg/mL if pattern B (even if SmPC gives mg/g).
Semi-solid preparations (cream, gel, foam, ointment, paste)	Value number should always be mg/g if pattern B (even if SmPC gives mg/mL).

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Business Rules Overview - units

Unit given in SmPC	Business Rule applied	Harmonized Examples
IU, U, units	When the strength is given in 'IU' ('UI', 'I.U.'), 'u' ('U') or 'units' the strength to be expressed is in 'IU'.	Oxytocin 20 **IU**/mL Calcitonin-Salmon 200 **IU** Insulins **IU**/mL
%	When the strength is given in '%', the harmonized strength is expressed in 'mg/mL' or 'mg/g'	Diclofenac sodium 1.5 % to 16.02 mg /ml
mg/g or mg/mL	When a strength is given as 'mg/g' or 'mg/mL' express according to dose form, eg mg/ml for solutions and mg/g for cream	Diclofenac sodium solution 16.02 mg /ml Hydrocortisone cream 10 mg/g
Unit variations for biosimilars, heparins and insulins	Unit variations is expressed in 'IU'.	Insulin lispro Sanofi® 100 Units/mL will be assigned as 100 UI/mL
Hormones	Hormones shall be either expressed as 'mg' or 'IU'.	Glucagon: mg Calcitonin: IU Oxytocin: IU

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Business Rules Overview: Pattern A

Pattern	Type of product	Product Presentation
A (Mandatory: Presentation Strength)	• Solid, countable • Solid dose forms in "container" • Portion soluble • Metered dose delivered by a metered actuation (dose cannot be adjusted)	example • Tablet, film-coated • Suppository • Gum • Implants • Intrauterine formulations (also known as intrauterine delivery system)
	• Single dose liquid and concentrate (in cases of 'total' use) • Powder for injections (total, partial and multi-dose) • When the powder is transformed into concentrate the pattern is based on powder, not concentrate.	e.g. Container (vial, syringes, nebules, etc.) • Nebulizer • Pre-filled syringes
	• Transdermal gel (unit and metered-doses)	• Testogel® unit dose

GIDWG Global Strength Definitions ID project

Example: Pattern A - Solid, countable

Phenergan®
(promethazine HCl)
Tablets and Suppositories

℞ only

DESCRIPTION

Each rectal suppository of Phenergan contains 12.5 mg, 25 mg, or 50 mg promethazine HCl with ascorbyl palmitate, silicon dioxide, white wax, and cocoa butter. Phenergan Suppositories are for rectal administration only.

Medicinal Product	SmPC Dose form	Harmonized BDF	SmPC Strength	Strength
Phenegran (promethazine HCl)	suppository	suppository	25 mg	25 mg

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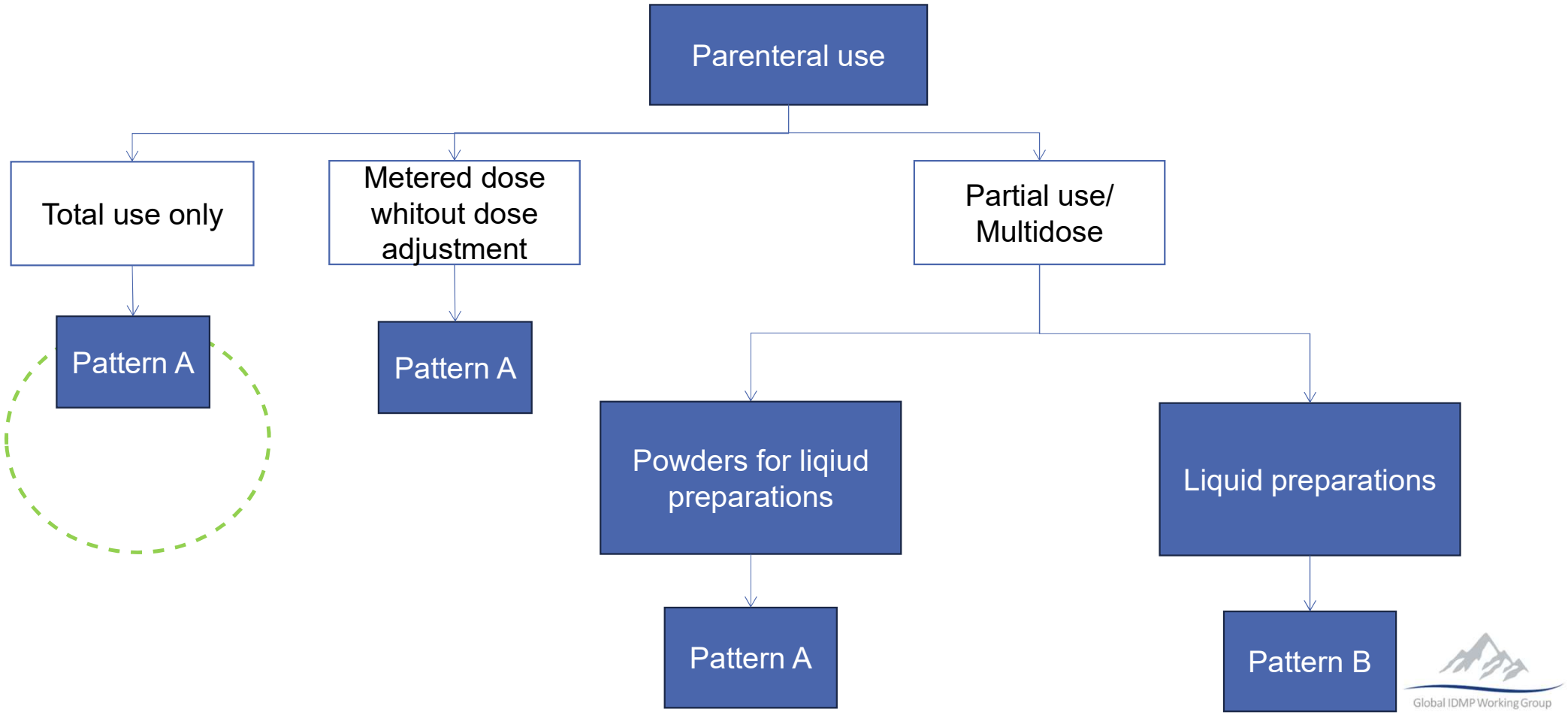
GIDWG Global Strength Definitions ID project

Business Rules Overview: parenteral products



Example: Pattern A - Single dose liquid and concentrate

----------DOSAGE FORMS AND STRENGTHS----------

100 mg/mL concentration (3.1):

- Prefilled syringes: 30 mg/0.3 mL, 40 mg/0.4 mL
- Graduated prefilled syringes: 60 mg/0.6 mL, 80 mg/0.8 mL, 100 mg/1 mL
- Multiple-dose vial: 300 mg/3 mL

150 mg/mL concentration (3.2):

- Graduated prefilled syringes: 120 mg/0.8 mL, 150 mg/1 mL

Medicinal Product	SmPC Dose form	Harmonized BDF	SmPC Strength	Harmonised strength
Lovenox (enoxaparin sodium)	Prefilled syringe	Solution	40mg/0.4 mL	**40 mg**

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Business Rules Overview: Pattern B

Pattern	Type of product	Product Presentation
B **(Mandatory: Concentration Strength)**	A single dose (partial use) and multi-dose of continuous presentation	Examples: • parenteral liquid and concentrate • oral powder multi-dose • bulk powders/granules • semi- solids "bulk" liquids (e.g., eye drops), • spray that is not metered-dose • cream • Nebulizer* (solution for nebulization) • Oral solutions* (vials or bottles): Haloperidol 2mg/ml bottle • Oromucosal solutions • Multi-dose vials
	Eye-drops single- and multi-dose	• Eye drops pipettes, vials or bottles: Saflutan 15mcg/mL (pipette or bottle)

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Example: Pattern B - multi-dose of continuous presentation

For topical use

DESCRIPTION

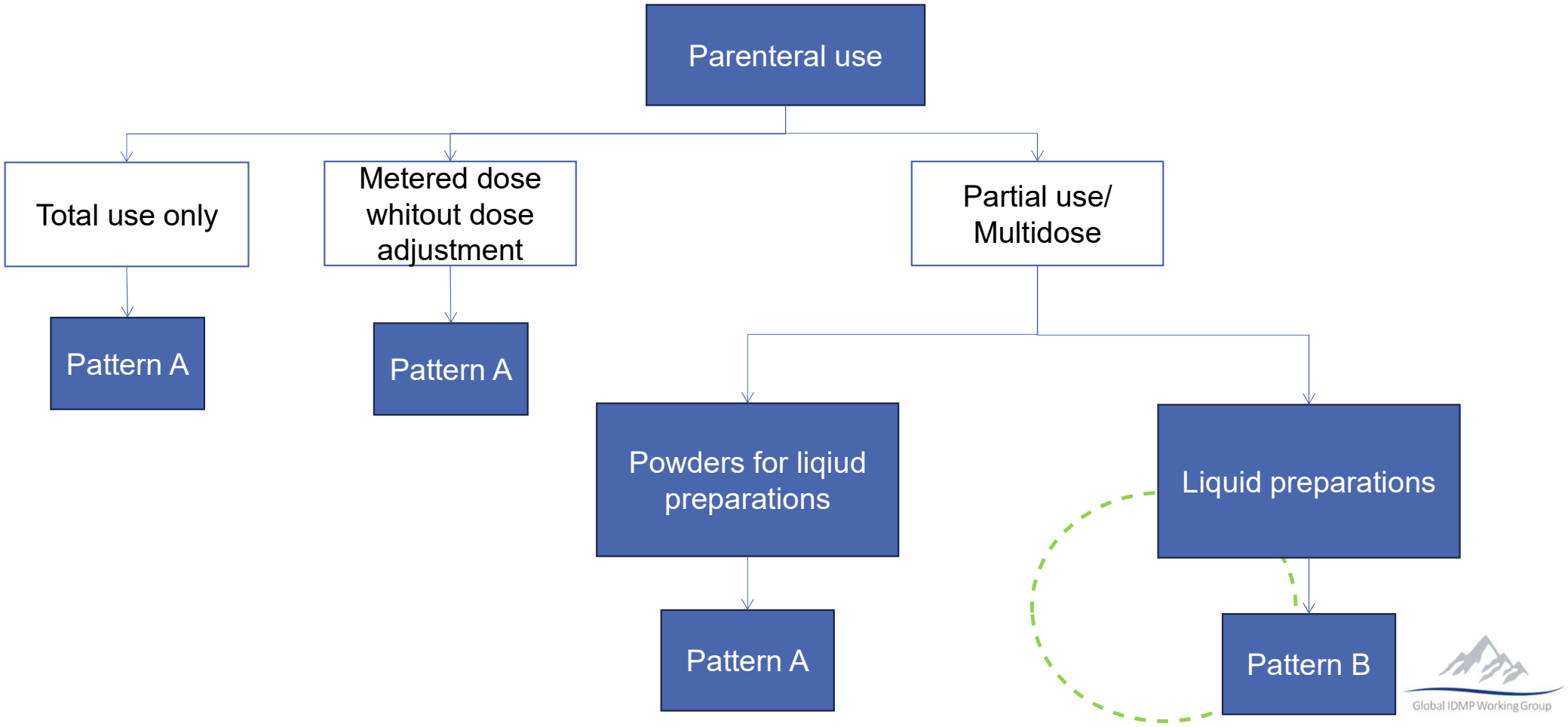
Locoid® (hydrocortisone butyrate) Cream, 0.1% contains the topical corticosteroid, hydrocortisone butyrate, a non-fluorinated hydrocortisone ester. It has the chemical name: 11β,17,21-Trihydroxypregn-4-ene-3,20-dione 17-butyrate; the molecular formula: $C_{25}H_{36}O_6$; the molecular weight: 432.54; and the CAS registry number: 13609-67-1.

Each gram of Locoid® Cream contains 1 mg of hydrocortisone butyrate in a hydrophilic base consisting of cetostearyl alcohol, ceteth-20, mineral oil, white petrolatum, anhydrous citric acid, sodium citrate, propylparaben and butylparaben (preservatives) and purified water.

Medicinal Product	SmPC Dose form	Harmonized BDF	SmPC Strength	Harmonized Strength
Locoid (hydrocortisone butyrate)	Cream	Cream	0,1%	**1mg/g**

GIDWG Global Strength Definitions ID project

Business Rules Overview: parenteral products



Example: Pattern B - single dose (partial use) and multi-dose of continuous presentation (dosing is individual or/ dosing varies depending on other factors)

----------DOSAGE FORMS AND STRENGTHS----------

100 mg/mL concentration (3.1):

- Prefilled syringes: 30 mg/0.3 mL, 40 mg/0.4 mL
- Graduated prefilled syringes: 60 mg/0.6 mL, 80 mg/0.8 mL, 100 mg/1 mL
- Multiple-dose vial: 300 mg/3 mL

150 mg/mL concentration (3.2):

- Graduated prefilled syringes: 120 mg/0.8 mL, 150 mg/1 mL

Medicinal Product	SmPC Dose form	Harmonized BDF	SmPC Strength	Strength
Lovenox (enoxaparin sodium)	Gradually prefilled syringe	solution	60 mg/0.6 mL	10 mg/mL

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GIDWG Global Strength Definitions ID project

Business Rules Overview: Pattern C

Pattern	Type of product	Product Presentation
C **(The strength expression by concentration is mandatory as a delivery rate over time)**	Products enclosed in a "presentation", where the dosing varies depending on other factors (e.g., weight, indication, administration method)	Transdermal patches and vaginal rings: • Fentanyl 25mcg/ 1 hour • Nuvaring® (Etonogestrel 120mcg/24 hour and Ethinylestradiol 15mcg/24 hour)

Global IDMP Working Group

GIDWG Global Strength Definitions ID project

Example: Pattern C - Products enclosed in a "presentation", where the dose dosing varies

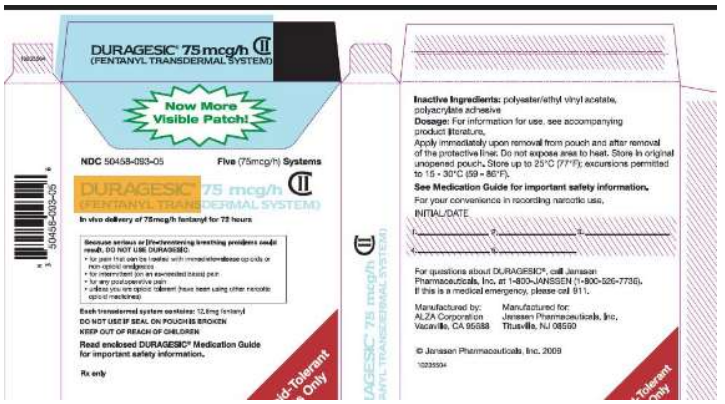
DESCRIPTION

DURAGESIC® (fentanyl transdermal system) is a transdermal system providing continuous systemic delivery of fentanyl, a potent opioid analgesic, for 72 hours. The

System Components and Structure

The amount of fentanyl released from each system per hour is proportional to the surface area (25 mcg/h per 10.5 cm^2). The composition per unit area of all system sizes is identical.

Dose* (mcg/h)	Size (cm^2)	Fentanyl Content (mg)
12**	5.25	2.1
25	10.5	4.2
50	21	8.4
75	31.5	12.6
100	42	16.8



*Nominal delivery rate per hour
**Nominal delivery rate is 12.5 mcg/hr

Global IDMP Working Group

GIDWG Global Strength Definitions ID project

Business Rules Overview: Harmonization

Medicinal Product	SmPC Dose form	Harmonized BDF	Pattern	SmPC Strength	Harmonized Strength
Durogesic (fentanyl)	Transdermal system	Patch	C Strength by presentation	25 mcg/h per 10.5 cm2	12.5mcg/h

Global IDMP Working Group

Example: Pattern C - Products enclosed in a "presentation", where the dose dosing varies

DESCRIPTION

DURAGESIC® (fentanyl transdermal system) is a transdermal system providing continuous systemic delivery of fentanyl, a potent opioid analgesic, for 72 hours. The

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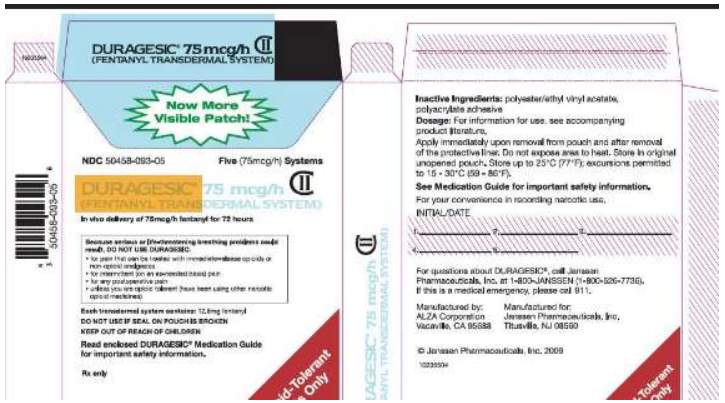
The amount of fentanyl released from each system per hour is proportional to the surface area (25 mcg/h per 10.5 cm^2). The composition per unit area of all system sizes is identical.

Dose* (mcg/h)	Size (cm^2)	Fentanyl Content (mg)
12**	5.25	2.1
25	10.5	4.2
50	21	8.4

*Nominal delivery rate per hour

**Nominal delivery rate is 12.5 mcg/hr



Medicinal Product	SmPC Dose form	Harmonized BDF	SmPC Strength	Harmonized Strength
Durogesic (fentanyl)	Transdermal system	Patch	25 mcg/h per 10.5 cm2	12.5mcg/h

Working Group

Thank you!

Global IDMP Working Group

GIDWG Operating Model

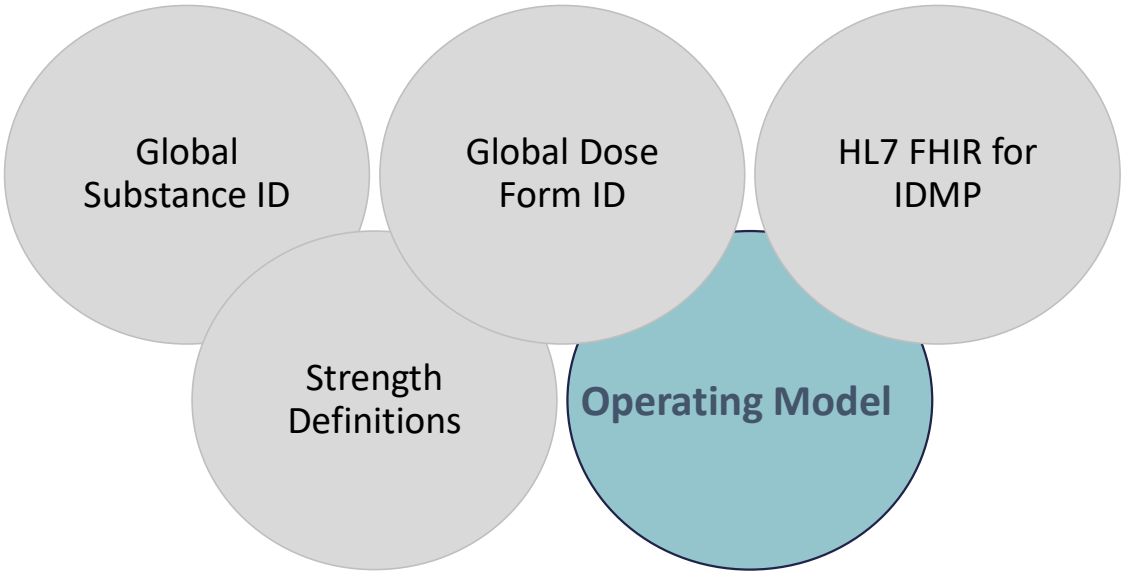
Malin Fladvad
Head of WHODrug Portfolio
Uppsala Monitoring Centre

October 16, 2023

GIDWG Operating Model

Project Scope and Deliverables

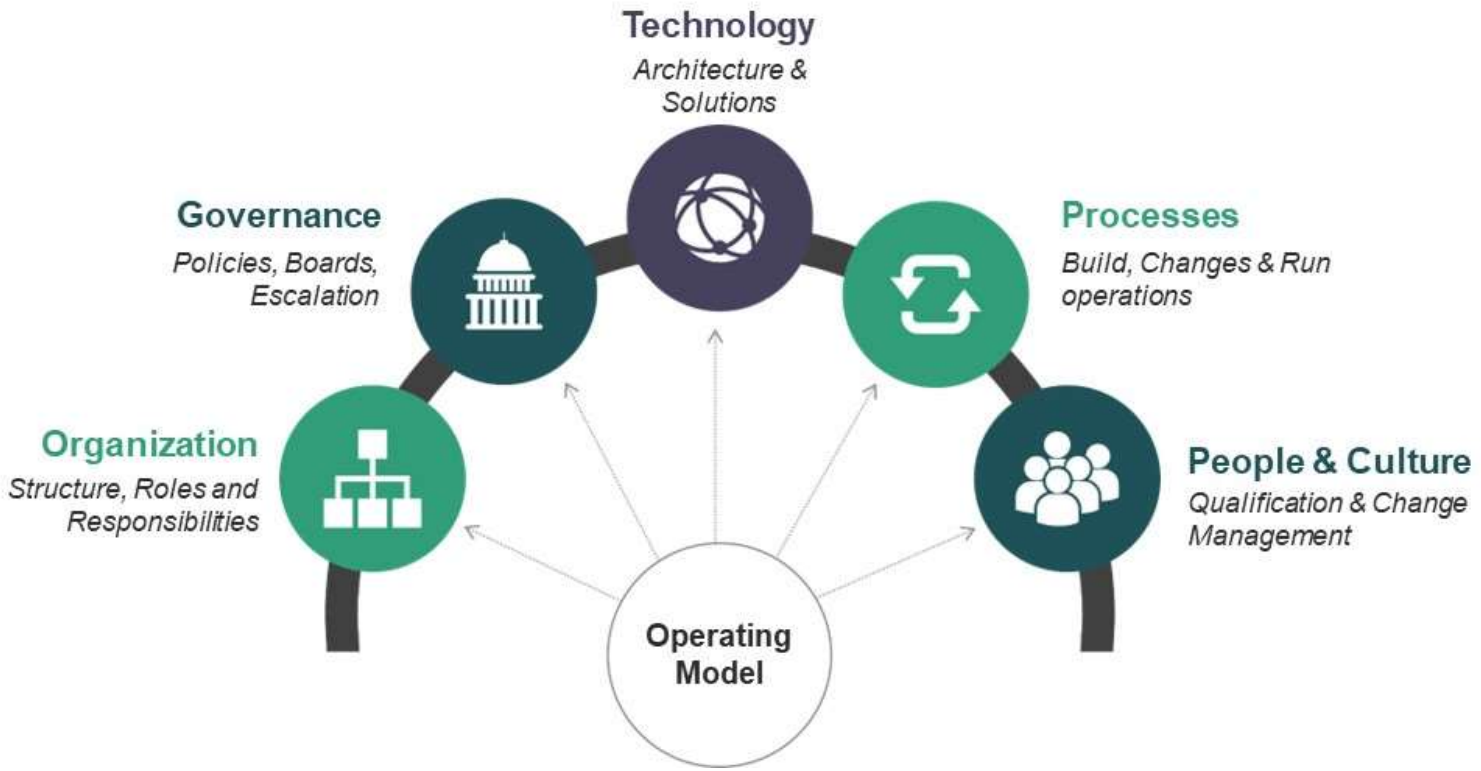
- Definition of the consensus-based operating model(s) for WHO-UMC as the international maintenance organization as an end-to-end pilot:
  - Demonstration of defined operating model(s) for global PhPID on a selection of the following use cases, including product level associations when applicable
    - Pharmacovigilance
    - Drug shortages
    - Drug utilization
    - Cross border prescription
  - Process definition by three jurisdictions (EMA, US-FDA AND ANVISA)



www.gidwg.org

Global IDMP Working Group

Global PhPID Operating Model



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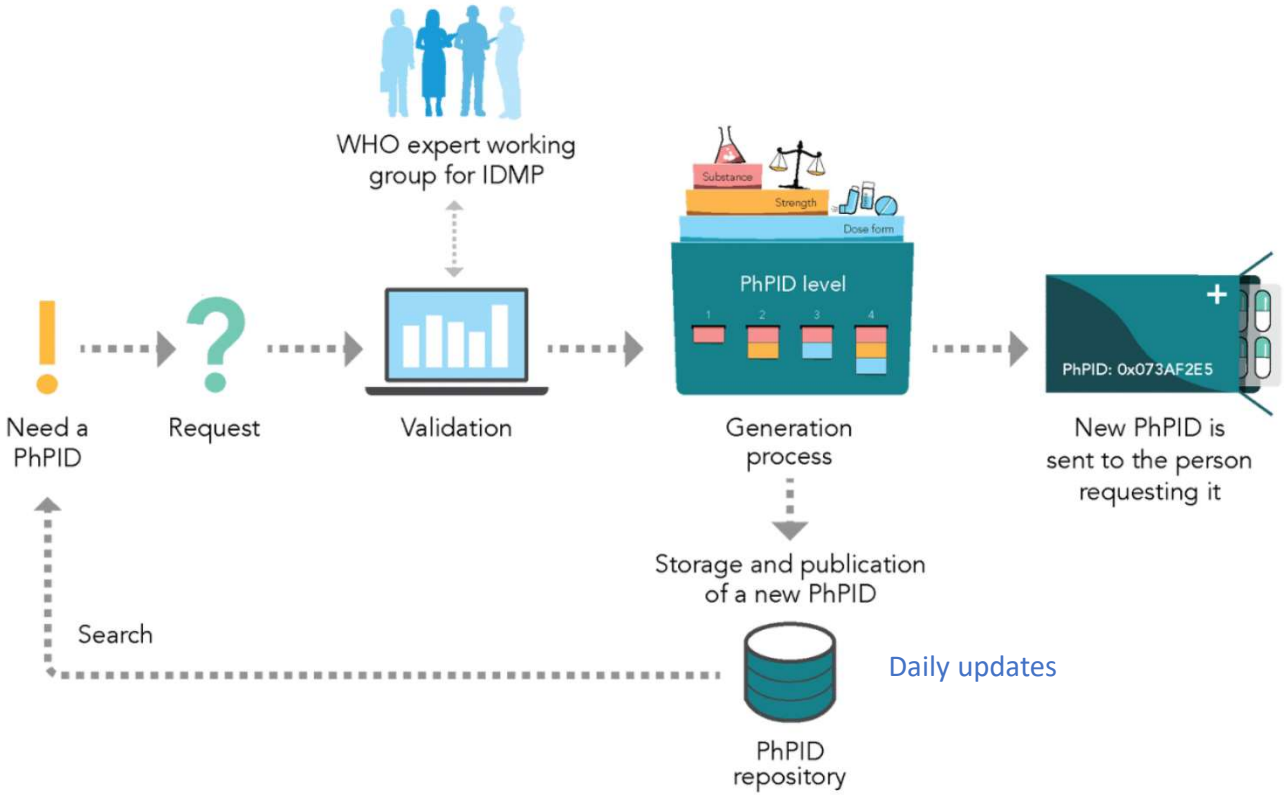
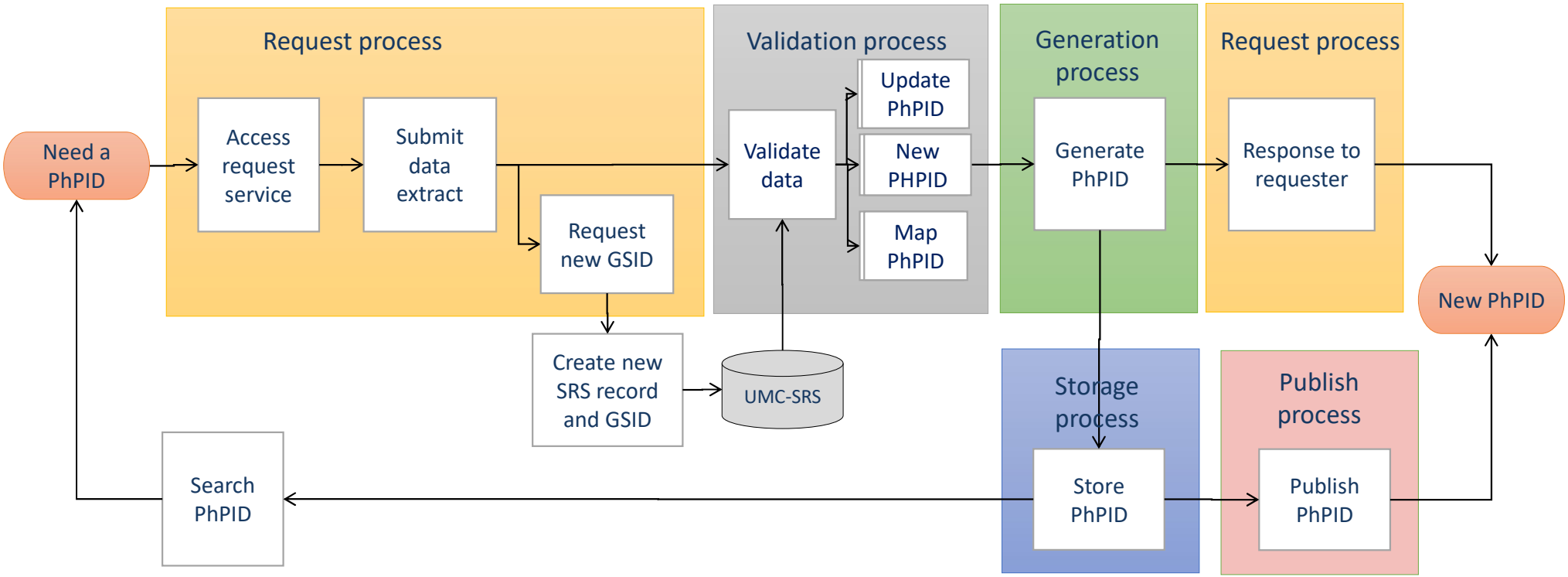
Operating model



PhPID Operating Model including GSID request technology & solutions



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Global PhPID *Request*

Please note that this service is in a development phase and more functionality will be released continuously. Contact IDMP@who-umc.org for any questions.

Welcome to the Global PhPID Request service!

The Pharmaceutical Product Identifier (PhPID) is defined by one of the five ISO standards for Identification of Medicinal Products (IDMP), which aims to increase clarity and efficiency in communications about medicines globally. PhPIDs are created based on the product information for substances, strengths, and dose forms. Some additional information, e.g. country and market authorization holder, are also needed for validation purposes.

In this service you will find two options for requesting PhPIDs for Pharmaceutical Products. Either to complete the form per product via the Single PhPID Request option, or to upload a file with multiple PhPID requests via the PhPID Batch Request option.

You also find an option to request a Global Substance Identifier (GSID). For pharmaceutical products with new substances you need to request a GSID before you can request a PhPID.

Uppsala Monitoring Centre

Global PhPID *Request*

Marilina Castellano - Uppsala Monitoring Centre

Submit PhPID Batch Request

Back to main page

Instructions

- Download the Excel template
- Enter the PhPID Requests according to the template format.
- Choose your file and click Submit.

Choose File | No file chosen

Submit

Global IDMP Working Group

Request
PhPID Batch

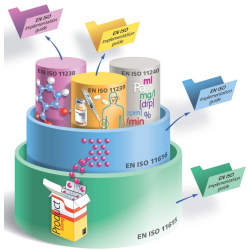
Medicinal Product Name	Country Code	MAH	e-SPC

Dose Form Terminology	Pharmaceutical Dose Form	Unit of Presentation	Route of Administration

Substance 1	Strength Value 1	Strength Unit 1	Reference Substance 1	Reference Strength Value 1	Reference Strength Unit 1

Substance 2	Strength Value 2	Strength Unit 2	Reference Substance 2	Reference Strength Value 2	Reference Strength Unit 2

Substance 3	Strength Value 3	Strength Unit 3	Reference Substance 3	Reference Strength Value 3	Reference Strength Unit 3



Global IDMP Working Group

Business rules for Global PhPID generation input string

General

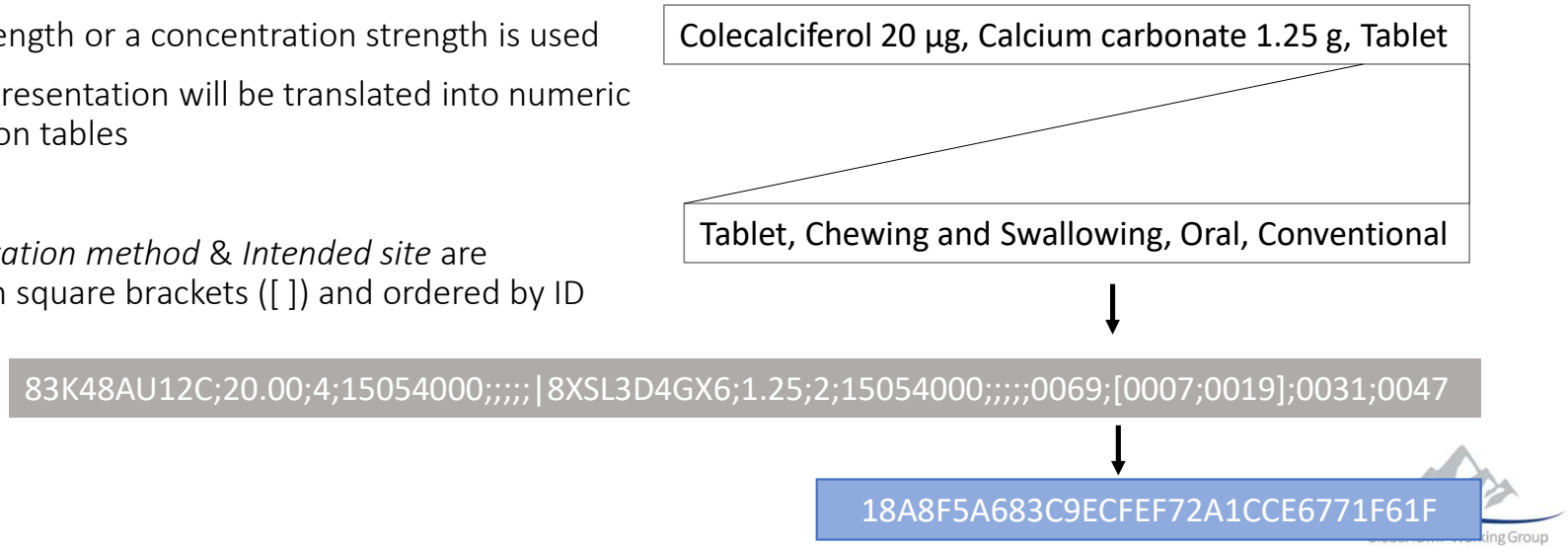
- The identifiers will be separated by a semicolon (;)
- Substances will be separated by a pipe (|) and ordered by GSID

Strength & Units

- Amount is represented with a point (.) and two decimals
- A presentation strength or a concentration strength is used
- Units and unit of presentation will be translated into numeric values by conversion tables

Form

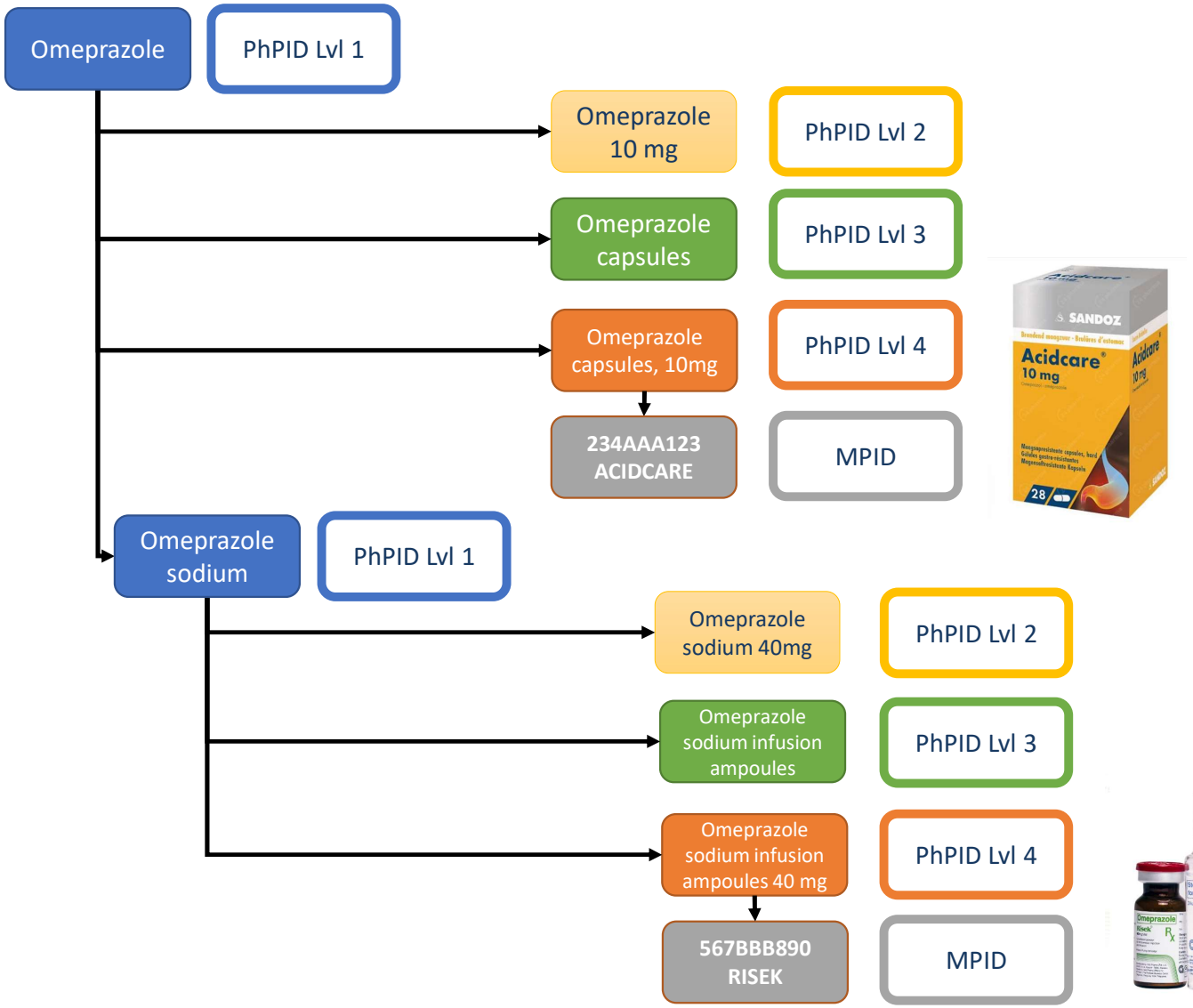
- Multiple *Administration method* & *Intended site* are represented within square brackets ([ ]) and ordered by ID (lowest to highest)



New features in Global PhPID Request

Please note that this application is in a development phase and more functionality will be released continuously. The data and assigned PhPIDs may be subject to change at any time. Please contact IDMP@who-umc.org for any questions.

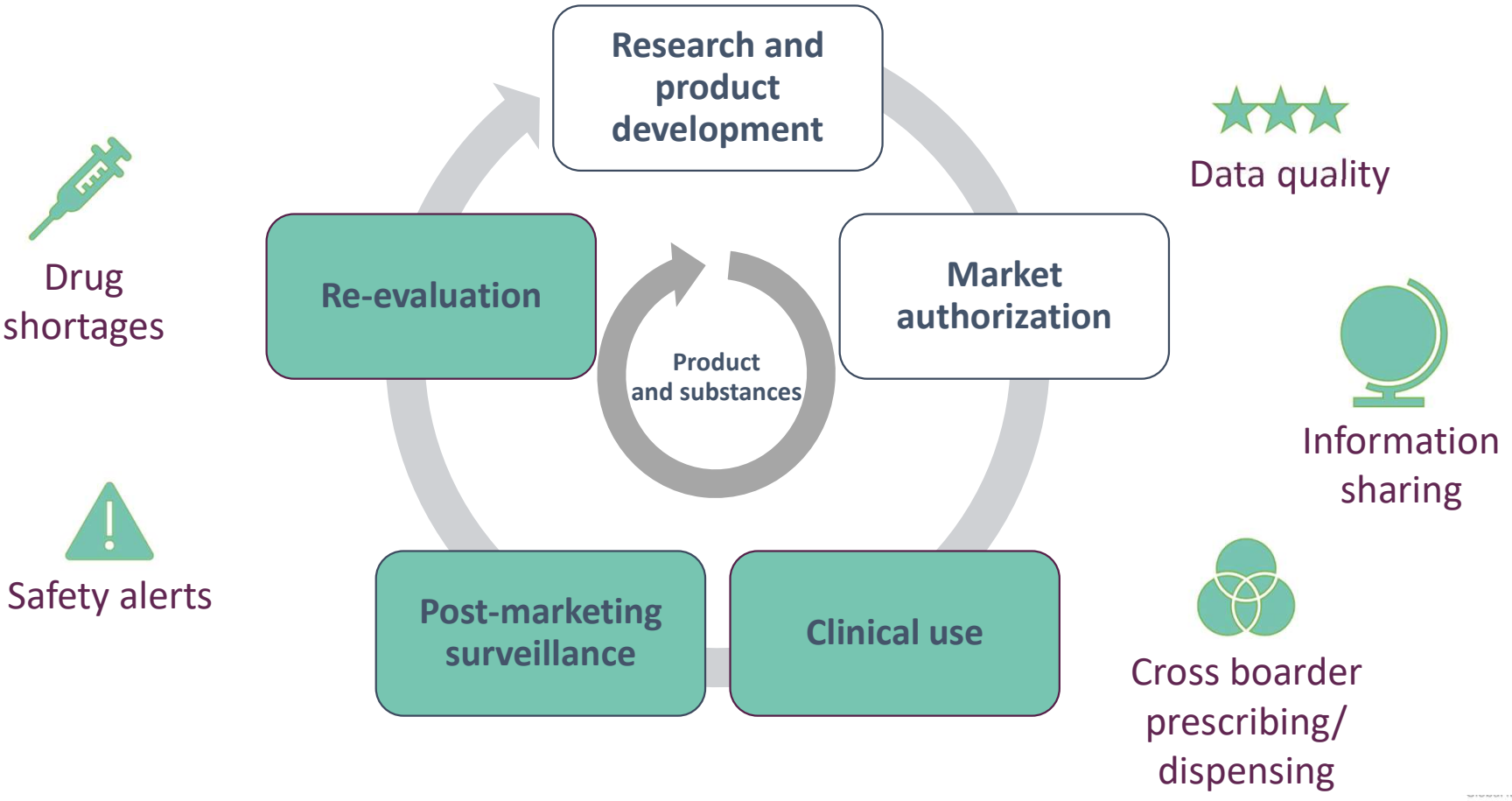
Level	PhPID	GSID	Substance	Strength (Reference Strength)	Basic Dose Form	Administration Method	Intended Site	Release Characteristics
1	B78B712FC26C629344AF2C513DE8E992	GSID-11ZJZ2XD4-U	Amlodipine benzoate					
.2	68CF8B03F8AC9FE6ABF51576BFEA95BE	GSID-11ZJZ2XD4-U	Amlodipine benzoate	1.3 mg/ml (1 mg/ml)				
..3	0E4EE7F1029FB4EF690BD029F7A85CC1	GSID-11ZJZ2XD4-U	Amlodipine benzoate		Suspension	Swallowing	Oral	Conventional
...4	96B0514A1D6F8B361772BDB5D26F39AD	GSID-11ZJZ2XD4-U	Amlodipine benzoate	1.3 mg/ml (1 mg/ml)	Suspension	Swallowing	Oral	Conventional
1	7422765EEE495A837241B2C3620AEF3E	GSID-3YJL6M9Z0-H	Amlodipine besilate					
.2	265D389BFF4C991C7165F8C9BF939DC7	GSID-3YJL6M9Z0-H	Amlodipine besilate	1.39 mg/ml (1 mg/ml)				
.2	4C8AC54E0207ACD9B2994FC3F0E1EB7B	GSID-3YJL6M9Z0-H	Amlodipine besilate	6.93 mg (5 mg) per tablet				
.2	AA39B88AA7D293692BBC235C9F09B5E6	GSID-3YJL6M9Z0-H	Amlodipine besilate	13.87 mg (10 mg) per tablet				
.2	B7769405423433FF1989B348CC143375	GSID-3YJL6M9Z0-H	Amlodipine besilate	3.47 mg (2.5 mg) per tablet				
..3	662A2B95D592B1387A50AB2D9D33465F	GSID-3YJL6M9Z0-H	Amlodipine besilate		Suspension	Swallowing	Oral	Conventional
..3	21E01B86E050659089E8E67A3C6E1363	GSID-3YJL6M9Z0-H	Amlodipine besilate		Tablet	Swallowing	Oral	Conventional
...4	04BAE98EC790205B37298ADB405E3D63	GSID-3YJL6M9Z0-H	Amlodipine besilate	1.39 mg/ml (1 mg/ml)	Suspension	Swallowing	Oral	Conventional
...4	A490DC664C872987E3CEEEFDAC59F034	GSID-3YJL6M9Z0-H	Amlodipine besilate	6.93 mg (5 mg) per tablet	Tablet	Swallowing	Oral	Conventional
...4	5B6880B7763EB0E8D0E127F6C54D26B7	GSID-3YJL6M9Z0-H	Amlodipine besilate	13.87 mg (10 mg) per tablet	Tablet	Swallowing	Oral	Conventional
...4	C92572AA1E2FD469E45C5A7ACD22CA1D	GSID-3YJL6M9Z0-H	Amlodipine besilate	3.47 mg (2.5 mg) per tablet	Tablet	Swallowing	Oral	Conventional
1	B76CF9DC518DF0C0BA42F7E002455F8D	GSID-88APA95ZH-L	Amoxicillin					
.2	20FE199CB0945846A25AEC9C6F41720A	GSID-88APA95ZH-L	Amoxicillin	500 mg per capsule				
.2	2FCEE6E7FA9CA9997DCB6517B2C352F0	GSID-88APA95ZH-L	Amoxicillin	125 mg per tablet				
.2	2FE9D4C41006731128F07CF2C0848EDE	GSID-88APA95ZH-L	Amoxicillin	25 mg/ml				



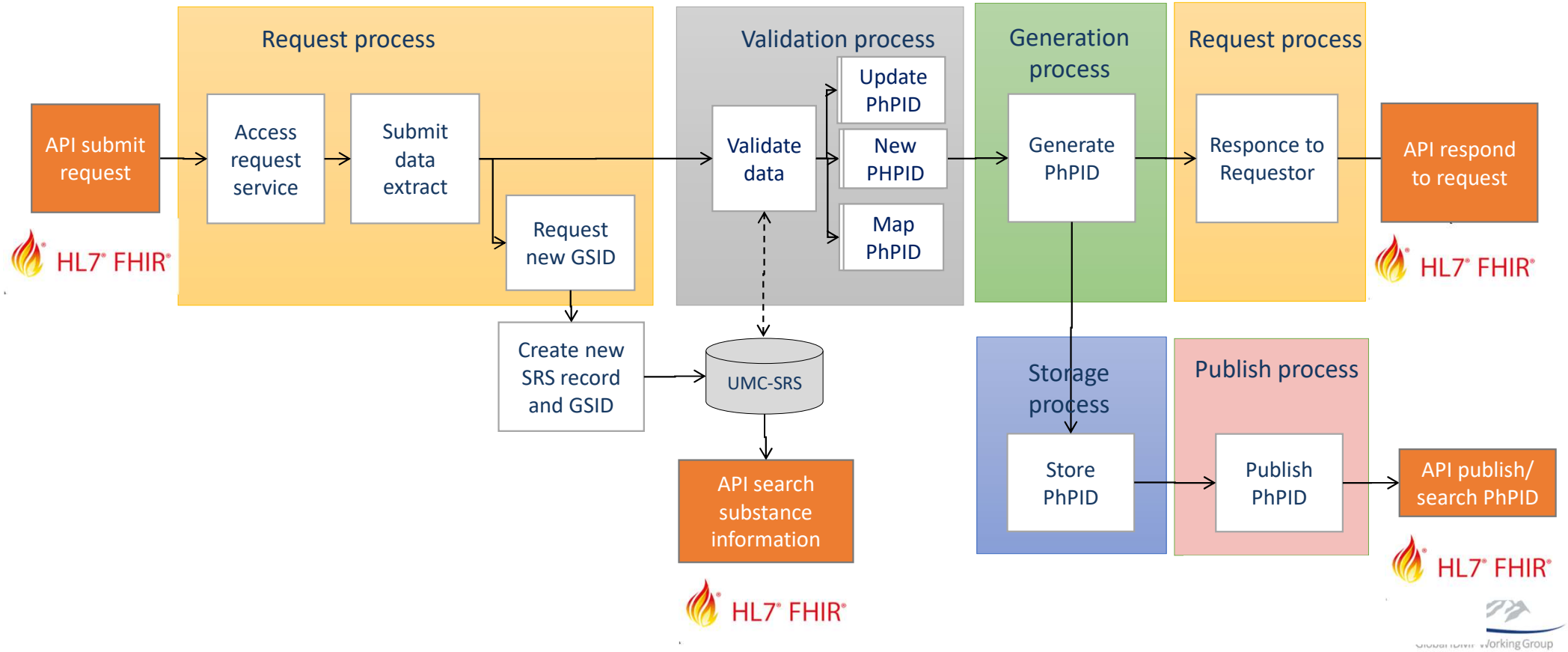
Example of PhPID levels and structural links to Medicinal Product Dictionary

Global IDMP Working Group

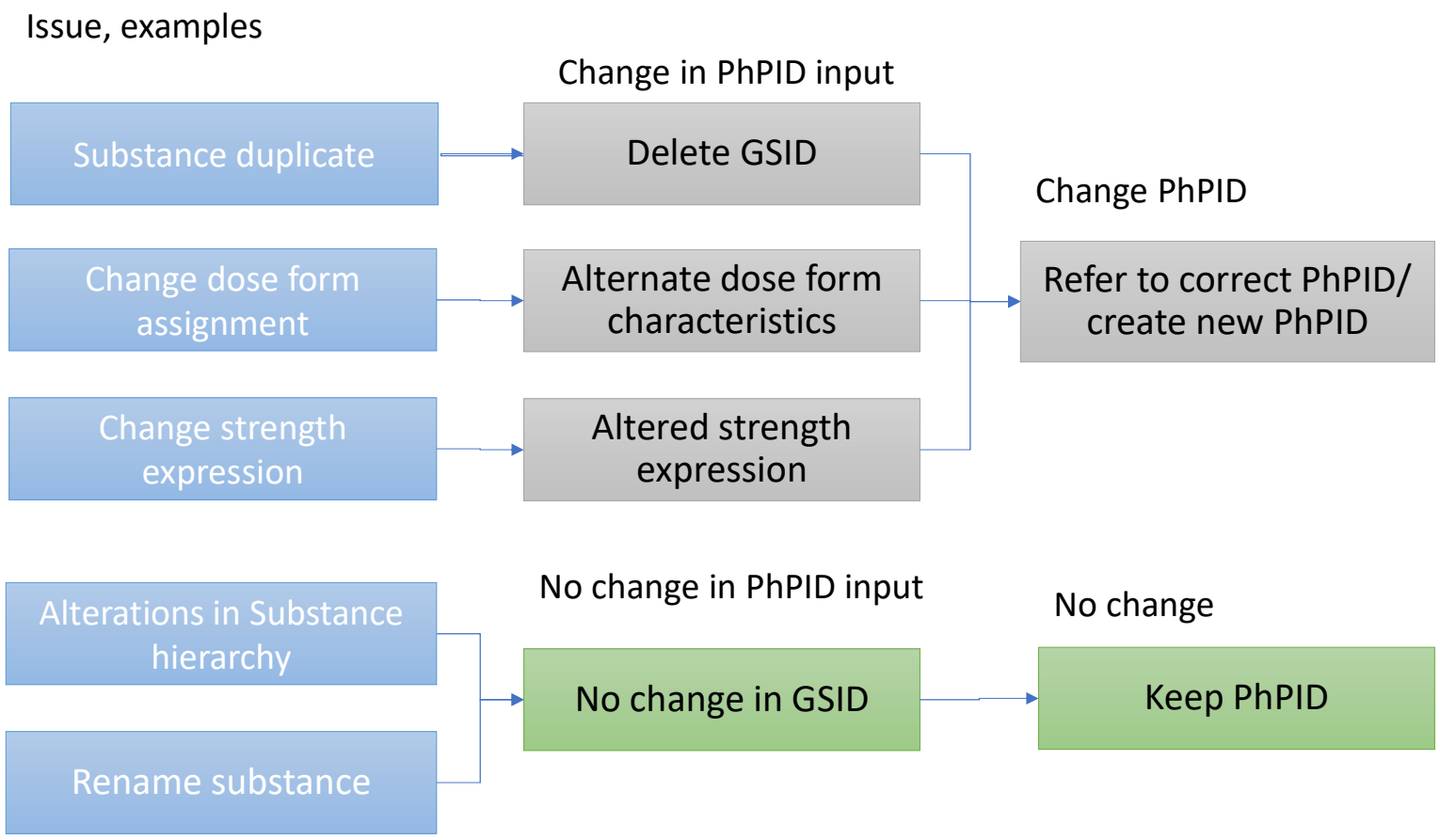
Use cases for end-to-end testing of global PhPID



PhPID Operating Model with FHIR



Proposed change management of PhPID



Suggestion PhPID change management

- Suggestion to implement non-current identifiers for PhPID and GSID

Outstanding challenges

- Process efficiency- actions to simplify data harmonisation process
  - SPC mining
  - Use SPOR registry to ensure better harmonisation of MAH information
- Cont. Change management

Global IDMP Working Group

Suggested updates of ISO IDMP

1. Kits

Suggestion: assign a PhPID for the 'Kits' since even if a marketed product is sold as a single strength or added in a 'kit', the AE must be able to be recorded. Also applies to kits with multiple substances.

2. Contraceptives and placebos

Suggestion: Contraceptives will be considered as a kit (multiple substances included per tablet).

TBD: Find better definition for placebo.

How to handle placebo in a kit, should we differentiate between a product with different numbers of placebo tablets as well as no placebo at all?

Suggested updates of ISO IDMP – cont.

3. Strength for PhPID generation input

Suggestion: ISO 11616 describes the use of both strength and reference strength for PhPID generation but after evaluation GIDWG suggests to only use strength, the addition of reference strength does not add any important information for discrimination in-between different PhPIDs and therefore only impose risk for errors.

4. Re-evaluation of the MD5 hash

Suggestion: to use a non-hash ID for the global PhPID to simplify ID maintenance and minimize risk of confusion between potential regional PhPID and global PhPID

Thank you!

Global IDMP Working Group

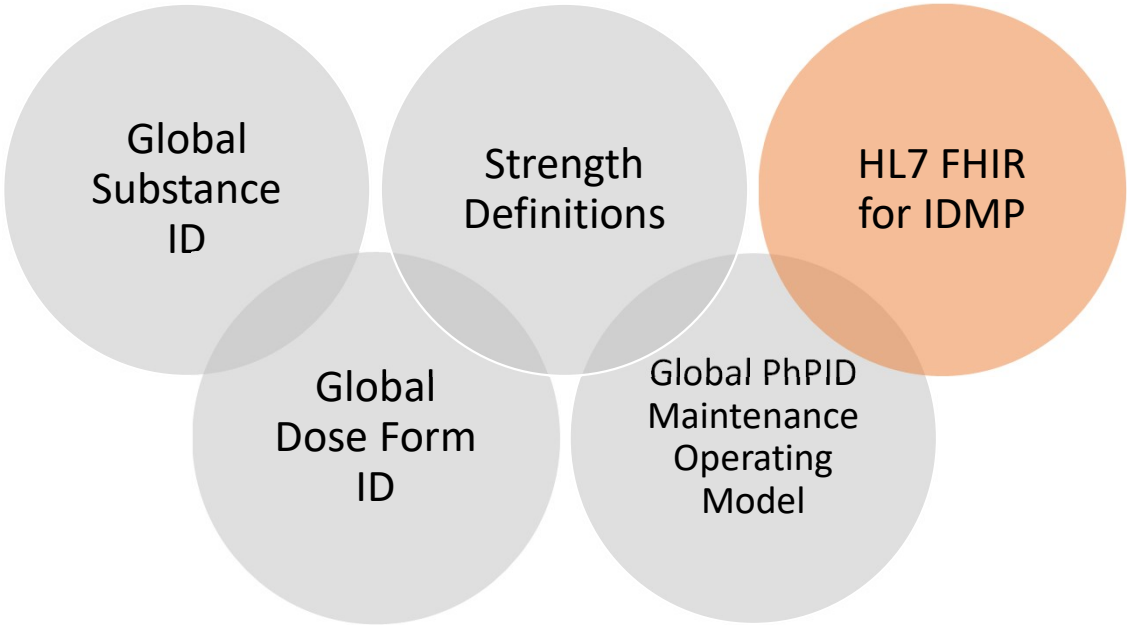
Status report on HL7 FHIR for IDMP

Panagiotis Telonis (EMA)

GIDWG IDMP in HL7 FHIR project

Project scope and deliverables

- Challenges regarding automatic exchange of medicinal product and substance information
- Participate in developing, verifying, and balloting HL7 FHIR resources related to IDMP based on the currently identified global use cases (pharmacovigilance, cross-border prescriptions, drug shortages)
- Exchange IDMP/product and substance data between the US, EU and WHO-UMC according to use cases
- Align to common product messages in FHIR
- Demonstrate in HL7 FHIR Connectathons and other stakeholder events



Global IDMP Working Group

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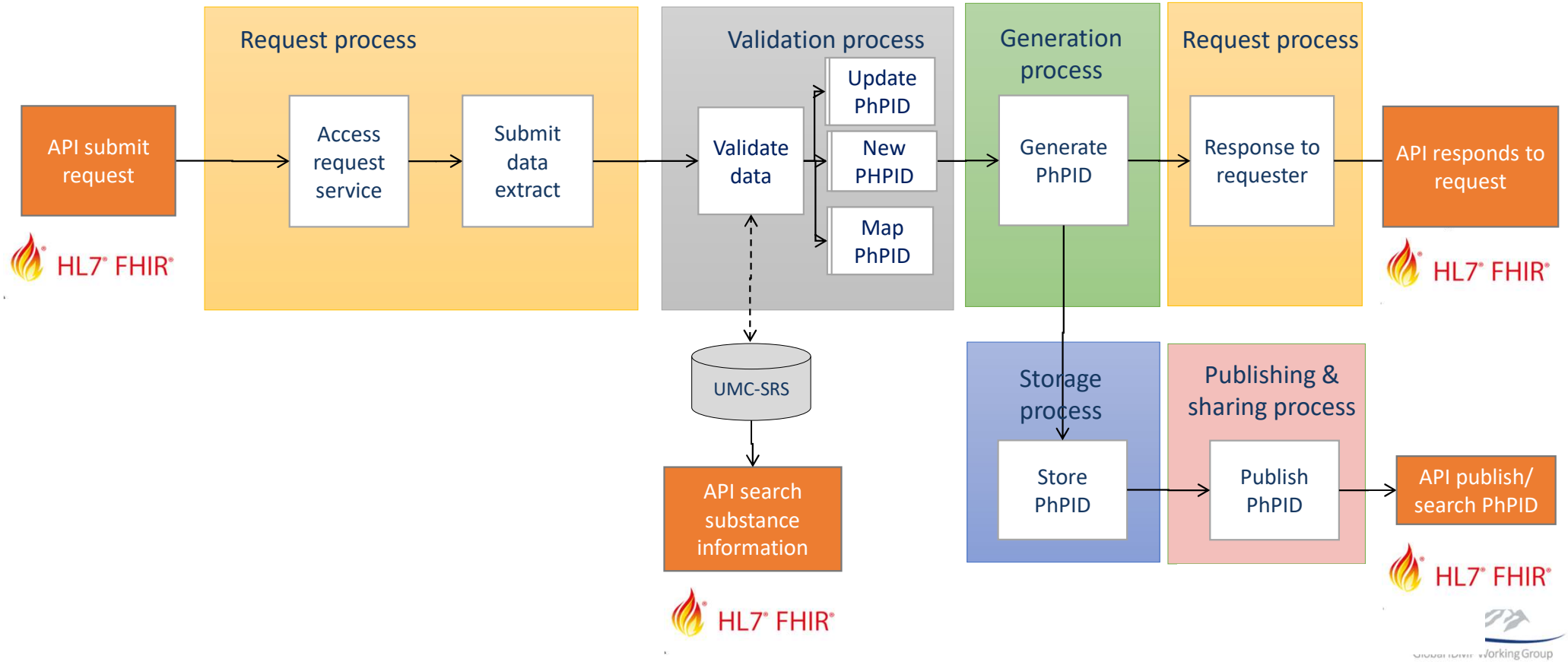
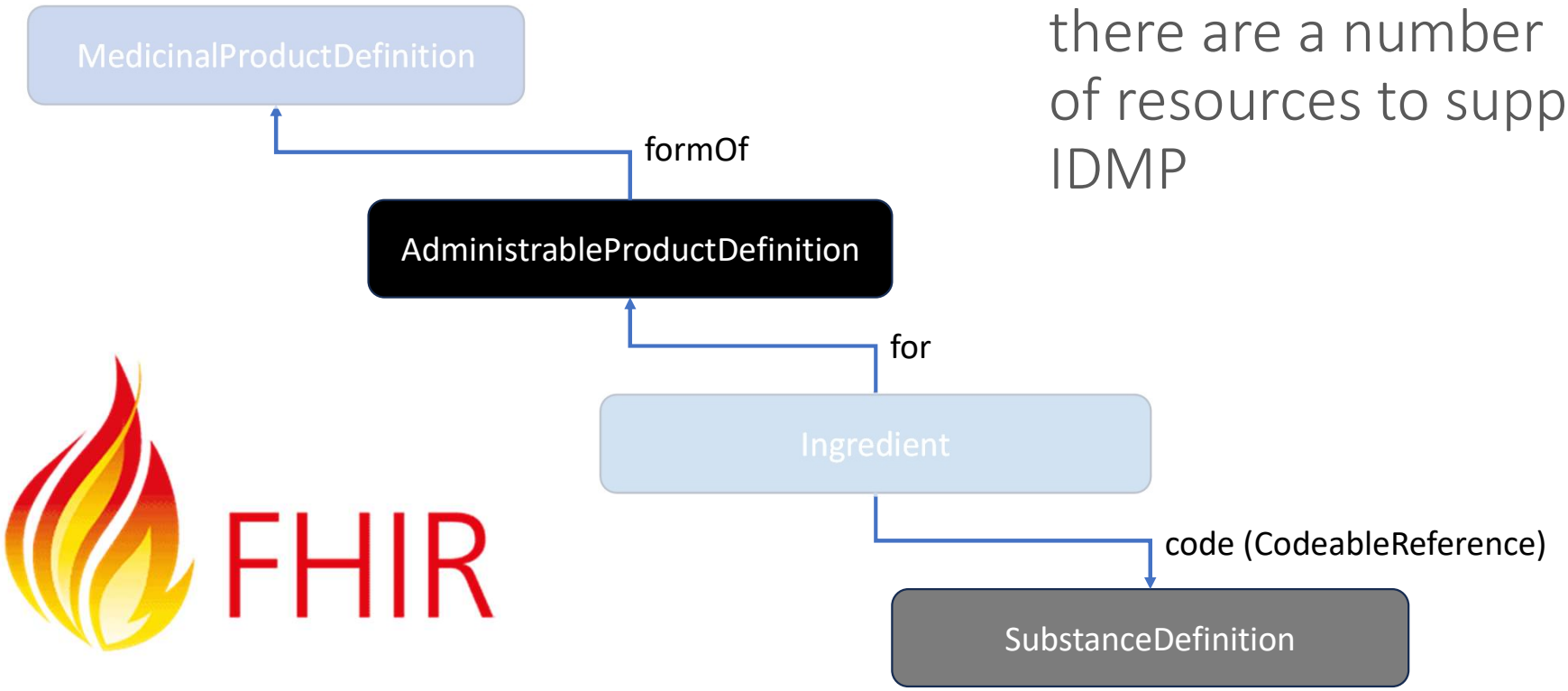
PhPID Operating Model with FHIR



PhPID on FHIR



- As part of HL7 FHIR release 5 there are a number of resources to support IDMP

Global IDMP Working Group

HL7 FHIR Connectathon 34 & HL7 WG meeting (9-15 Sep 2023)

Connectathon (What)

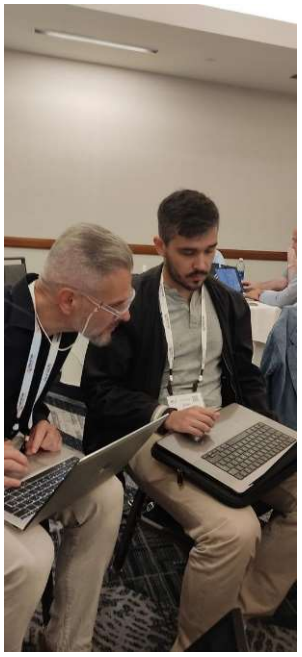
- HL7 FHIR Connectathons feature hands-on FHIR development and testing.
- Implementers and developers come together to hold technical discussions that advance the FHIR specification, develop FHIR-based solutions, and exchange data with other FHIR interfaces.
- Connectathons are a great opportunity to work directly with FHIR developers and senior members of the FHIR standards development team

Track Objective

- Scenarios to Test and gather feedback on the following:
- Test scenario #1: Confirm how to make connections between the Vulcan ePI and SPL-FHIR by manually transforming an ePI to a SPL-FHIR.
- Test scenario #2: A patient travels from Europe to US and has to find the similar US medicinal product to their European prescription.
- Test scenario #3: A patient travels from Japan to US and has to find the similar US medicinal product to their Japanese prescription.
- Test scenario #4: Incorporate ISO IDMP identifiers into the ePIs to facilitate international connections. Focus on the PhPID generation; lookup and usage; and matching identifiers cross-border to support the relevant test scenarios above.

2023 - 09 Connectathon 34 - FHIR - Confluence (hl7.org)

Connectathon 34 Report Out 9.25.23.docx (live.com)



FHIR

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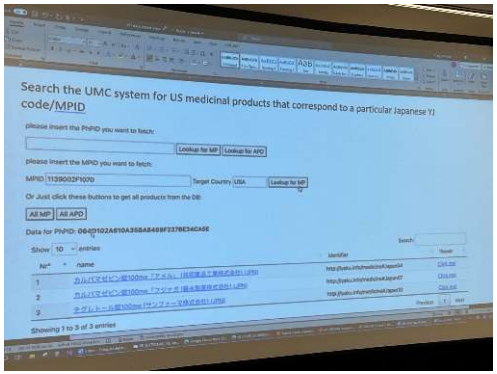

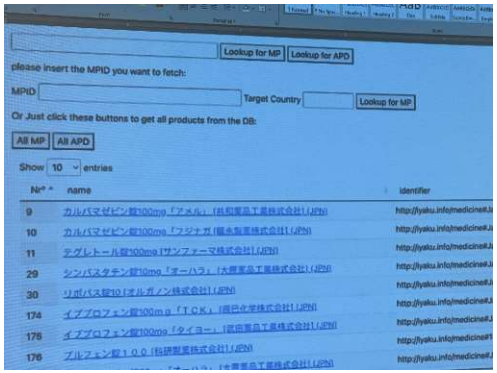

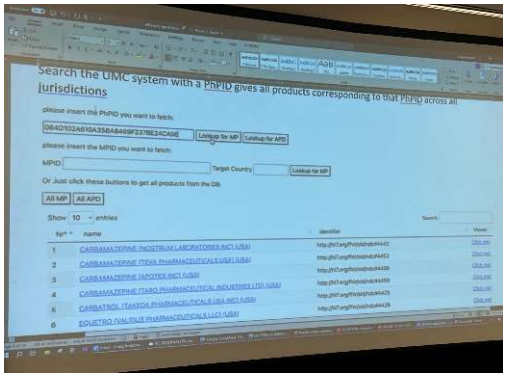

Use Case

シンバスタチン錠５mg「オーハラ」
2189011F1262

?

Get the PhPID for the Japanese MPID

https://umc-ext-dev-phponfhirdemo-preview-rg01-webapp.azurewebsites.net/AdministrableProductDefinition?form-of.identifier=http://iyaku.info/medicine|2189011F1262

Given the retrieved PhPID we can now retrieve the corresponding MPID in USA

https://umc-ext-dev-phponfhirdemo-preview-rg01-webapp.azurewebsites.net/MedicinalProductDefinition?_has:AdminstrableProductDefinition:form-of:identifier=http://www.who-umc.org/phpid|F92168108C432D63DACDD70444176BB3&name-country=USA


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      "url": "htt
    }
  ],
  "entry": [
```

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    "domain": {},
    "status": {},
    "contact": [],
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        "usage": [
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  }
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```

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"identifier": [
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        }
      ]
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    }
  ]
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```


Global IDMP Working Group

GIDWG Communications Plan Discussion

October 2023

Thoughts

- Does GIDWG need a Communications Plan?
  - They seem simple to develop, but they are not. Why? They need monthly maintenance.
- For meetings, we need to have a process for assigning the lead, development, review, and submission and tracking of abstracts.
- Should we compile a core set of slides to draw from and keep it updated.
- Do we need to have a peer-reviewed article(s)? Or can we publish in various organization newsletters, e.g., DIA Forum
- Social Media – we need a plan ahead of meetings and on-going basis.
- We need someone to coordinate / lead the Communications Plan team.

Global IDMP Working Group

Sample Grid for Professional Meetings

	Professional Meetings				
	AUDIENCE	MESSAGE TYPE	DELIVERY METHOD	ABSTRACT DUE DATE	MEETING DATE
DIA Global	Mixed	Data Standards / PV	Podium Presentation	September 2023	June 2024
DIA RSDIM USA	Regulatory Ops, tech companies	Data Standards	Podium Presentation	June 2023	Feb 2024
DIA Europe	Mixed	Data Standards / EU SPOR / PV	Podium Presentation	May 2023	March 2024
DIA Canada	Mixed	Data Standards / PV	Podium Presentation	Text Here	Text Here
DIA China	Mixed	Data Standards / PV	Podium Presentation	Text Here	Text Here
DIA Japan	Mixed	Data Standards / PV	Podium Presentation	Text Here	Text Here
DIA Global Pharmacovigilance and Risk Management Strategies	PV	PV	Podium Presentation	June 2023	February 2024
34th Pharmacovigilance UK & EU	PV	PV	Podium Presentation	Sept 2023	Jan 2024

Acceptance / rejection date

Chair / speakers

Global IDMP Working Group

Thank you!

Global IDMP Working Group

Q&A

Global IDMP Working Group

Wrap Up and Review Action Items/Decisions

Thank you for your work on IDMP!