Global IDMP Working Group (GIDWG) Public Meeting

3 October 2025

"Global IDMP – from dream to reality"

Opening Remarks

Panagiotis Telonis (EMA)
Co-chair

5th Global Identification Working Group (GIDWG) Public Stakeholders Meeting, European Medicines Agency, Amsterdam, 3 October 2025

GIDWG - PhPIDs for supporting Global use cases

Global IDs - Approaching Global Target Operating Models

Exchange information globally:
- Exchanges: will rely on ISO IDMP standards and HL7 FHIR messaging standards.
- Substances: according to regulatory frameworks, they will be identified/managed regionally (*e.g.* FDA, EMA, TFDA) and mapped globally by UMC.
- Medicinal products: according to regulatory frameworks, they will be managed regionally (*e.g.* EMA, FDA, TFDA) and provided to UMC.
- PHPIDs – Will be managed by UMC.

Source: Panagiotis Telonis, Isabel Chicharo, Julia Nyman, Magnus Wallberg, International data standardisation activities, I-Division all staff meeting, European Medicines Agency, 13 March 2024 (adapted)

5th GIDWG meeting – Counting down to Go-Live

- Lessons learned and alignment status?

- Global PhPID and GSID Service Go-live – what does this mean? how can you use it, what for?

- How do we envisage PhPID to be used in future – what are the use cases/opportunities/benefits?

- The future – our role in it?

Agenda

- IDMP use cases

- GIDWG and our journey

- Member Updates from EMA

- Closing Remarks

Our story: Emergency Care Abroad

Somchai is travelling to Norway for a ski vacation.

1

How to identify Somchai´s meds?

วันที่
03 ส.ค. 2025
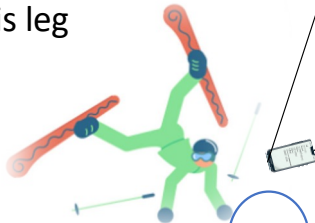ชื่อแพทย์
นพ. กิตติศักดิ์ วงศ์สุวรรณ
ชื่อผู้ป่วย
สมชาย ศรีวัฒน์
ชื่อผู้ป่วย
ใบสั่งยา
รับประทานยา เดกซาเมทายา
หยอดตา 1 มก./มล.

ADRs are to be reported.

6

Somchai experiences a few ADRs.

2

5

Somchai breaks his leg and arrives at the hospital.

Somchai must stay for a while in Oslo.

3

4

Somchai needs to undergo surgery. HCPs know nothing about him but are pressed to start, so take the risk.

Local IDs

Local Medicinal Product ID 096.AAA
Package ID 096.AAA.101

Local Medicinal Product ID 277.BBB
Package ID 277.BBB.102

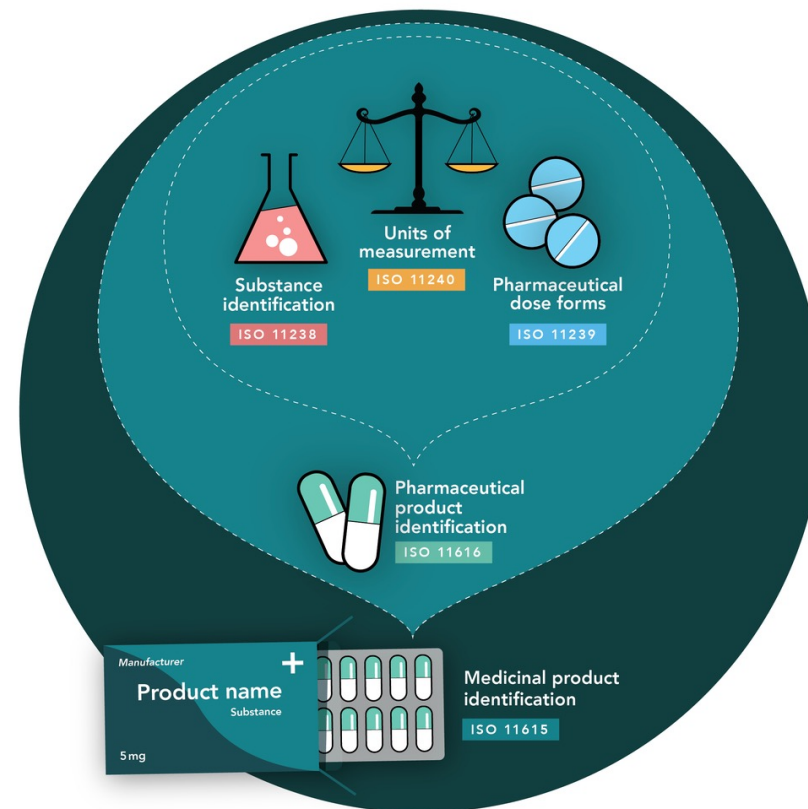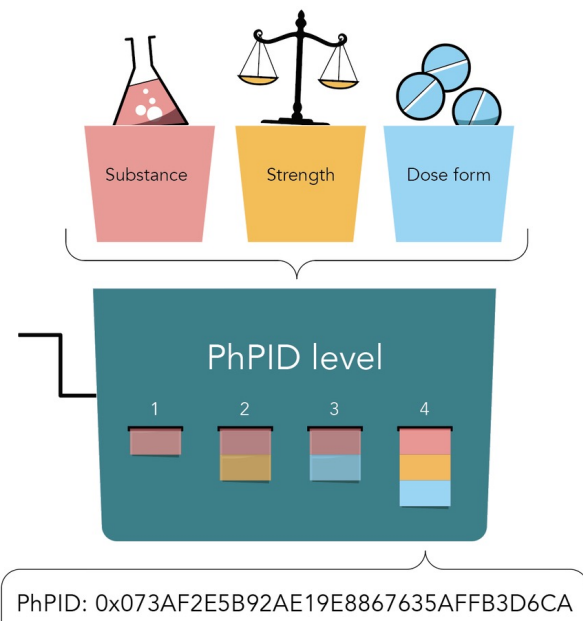Local Medicinal Product ID 021.CCC
Package ID 021.CCC.103

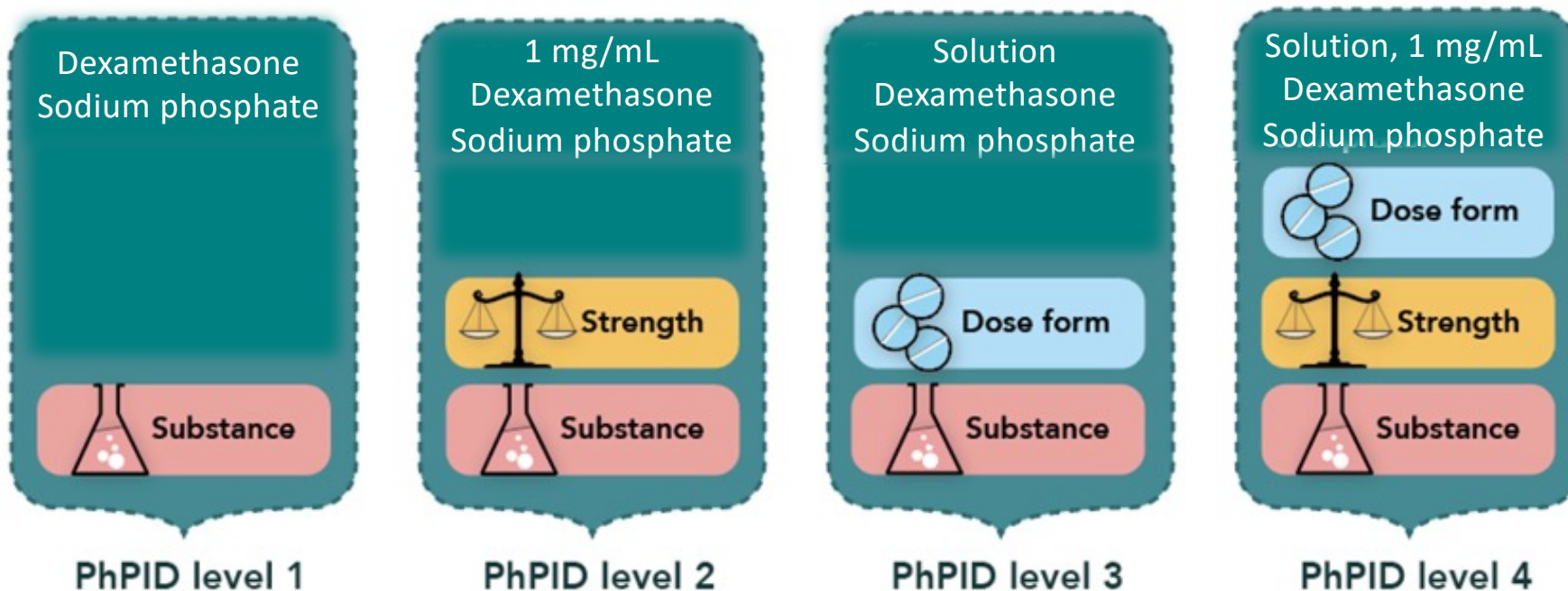Local Medicinal Product ID 301.DDD
Package ID 301.DDD.104

Pharmaceutical industry is ´global´ but not all ´Identifiers´ are global. The identification of medicinal products is a global problem that calls for a global solution.

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ISO identification of medicinal products

The Pharmaceutical Product ID (PhPID) and its levels

ISO 11616:2017

Local and global IDs

Local Medicinal Product ID 096.AAA
Package ID 096.AAA.101

Local Medicinal Product ID 277.BBB
Package ID 277.BBB.102

Local Medicinal Product ID 021.CCC
Package ID 021.CCC.103

Local Medicinal Product ID 301.DDD
Package ID 301.DDD.104

PhPID 5F82B6AE9059F28A19CC5C3D945358EE
GSID85RFP2XGF3X29

PhPID5F82B6AE9059F28A19CC5C3D945358EE
GSID85RFP2XGF3X29

PhPID5F82B6AE9059F28A19CC5C3D945358EE
GSID85RFP2XGF3X29

PhPID5F82B6AE9059F28A19CC5C3D945358EE
GSID85RFP2XGF3X29

Pharmaceutical industry is ´global´ but not all ´Identifiers´ are global. The identification of medicinal products is a global problem that calls for a global solution.

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ePrescription linked to PhPID

DEXAMETHASONE SODIUM PHOSPHATE - A8AA58D0C21F3C8927CBD4B397980352

PhPID	A8AA58D0C21F3C8927CBD4B397980352
Level	4
Linked PhPIDs:	Level 1: BDA1509CA47A20E648284C4F29974B6E
	Level 2: BCC39A0A2B66D995E3446CD940ED8293
	Level 3: 0CE72EA15DF8386C6E462267F166FE26

Administrable Dose Form

Basic Administrable Dose Form	Solution
Administration Methods	Instillation
Intended Sites	Ocular
Release Characteristics	Conventional

Substances

Substance Name	GSID	Strength	Reference Strength
DEXAMETHASONE SODIUM PHOSPHATE	GSID58DC4LXE56SB0	1 mg/mL	0.76 mg/mL

วันที่

03 ส.ค. 2025

ชื่อแพทย์

นพ. กิตติศักดิ์ วงศ์สุวรรณ

ชื่อผู้ป่วย

สมชาย ศรีวัฒน์

ชื่อผู้ป่วย

ใบสั่งยา

รับประทานยา **เดกซาเมทายา
หยอดตา 1 มก./มล.**

**The Global PhPID
A8AA58D0C21F3C89
27CBD4B397980352**

Global IDMP Working Group

Our Story: Codeine shortage

1 Not only Somchai is travelling to Norway for a ski vacation.

2 It is a busy ski season; Norwegian hospitals face a spike in injuries requiring surgery.

3

4 Normally, **codeine tablets** are the go-to option for post-surgical pain — effective and safer than stronger opioids. Unfortunately, they **are on shortage in Europe this year**.

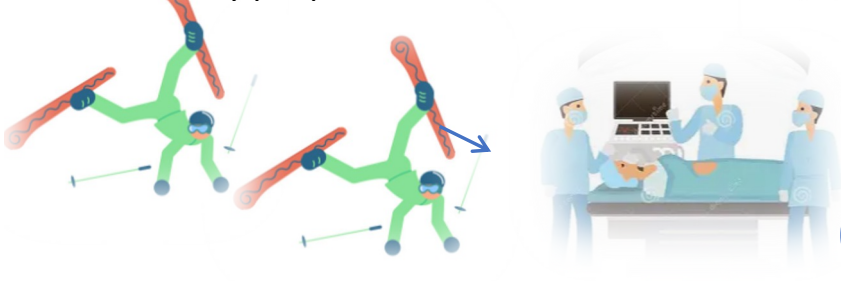| Medicinal Product Name	Drug Code	Active Ingredient(s)	ATC	WHODrug MPID	Authorization Country	MAH	Dose Form ⓘ	Strength (Reference Strength)
		derivatives						
Adorea	12857102385	Codeine phosphate;Paracetamol	N02AJ, Opioids in combination with non-opioid analgesics	5887276	Italy	Abiogen pharma	Tablet	500 mg;30 mg (22.6 mg)
Altermol	12857105019	Codeine phosphate;Paracetamol	N02AJ, Opioids in combination with non-opioid analgesics	3959295	Norway	Alternova	Tablet	500 mg;29.33 mg (22.1 mg)
Antolif	12857105104	Codeine phosphate;Paracetamol	N02AJ, Opioids in combination with non-opioid analgesics	5889413	Portugal	Neogen	Tablet	1 g;58.67 mg (44.2 mg)
Antolif	12857105104	Codeine phosphate;Paracetamol	N02AJ, Opioids in combination with non-opioid analgesics	5889424	Portugal	Neogen	Tablet	500 mg;29.33 mg (22.1 mg)
Aspaco	13605704003	Acetylsalicylic acid;Codeine phosphate;Paracetamol	N02AJ, Opioids in combination with non-opioid analgesics	3956441	Romania	Bioeel	Tablet	250 mg;300 mg;11.73 mg (8.84 mg)

Our story: Codeine shortage with PhPID

On the horizon

1. Not only Somchai is travelling to Norway for a ski vacation.

Somchai gets a substitute from US.

2. Many people seek medical care.

Medicinal Product Name	Drug Code	Active Ingredient(s)	ATC	WHODrug MPID	Authorization Country	MAH	Dose Form ⓘ	Strength (Reference Strength)	PhPID	PhPID Level
Acetaminophen and codeine	12857102186	Codeine phosphate;Paracetamol	N02AJ, Opioids in combination with non-opioid analgesics	5611226	United States of America	RedPharm drug	Tablet	300 mg;30 mg (22.6 mg)	CDA56816C2B3B09CF8892BBF80344DA5	4
Acetaminophen and codeine	12857102186	Codeine phosphate;Paracetamol	N02AJ, Opioids in combination with non-opioid analgesics	4178056	United States of America	RxChange Co	Tablet	300 mg;30 mg (22.6 mg)	CDA56816C2B3B09CF8892BBF80344DA5	4
Acetaminophen and codeine	12857102186	Codeine phosphate;Paracetamol	N02AJ, Opioids in combination with non-opioid analgesics	5626675	United States of America	Aphena Pharma Solutions	Tablet	300 mg;30 mg (22.6 mg)	CDA56816C2B3B09CF8892BBF80344DA5	4
Acetaminophen and codeine phosphate	12857102133	Codeine phosphate;Paracetamol	N02AJ, Opioids in combination with non-opioid analgesics	5660912	United States of America	Strides pharma	Tablet	300 mg;30 mg (22.6 mg)	CDA56816C2B3B09CF8892BBF80344DA5	4

4.

3. Thanks to PhPID (Pharmaceutical Product Identifier), regulators and pharmaceutical companies can act quickly. Within minutes, they identify an equivalent product available in US and arrange for emergency import.

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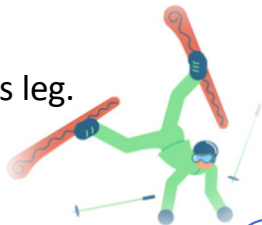
Our story: ADR to report and analyze

1 — Somchai is travelling to Norway for a ski vacation.

2 — Somchai breaks his leg.

3 — Somchai needs to undergo surgery and stay for a while in Oslo.
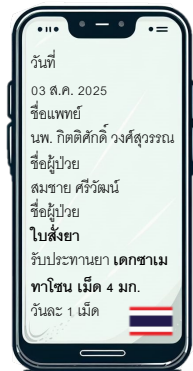
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ใบสั่งยา
รับประทานยา **เดกซาเม**
ทาโซน เม็ด 4 มก.
วันละ 1 เม็ด

4 — Since he doesn't have enough meds to cover the last 8 days before traveling home, he is prescribed substitutes.

5 — Somchai experiences an ADR when given a **substitute for his eye drops.**

6 — ADR is to be reported.

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Our story: ADR reported and analyzed with PhPID

On the horizon

Somchai is travelling to Norway for a ski vacation.

1

Somchai breaks his leg.

2

Somchai needs to undergo a surgery and stay for a while in Oslo.

3

Since he doesn't have enough meds to cover the last 8 days before traveling home, he is prescribed substitutes.

Somchai experiences an ADR when given a **substitute for his eye drops**.

4

ADR is reported correctly and seamlessly.

5

6 Using extra information such as ´additional/overarching´ PhPIDs and dose form attributes in statistical signal detection facilitates the aggregation and helps to detect specific safety concerns and reveal clearer pictures of the medicines safety profiles.

VigiLyze TEST Uppsala Monitoring Centre

Filter on drug, reaction, patient age, patient sex

117 089 cases match your filter

Overview   Cases   Disproportionality   Related investigations (0)

Basic dose form | Intented site | Administration method

Drug (WHODrug) | Reaction (MedDRA)

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Our story: ADR reported and analyzed with PhPID

The hidden problem

Many substance variants ⟵ One substance ⟶ Many products with many formulations
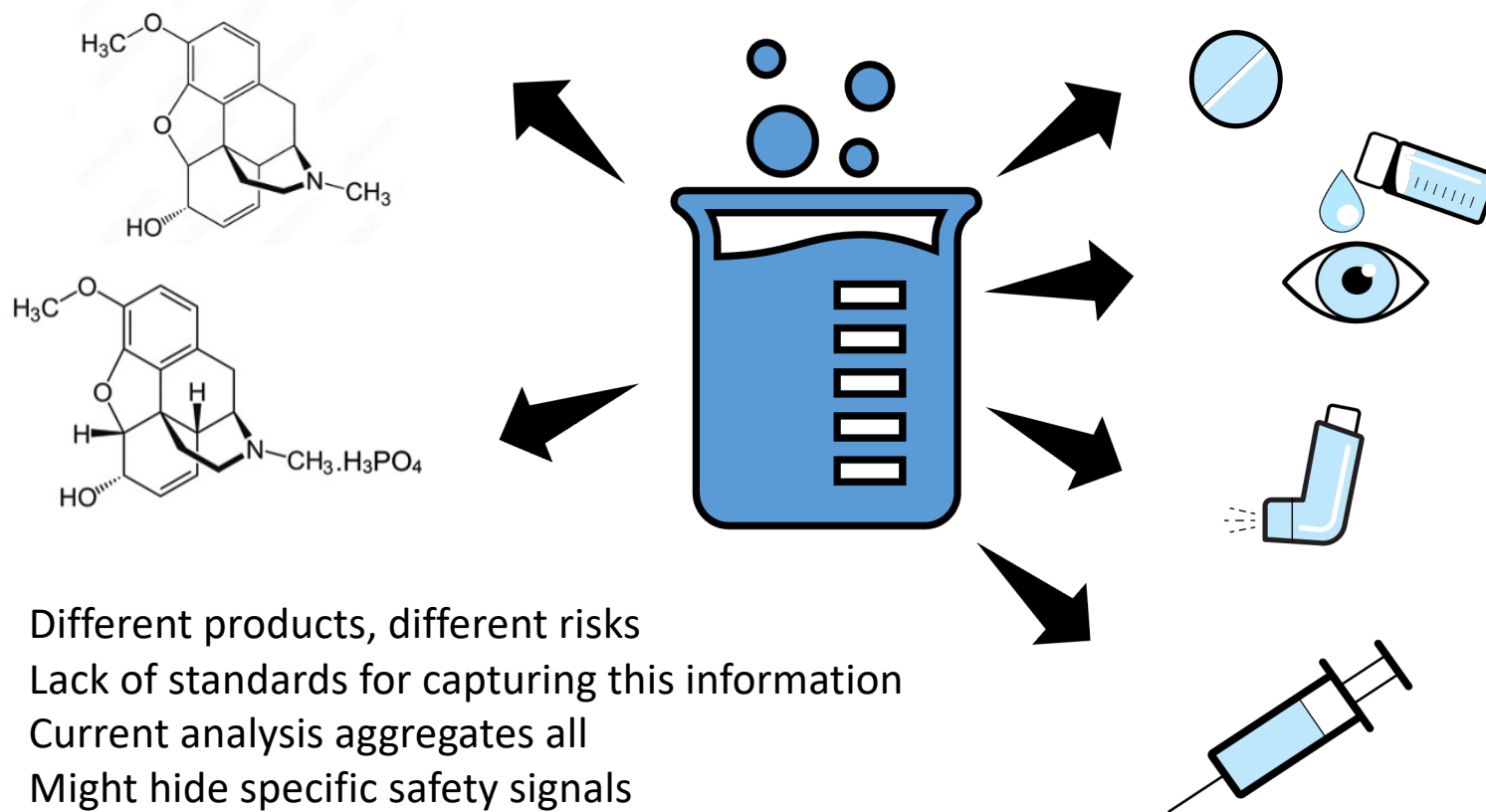
- Different products, different risks
- Lack of standards for capturing this information
- Current analysis aggregates all
- Might hide specific safety signals

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Our story: ADR reported and analyzed with PhPID

User Scenario for PhPID

After receiving a case report linking dexamethasone to cataract, a pharmacovigilance assessor at a national centre, needs to be able to aggregate all reports that are related to an active moiety, regardless of salt variation but in a specific form or strength, then logs into PV system to explore whether this might reflect a broader pattern

Our story: ADR reported and analyzed with PhPID
A case study on dexamethasone

Standardization

Disproportionality

VigiBase data

Aggregation

Ocular

Oral

Substance

Parenteral

Aggregation: Substance + Route

Signal

Background

Ocular

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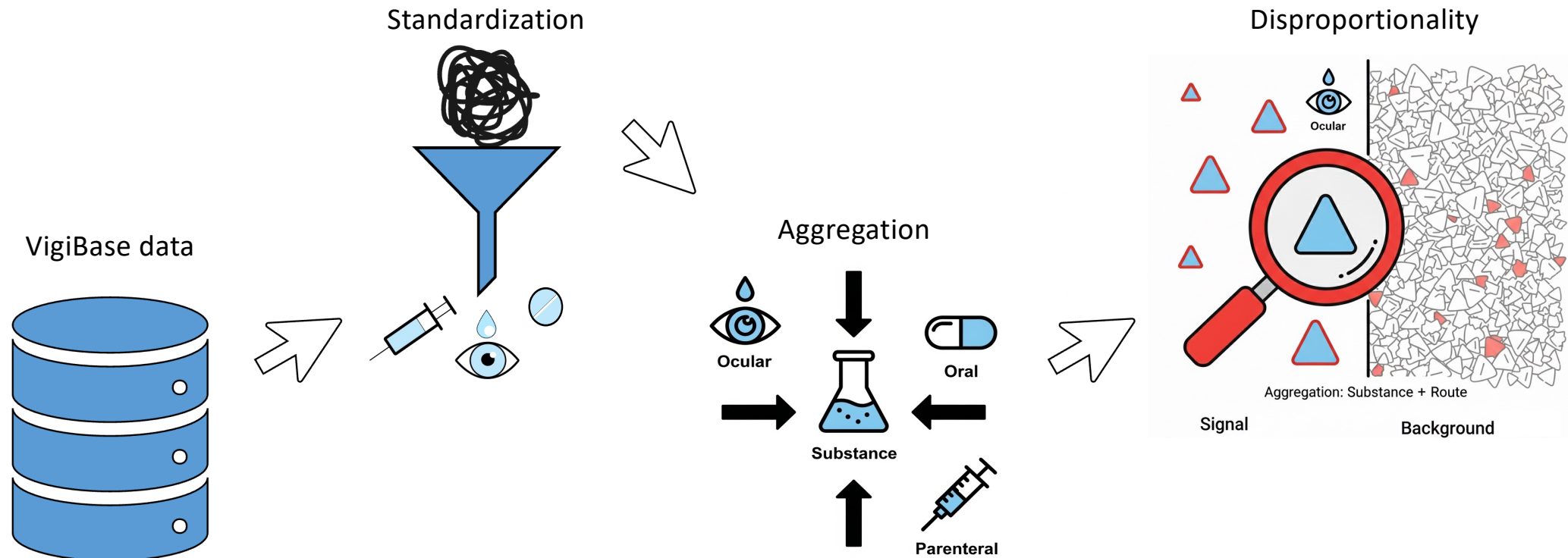
Our story: ADR reported and analyzed with PhPID

User Scenario for PhPID in a PV analysis tool*

Pharmacovigilance assessor continues to explore and focuses on dose form and dose form attributes

*exemplified by UMCs VigiLyze application

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Our story: ADR reported and analyzed with PhPID

What Lina could find

Cataract

Points = IC, lines = 95% interval (IC25–IC975)

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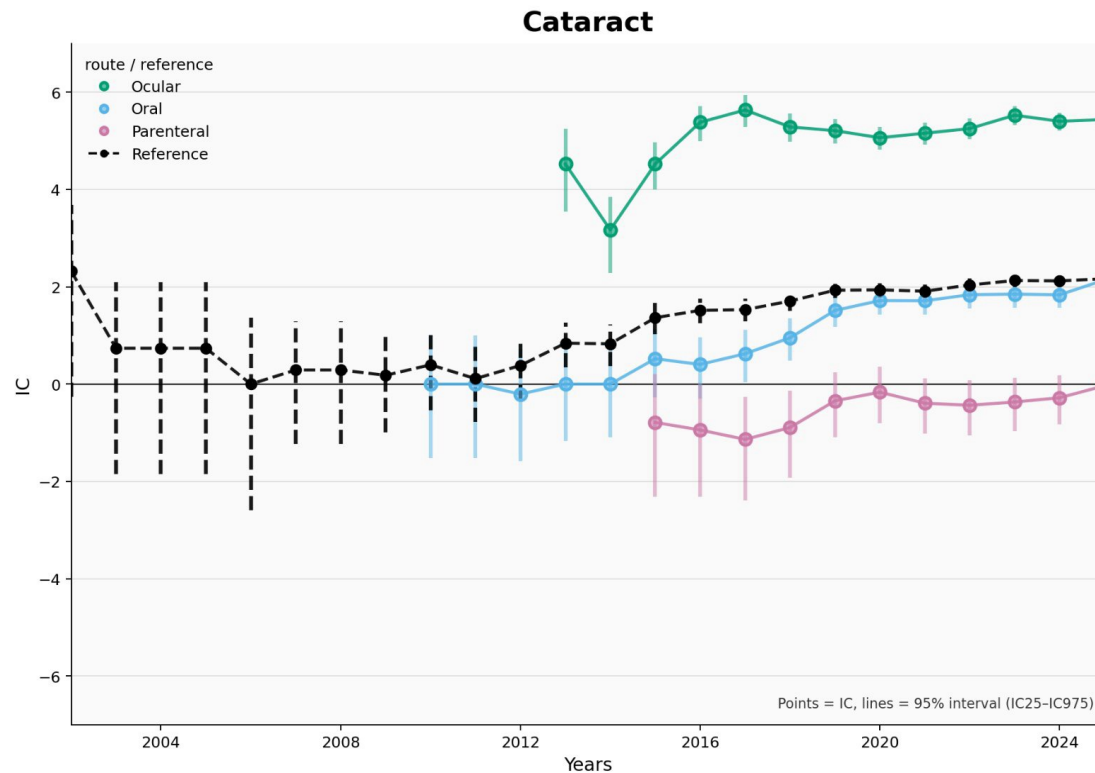
She opens the **Qualitative tab** and first searches for **Dexamethasone**.

VigiLyze **TEST** Uppsala Monitoring Centre   Quantitative   Qualitative   Investigations   VST ⌄

Filter on drug, reaction, patient age, patient sex ⓘ   🕑   Filter ⌄   Clear filters   Sweden | Global view

∷ *AI: Dexamethasone* ✖   **117 089** cases match your filter

📊 **Overview**   ☰ Cases   *f(x)* Disproportionality   🗁 Related investigations (0)   Export ⌄

Basic dose form

Tablet
Cream
Solution
Cachet
Implant

0   10   20   30   40   50   60

Intented site

Oral

Parenteral

Ocular

0 10 20 30 40 50 60 70 80

Administration method

Swallowing

Application

Injection

0 10 20 30 40 50 60 70 80

Drug (WHODrug)

AI variant: Dexamethasone
AI variant: Dexamethasone sodium p...

Reaction (MedDRA)

SOC: Blood and lymphatic system di...
SOC: Cardiac disorders

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Lina then narrows the search by adding **Cataract** as the reaction PT term.

VigiLyze TEST   Uppsala Monitoring Centre

Quantitative   Qualitative   Investigations   VST

Filter on drug, reaction, patient age, patient sex   ⟲   Filter ⌄   Clear filters

Sweden   Global view

⠿ *AI:* Dexamethasone ✕   ⠿ *PT:* Cataract ✕

610 cases match your filter

📊 Overview   ☰ Cases   ƒ(x) Disproportionality   🗂 Related investigations (0)

Export ⌄

Basic dose form

Tablet
Cream
Solution
Cachet
Implant

0 10 20 30 40 50 60

Intented site

Ocular
Parenteral
Oral

0 20 40 60 80 100 120

Administration method

Swallowing
Application
Injection

0 10 20 30 40 50 60 70 80

Drug (WHODrug)

AI variant: Dexamethasone

Reaction (MedDRA)

LLT: Cataract
LLT: Cataract aggravated

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She switches to the **Disproportionality** sub-tab, where IC values are shown by default at the **substance level**.
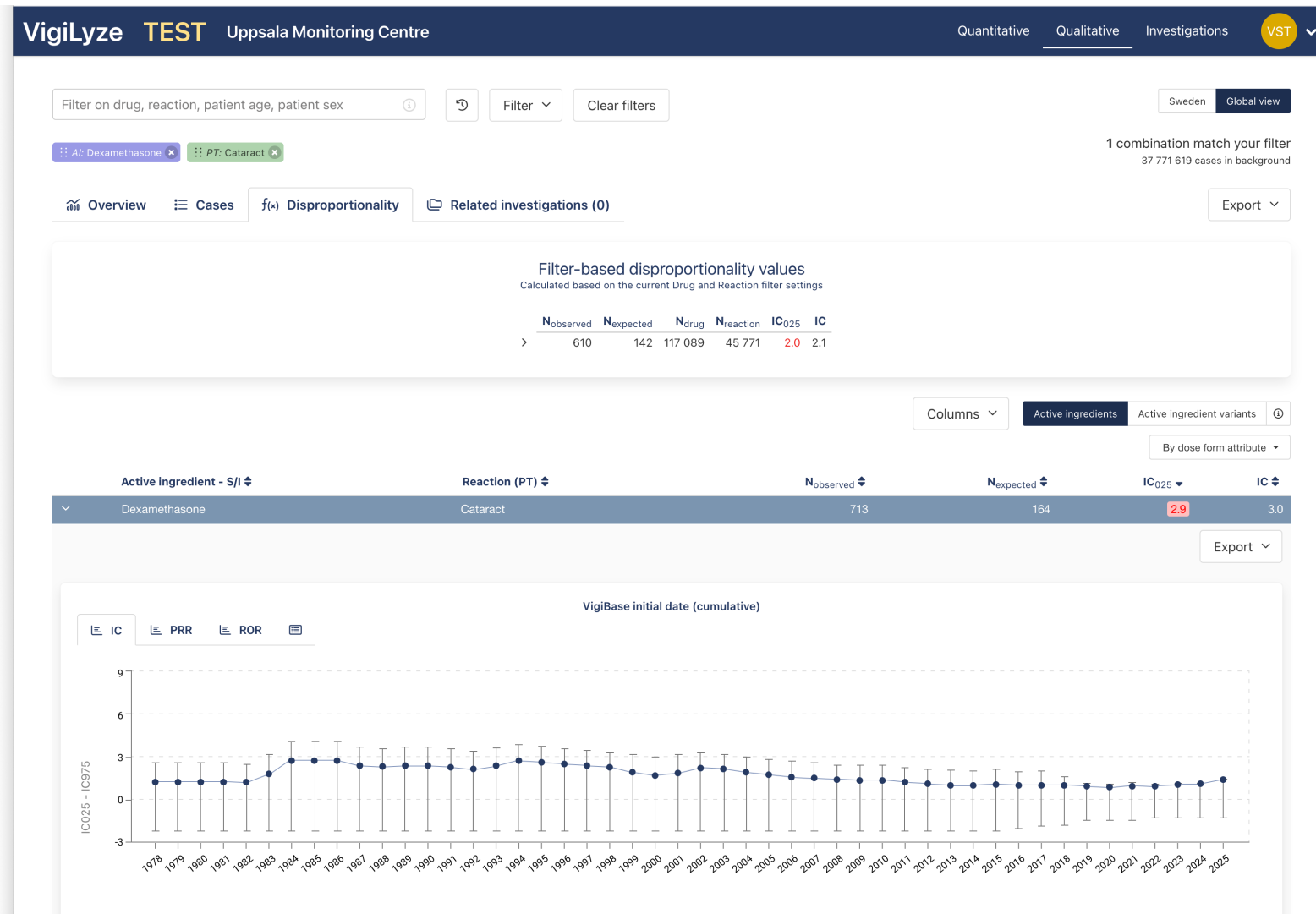
She clicks a dropdown "By Dose Form Attribute" and selects "Intended Site."
The IC values recalculate, now split by administration site:
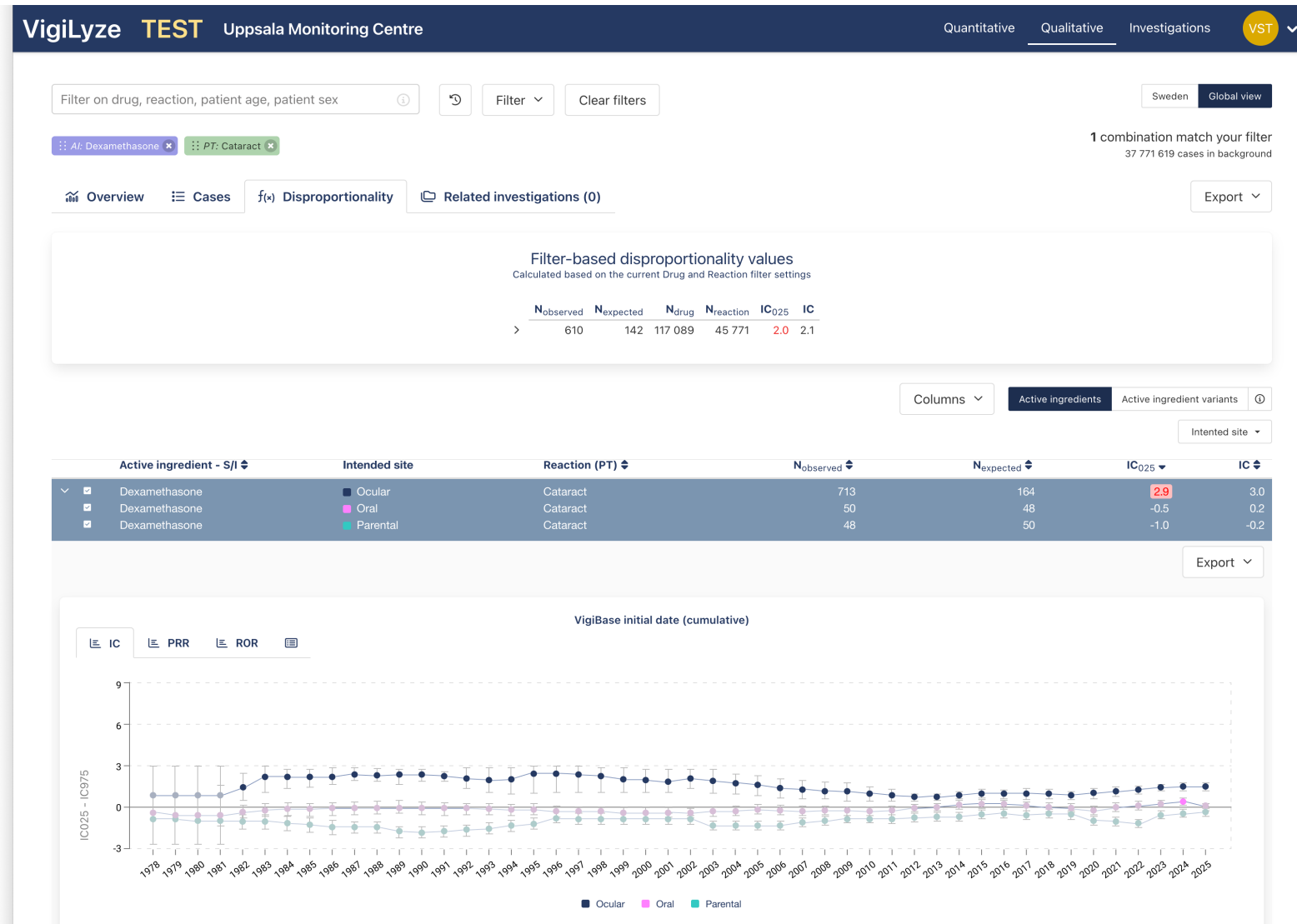
PhPID value to Pharmacovigilance

Using extra information such as form or route in statistical signal detection could help us **detect specific safety concerns** and reveal **clearer pictures of the medicines safety profiles.**

In other words, **if PhPIDs were to be used** for reporting of adverse events, it would **add value to Pharmacovigilance**

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IDMP landscape

GIDWG
Plan and execute projects on global implementation and maintenance

The voice of the pharmaceutical industry in the global IDMP/PhPID ecosystem

efpia
IFPMA

Industry input into standardization efforts

GLOBAL Implementation

Global ID maintenance

UMC
Global PhPID and GSID Maintenance Organization

ICMRA

Enhancement of the availability of quality medicines.

Global Regulatory Strategy

Guidance

WHO
Guidance through globally-applicable norms and standards.

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

IPRP
International Pharmaceutical Regulators Programme

IDMP Readiness

Readiness & Share Knowledge & Strategies

Implementation across Regulatory Authorities

EMA/EU
IDMP/ SPOR master data management services

EU-SRS

ICH
harmonisation for better health

Guidelines for pharmaceutical product registration
-M4Q Quality Data Standards
-E2B ICSR

IDMP Standards for regulatory submission

SDOs (Standard Development Organizations)

FDA
GSRS

ISO
IDMP standards, technical specifications and reports

HL7
FHIR
IDMP messaging standards

Global IDMP Working Group

Global IDMP Working Group

- Launched in 2021 — outcome of the 2019 WHO IDMP Workshop (Geneva)

- Why?
  No global body was demonstrating real-world IDMP implementation.

- Our Focus:

  Deliver projects proving IDMP is *globally implementable*

  Build a practical framework: business rules, best practices, and operating model

  Support global use of IDMP identifiers for marketed products

GIDWG Member Organizations

PhPID Journey – Global PhPID Service goes live

Go-live

| Proof of Concept | | Testing | | Pre- Production | |

GIDWG Launch

Production Business Rules

Q1 2026

2023

2024

Q1 2025

2021
"Dose form pilot"
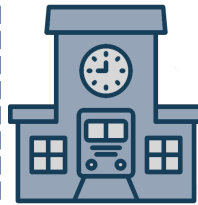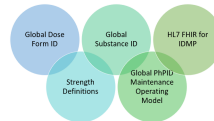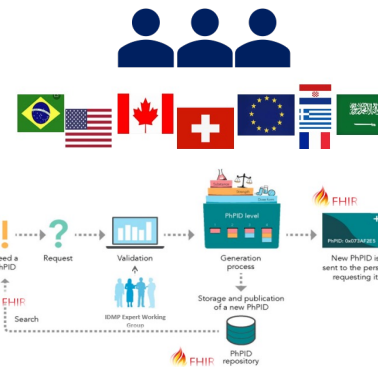
2020
"Feasibility Study Project"

2022–2023
"GIDWG Project"

PhPID adoption

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Uppsala Monitoring Centre

FDA

Global Dose Form ID · Global Substance ID · HL7 FHIR for IDMP · Strength Definitions · Global PhPID Maintenance Operating Model

"End-to-End testing Project"

Datasets on prioritized substances* from 16 countries

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PhPID Journey – Global PhPID Service Go-Live

Dataset for marketed medicinal products linked to GSID and Pre-production Global PhPIDs, linked to Local National Medicinal Product IDs released for 16 countries for adoption by March 2026

1st Roll out of Global PhPID

GLOBAL PHPID

LOCAL NATIONAL ID

GSID   SDID   DFID

Medicinal Product Name	Drug Code	Active Ingredient(s)	ATC	WHODrug MPID	Authorization Country	MAH	Dose Form ⓘ	Strength (Reference Strength)	PhPID	PhPID Level
Dexamethasone	00016002023	Dexamethasone sodium phosphate	D07AB, Corticosteroids, moderately potent (group II)	4751756	United Kingdom of Great Britain and Northern Ireland	Panpharma ltd	Solution	4.37 mg/mL (3.32 mg/mL)	EAB80324942E304AE87A8F053485D7F4	4
Dexamethasone	00016002023	Dexamethasone sodium phosphate	H02AB, Glucocorticoids	5608449	United Kingdom of Great Britain and Northern Ireland		Solution		11810EF06F78C9F7A6F46512531D9174	4

1   BDA1509CA47A20E648284C4F29974B6E
2   7F86BA37C8AFB6BA3F98D095459663AC
3   3F01847C0DAC4F3BE35C3FB410458FB5
4   11810EF06F78C9F7A6F46512531D9174

Dexamethasone	00016002023	Dexamethasone sodium phosphate	H02AB, Glucocorticoids	5608608	United Kingdom of Great Britain and Northern Ireland	Glenmark Generics Ltd.	Solution	10.53 mg (8 mg)	6A0B03942E6250CFF43DDABFE04946AB	4
onopex	00016002264	Dexamethasone	5015	5026070	Norway	Laboratoires	Solution	1 mg/mL (0.76 mg/mL)	A8AA58D0C21F3C8927CBD4B397980352	
									...0052D7167DF973631	4

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PhPID Journey – How did we get there?

Proof of Concept

Testing

Pre- Production

2021
"Dose form pilot"

Uppsala Monitoring Centre   FDA

2020
"Feasibility Study Project"

Global IDMP Working Group

PhPID Journey – How did we get there?

US FDA/UMC pilot for Global PHPIDs: feasibility of using EDQM dose form attributes for mapping to regional terminologies
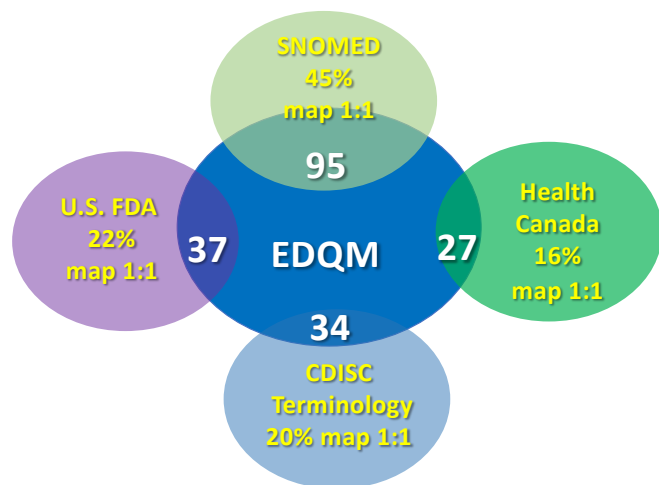
Mapping of regional terminologies to EDQM PDF
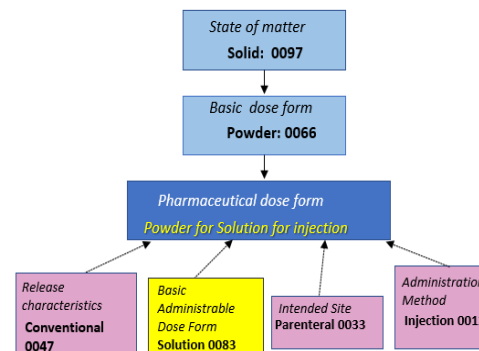
The pilot validated 1,289 US marketed medicinal products corresponding to 37 selected substances identified in the UNICOM pilot product list.

Global dose form attributes

Basic dose form
Intended site
Administration method
Release characteristics

PhPID Journey – How did we get there?

US FDA/UMC pilot for Global PHPIDs: feasibility of using EDQM dose form attributes for mapping to regional terminologies

RESULTS

- A centrally maintained (EDQM) set of dose form attributes is a viable solution for global IDMP

- Regulatory authorities can continue to use their local dose form terminology

- Mapping between local dose form terminology and dose form attributes done by UMC as part of generation of Global PhPID

US FDA/UMC pilot

Global dose form attributes

Basic dose form
Intended site
Administration method
Release characteristics

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PhPID Journey – How did we get there?

Proof of Concept

Testing

Pre- Production

GIDWG Launch

2023

2021
"Dose form pilot"

2020
"Feasibility Study Project"

2022–2023
"GIDWG Project"

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Uppsala Monitoring Centre

FDA

Global Dose Form ID

Global Substance ID

HL7 FHIR for IDMP

Strength Definitions

Global PhPID Maintenance Operating Model

Global IDMP Working Group

PhPID Journey – How did we get there?

Proof of Concept

Testing

Pre- Production

GIDWG Launch

2023

2021
"Dose form pilot"

2020
"Feasibility Study Project"

2022–2023
"GIDWG Project"

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

Global Dose Form ID

Global Substance ID

HL7 FHIR for IDMP

Strength Definitions

Global PhPID Maintenance Operating Model

First set of Business rules for Global PhPID
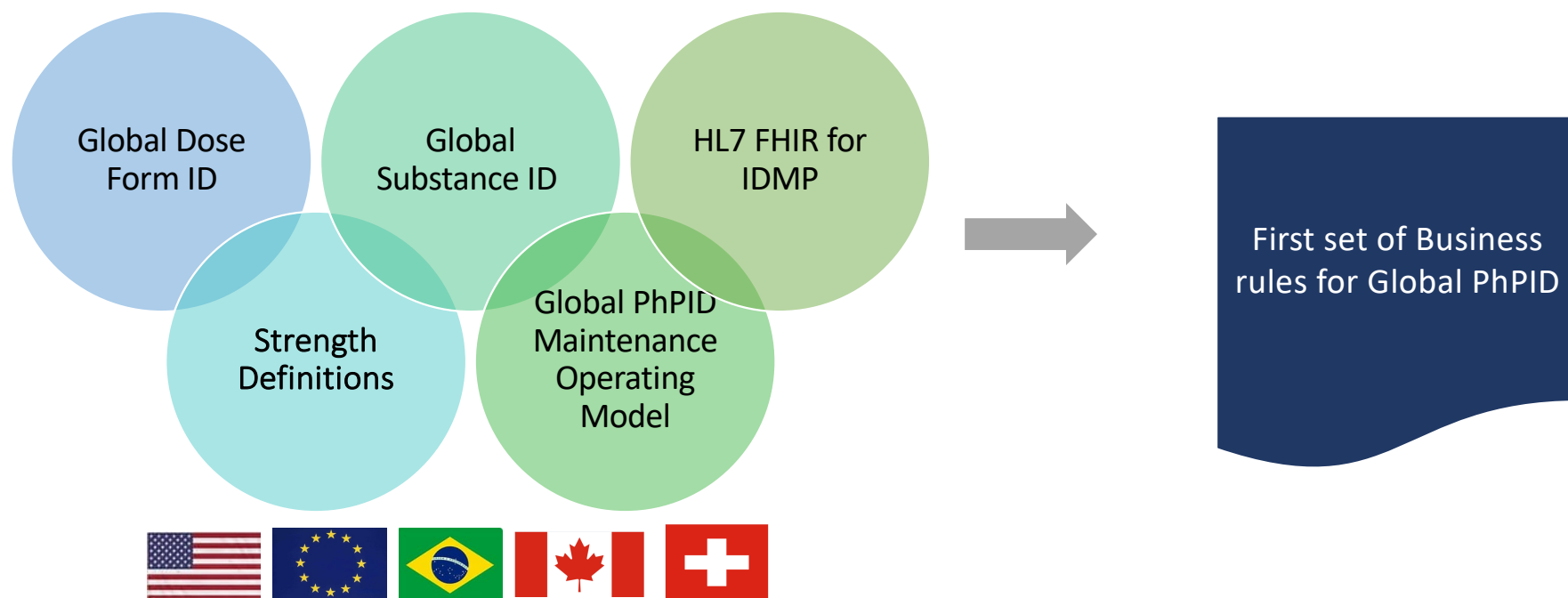
SMEs from US FDA, EMA, ANVISA, Health Canada, Swissmedic, UMC, WHO-PVG, EDQM,WHO-INN, USP, HL7, HMA-SVG, US-NIH, IFPMA, ISO/CEN, USP
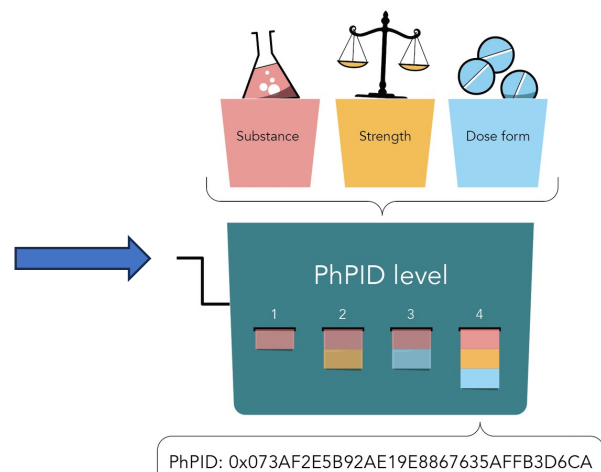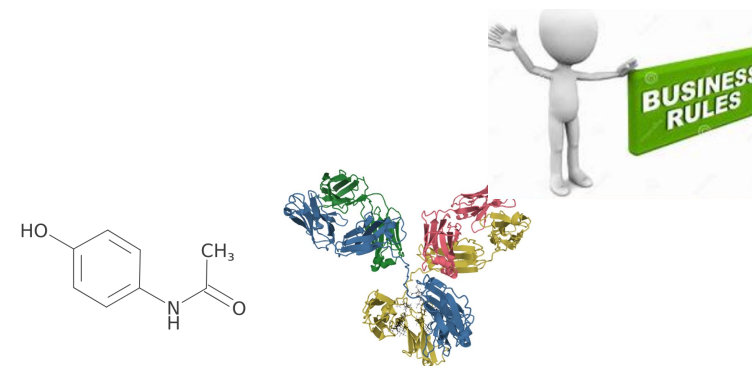
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PhPID assignment

Substance | Strength | Dose form

PhPID level

1 | 2 | 3 | 4

PhPID: 0x073AF2E5B92AE19E8867635AFFB3D6CA

Data validation

BUSINESS RULES

Global dose form attributes
Basic dose form
Intended site
Administration method
Release characteristics

Type of product

How to express Strength? Pattern

Strength by Presentation (Pattern A)

Strength by Concentration (Pattern B)

Strength with delivery rate over time (Pattern C)

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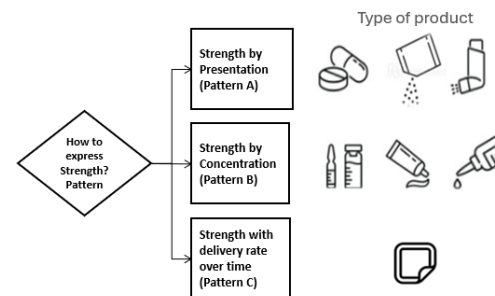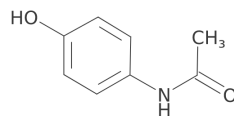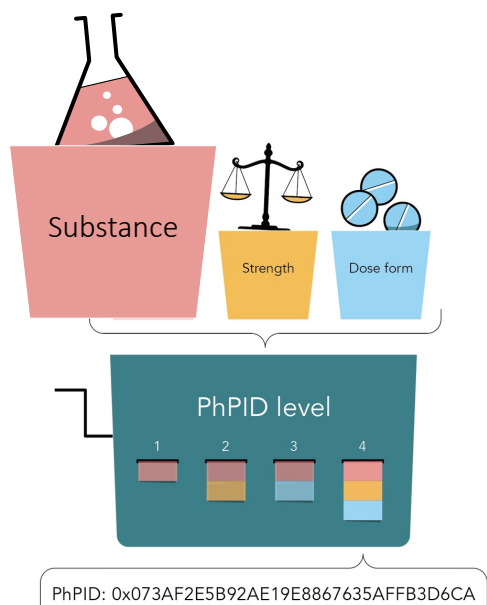
GSID assignment

- GSID assignment based on ISO 11238 and ISO/TS19844
- UMC-SRS is used for assigning GSID
- Business rules to govern which GSID that should be used for PhPID

Substance

Strength   Dose form

PhPID level

1   2   3   4

PhPID: 0x073AF2E5B92AE19E8867635AFFB3D6CA

Global IDMP Working Group

Units of measurements and strength

PhPID: 0x073AF2E5B92AE19E8867635AFFB3D6CA
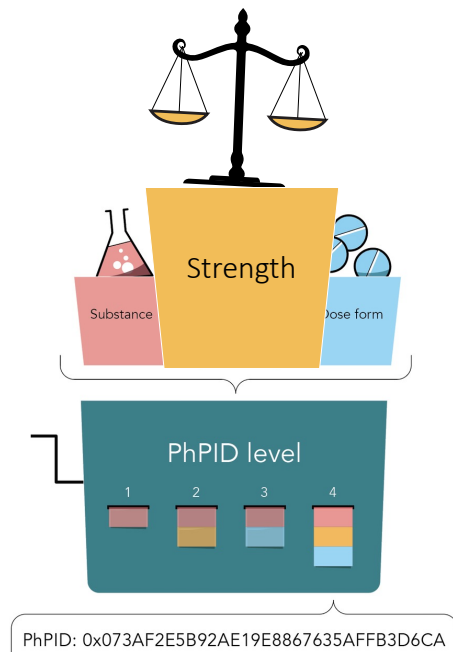
- UCUM units are used as a foundation

- Non-UCUM units are used when appropriate

- Business rules for conversion of units

- Business rules for strength expression based on product type are used to increase consistency

Dose form

Global dose form attributes
Basic dose form
Intended site
Administration method
Release characteristics

BUSINESS RULES

Substance Strength Dose form

PhPID level

1 2 3 4

PhPID: 0x073AF2E5B92AE19E8867635AFFB3D6CA
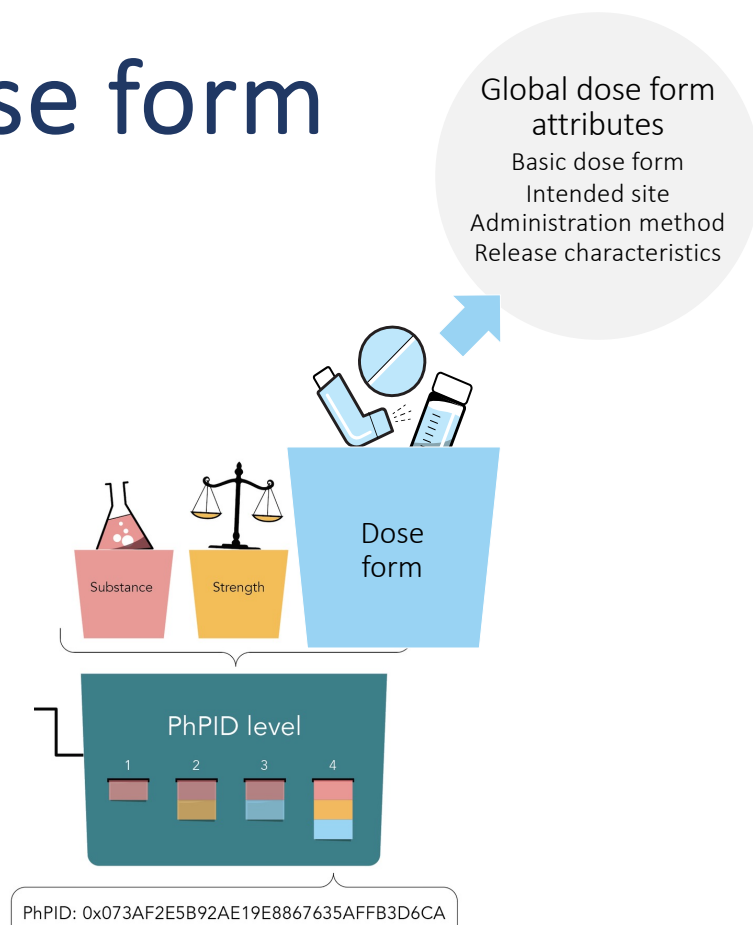
- No centralized/common terminology for Dose Form is used globally
  - Differences in granularity
  - Regulators approve different terms for the same form
- The global dose form attributes are used to express the PhPID dose form in a consistent way

Ahnfelt, E., Lagerlund, O., Klint, J. *et al.* Advancing Global Harmonization: Implementing Global Dose Form Attributes for Medicinal Products Identification. *Ther Innov Regul Sci* (2025). https://doi.org/10.1007/s43441-025-00838-3

Global IDMP Working Group
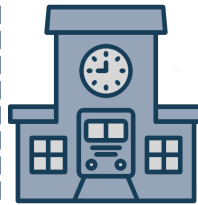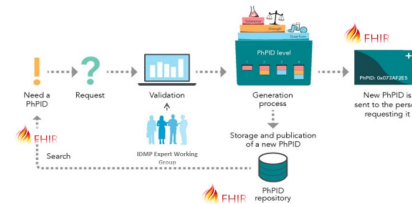
PhPID Journey – How did we get there?
Global PhPID Service Operating Model End-to-End Testing

PURPOSE:

Testing framework, including business rules, best practices, software and operating model, for the global IDMP implementation and maintenance of global identifiers for marketed products.

SCOPE included both load and stress testing:

• Selected Substances Dataset (150 substances: 345 records including substance variations)

•EDQM + non-EDQM countries

•Similar products from different countries

•Testing of Pharmacovigilance, Drug Shortages and Cross-border Healthcare use cases

STATUS: concluded

SUCCESS RATE: ~90% of medicinal products processed successfully

DELIVERABLE: Robust Global PhPID Operating Model

GIDWG

Global IDMP Working Group
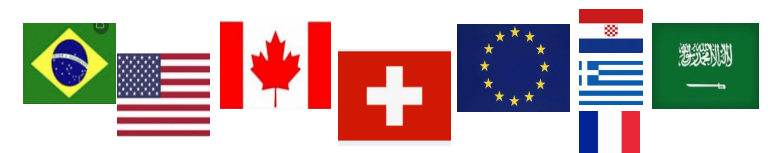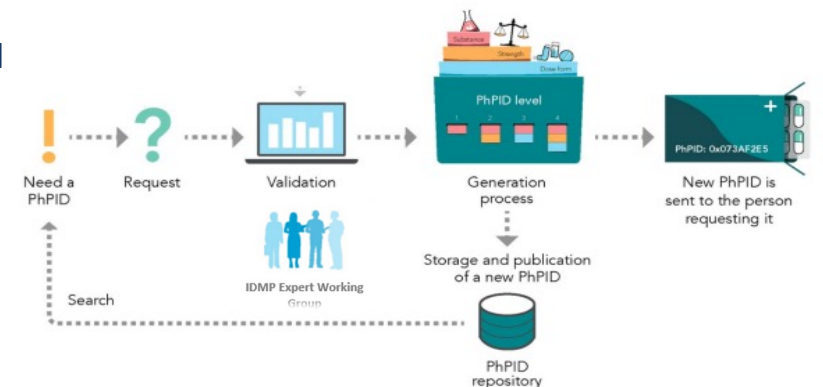
PhPID Journey – How did we get there?

Readiness after End-to-End Testing

Global PhPID Service Operating Model Go-Live Readiness

Technical Readiness 92%

Operational Readiness 90%

Action required 8–10%

Global IDMP Working Group

PhPID Journey – How did we get there?

Global PhPID Service Operating Model

IDMP Search in WHODrug Insight: Global PhPID linked to Medicinal Products
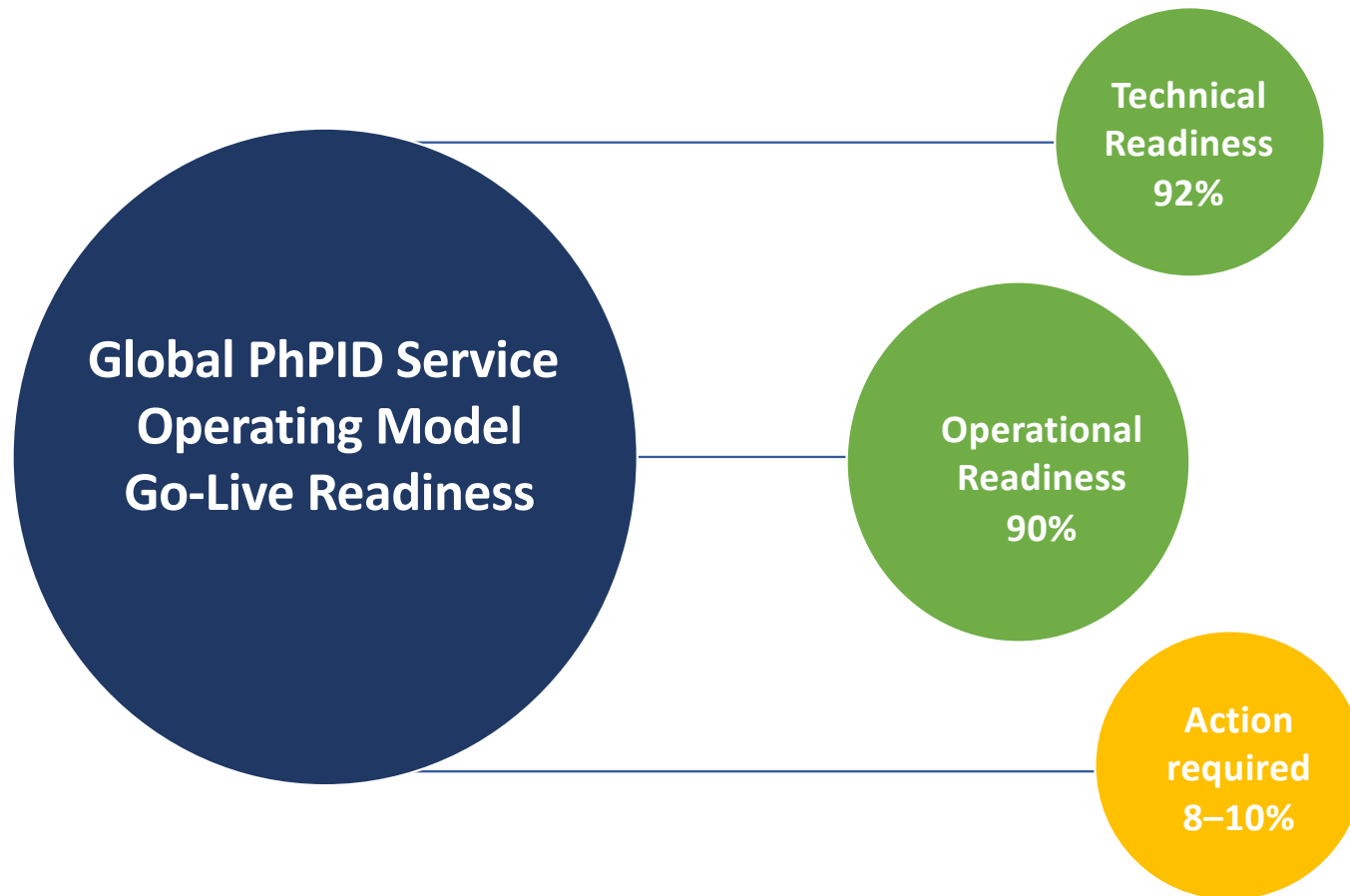
Step 1

Global IDs Requesting

Step 2

Global IDs Assignment

PhPID Publisher: Global PhPID dedicated repository
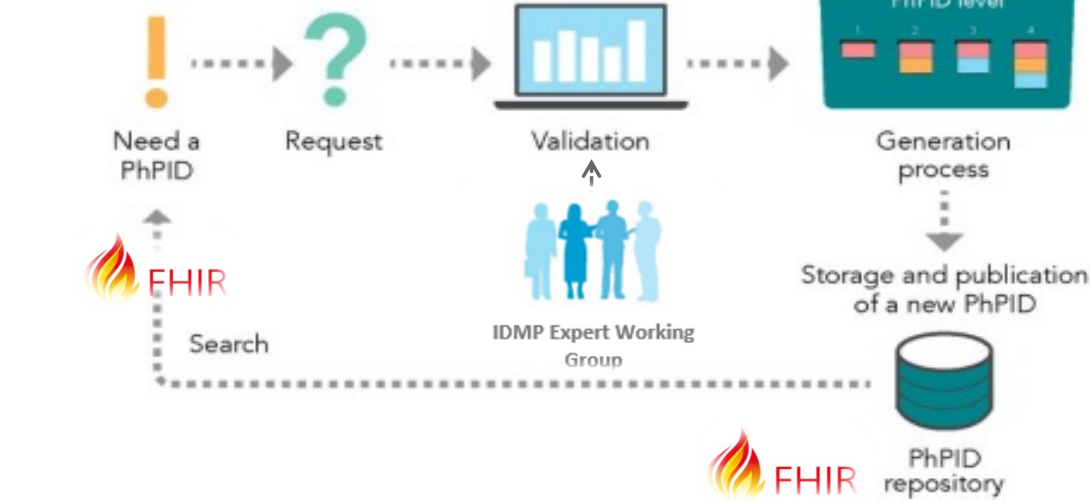
PhPID Journey – How did we get there?

Technical readiness

SYSTEM TESTING
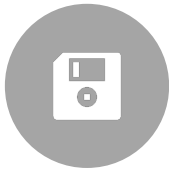
BACKUP AND RECOVERY

INFRASTRUCTURE

SECURITY AND MONITORING

CONFIGURATION MANAGEMENT

INTEGRATION READINESS: INTERFACES WITH THIRD-PARTY SYSTEMS, APIS, AND OTHER OPTIONS **ARE STILL UNDER DEVELOPMENT.**

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PhPID Journey – How did we get there?

Operational readiness
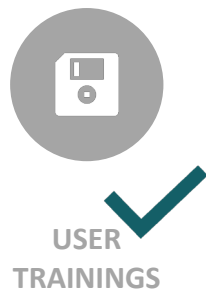
PROCESSES

USER TRAININGS

HELP DESK & CUSTOMER SUPPORT

COMMUNICATION PLANS

CHANGE MANAGEMENT

IMPLEMENTATION GUIDE

SERVICE LEVEL AGREEMENTS WITH EACH REGULATOR

Global IDMP Working Group

PhPID Journey – How did we get there?

Proof of Concept

Testing

Pre- Production

GIDWG Launch

**Production Business Rules approved**

2023

2024

Q4 2024

2021
"Dose form pilot"

2020
"Feasibility Study Project"

2022–2023
"GIDWG Project"
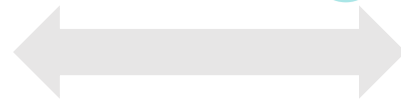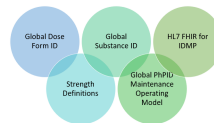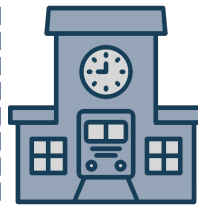
"End-to-End testing Project"
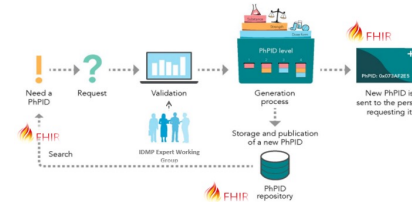
Global IDMP Working Group

PhPID Journey – How did we get there?

Business rules for Global PhPID construction approved

PhPID Journey – Next steps?

Proof of Concept

Testing

Pre- Production

GIDWG Launch

Production Business Rules approved

2023

2024

Q4 2024

2021
"Dose form pilot"

2020
"Feasibility Study Project"
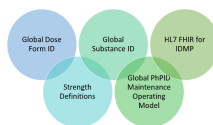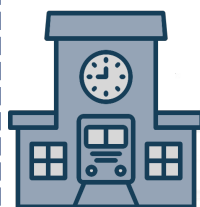
2022–2023
"GIDWG Project"
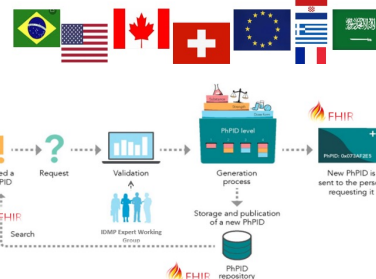
"End-to-End testing Project"

PhPID adoption

Datasets on prioritized substances* from 16 countries

PhPID Journey – How did we get there?

Pre-production PhPID Adoption initiative

Pre-production project plans

Q1 2025

Datasets on prioritised substances* from 16 countries

Q2 2025 – Q4 2025

1st Global PhPIDs Roll out

Q1 2026
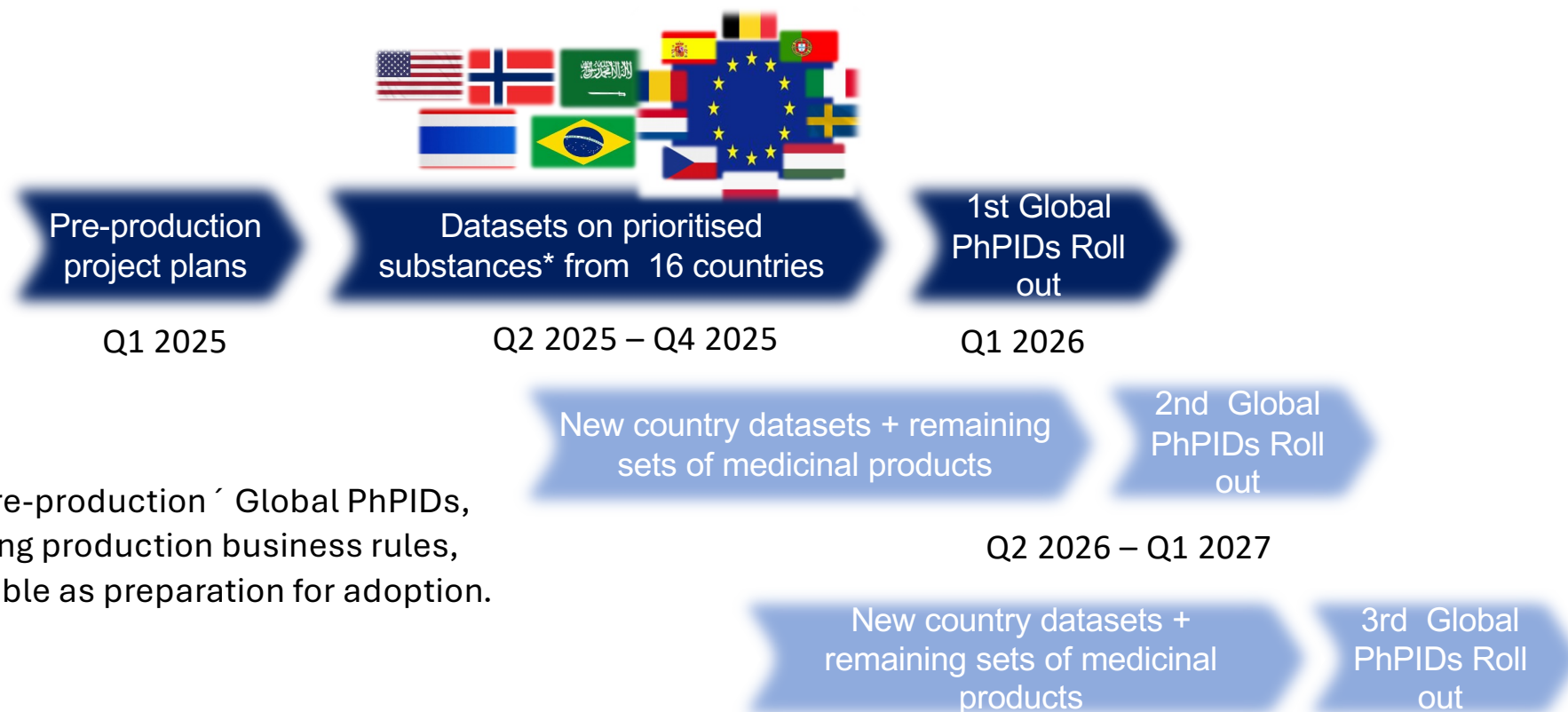
The 2025 ´pre-production´ Global PhPIDs, assigned using production business rules, will be available as preparation for adoption.

New country datasets + remaining sets of medicinal products

2nd Global PhPIDs Roll out

Q2 2026 – Q1 2027

New country datasets + remaining sets of medicinal products

3rd Global PhPIDs Roll out

Q2 2027 – TBC

*The prioritized substance sets used for selection of a Medicinal Product data set from US FDA ARMI Essential Medicines List, EMA List of Critical Medicines, 200 most reported substances within PV and WHO Essential Medicines List

Global IDMP Working Group

PhPID Journey – How did we get there?

GIDWG Work in a new format
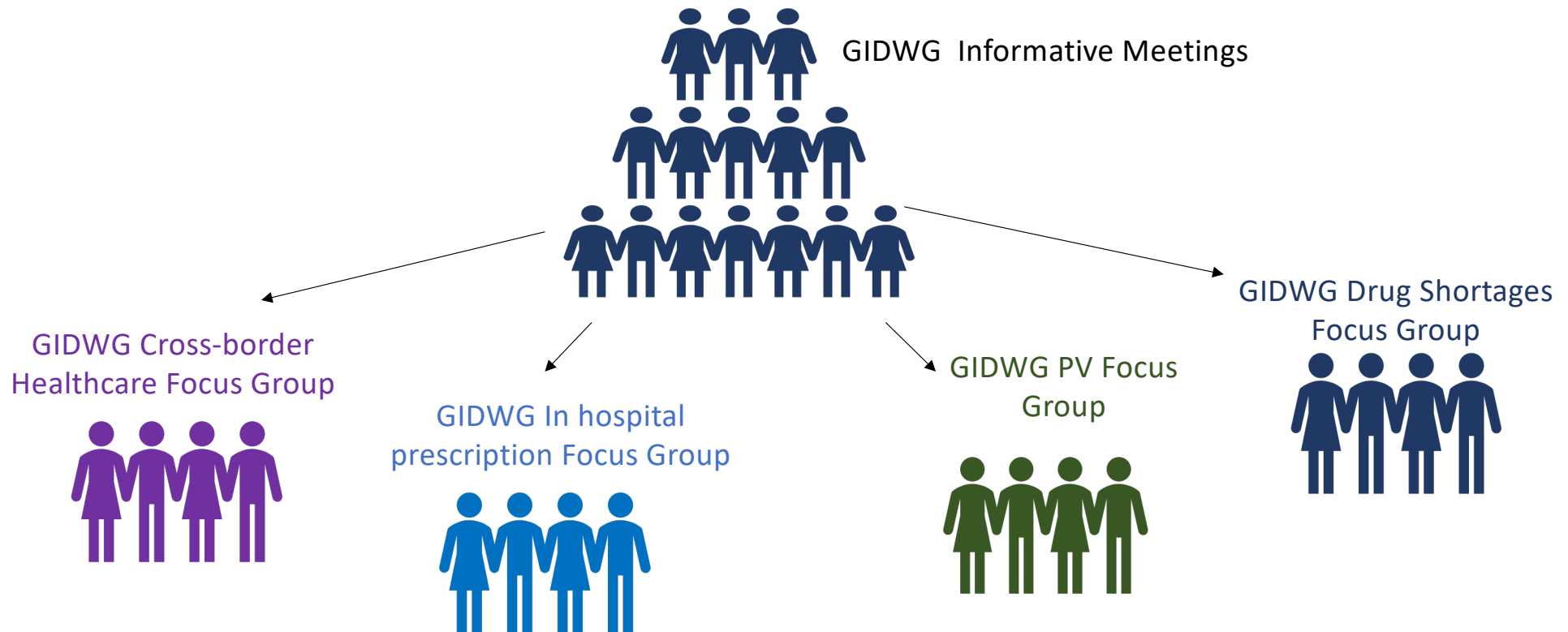
PhPID Journey – How did we get there?

Our work: GIDWG Focus Groups goals and key deliverables for 2025

Analyse GIDWG-approved Global PhPID Assignment Business Rules

from use cases´ perspective to use as INPUT into Implementation Guide to facilitate Global Pre-production PhPID Adoption.
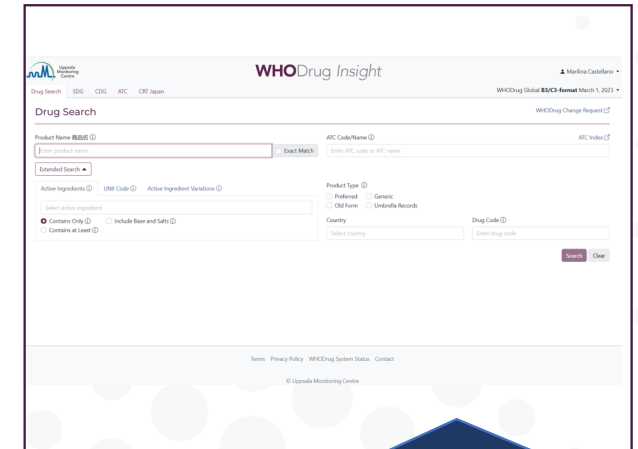

Business Rules

ANALYSIS

INPUT →

Implementation Guide on PhPID

SUPPORT →

Adoption of PhPID

Global IDMP Working Group
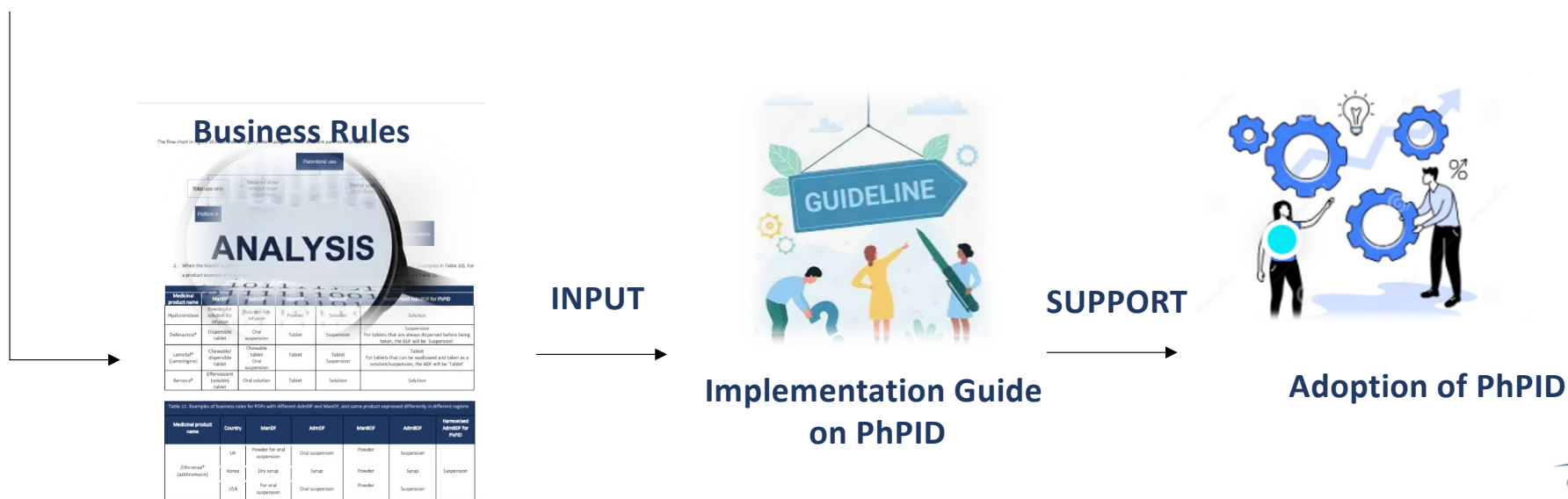
UMC´s role

Act as ambassador and collaborator
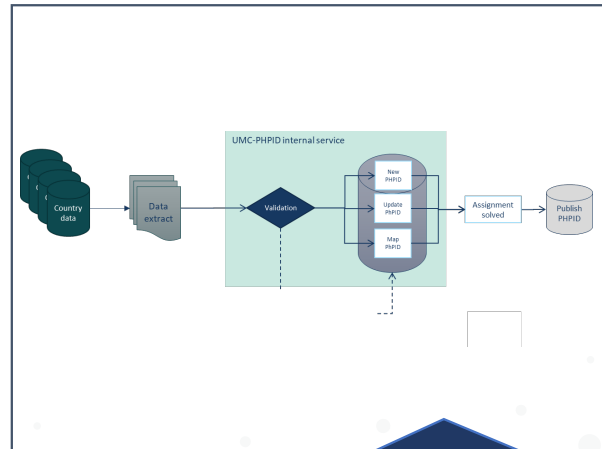
Provide Global PhPID and GSID

Link Global PhPID, GSID, and medicinal products via WHODrug Global

Global PhPID and connection to medicinal products

PhPID Journey – Next steps?

UMC needs to maintain license agreements with main stakeholders

For coding and analysis of ICSRs and clinical trial data. License with no cost for regulatory authorities.

For additional national and regional use cases. License with no cost for regulatory authorities and #national health care sector"

No additional cost for commercial parties on top of their WHODrug license.

WHODrug Global

National identifiers

Substance
Strength
Dose form
PhPID
1 2 3 4
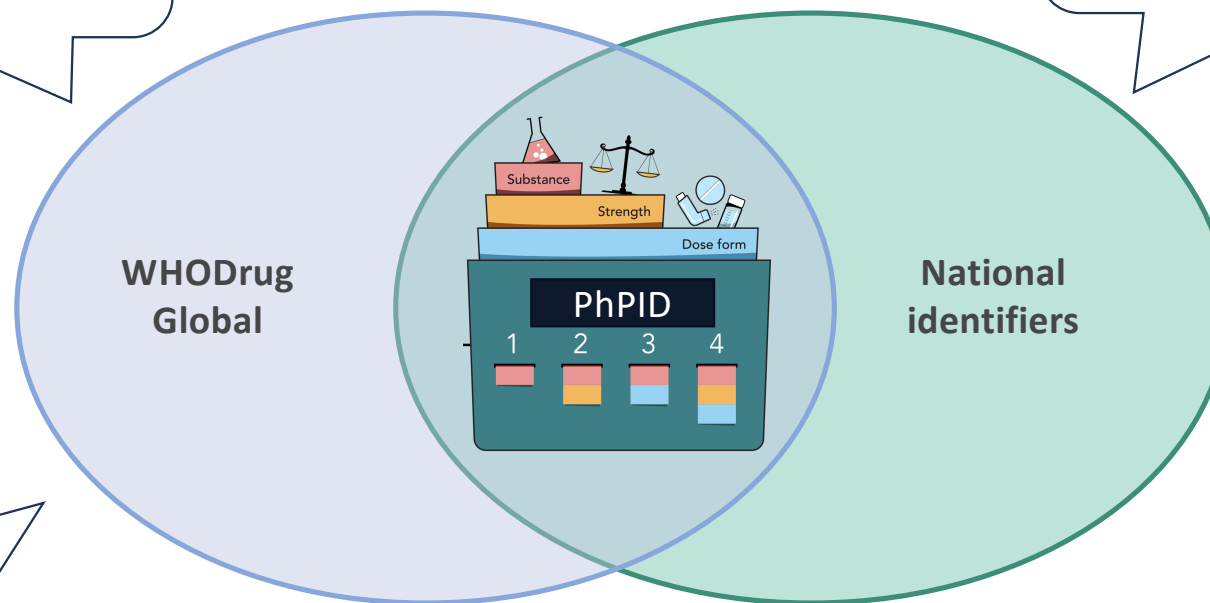
PhPID Journey – Next steps?

GIDWG Goals: providing support for

- Demonstrating that the IDMP standards are "fit" for global implementation
- IDMP use cases implementation and operationalization
- Production Global PhPIDs Roll-outs
- Development of the ISO IDMP standards

- Piloting Production Global PhPIDs for use cases
- Production Global PhPIDs 2nd Roll-out
- Business Rules revision process
- Engaging stakeholders in GIDWG work

- Global PhPID Implementation Guide development
- Global PhPIDs 1st Roll-out
- Business Rules revision process

2025-2026   2027-2028   2028 and onwards

Global IDMP Working Group
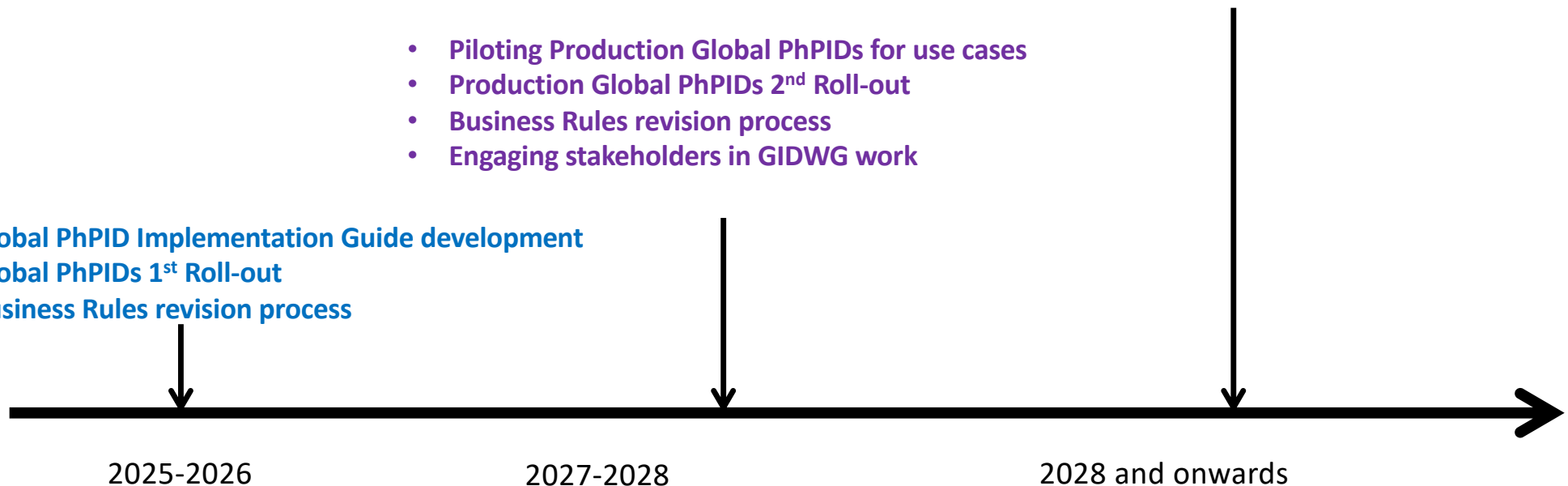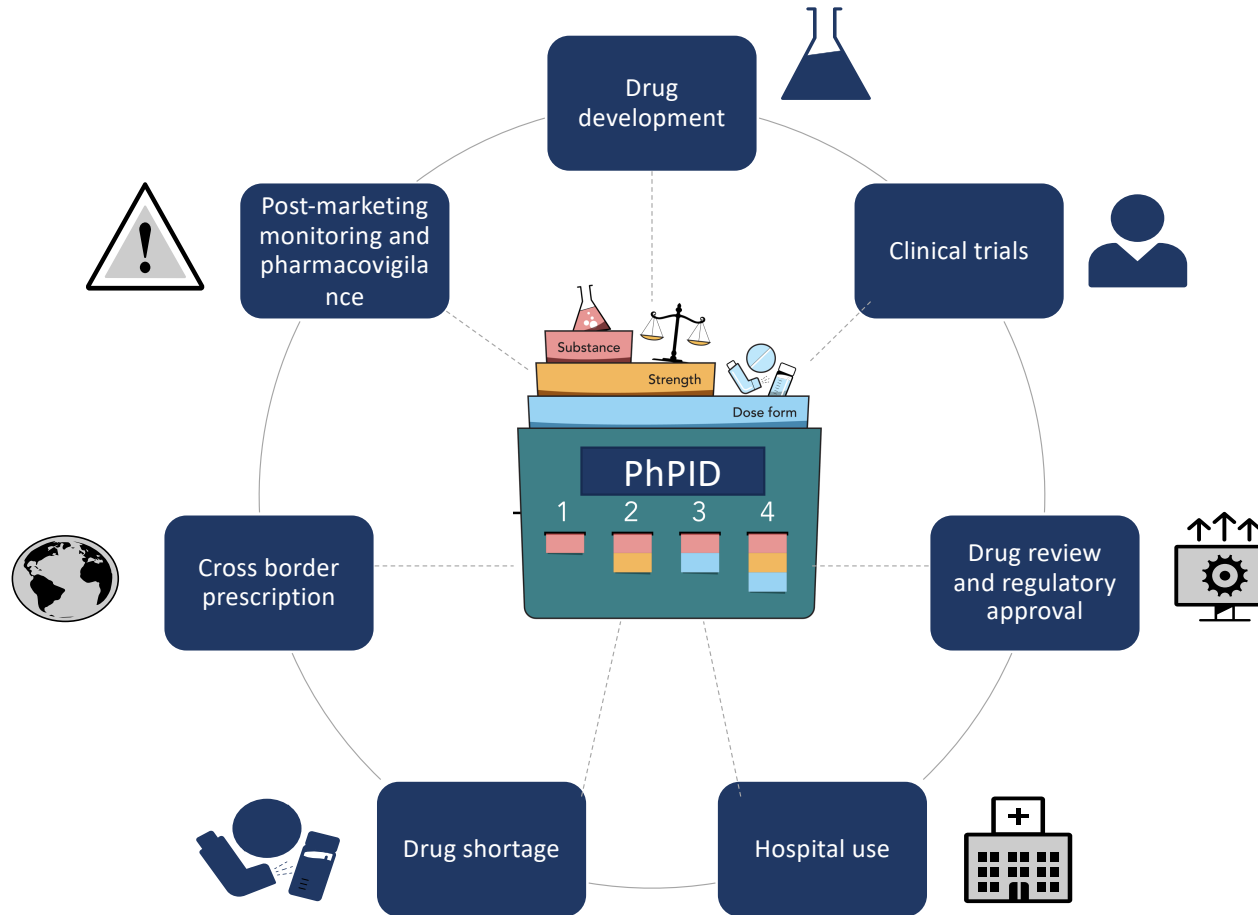
Follow us on GIDWG website!

- www.gidwg.org
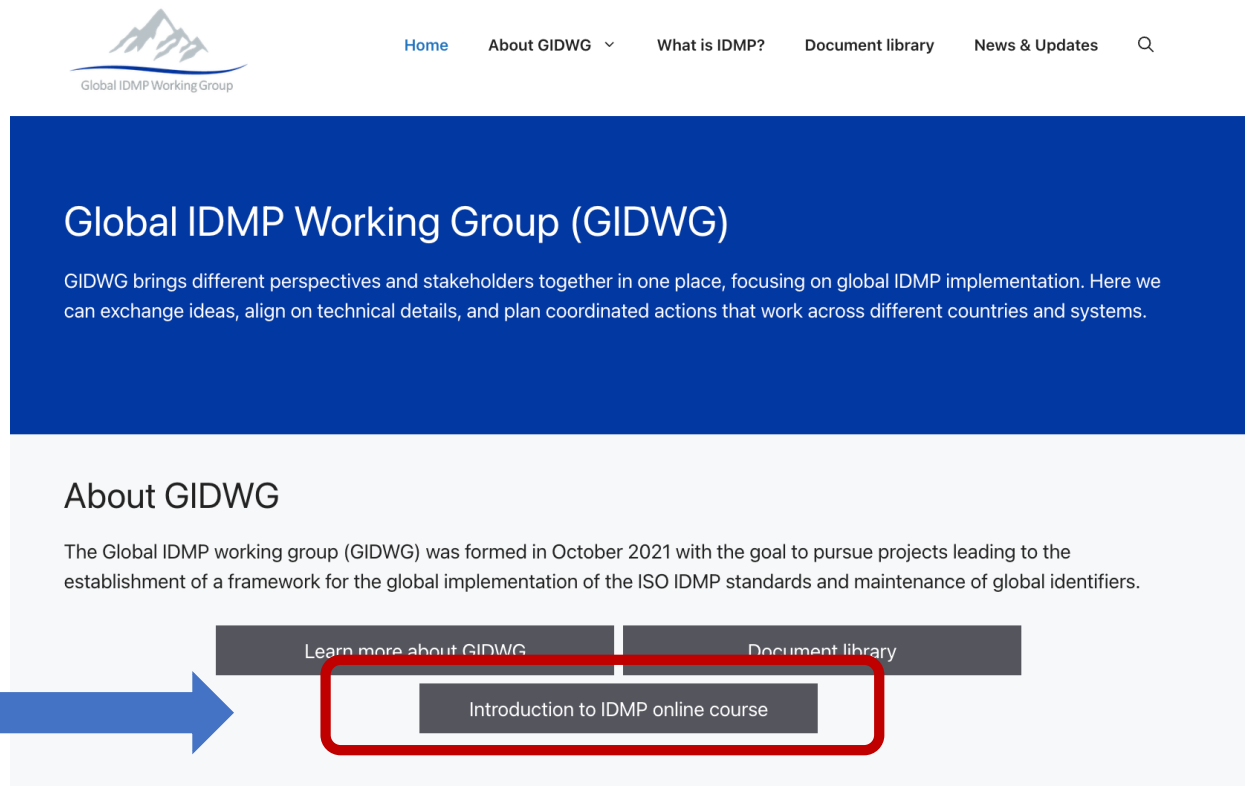
Online - IDMP training course

https://idmpinfo.who-umc.org/training/index.html#/

UMC Training

Introduction to ISO Identification of Medicinal Products (IDMP)

START

THEORY

1. Why do we need global identifiers?

2. What is the purpose of ISO Identification of Medicinal Product standards?

3. How will pharmaceutical product identification link medicines globally?

4. How are the ISO standards used for generation of pharmaceutical product identifiers?

5. How will pharmaceutical product identifiers be generated?

6. What steps does one need to consider when implementing these standards?

7. Summary

FREQUENTLY ASKED QUESTIONS

FAQs

Global IDMP Working Group

5th Global Identification Working Group (GIDWG) Technical and Stakeholders Meetings

EMA building, Amsterdam, 1-3 October 2025

Presented by

Isabel Chicharo (I-CS-RDM)

Table of contents

IDMP implementation in EU
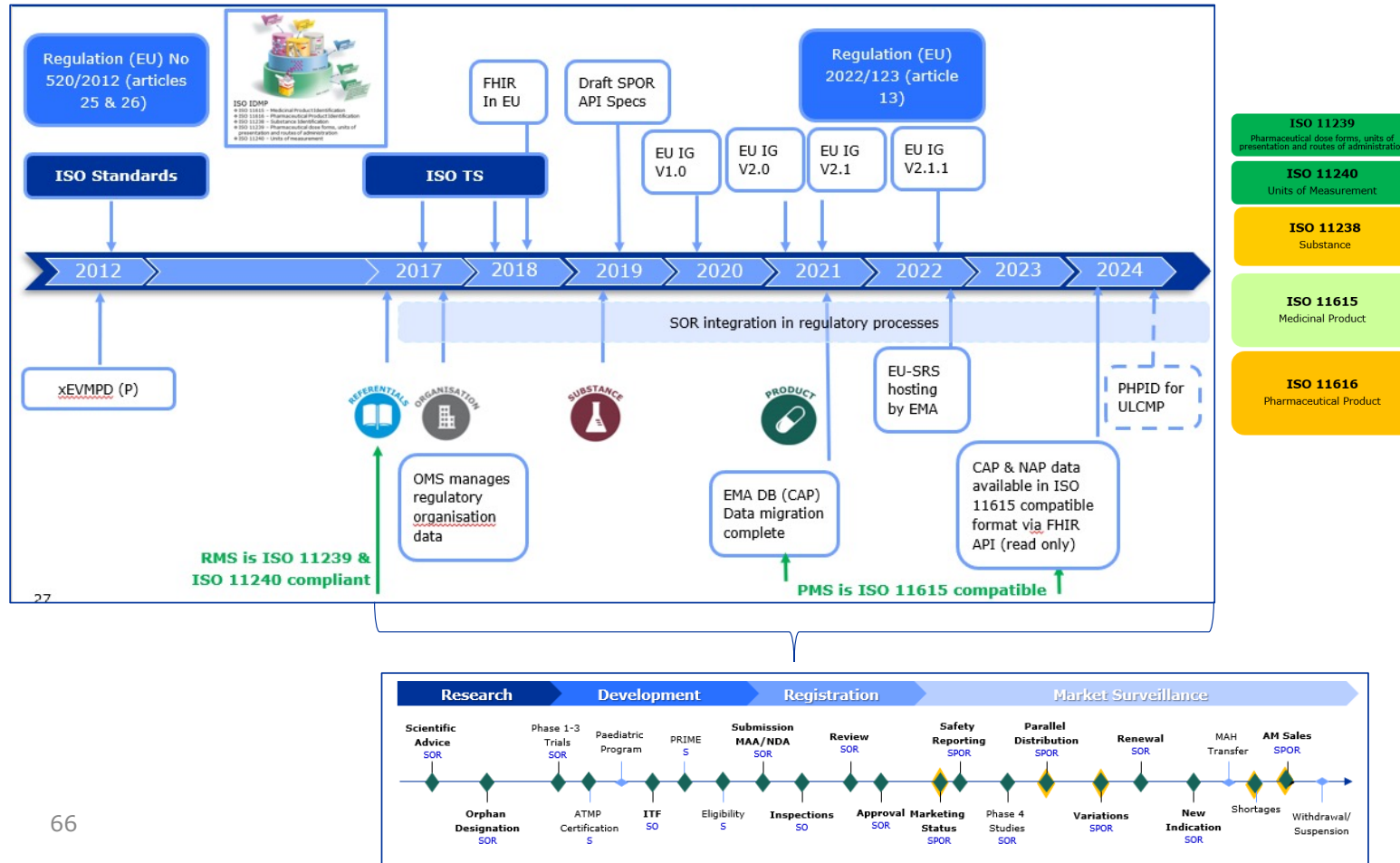
- ➢ IDMP implementation legal basis
- ➢ Phased implementation programme
- ➢ Extensive guidance and change management for Stakeholders
- ➢ Most regulatory processes throughout the product lifecycle are using data from SMS, OMS, RMS – PMS (IDMP) product data is also in use

66

Product Management Service (PMS) Vision

Product Management Service (PMS) is a ISO IDMP-compatible database that **consolidates investigational, authorised and registered human medicinal products** across the European Union.

PMS data is available to regulators, industry and the general public to **support regulatory and non-regulatory procedures** as well as **public consultation of data**, ensuring data accuracy, transparency, standardisation and accessibility.

Key changes
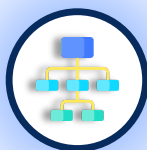
Enriched data set in ISO IDMP-compliant structure

Integrated data journey through regulatory procedures

Trustworthy and quality data in one single source

PMS implementation approach and status

> Up to now: migrate/transform/ consolidate product data -> use/integrate it in processes

> Current focus: analyse and improve Data quality

> Future looking: look outside regulatory use cases – EHDS opportunity in EU, value of Global implementations

What is available to use?

What we have in place

- **Product User Interface (PUI)**
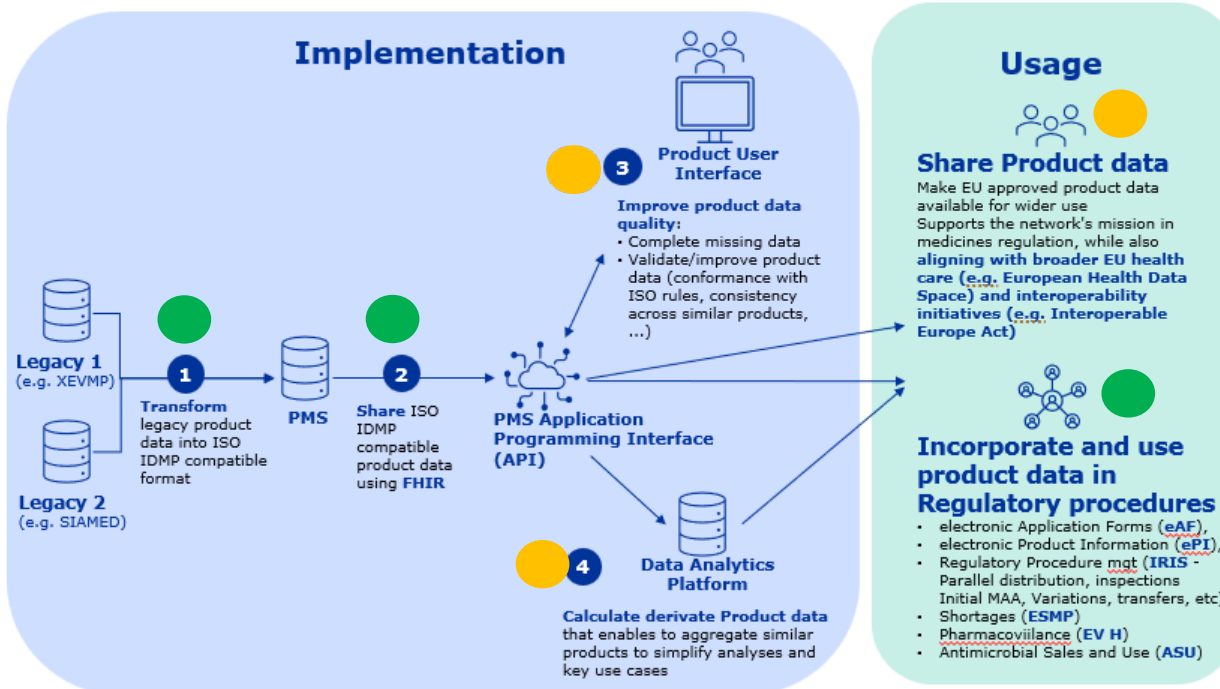 - **Public**/NCAs/Industry can search and browse all authorised medicinal product data - here
  - Industry/NCAs can use BI reports and exports – here
  - Industry can edit manufacturers and structured pack sizes data for single or multiple non-CAP products - here

- **PMS (FHIR) Application Programming Interface (PMS API)**
  - NCAs/Industry can search and browse medicinal product data
  - Industry can edit manufacturers and structured pack sizes data for their non-CAP products

What we are working on

- **Product User Interface (PUI)**
  - Export of the **public** dynamic report for general Public – here - **Q1 2026**

- **PMS (FHIR) Application Programming Interface (PMS API)**
  - PMS **Public** API so anyone that can search and browse public medicinal product data – **Q1 2026**

What is next

› **PMS API FHIR R5 upgrade (read/write)** – needed for technical alignment to latest FHIR version

› **PMS API - Full write API for MAHs** – needed to complete/maintain all product data

› *Not yet planned - FHIR Tasks/PHPID/push model*

EMA

For EU... Why PHPID?

Substance ID

Strength

AdmDF Dose form

or

ManDF Dose form

PhPID Service

Pharmacovigilance

Safety Alerts

- Improve ability to identify, assess and respond to patient safety medication incidents.

- Improved surveilling of counterfeits

- Improved monitoring global supply chains for product quality issues and risk analytics

Drug Shortages

Medicinal Product Shortages

- Make it easier to find alternative products in microbial resistance or drug shortages.

- Allows the identification of pharmaceutically equivalent across regions to support mitigation of drug shortages

Cross-border Prescription

Cross Product Comparisons

- Make it easier to compare products across jurisdictions for cross-border healthcare

- Reduce or share the cost of managing the same medicinal product information.

Shortages and PHPID

Level 1 — *Active substance(s)*

Level 2 — *Active substance(s) - Strength(s) - Strength unit(s)*

Level 3 — *Active substance(s) - Pharmaceutical Dose Form*

Level 3.1 — *Active substance(s) - **Pharmaceutical Dose Form Group***

Level 4 — *Active substance(s) - Strength(s) - Strength unit(s) - Pharmaceutical Dose Form*

Level 4.1 — *Active substance(s) - Strength(s) - Strength unit(s) - **Pharmaceutical Dose Form Group***

Level 5 — ***Multidose oral liquids** - Active substance + **Pharm DF group*** + strength + **container size***

Level 6 — ***Interchangeable Vaccines - ATC code***

***Pharmaceutical form group** - Manual grouping of interchangeable pharmaceutical dose forms based on the business needs.*

- ➢ Alignment with Global PHPID at higher levels

- ➢ Need for variants and additional PHPID levels to address the needs of shortages

- ➢ Differences across PHV and shortages implementation

- ➢ Multiple "PHPID sets" can coexist, they serve and are used in different context

EMA

Thank you

EMA

Closing Remarks

Isabel Chicharo

EMA

Our conclusions

- Increased outreach
- Valuable platform for lessons learned and alignment
- PhPID and global IDMP Implementation
  - Global PhPID Service Go-live
  - What does Go-live mean to you
- How do we envisage PhPID to be used in future – what are the use cases/opportunities/benefits
  - PHV
  - Drug Shortages
  - Cross-border Healthcare
  - Regulatory
- The future

Global IDMP Working Group

Thank you for your work on IDMP!