Toward Global IDMP Implementation: A Focus on Global Use Cases

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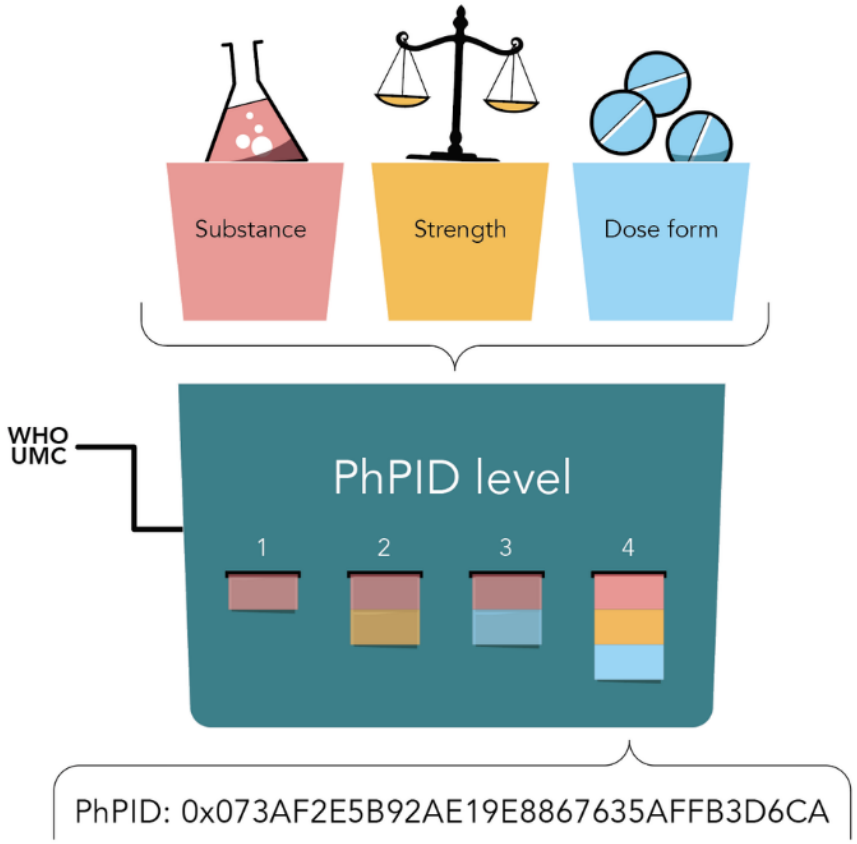
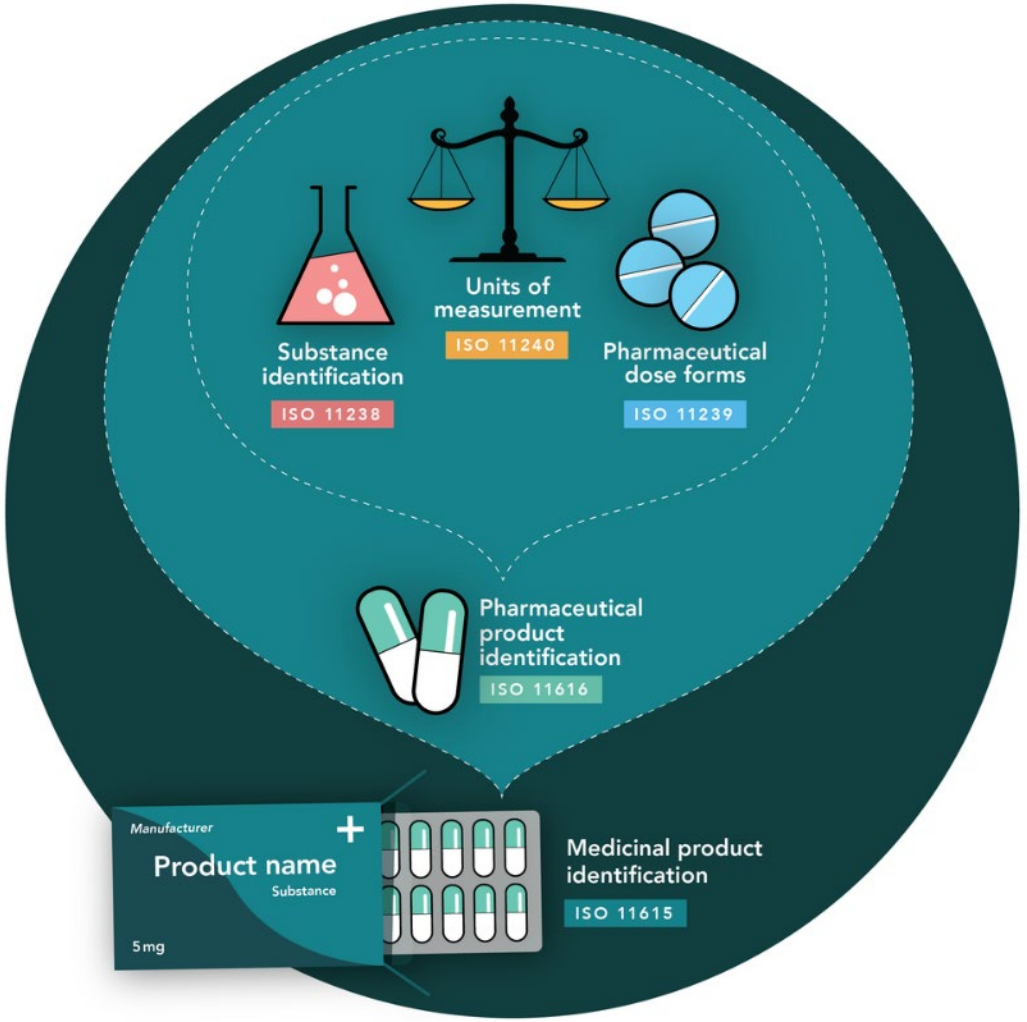
CDER Small Business & Industry Assistance (SBIA)

What is IDMP?


Substance
Strength
Dose form
WHO UMC
PhPID level
1
2
3
4
PhPID: 0x073AF2E5B92AE19E8867635AFFB3D6CA


Substance identification
ISO 11238
Units of measurement
ISO 11240
Pharmaceutical dose forms
ISO 11239
Pharmaceutical product identification
ISO 11616
Manufacturer
Product name
Substance
5mg
Medicinal product identification
ISO 11615

Guidance on

Identification of Medicinal Products — Implementation and Use

MARCH 2023

Purpose of the Guidance

- Until this guidance, FDA had no formal policy on the implementation and use of the IDMP standards

- Provides FDA's position and progress on aligning the Agency's standards to Identification of Medicinal Products (IDMP) standards

- FDA's goal is the harmonization of the standards for the international exchange of medicinal product data

Objectives of the Guidance (1/2)

To inform sponsors, applicants and registrants:

1. FDA has used, for many years, standards that conform to the ISO IDMP standards
   - *National Drug Code (Medicinal Product ID)*
   - *Unique Ingredient Identifier (Substance ID)*
   - *Unified Code for Units of Measure (Strength)*

2. FDA sees 3 key benefits to global IDMP
   - *Drug Safety & Pharmacovigilance*
   - *Medicinal Product Traceability and Supply Chain Integrity*
   - *Exchange of Medicinal Product Information*

Objectives of the Guidance (2/2)

3. FDA will continue to work with international stakeholders (e.g., WHO-UMC, HL7, ISO, GIDWG, ICH) to ensure the standards can be implemented for the key use cases above

4. FDA's focus is on a global phased approach to IDMP implementation when the standards are "fit for purpose"

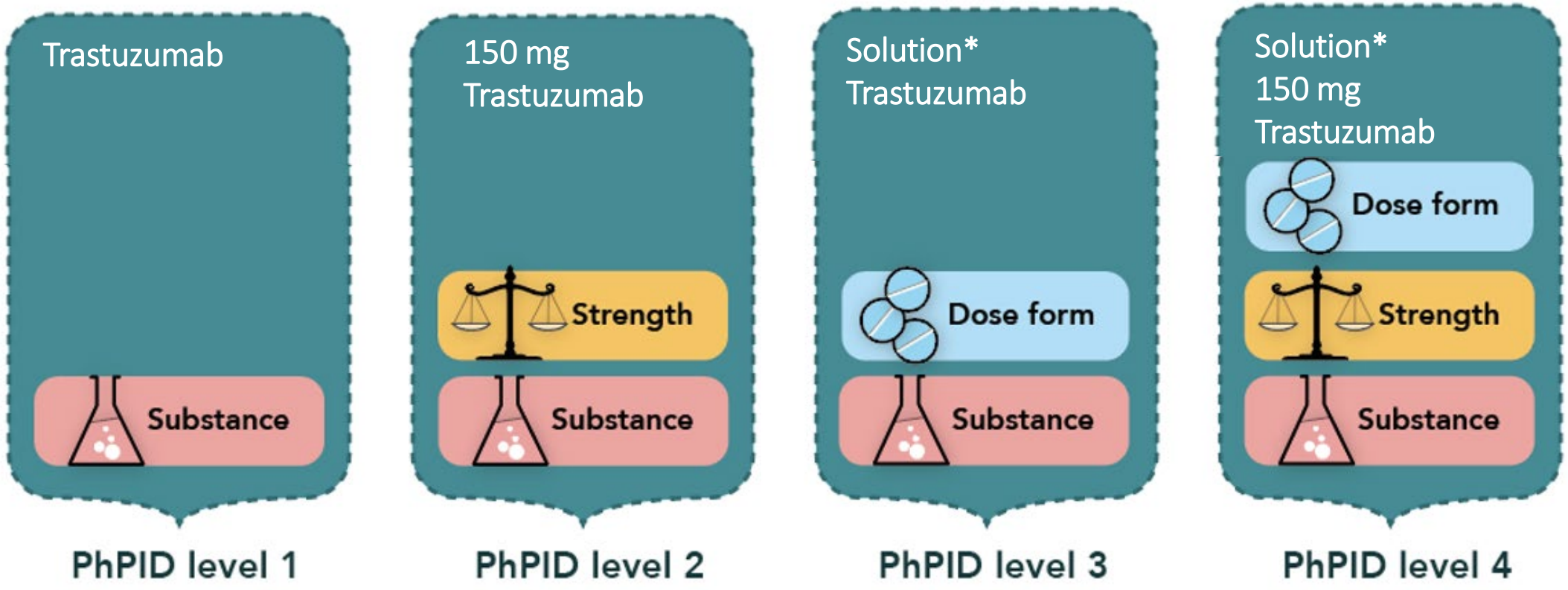
5. FDA supports the establishment of a framework for the maintenance of the global IDMP identifiers

Framework for Global Identifier Maintenance

- 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, Swissmedic (pending)
  - **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

GIDWG is a collaborative initiative

The PhPID and its levels

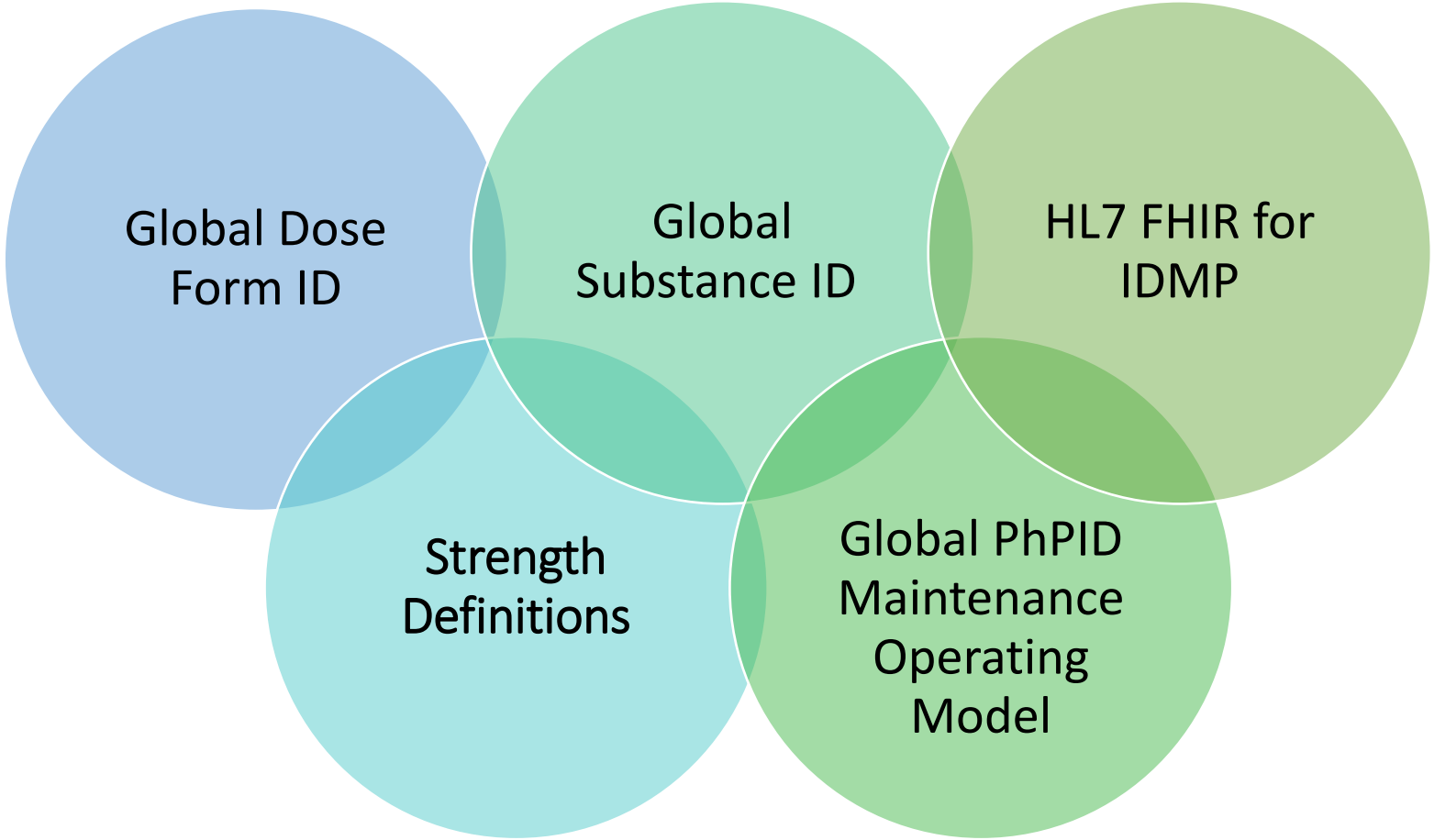


*Dose form characteristics: Solution, Injection, Parenteral, Conventional

Global PhPID connecting the dots

GIDWG projects

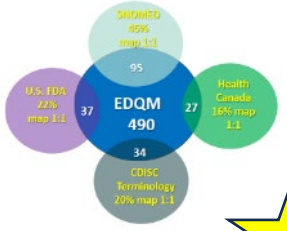
Aim to define and reach consensus on processes, best practices and an operating model for maintenance of global identifiers for marketed medicinal products



GIDWG's Journey so far…

ISO IDMP

ISO 11239 – Dose Form for Global implementation

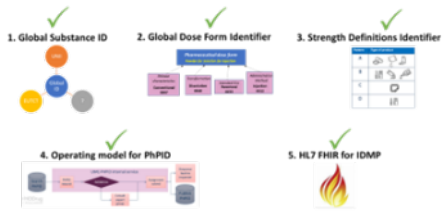


WHO Workshop

GIDWG

Global IDMP Working Group

GIDWG Projects



Use Cases

End to End Testing

2012 | 2018 | 2019 | 2021 | 2022 | Q4 2023 | 2024

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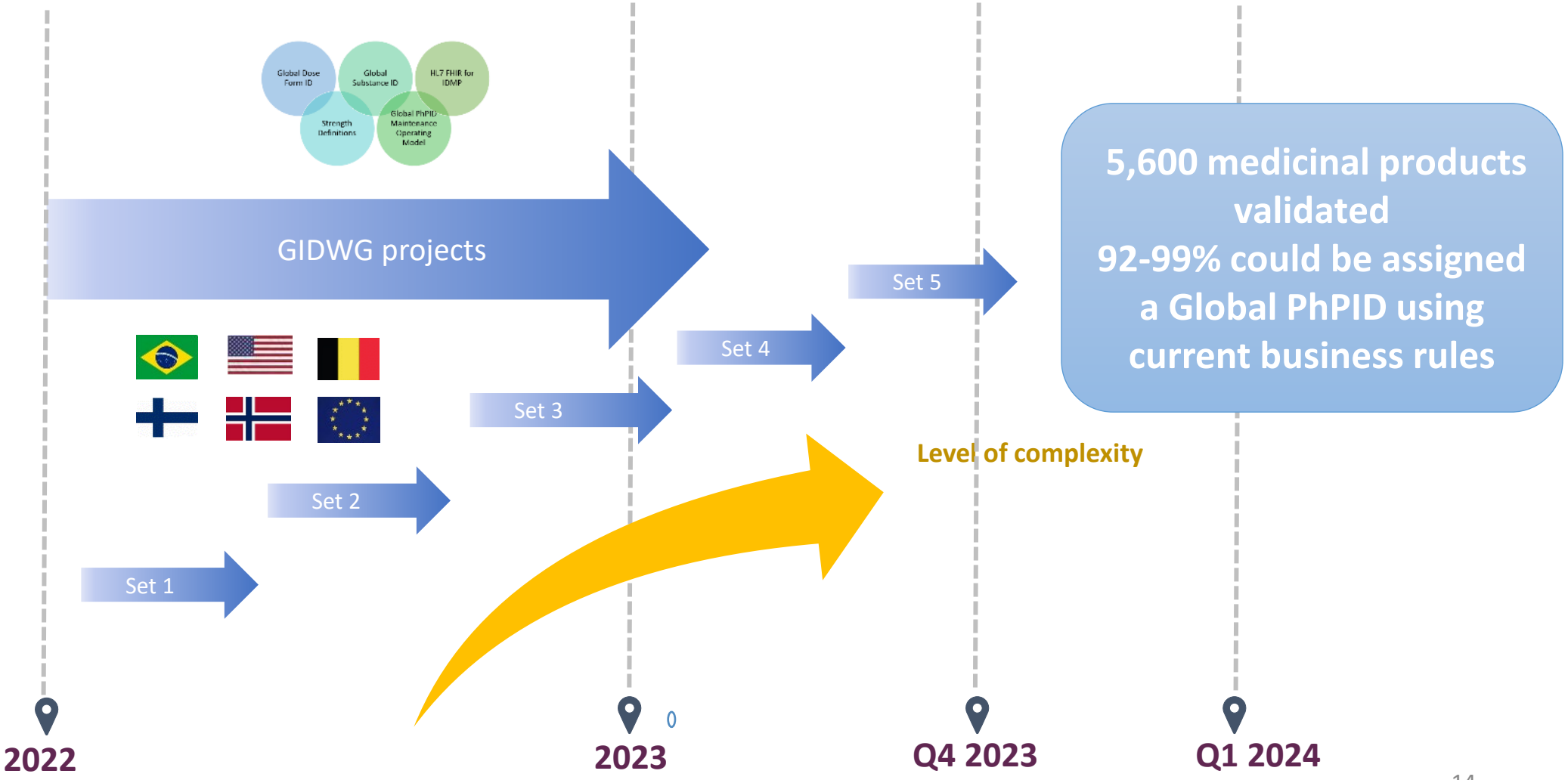
Center for Drug Evaluation and Research (CDER) | FDA

GIDWG validation overview

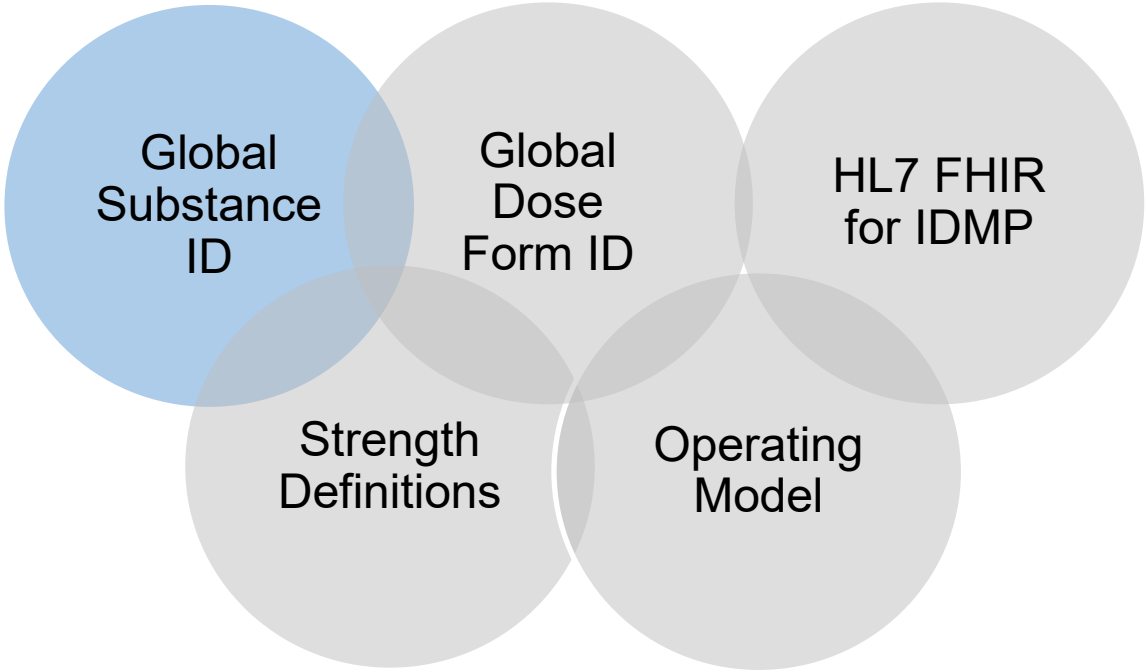


Project 1: Global Substance ID (GSID)

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



General business rules for GSID and PhPID

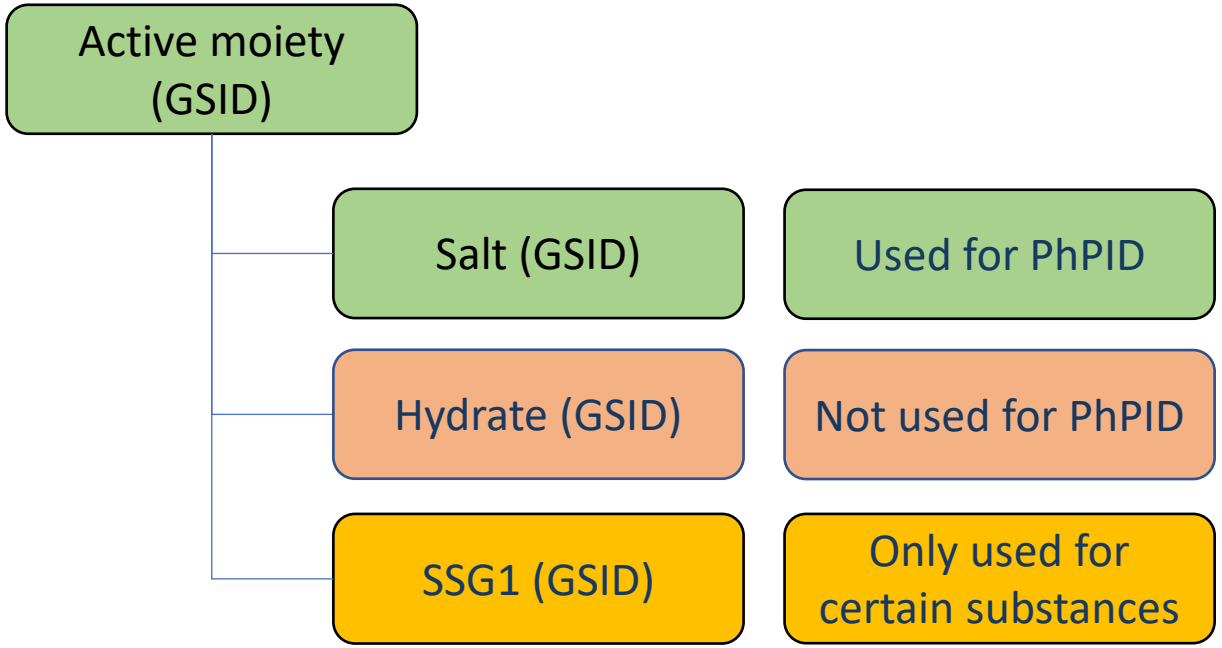
GSID

- The **GSID** assignment is based on **ISO 11238** and **TS 19844**
- The business rules should clarify the standards when needed
- The defining substance information needs to be in the public domain to assign a GSID

PhPID

- **PhPID** assignment is based on **ISO 11616**
- **PhPID is assigned to marketed products**
- Using the appropriate GSID when generating a PhPID in a consistent manner
- All active ingredients and their corresponding GSIDs will be used in PhPID assignment
- Follow the process for PhPID harmonisation/assignment

GIDWG pilot – Business rules for GSID in Global PhPID



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

GSID can be assigned at both substance and SSG1 level

SSG1 is only used in certain cases where SSG1 is important to distinguish between different PhPIDs

Input string: GSID; strength; dose form

Business rules for GSID for Insulins

Fast acting product

Intermediate acting product

To accurately describe the difference between the two products, the GSID for both substance level and SSG1 level will be used for PhPID generation

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

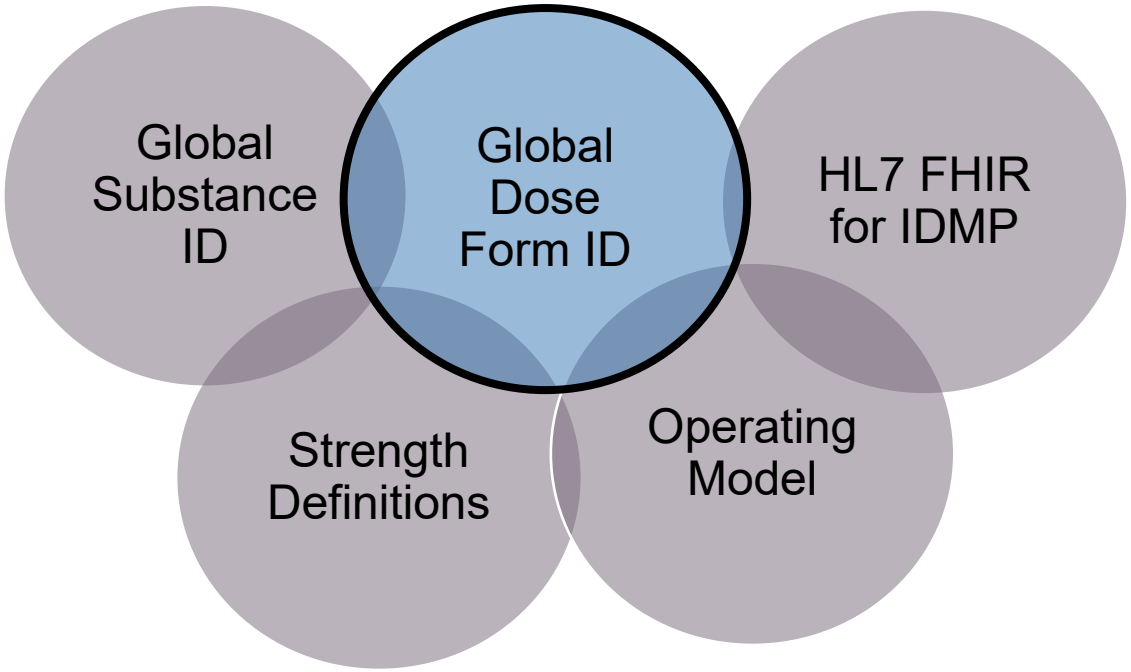
GSID9ST5UC24F36TN

- 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

Project 2: Dose Form Identifier

Project Scope and Deliverables

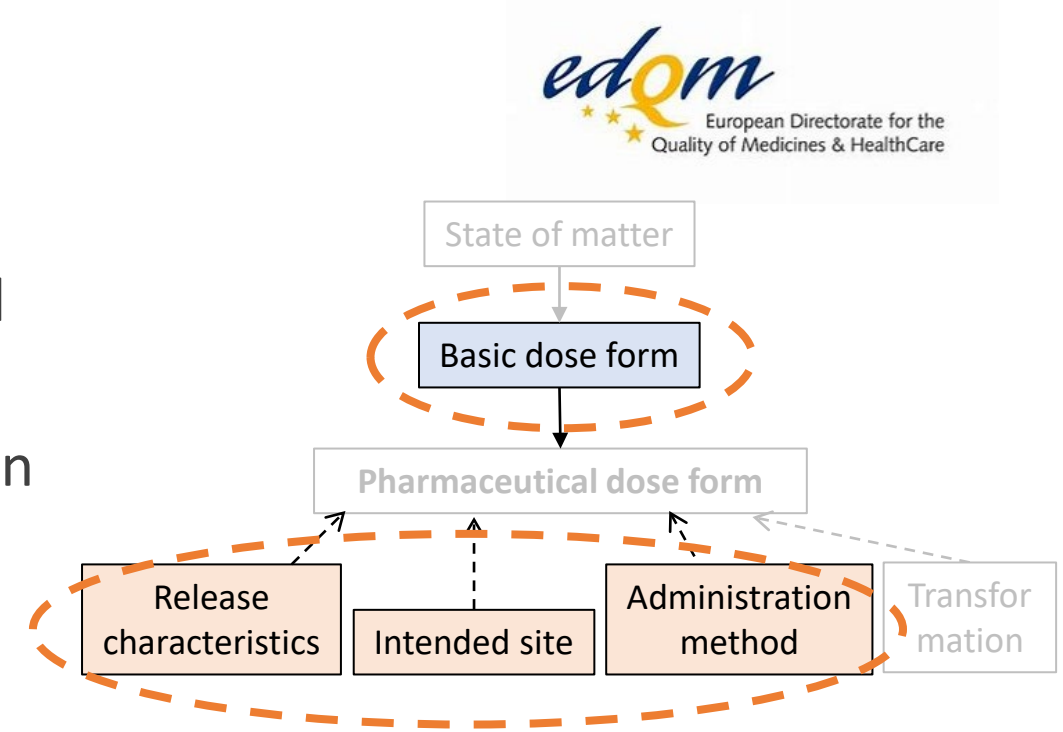
- Further investigate 4 dose form characteristic approach on larger datasets for at least one another region
- Assert the scalability and automation of the process
- Develop and Formalize Business Rules



www.gidwg.org

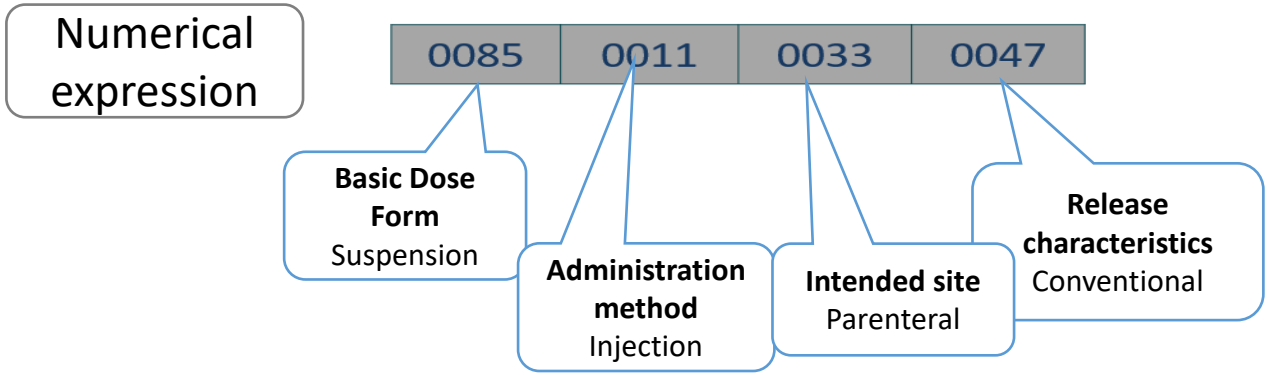
Business rules for dose form identifier

- There is no globally accepted dose form terminology set
- The **basic dose form** together with 3 **dose form characteristics** (EDQM) are used to characterize the **administrable dose form** for Global PhPID
- The dose form characteristics are generally assigned based on product label information
- Where a medicinal product can be used in more than one way, the focus should be on the **primary use** or the term with the strictest microbiological requirements
- **Administration method** and **Intended site** characteristics can be assigned **more than one term** where it is not possible to identify a primary use

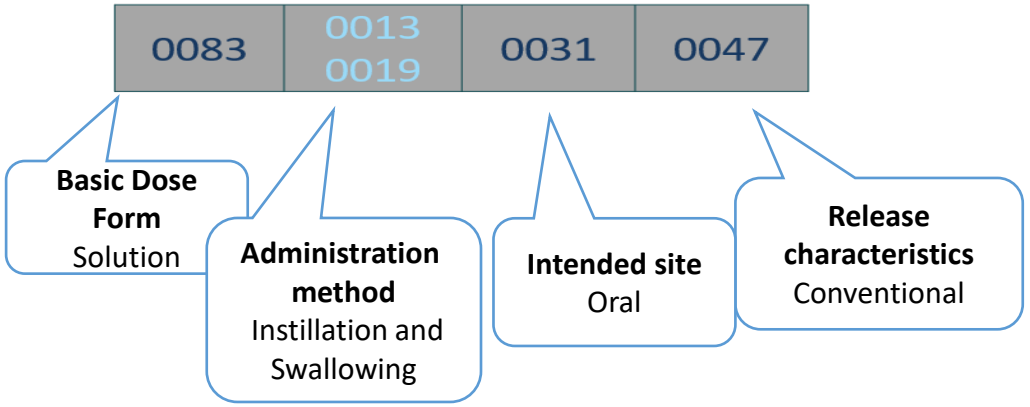


Example of multiple characteristics for Dose Form

Single characteristics:
Suspension for Injection



Multiple characteristic:
Oral drop, suspension

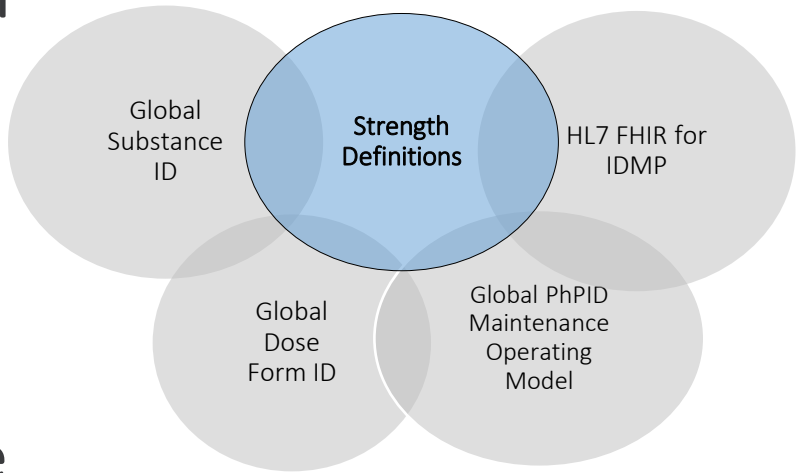


Example of multiple characteristics for Release : Extended release oral tablets: assigned one release characteristic according to clinical relevance

Project 3: Global Strength Definitions ID

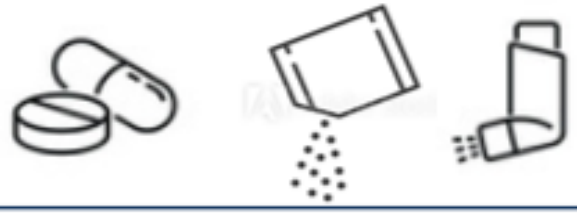
Project scope and Deliverables

- Identify and address different representations 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 the additional product data set are covered
- Leverage the scalability and automation of the process
- Formalize business rules for each pattern and investigated dose forms



Business rules for Strength and Units

Pattern framework

Pattern	Type of product
A	
B	
C	

Numerical values

2.02 250 $1*10^8$

12,25 1000

Units

mg/ml viral particles

UI Beq

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	Harmonised BDF	SmPC strength	Strength
Lovenox (enoxaparin sodium)	Prefilled syringe	Solution	40 mg/0.4 mL	**40 mg**

Example: Pattern B – multi-dose of continuous presentation

For topical use

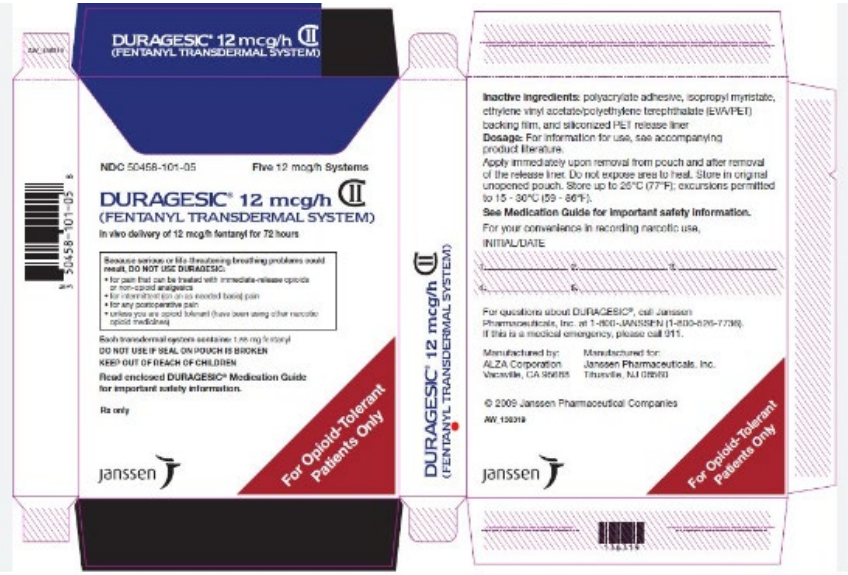
DESCRIPTION

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	Harmonised BDF	SmPC strength	Harmonised strength
Locoid (hydrocortisone butyrate)	Cream	Cream	0.1%	**1 mg/g**

Example: Pattern C – products enclosed in a ‘presentation’, where the dose has a delivery rate



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

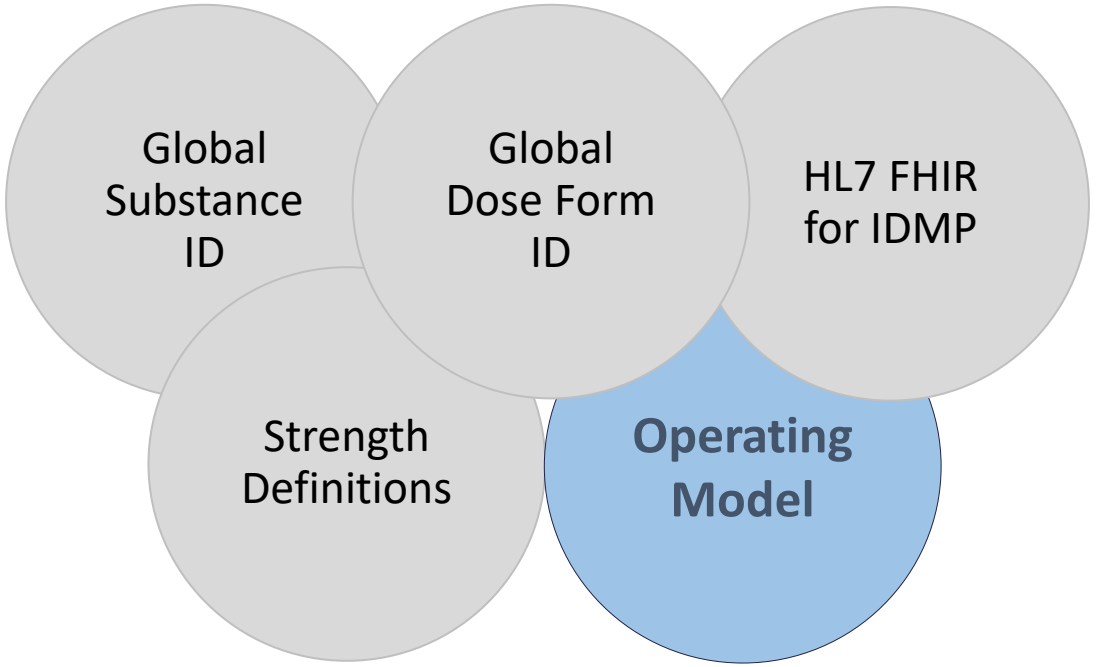
*Nominal delivery rate per hour
**Nominal delivery rate is 12.5 mcg/hr

Medicinal product	SmPC dose form	Harmonised BDF	SmPC strength	Harmonised strength
Durogesic (fentanyl)	Transdermal system	Patch	25 mcg/h per 10.5 cm2	12.5mcg/h

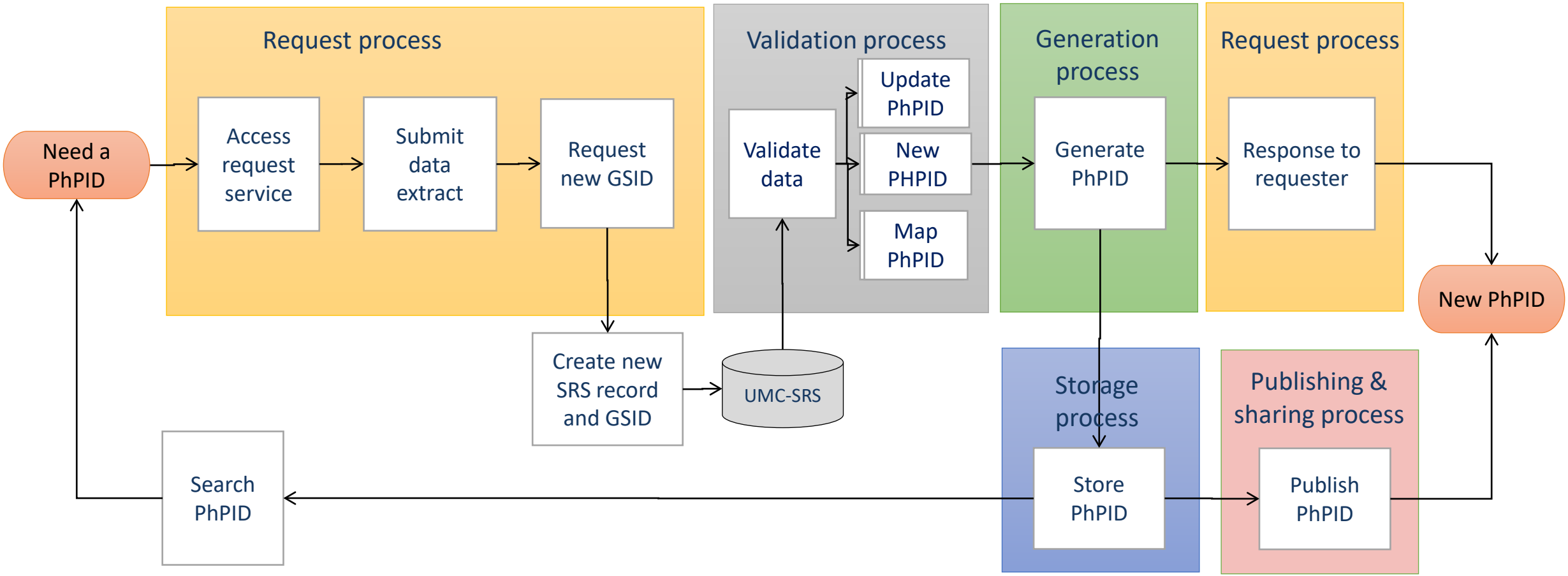
Project 4: Operating Model

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 healthcare
  - Process definition by three jurisdictions (EMA, US-FDA, ANVISA)



PhPID Operating Model including GSID request technology & solutions

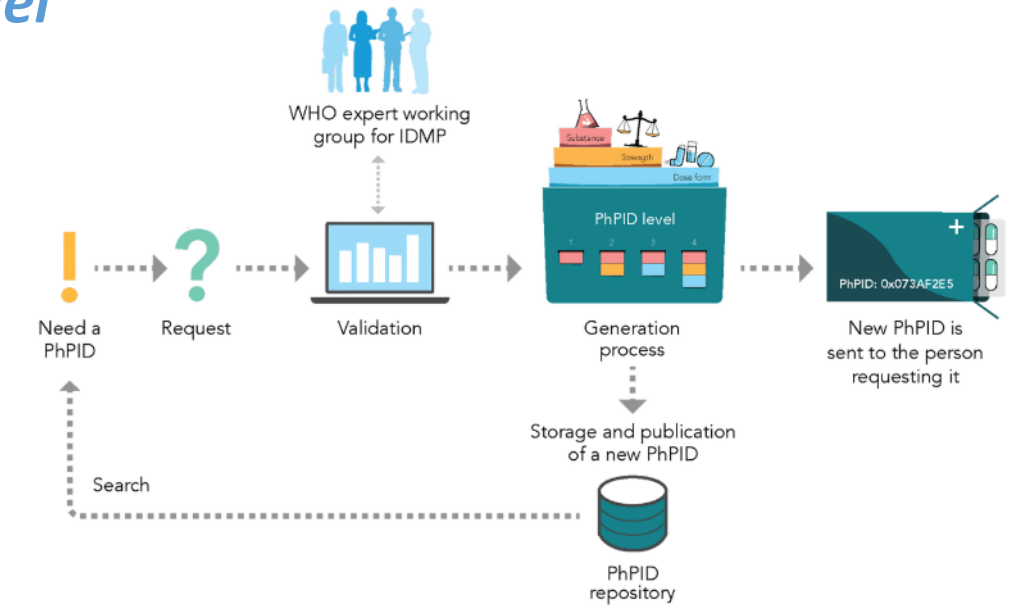


End-to-End Demonstration Q4 2023 – Q1 2024

Testing of use cases for GSID/PhPID operating model

SCOPE

- Validate and generate PhPIDs for products based on 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, ‘mixtures’

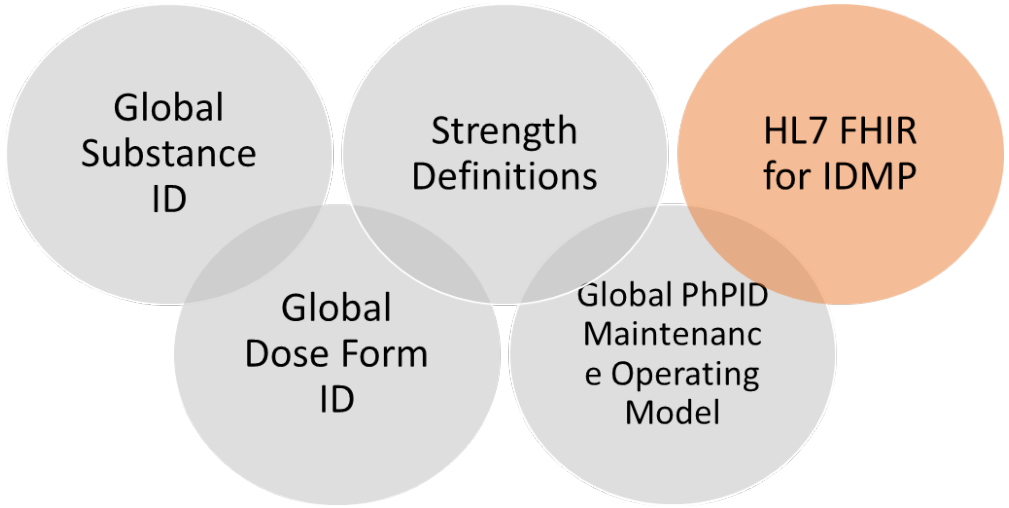


Proposed candidate countries:

Project 5: IDMP in HL7 FHIR

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



GIDWG End-to-End Use Cases

Cross Border Healthcare

TJ Chen

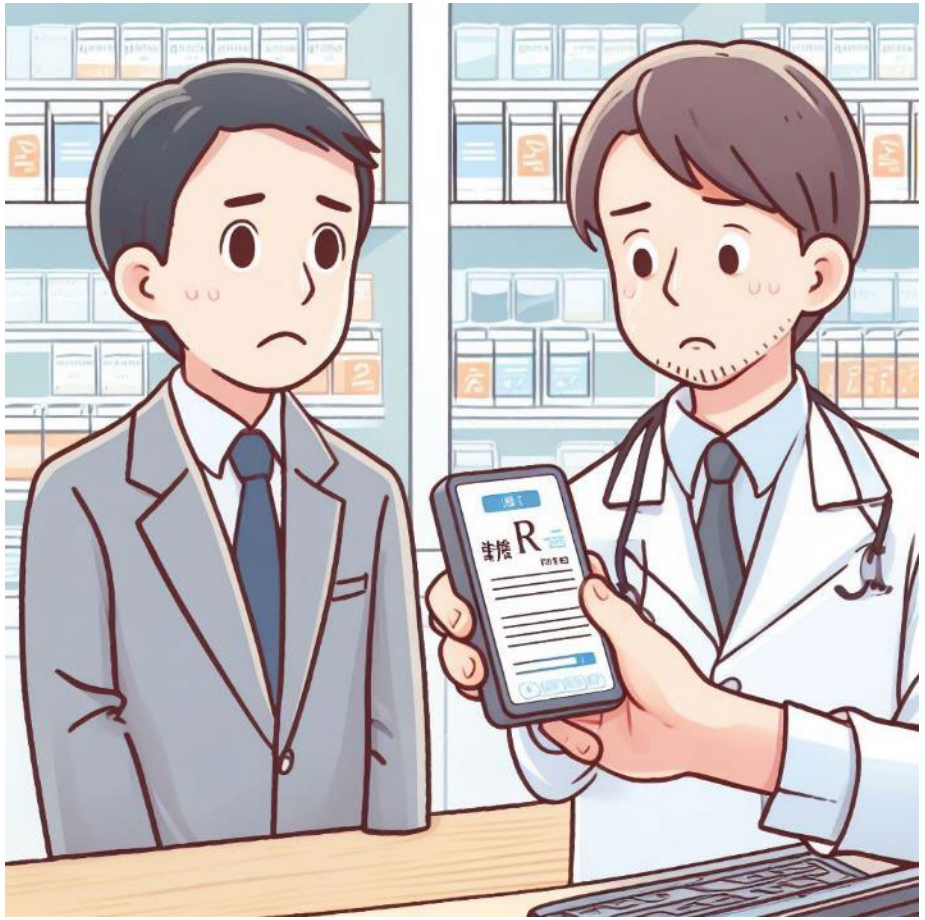
Travel from Japan to USA

Tanaka embarks on an international journey from Japan to the United States, poised for his anticipated vacation.

Japanese ePrescription

Luckily, Tanaka can leverage a healthcare mobile app to access an electronic prescription for his medication, which he can presents to a U.S. pharmacist.

Challenge: Dispensing a foreign prescription in the US



There are only few pharmacies in the US that can dispense a foreign prescription.

The pharmacist in US cannot type the Japanese brand name in his own software system.

This provokes genuine concern over potential prescription misinterpretation and erroneous medication dispensation.

If we had a global PhPID

Global PhPID level 4 is luckily available in the Japanese prescription.

Tanaka now holds out the prescription confidently, a bridge between languages and cultures.

Therapy compliance is successfully ensured preserving patient's health.

Global PhPID connecting the dots

Global PhPID level 4, connected to a federated resource of medicinal products can help to identify medicinal products that are *like each other*

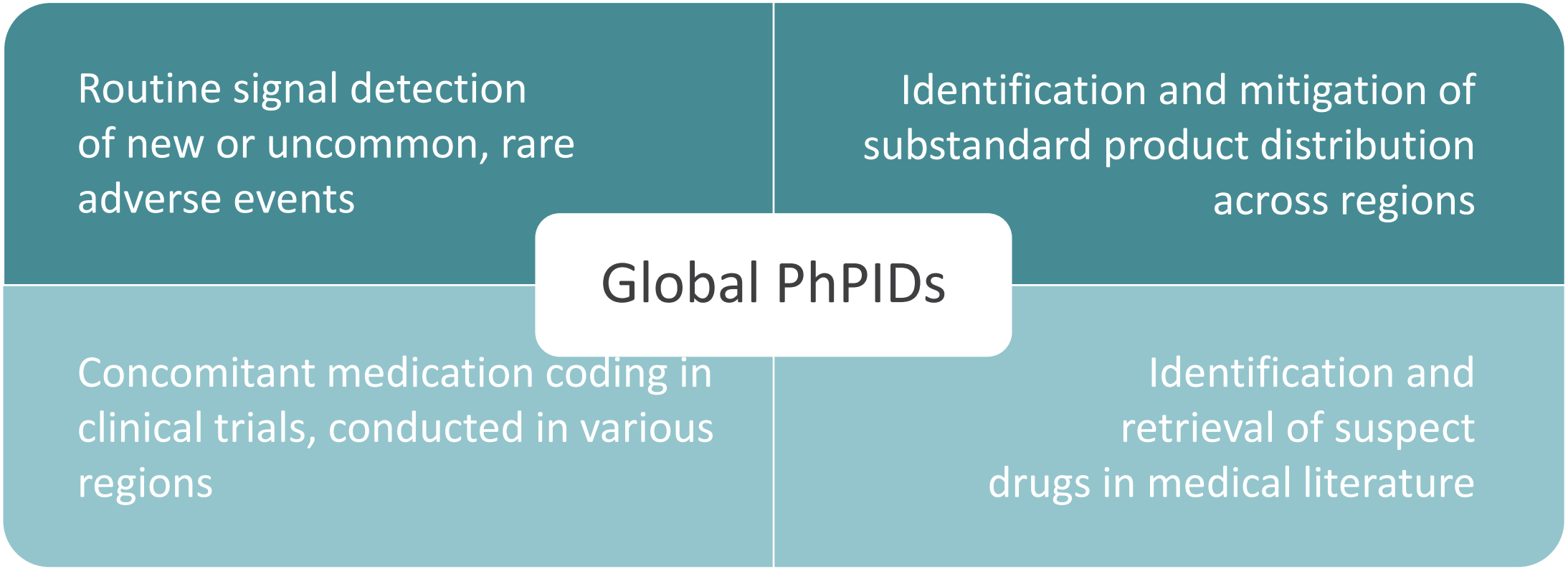
The PhPID becomes the medicinal product's "common denominator" from country-to-country

GIDWG End-to-End Use Cases

Pharmacovigilance

Sonja Brajovic, MD
Medical Officer
Regulatory Science Staff (RSS)
Office of Surveillance and Epidemiology (OSE)
CDER | FDA

Overview of use cases in pharmacovigilance where global PhPIDs add value



Global IDMP Working Group

FDA

Routine signal detection of new, uncommon or rare adverse events

Reports of “Muscle spasms” after injections of methotrexate

Methotrexate administered via a single-dose pre-filled pen,
15 mg once a week, for the treatment of rheumatoid arthritis.

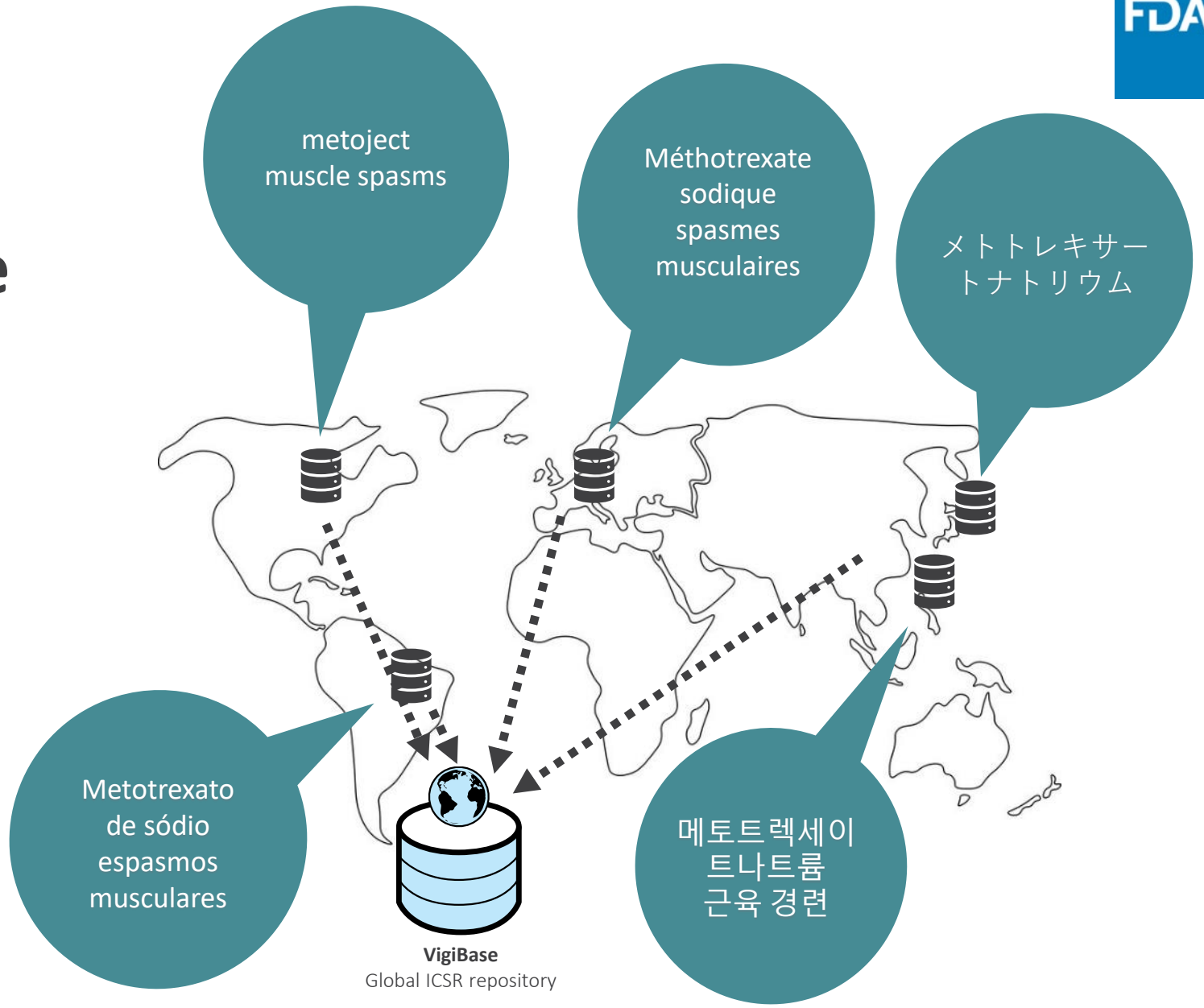
- Reported:

Disabling and painful arm and / or leg spasms, with varying frequency, 1 to 3 times a day. The event was described as very intense.

Note:
Muscle spasms are not stated in the current Prescribing information (label) for methotrexate

Spontaneous reports contain local language

Similar reports received at various national centres globally, including the Netherlands, US, Canada, Brazil, and Republic of Korea. The information is received in digital format containing local language in free text data elements.



*https://who-umc.org/vigibase/

Different terminology used for regional analysis

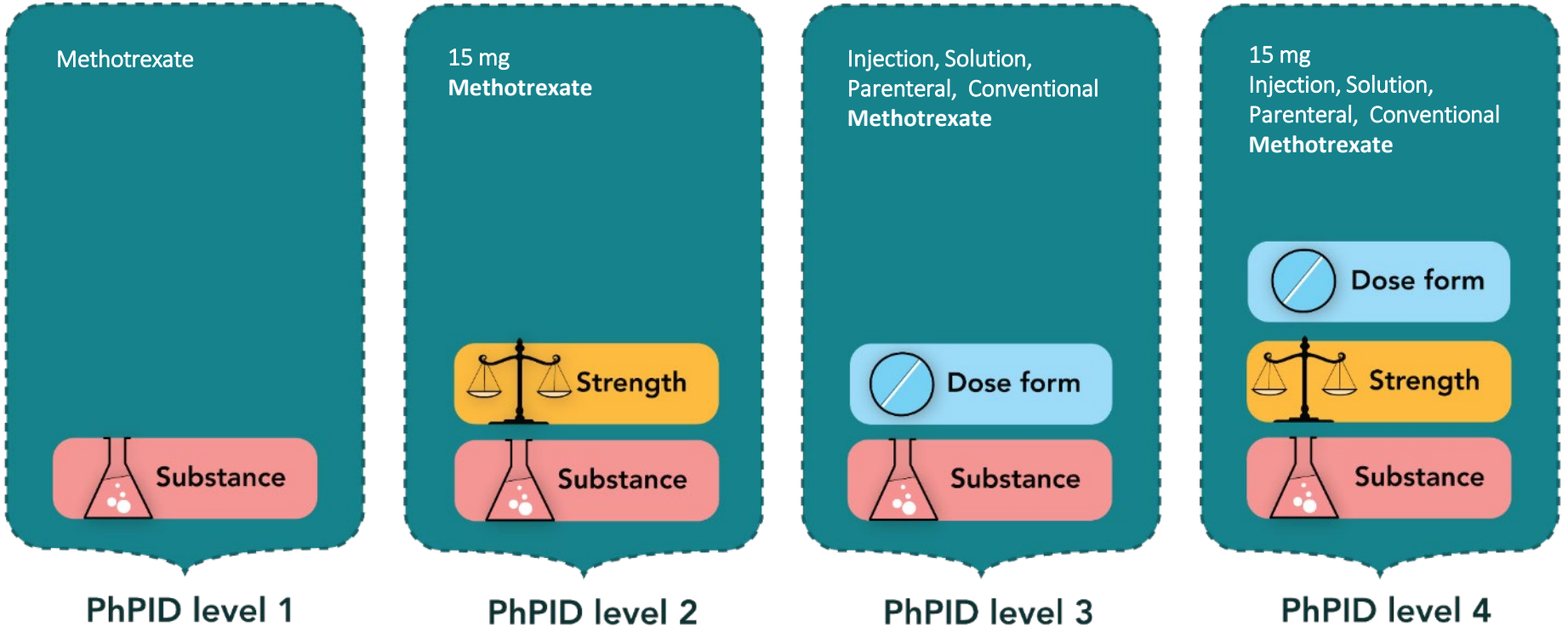
ICSRs undergo standard regional coding to facilitate analysis at each respective Pharmacovigilance center, with variations in coding standards across countries (Netherlands, Brazil, Republic of Korea, Canada, US, etc.)

Note: FAERS data for suspect products is coded to the FAERS Product Dictionary

Additional recoding to global standards at UMC

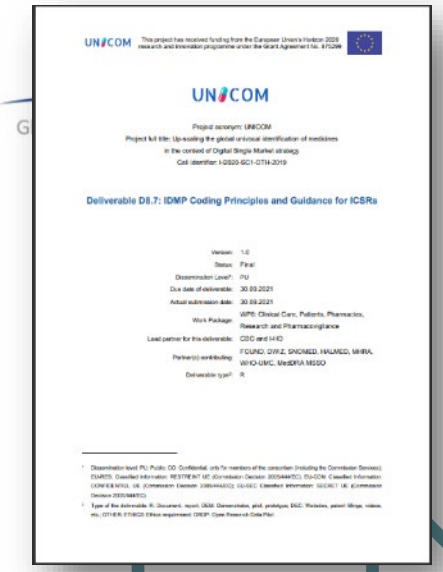
- UMC receives these ICSRs continually in VigiBase, WHO global database of reported potential side effects /adverse events of medicinal products
- Manual recoding to a global standard with WHODrug dictionary takes time, thus delays analysis

What if we had global PhPIDs?



If products were assigned to global PhPID standards, each product name would automatically be linked to active ingredient, strength, dose form.

ICSRs with heterogeneous information are coded to common PhPIDs


UNICOM

Deliverable D8.7: IDMP Coding Principles and Guidance for ICSRs

Metotrexato de sódio 15 mg uma vez por semana Solução injetável

PhPID Level 4

Méthotrexate sodique; AUTO-INJECTEUR PRÉREMPLI À DOSE UNIQUE, 10 mg/week

PhPID Level 4

Metotrexato de sódio

PhPID Level 1

메토트렉세이트 나트륨 ; 주 1회 15mg 주사 ; 주사액

PhPID Level 4

Methotrexate sodium, injections, 15 once a week

PhPID Level 4

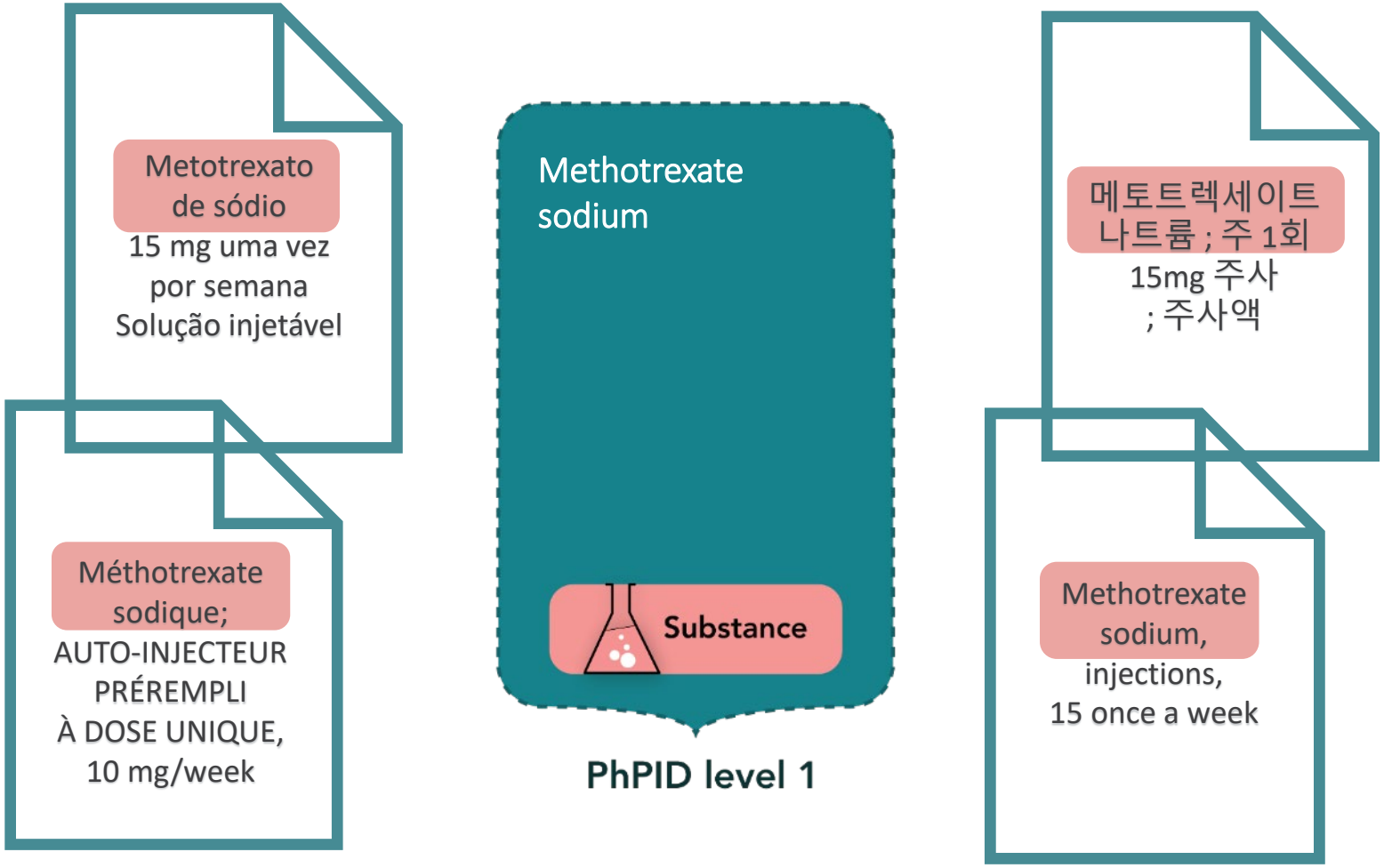
methotrexate 15 once a week

PhPID Level 2

*Deliverable D8.7: IDMP Coding Principles and Guidance for ICSRs: https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D8.7_IDMP-coding-principles-and-guidance-for-ICSRs.pdf

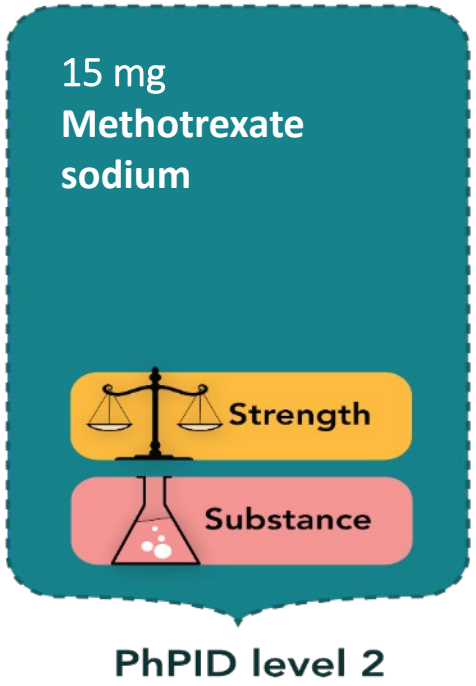
Signal generation with Global PhPID level 1

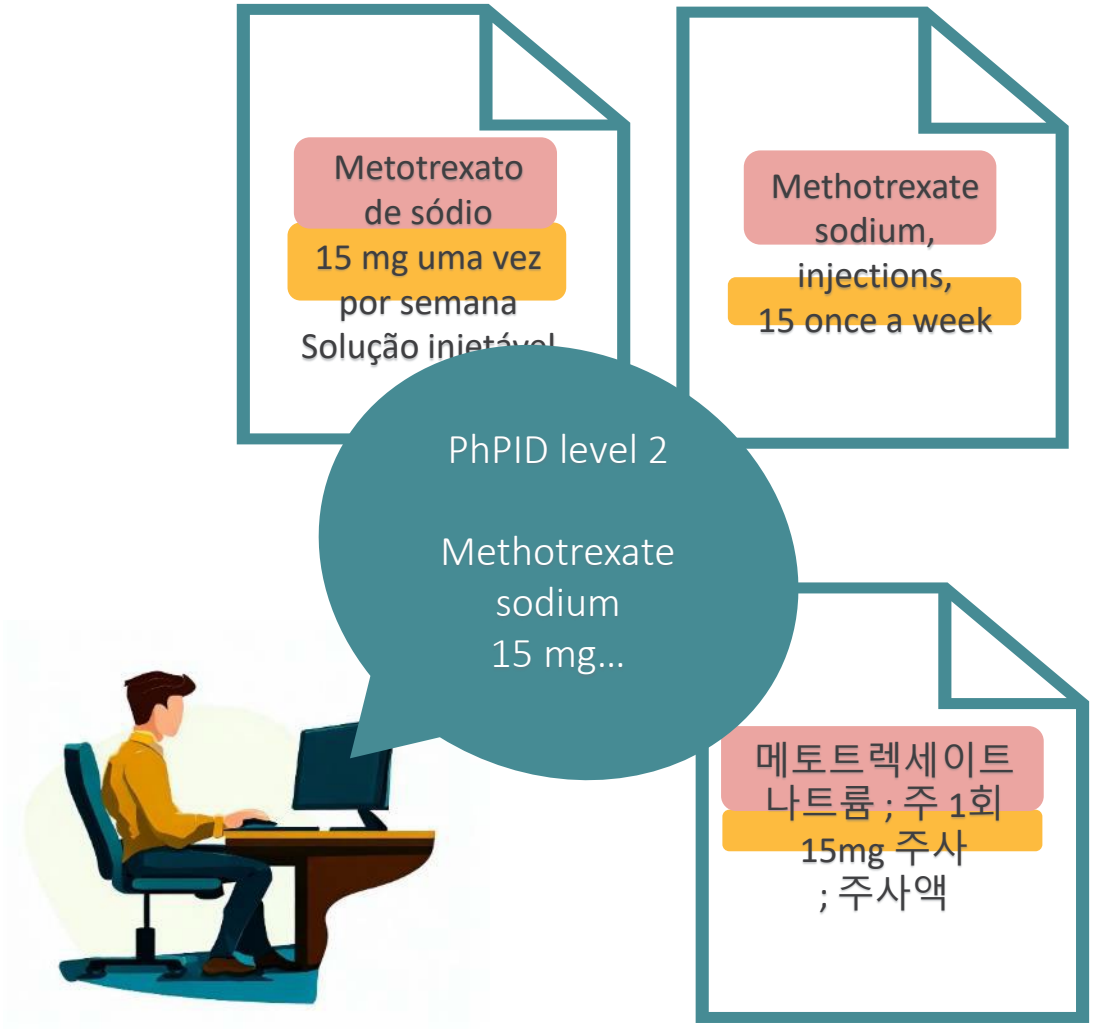
If national centers' coding processes start with **global PhPIDs**, this would speed up analysis and data sharing between regulators.



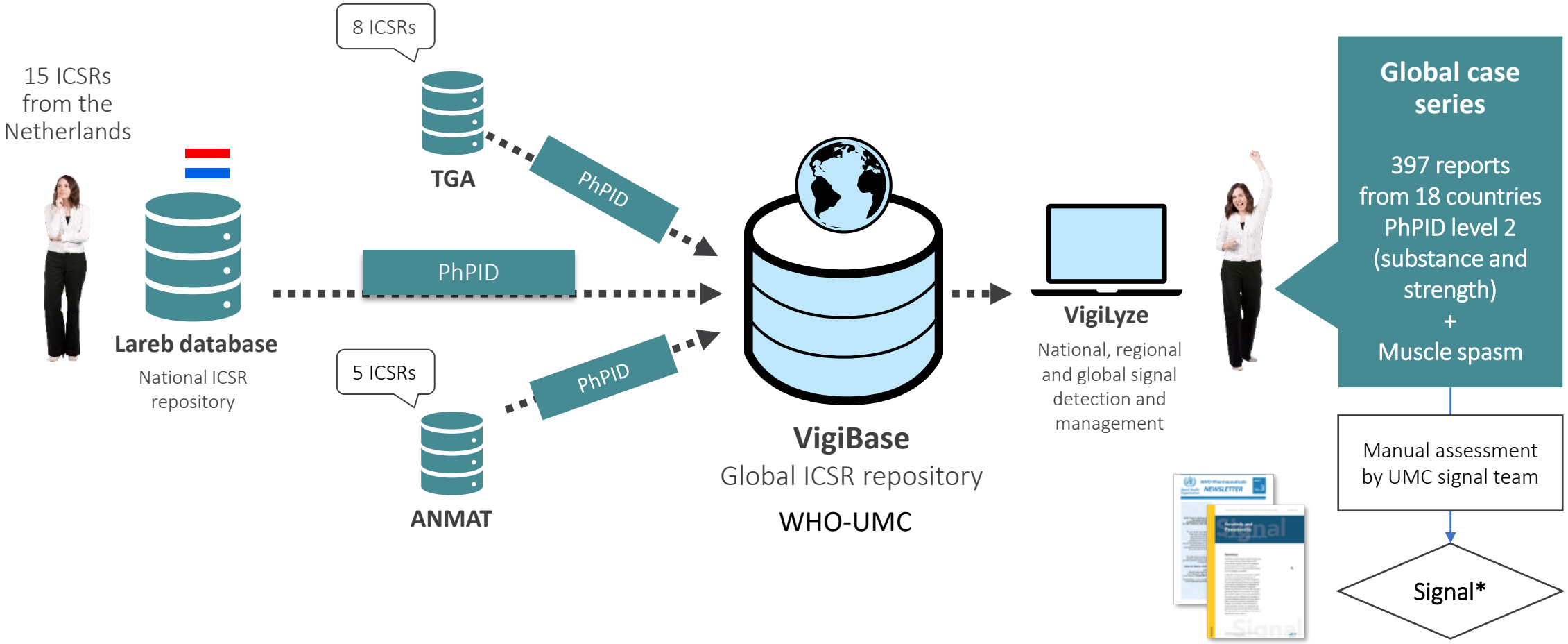
Signal generation with additional Global PhPID levels

- Data already coded to the appropriate PhPID level when reports come in facilitates more nuanced analysis, particularly regarding strength or dose form.
- This enables faster and more granular signal generation, evaluation and, if appropriate, regulatory action to prevent harm to patients.





If we had global PhPIDs



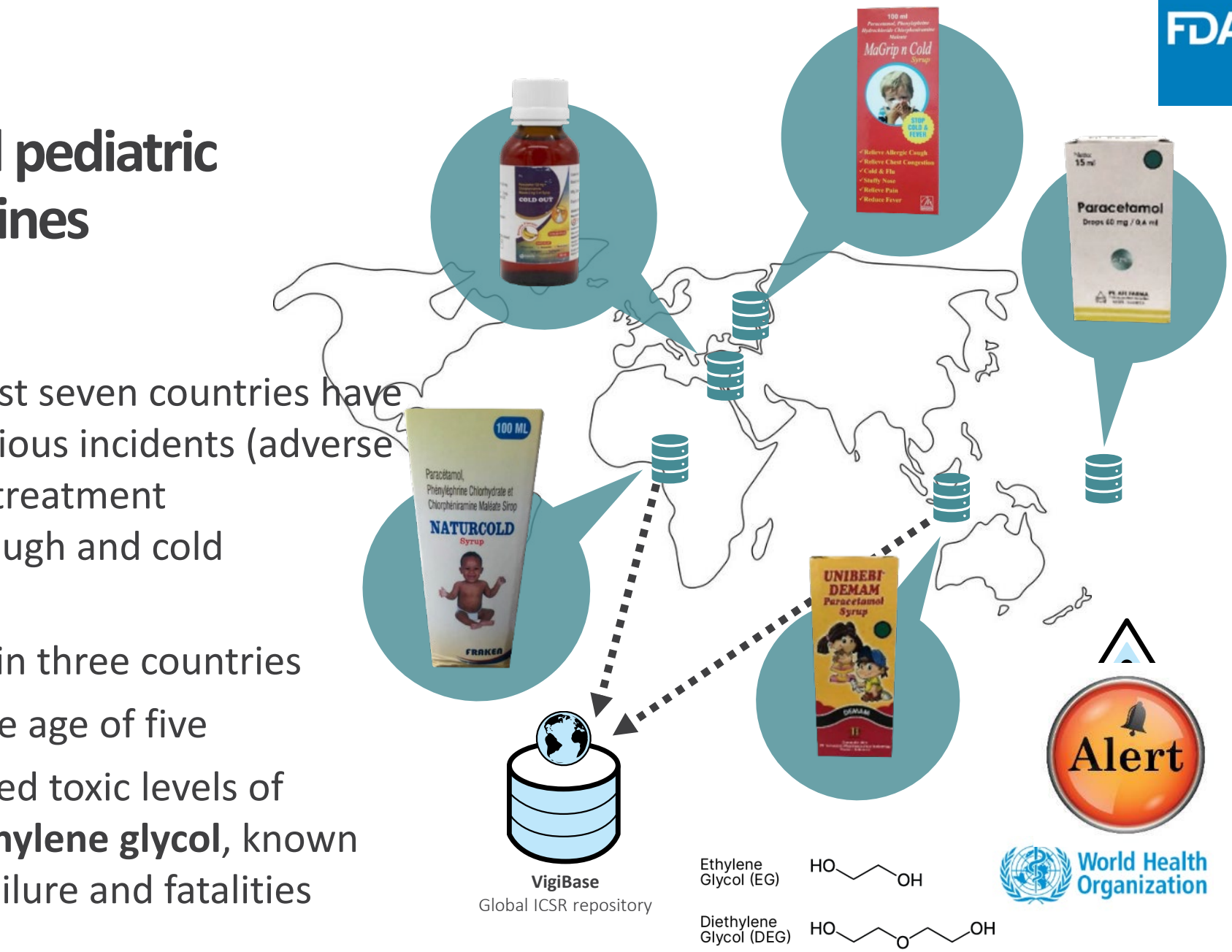
*Source: WHO Pharmaceuticals Newsletters

Identification and mitigation of substandard product distribution across regions

Global IDMP Working Group

Several substandard pediatric liquid dosage medicines caused fatalities

- As of August 2023, at least seven countries have reported unexpected serious incidents (adverse events) in children after treatment with over-the-counter cough and cold medications
- More than 300 fatalities in three countries
- Mostly children under the age of five
- The investigation identified toxic levels of **diethylene glycol and ethylene glycol**, known to result in acute renal failure and fatalities

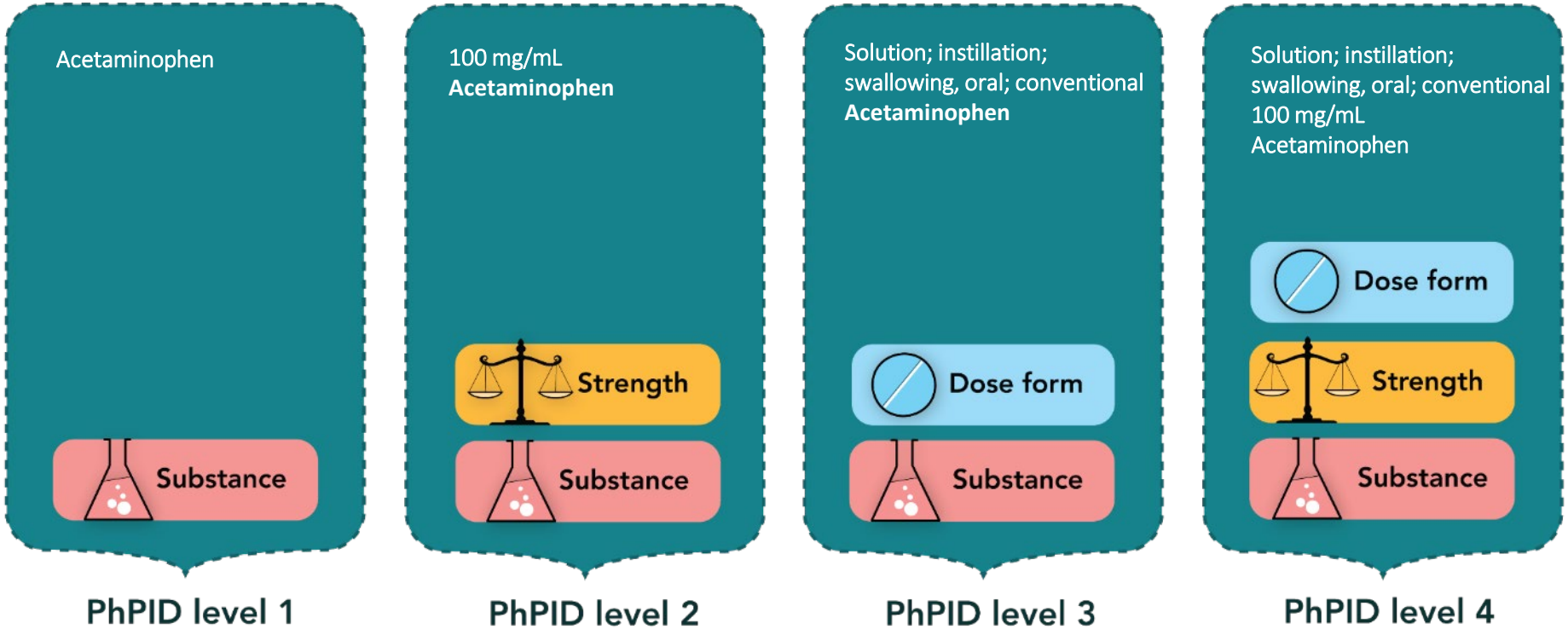


What other regions could be affected?

WHO Medical Product Alerts refer to specific batches of substandard/ contaminated products identified in a specific country, but these products may have marketing authorizations in other countries or regions, plus could have been distributed through informal markets to additional countries

What if we had global PhPIDs?

If products were assigned to global PhPID standards, each product name would automatically be linked to active ingredient, strength, dose form.



Signal generation with Global PhPID level 1

Alert on unexpected child fatalities after treatment with acetaminophen as single and multi-ingredient products:

Without Global PhPID level 1 (substance), different reported product names necessitate further investigation to determine the active ingredient(s).

Acetaminophen (USAN) = Paracetamol (INN): ~20,000 medicinal products globally

19635 rows

Export | CDG | Add Columns

Product Name B3	Drug Code	Active Ingredients	ATC	Country of Sales	MAH	Pharmaceutical Form	Strength
LITTLE FEVERS	000200 01 954	Paracetamol	**N02BE,** Anilides *official*	Puerto Rico • United States of America	Medtech • Medtech labs • Prestige brands • Vetco	LIQUIDS • LIQUIDS, DROPS	80 mg • 80 mg/ml
INFANTS LITTLE REMEDIES FOR FEVERS	000200 01 A0R	Paracetamol	**N02BE,** Anilides *official*	Canada	Prestige brands	LIQUIDS	80 mg/ml
ACETAMINOPHEN NAEWOE	000200 01 A3J	Paracetamol	**N02BE,** Anilides *official*	Korea (the Republic of)	Nae woi	TABLETS	80 mg
BUBDEL	000200 01 BK3	Paracetamol	**N02BE,** Anilides *official*	Taiwan (Province of China)	Winston	TABLETS	80 mg
CAUSALON [PARACETAMOL]	000200 01 212	Paracetamol	**N02BE,** Anilides *official*	Argentina	Phoenix	LIQUIDS • LIQUIDS, DROPS • SUPPOSITORIES, ADULT • TABLETS • TABLETS, CHEWABLE	80 mg
CHILDREN'S CHEWABLE ACETAMINOPHEN	000200 01 982	Paracetamol	**N02BE,** Anilides *official*	Canada	Vita health products inc	TABLETS, CHEWABLE	80 mg
CHILDRENS MAPAP	000200 01 AXR	Paracetamol	**N02BE,** Anilides *official*	Puerto Rico • United States of America	Major Pharmaceuticals	TABLETS, CHEWABLE	80 mg
CORIVER INFANTIL	000200 01 BBI	Paracetamol	**N02BE,** Anilides *official*	Mexico	Maver	TABLETS	80 mg

Signal generation with Global PhPID level 3

Global PhPID level 3 would enable identification of all medicinal products that share the same substance (acetaminophen) and dose form (drops or syrup).

*products circled in blue: Solution; instillation; swallowing, oral; conventional
products circled in red: Suspension; swallowing, oral; conventional

Global PhPID take-home message

- Faster, more reliable signaling of rare and uncommon adverse events
- Global data display and analysis at different levels of granularity
- Real-time identification of unexpected serious adverse events / incidents in PV databases using global standards
- **Effective alert communication to stakeholders**
- Immediate generation of accurate safety data for further regulatory investigation, evaluation and action

Global IDMP Working Group

FDA

Thank You

GIDWG End-to-End Use Cases
Drug Shortages

Ron Fitzmartin, PhD, MBA
Sr. Informatics Advisor
Data Standards Branch (DSB)
Division of Informatics (DI)
Office of Regulatory Operations (ORO)
Center for Biologics Evaluation and Research (CBER) | FDA

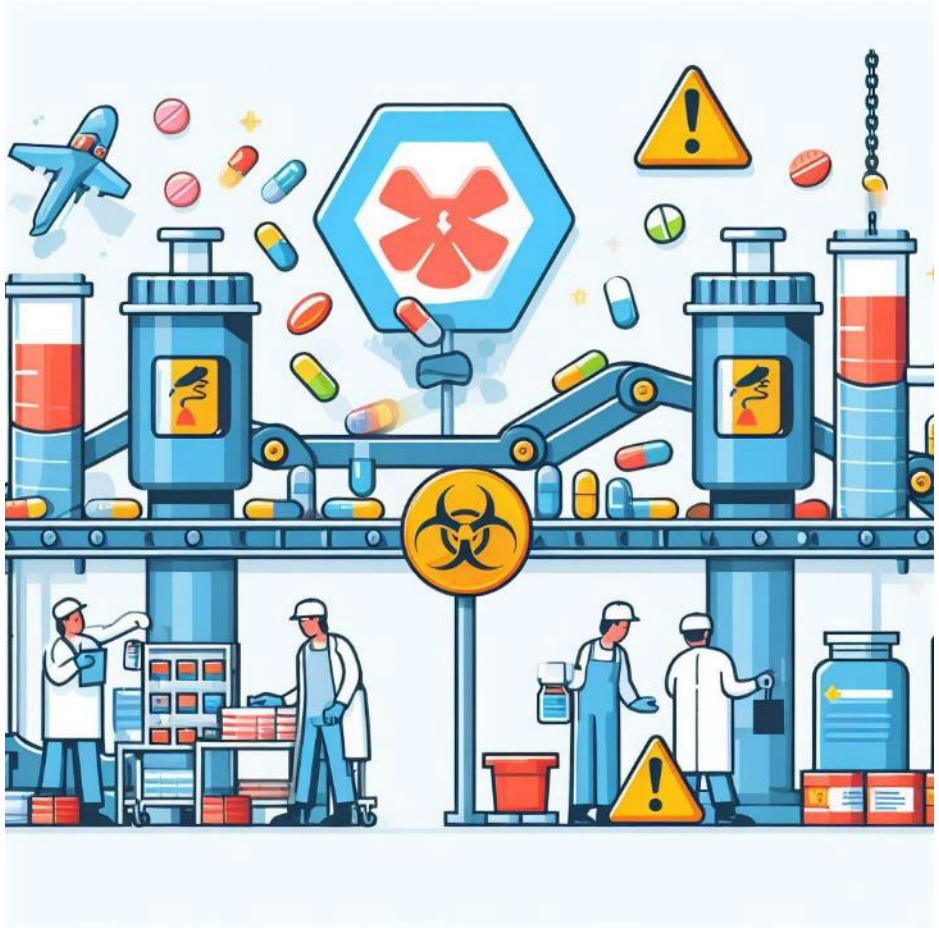
Cisplatin

- Used to treat a wide range of cancers, including breast, ovarian, throat, lung, testicular, prostate and colorectal cancers

- For many cancer patients, it is the standard of care

Healthcare demand outstrips MAH's cisplatin supply

- A quality-related manufacturing halt at one of the primary foreign production facilities for cisplatin with a US FDA approval causes a ripple effect[1,2]
- Other approved marketing authorization holders (MAHs) are unable to meet the demand for this product



Regulatory agencies informed of cisplatin shortage

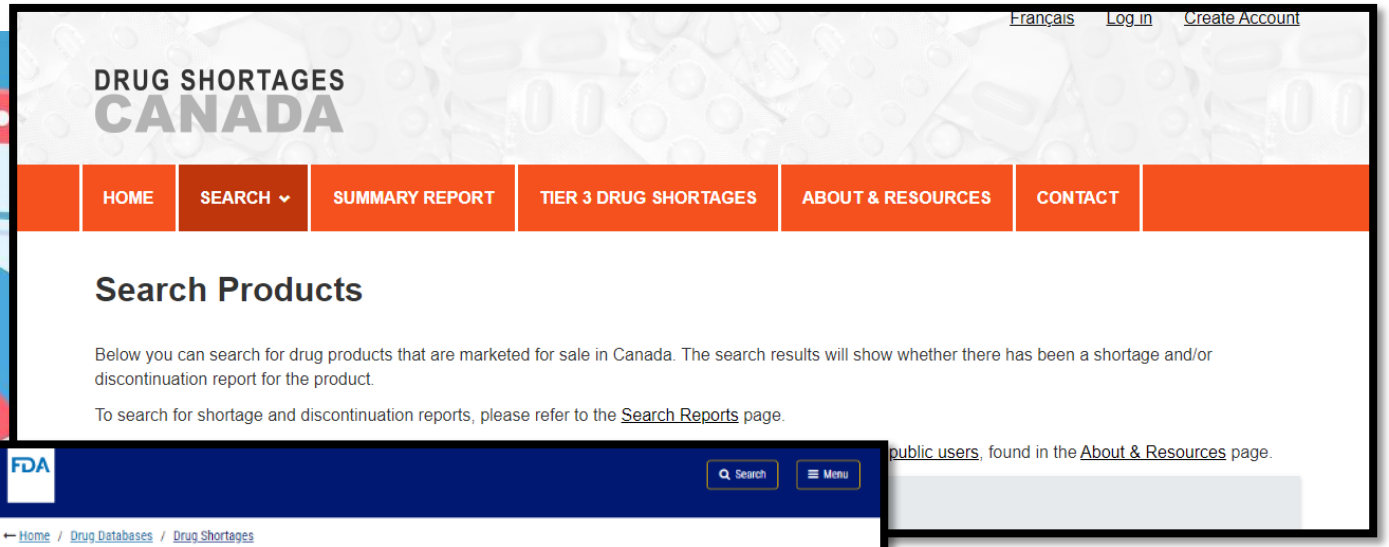
- MAHs notify regulatory agencies of the shortage
- Regulators cannot require MAHs to increase production of a drug to meet demand

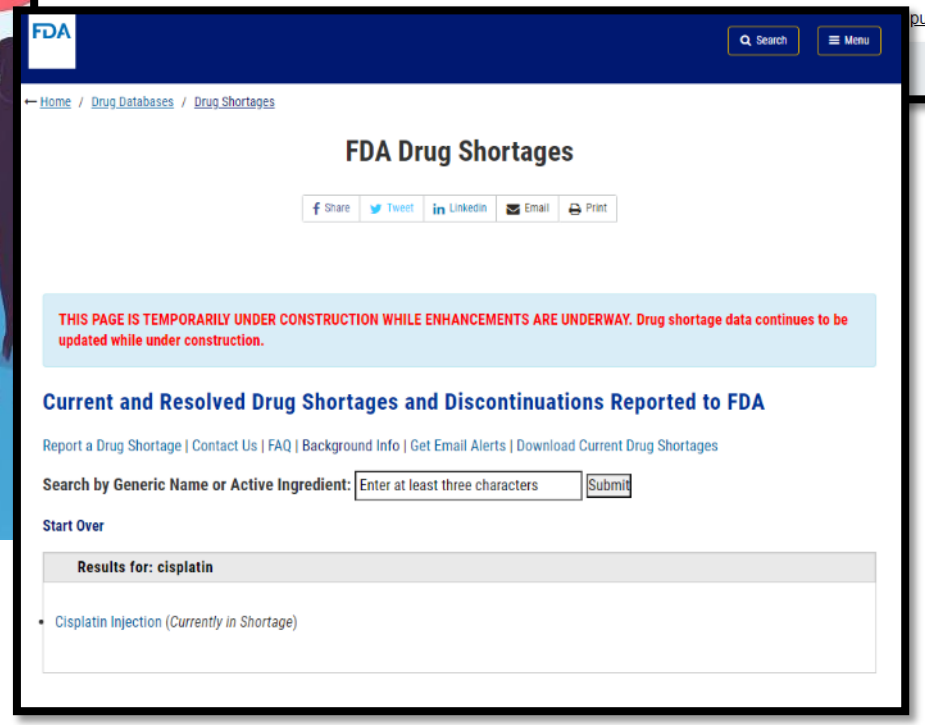
Cisplatin shortage investigated

- Once notified regulatory response is swift
  - Initial outreach to approved/pending US application holders
  - Outreach to other international jurisdictions
- 3 potential non-US approved products identified
- **Challenges:**
  - ✓Quantity available
  - ✓Different strength
  - ✓Lack of prospective US distributors
  - ✓Time for proposal submission

Shortage communicated to stakeholders

Cisplatin U.S. Drug shortage:
Date first posted:
February 2023





Cancer patient unable to start therapy

March 2023

- Stage 3 cancer patient informed by his doctor that he will not be able to commence treatment with cisplatin due to an ongoing shortage

- *70% of healthcare centers acknowledged a shortage of cisplatin*[3]

Impact of cisplatin shortage

- The cisplatin shortage potentially affects **100,000- 500,000 patients** annually[2]
- Consequences may include treatment delays, dose adjustments, and transitions to alternative therapies
- Such alterations increase the risk of medication errors and adverse events[4]

Challenges and time delay in finding an alternative

- Regulatory action is prompt
- However, identification of non-US substitutes is challenging and **time** consuming

Unavailable global resource

A comprehensive evaluation of available cisplatin products proves challenging due to the lack of a global resource containing information about equivalent medicinal products harmonized with global identifiers

Drug alternatives and non-US labelling/packaging

- The announcement of the temporary importation of non-US labelled Cisplatin Injection, occurring four months later in **May 2023**, offers a potential solution[5]

- The medicinal product, Cisplatin Injection (50mg/50ml), is manufactured by Qilu Pharmaceutical Co Ltd in China[6]

Healthcare professionals notified in May timeframe

IMPORTANT PRESCRIBING INFORMATION

May 24, 2023

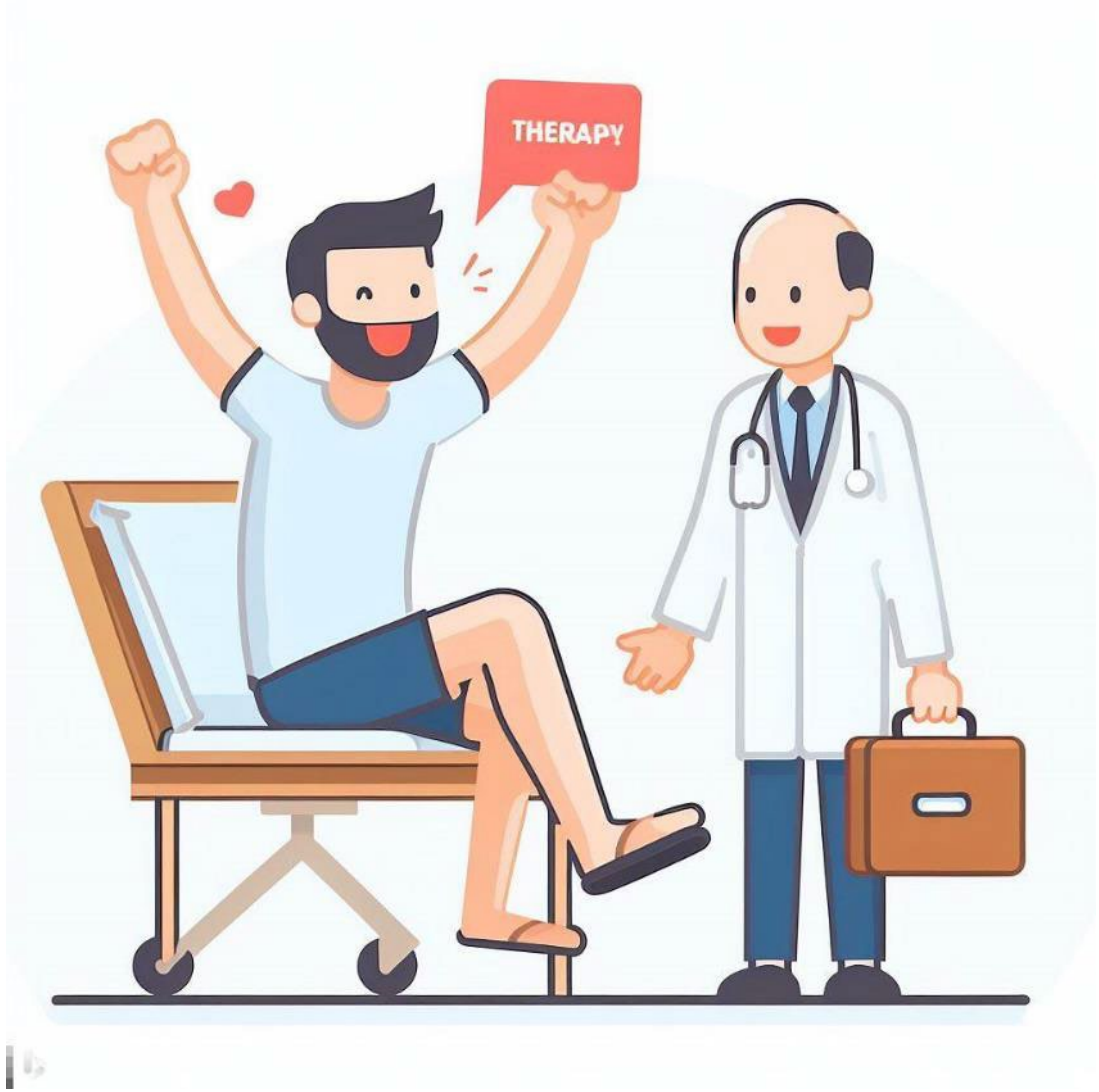
Subject: Temporary Importation of CISplatin Injection with non-U.S. Labeling to Address Drug Shortage

Dear Healthcare Professional,

Due to the critical shortage of CISplatin Injection in the United States (U.S.), Qilu

	U.S. FDA Approved Product	Imported Product
Carton Labeling	NDC 44567-511-01 200 mL multidose vial CISplatin Injection 200 mg/200 mL (1 mg/mL) For Intravenous Use N 3 44567 511 01 3	

A Dear Healthcare letter is sent out to relevant stakeholders, explaining labelling and packaging distinctions[5]



Start of patient therapy

- Following these developments, patients, doctors, pharmacists, and healthcare centers are now equipped to access the necessary medication
- The cancer patient can finally begin therapy

The value of global PhPID in drug shortages

USA Shortage

Cisplatin
1 mg/ml
Concentrate for
Solution for
infusion

China

顺铂注射液
50ml:50mg
Cisplatin
Injection

Global PhPID level 4

D934E701B1FF6B452828E1C6703B257E

Substance	Strength	Basic Dose Form	Administration method	Intended site	Release characteristics
Cisplatin	1mg/ml	Solution	Injection	Parenteral	Conventional

Potential added value of global PhPID Identifiers

- Initial identification stages – Faster & more accurate
- Drug shortages staff need to know who is **currently marketing** a medicinal product.
  - GPhPID must be connected to MPID

- Global PhPID can be useful in identifying non-US product sources to assist with drug shortages

Potential added value of global PhPID (cont.)

Potential to Save days to weeks finding a substitute

- Quick identification of equivalent medicinal products allows drug shortages staff to invest their time more efficiently and effectively

Better use of resources at healthcare facilities

- Staff hours allocated to managing drug shortages at healthcare facilities can be reduced or used elsewhere

Prevent harm to patients

- By eliminating the need for alternative regimens, the risk of medication errors and patient harm stemming from less familiar or less effective treatments can be mitigated

Cisplatin Use Case References

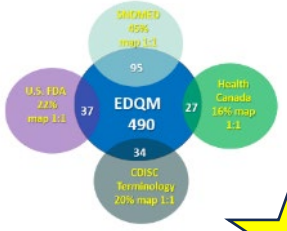
1. Cisplatin U.S. Drug shortage. Date first posted: 02/10/2023 https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Cisplatin%20Injection&st=c
2. Julie R. Gralow, Chief Medical Officer & Executive Vice President, Association for Clinical Oncology testimony to congress. https://cancerletter.com/the-cancer-letter/20230526_2/ https://d1dth6e84htgma.cloudfront.net/Julie_Gralow_Witness_Testimony_06_13_23_7d56adc776.pdf?updated_at=2023-06-12T15:59:08.173Z
3. Survey by the National Comprehensive Cancer Network: https://www.nccn.org/docs/default-source/oncology-policy-program/NCCN-Drug-Shortage-Survey.pdf
4. National survey on the effect of oncology drug shortages on cancer care, McBride et all, 2013 https://academic.oup.com/ajhp/article-abstract/70/7/609/5112445?redirectedFrom=fulltext&login=false
5. Temporary Importation of CISplatin Injection with non-U.S. Labeling to Address Drug Shortage: https://www.fda.gov/media/168657/download
6. Qilu Pharmaceutical cisplatin product: https://www.qilu-pharma.com/products_details/9758137247175393 28.html

GIDWG's Journey Continues…

We are here

ISO IDMP

ISO 11239 – Dose Form for Global implementation

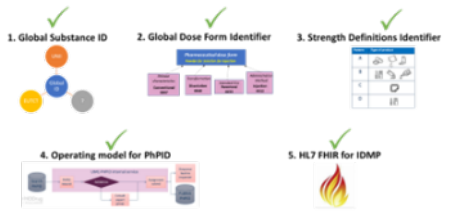


WHO Workshop

GIDWG

Global IDMP Working Group

GIDWG Projects



Use Cases

End to End Testing

2012 | 2018 | 2019 | 2021 | 2022 | Q4 2023 | 2024

Acknowledgements

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Past SBIA IDMP Webinars

- 2019
  - What is IDMP and Why Should I Care?
- 2021
  - IDMP: Path to Global Implementation
- 2022
  - Toward Global IDMP Implementation: A Focus on Biologics

Thank You