4th Global IDMP Working Group (GIDWG) Stakeholders Public Meeting

12 September 2024

Meeting Location

Sheraton Sao Paulo WTC Hotel,

São Paulo, Brazil

Day 4

AGENDA

07:30 – 07:40	**GIDWG Public Meeting** Opening Remarks	Ron Fitzmartin (US FDA)
07:40 – 08:20	**LATAM Perspectives:** Regulator	Nelio Aquino (ANVISA)
08:20 – 09:00	**LATAM Perspectives:** Industry	Sheila Inada (AstraZeneca)
09:00 – 09:30	**Global IDMP Perspective** US FDA & EMA Leadership Perspective	Peter Marks (US FDA) /Isabel Chicharo (EMA)
	Break	
10:00 – 11:00	**Report:** End-to-End Testing & Use Cases	Karin Hay (Health Canada)/ Leonardo Santos (ANVISA)
11:00 – 11:45	**Report:** Status Global IDMP Identifiers	Olof Lagerlund (UMC)
	Lunch	
12:30 – 13:50	**Report:** HL7 FHIR	Panagiotis Telonis (EMA)
13:50 – 13:30	**Report: Global Framework IDMP Implementation & Maintenance of global identifiers**	Malin Fladvad (UMC)
13:20 – 13:30	**Closing Remarks** **Public Meeting Adjourned**	Ron Fitzmartin (US FDA)

GIDWG Public Meeting
Opening Remarks

Ron Fitzmartin, PhD, MBA
Sr. Advisor
Office of Regulatory Operations
Center for Biologics Evaluation & Research
U.S. Food & Drug Administration

Malin Fladvad, PhD
Product Portfolio Officer
Uppsala Monitoring Centre

Panagiotis Telonis
Scientific Administrator
Chief Information Office
European Medicines Agency

Welcome & Acknowledgments

- Welcome to the annual GIDWG Stakeholder Meeting.
- **Special Thanks** to ANVISA and UMC for graciously hosting this meet in São Paulo.
- A special shout out to Pori Rieanjarernsuk for doing so much of the Zoom ‘heavy lifting.”
- We had a terrific week of technical meetings, along with regulator and industry meetings.
- We are very excited because there has been enormous progress, as you will see today.

Global IDMP Working Group

- 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.
  - **What is the 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 Member Organizations

Global IDMP Working Group

FDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Uppsala Monitoring Centre

swissmedic

Health Canada
Santé Canada

Agência Nacional de Vigilância Sanitária

SFDA

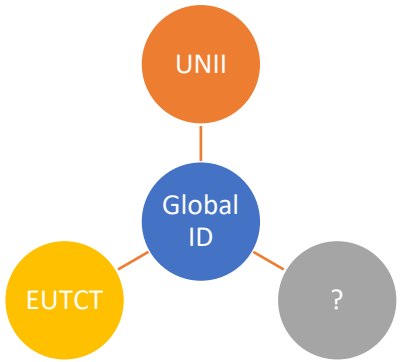
Norwegian Medical Products Agency

IFPMA

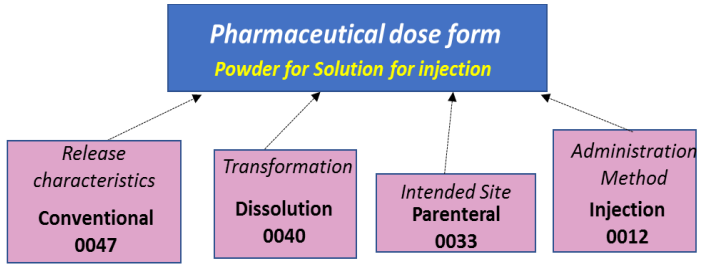
GIDWG Projects: 2021-2024

Global IDMP Working Group

1. Global Substance ID



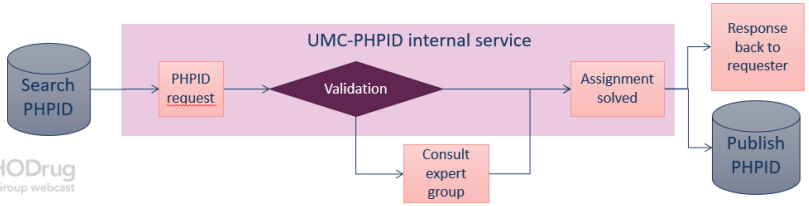
2. Global Dose Form Identifier



3. Strength Definitions Identifier

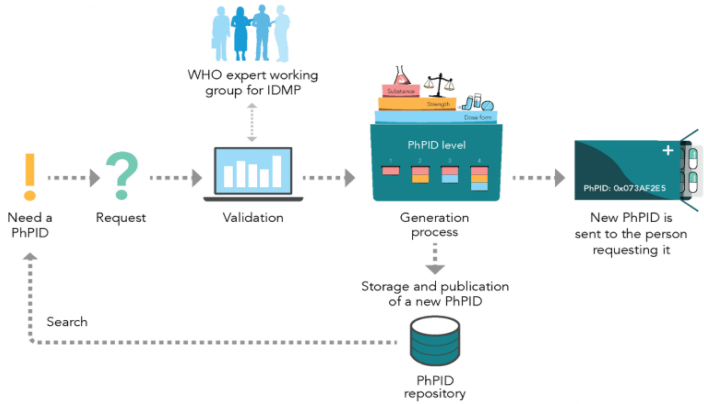
Pattern	Type of product
A	
B	
C	
D	

4. Operating model for PhPID



5. HL7 FHIR for IDMP

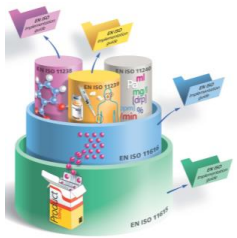
6. E2E Testing / Use Cases



GIDWG's Journey so far…

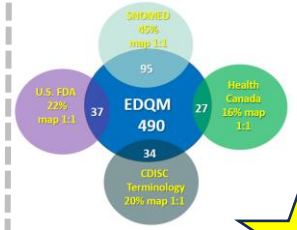
Global IDMP Working Group

ISO IDMP



2012

ISO 11239 - Global implementation



2018

WHO Workshop

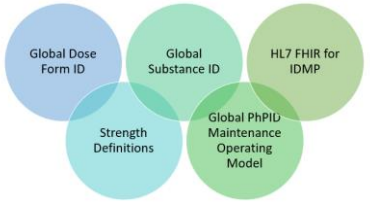
2019

GIDWG

Global IDMP Working Group

2021

GIDWG Projects



2022

GIDWG E2E Testing & Report

Q4 2023

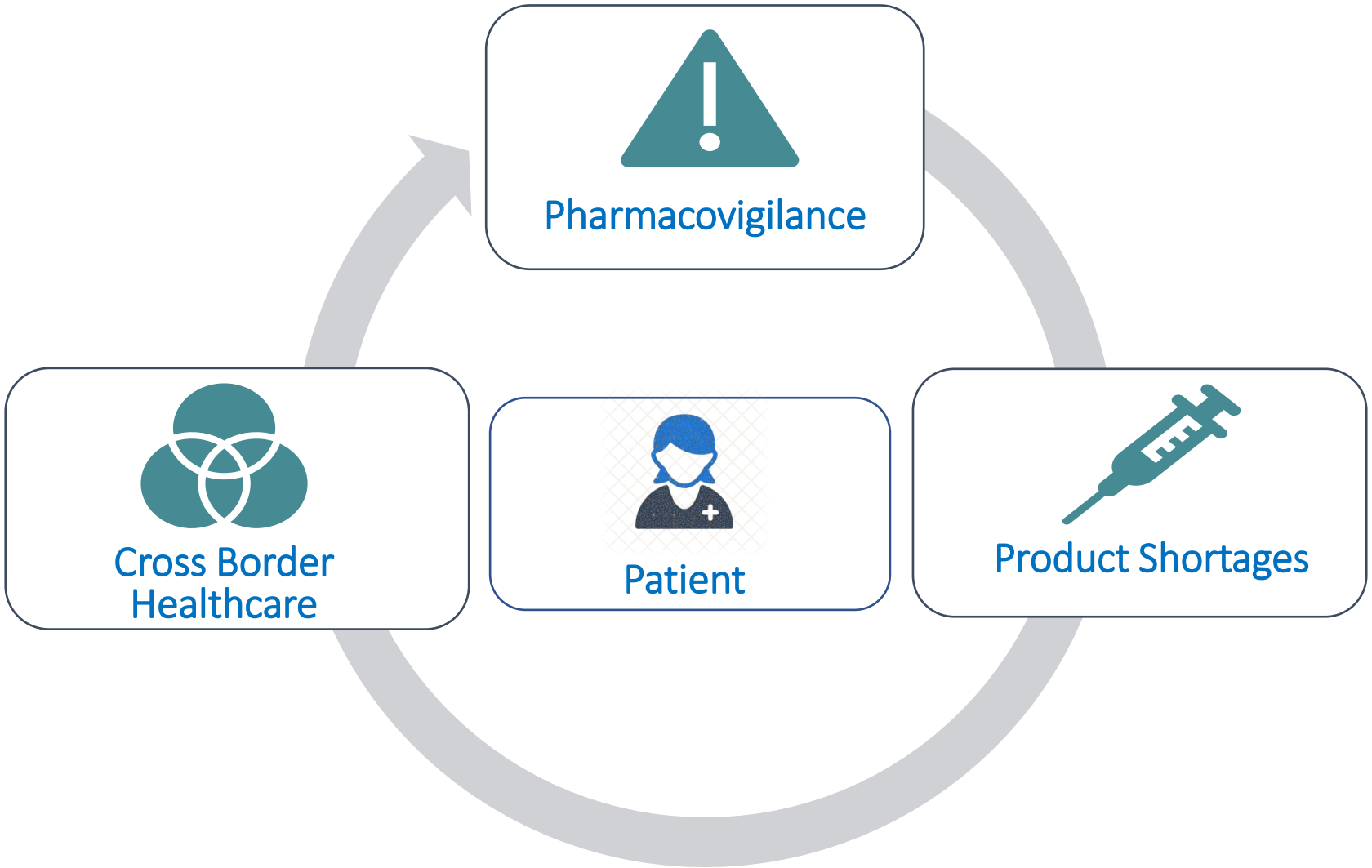
2024

What you will hear today

Global IDMP Working Group

- Last year GIDWG informed that it would conduct End-to-End testing on:
  - Thousands of products across 5 regional regulatory medicinal product datasets.
  - With the goal to evaluate and validate the generation of PhPIDs.
- Today we will report out on the results of the End-to-End testing.
- You will hear the details on GIDWG's work that has led to the development of the global IDMP maintenance framework for global IDMP identifiers.

Global IDMP for Global Healthcare



Global IDMP Working Group

Thank you

Global IDMP Working Group

LATAM Perspective: Regulator

Nelio Aquino (Anvisa)

Global IDMP Working Group

GIDWG

Technical & Stakeholders Meetings

hosted by

National Health Surveillance Agency (ANVISA)

&

Uppsala Monitoring Centre

Nélio Cézar de Aquino – General Manager of Medicines

LATAM Perspective: Regulator

ANVISA
Agência Nacional de Vigilância Sanitária

IDMP as a strategic project

Carteira de Projetos Estratégicos

Plano Estratégico Anvisa 2024-2027

P4. IDMP Implementation

Timeline

Product	Year	Quarter
Review of the controlled vocabulary of dose forms, routes of administration and medication packaging	2025	Q2
Purchasing the software for IDMP data management	2025	Q3
Implementation of IDMP standard data models for substances, products, organizations and references	2025	Q4
Normative changing to require data in the IDMP standard	2026	Q2
Implementation of the solution for receiving data in the IDMP standard	2026	Q4
Legacy mapping for FHIR for migration to the IDMP standard (~12 thousand registrations)	2027	Q2

Welcome

- Covers approximately 8.5 million square kilometers (3.3 million square miles).
- 5° largest country in the world by land area.
- Population of approximately 214 million people.
- Language: Portuguese.

SUS (Unified Health System)

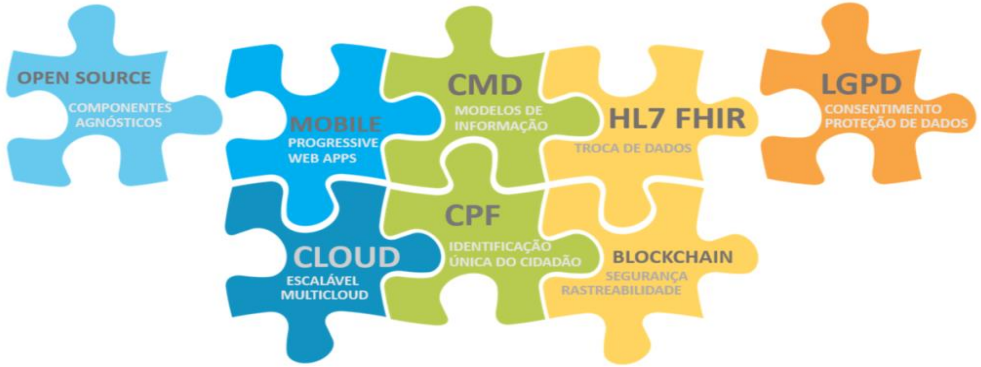
The world's largest public health system, SUS will be 34 years old on September 19.

SUS serves 210 million people across municipalities, states, and at the federal level.

It promotes, protects, and saves lives, through both emergency care and preventive health actions

Healthcare Data Governance

RNDS: National Health Data Network



Information Model

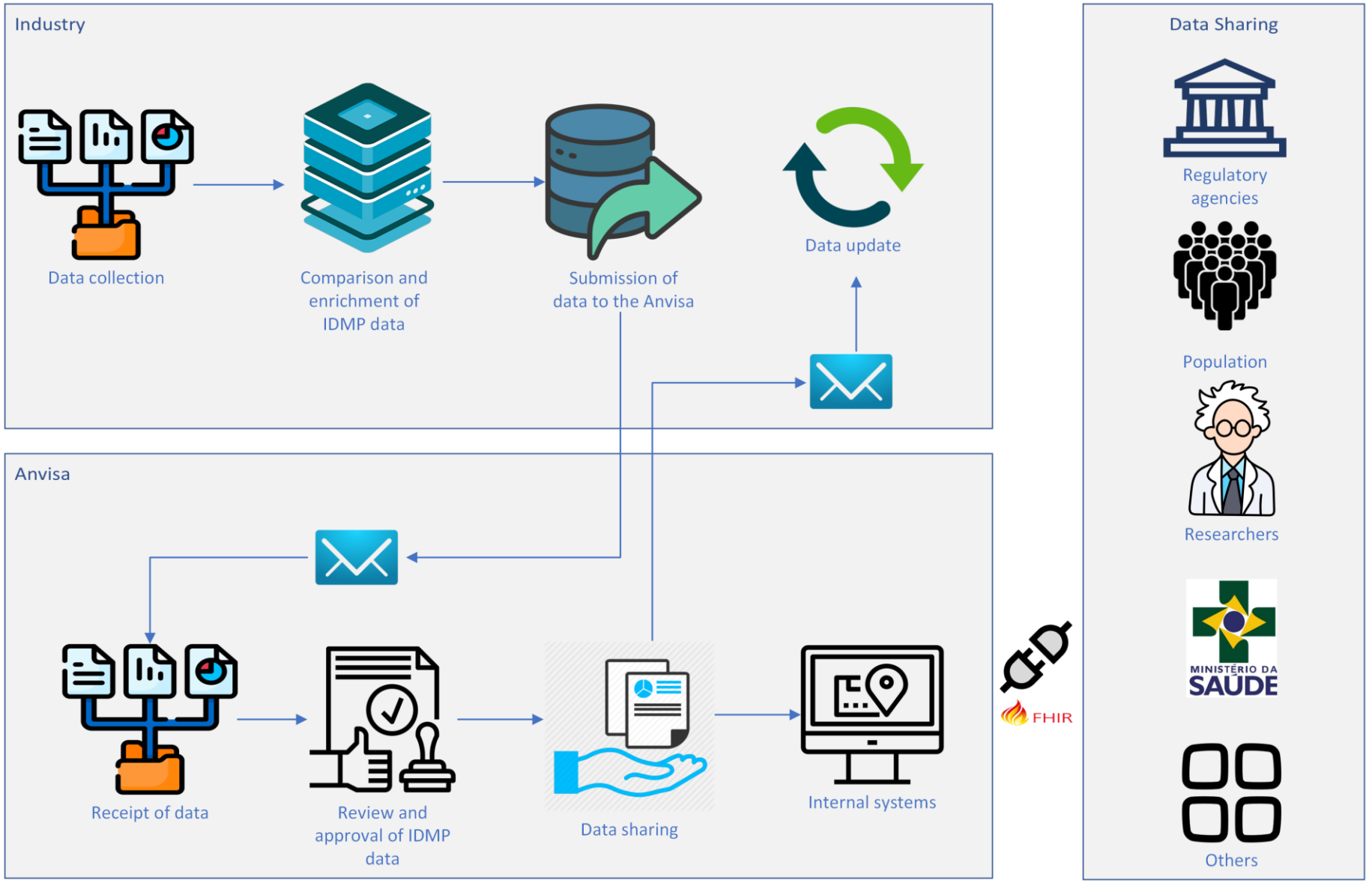
RNDS: National Health Data Network

Level	Occurrence	Section/Item	Data Type	Concept/Observations (Business Rules)
1	[0..1]	Electronic Prescription Record Identification	Alphanumeric sequence	RN01: The electronic prescription record identification sent to RNDS includes "Individual Identification," "Prescription Date," "Prescribing Professional," and "Medication or Product."
3	[1..1]	Name and version of drug terminology	Encoded Text	ANVISA Drug Registration List - Brazilian Drug Ontology (OBM) - Federal Government Materials Catalog (CATMAT) -Barcode (GTIN) - IUM (Unique Drug Identifier)
3	[1..1]	Dispensed item identifier	Text encoded by external terminology	CATMAT or GTIN Code (barcode) of the dispensed product. RN12: validate with OBM (AMPP)

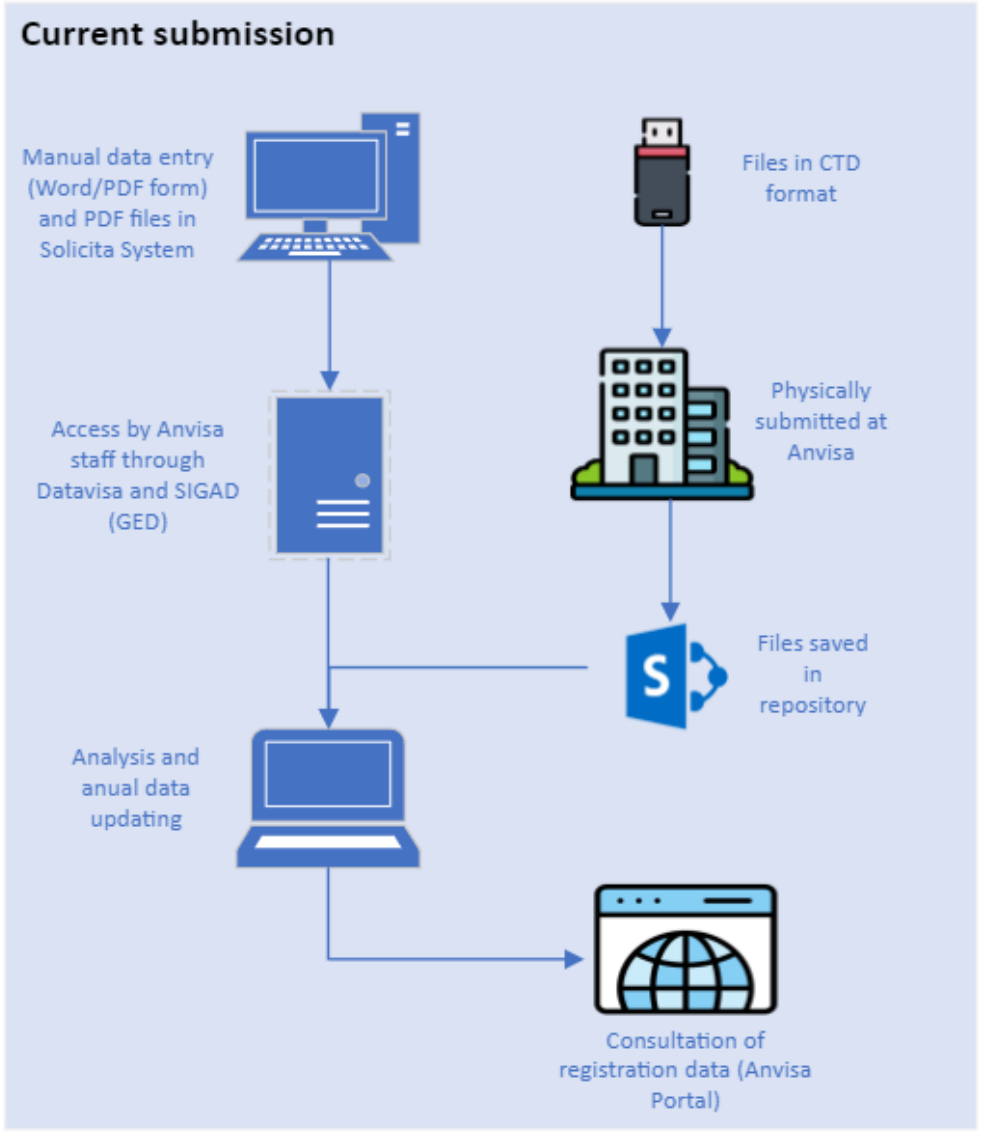
Mapping of ANVISA Domains to the ISO IDMP Standard

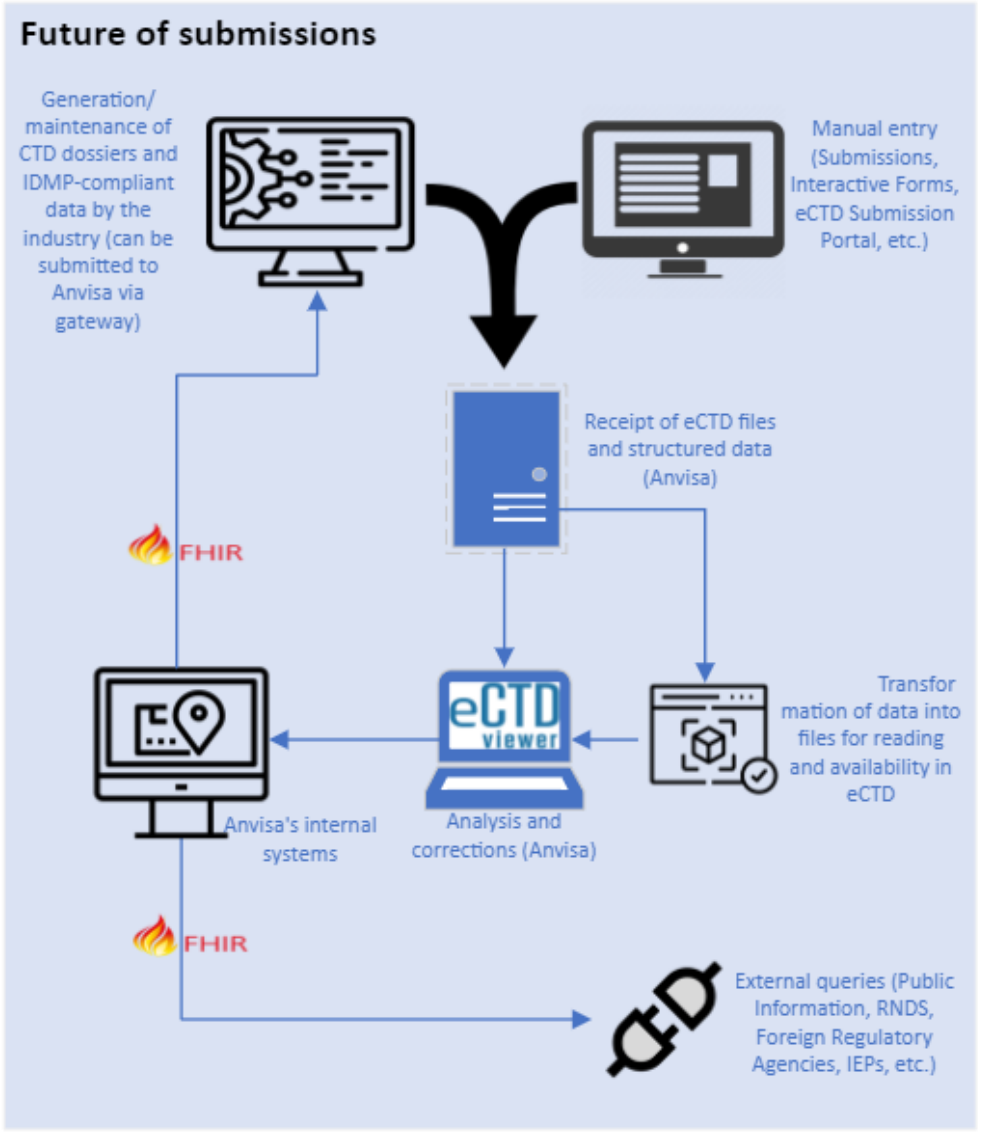
Silva, D. P., Molla, M. de A., Pavini, L. L., Leão, B. de F., & Marin, H. de F. (2021). Mapeamento dos domínios da ANVISA para o padrão ISO IDMP. *Journal of Health Informatics*, *13*(3). Retrieved from https://jhi.sbis.org.br/index.php/jhi-sbis/article/view/797

Flow of Information Reception and Validation for IDMP



Future of Information Submission





Anvisa’s challenges to the IDMP

- IT systems in place to support IDMP data requirements
- Quality and completeness of your current medicinal product data
- Understanding of IDMP Standards
- Stakeholder Engagement
- Regional regulatory policies/laws that pertain to IDMP
- Global Consistency requires coordination with different regulators
- Digital Shift - Moving from traditional document reviews to digital systems can be difficult.

Opportunities

- Pharmacovigilance
- Product shortages
- Cross border healthcare
- Regulatory efficiency
- Health system interoperability
- Patient safety
- International trade of medicines

Thank You!

Global IDMP Working Group

LATAM Perspective: Industry

Sheila Inada (AstraZeneca)

IFPMA

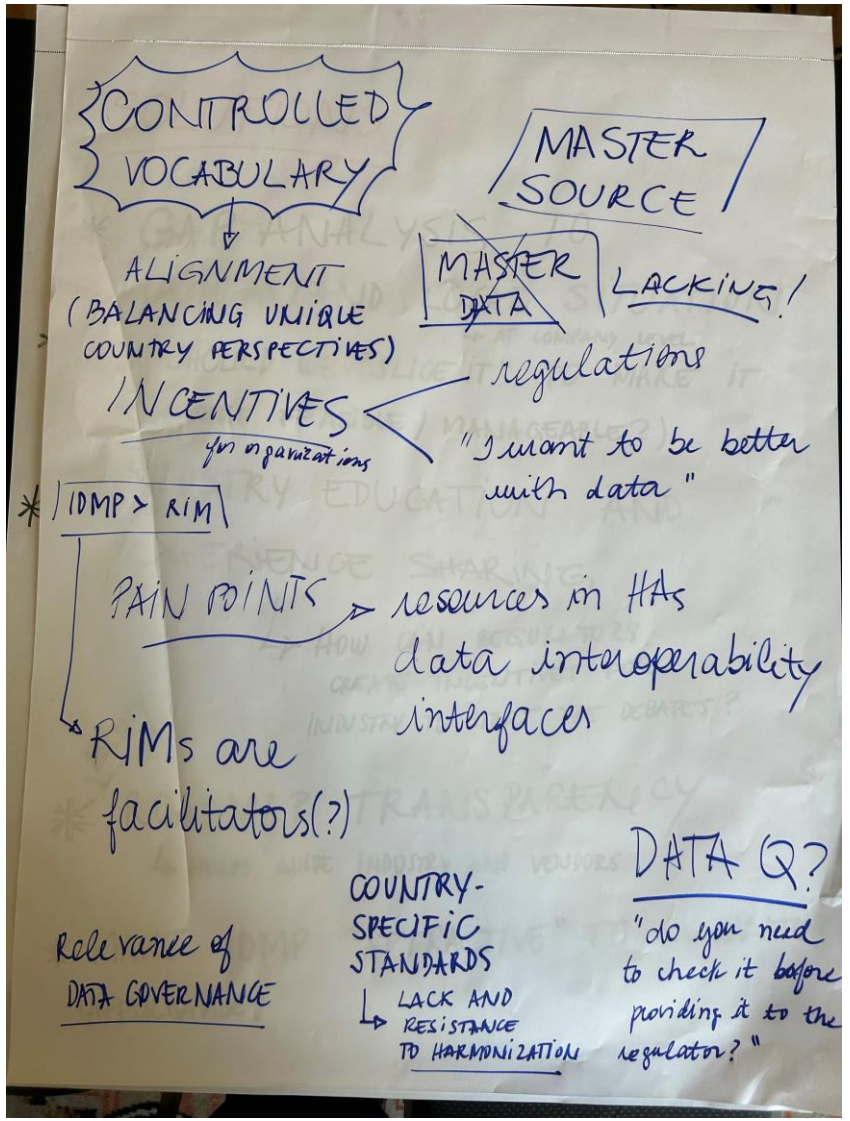
Mini-Workshop: IDMP in LATAM Region

Industry Outcome

11 Sept 2024

IDMP Status and Challenges

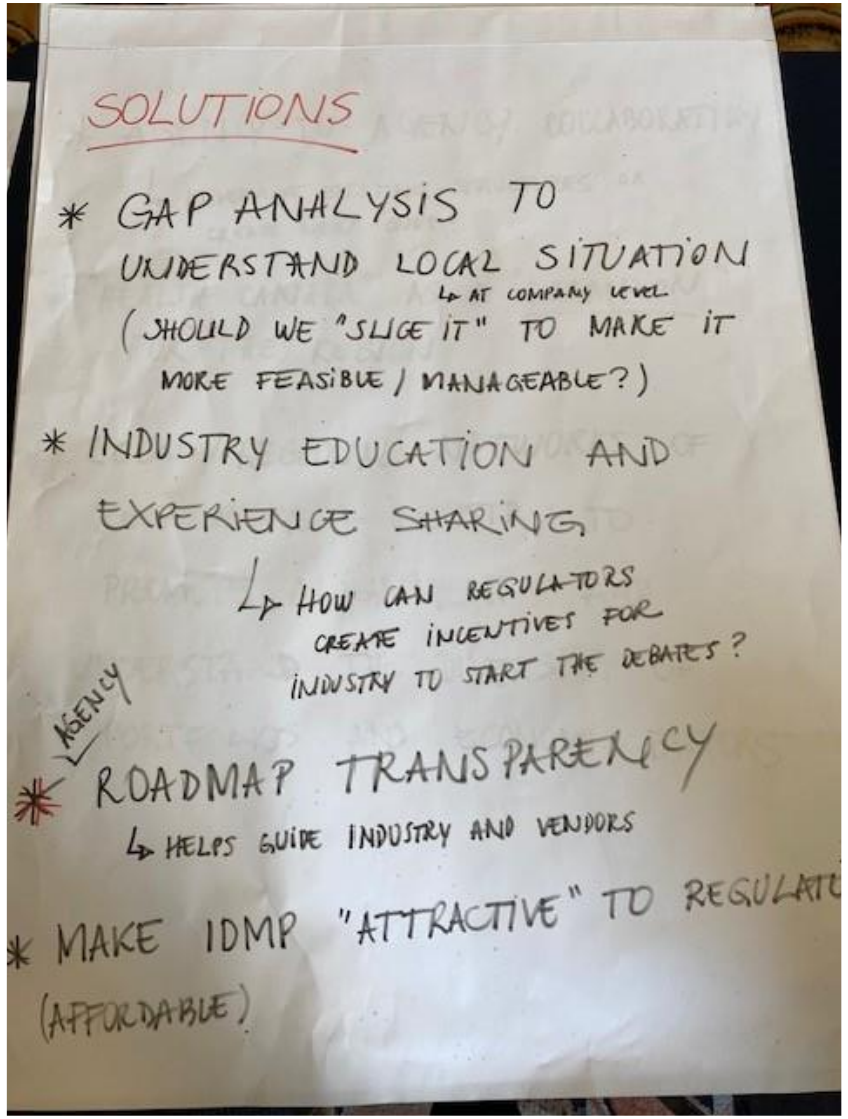
- **Initial Information Sessions:** Held last year by IFPMA, Interfarma, Anvisa, and Sindusfarma for the industry in Latin America.
- **Lack of Understanding:** There is not a clear understanding of the IDMP standards.
- **Data Quality Issues:** Local data is not fully under control or at the right quality level.
- **Absence of Master Data Systems:** Most organizations lack master data systems or governance processes.
- **Data Silos:** Data silos exist by function, which are fit for specific purposes.



IFPMA

IDMP Status and Challenges

- **Affiliates vs. Local Companies:** Affiliates of global companies generally have a better understanding of IDMP than local companies.
- **Industry Readiness:** Overall, the regional industry is not ready for IDMP.
- **No Legal Trigger:** There is no legal requirement in place to start IDMP activities.
- **Mindset and Culture:** A data-driven culture and the mindset that IDMP has internal benefits independent of regulations are missing.
- **Investment and Roadmap:** Significant investment needed for implementation is not currently in place, and there is no roadmap to plan investments and activities.



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Enablers and Opportunities

- **GAP Analysis:** Conduct a GAP analysis to understand the local situation at the company level.
- **Industry Education:** Promote industry education and experience sharing through local and global trade associations and focus groups.
- **Adopt Global Standards and Technologies:** Take inspiration from E2B and ICH guidelines and leverage appropriate technologies to support IDMP implementation.
- **Harmonization Across Regions:** EU & US alignment of standards provides a model for regional harmonization.
- **Regulator-Level Assessment:** Understand the current state at the regulator level, such as comparing DCB (Brazilian Common Name) with GSRS (Global Substance Registration System).
- **Transparent Roadmap:** Develop a clear and transparent agency roadmap with harmonized, incremental improvements prioritized by feasibility.

Enablers and Opportunities

- **Link to Local Incentives:** Connect IDMP implementation to existing incentives for the local industry, such as those from BNDES (Brazilian Development Bank) and digital health initiatives.
- **Affordable Implementation:** Explore ways to make IDMP implementation more affordable and attractive for regulators, possibly through systems like Vigiflow.
- **International Support:** Seek international funding, training, and expertise to support the implementation process.
- **Agency Collaboration:** Foster agency-to-agency collaboration by leveraging existing structures or creating new ones for better coordination.
- **Integration with Existing Programs:** Link IDMP implementation to existing programs like WHODrug and eCTD (electronic Common Technical Document).
- **Regional Discussions and Experience Sharing:** Open discussions at forums like MercoSur and PAHO, leverage experiences from other regulators, and create joint industry/regulator task forces to promote alignment and understand portfolio diversity.

Contributors

- Interfarma
- Sindusfarma
- IGBA
- Fifarma
- PhRMA
- EFPIA

IFPMA

Global IDMP Working Group

EMA & US FDA Leadership Perspective

Peter Marks online(US FDA) &
Isabel Chicharo (EMA)

Global IDMP Implementation

Global IDMP Working Group

End-to-End Testing & Use Cases

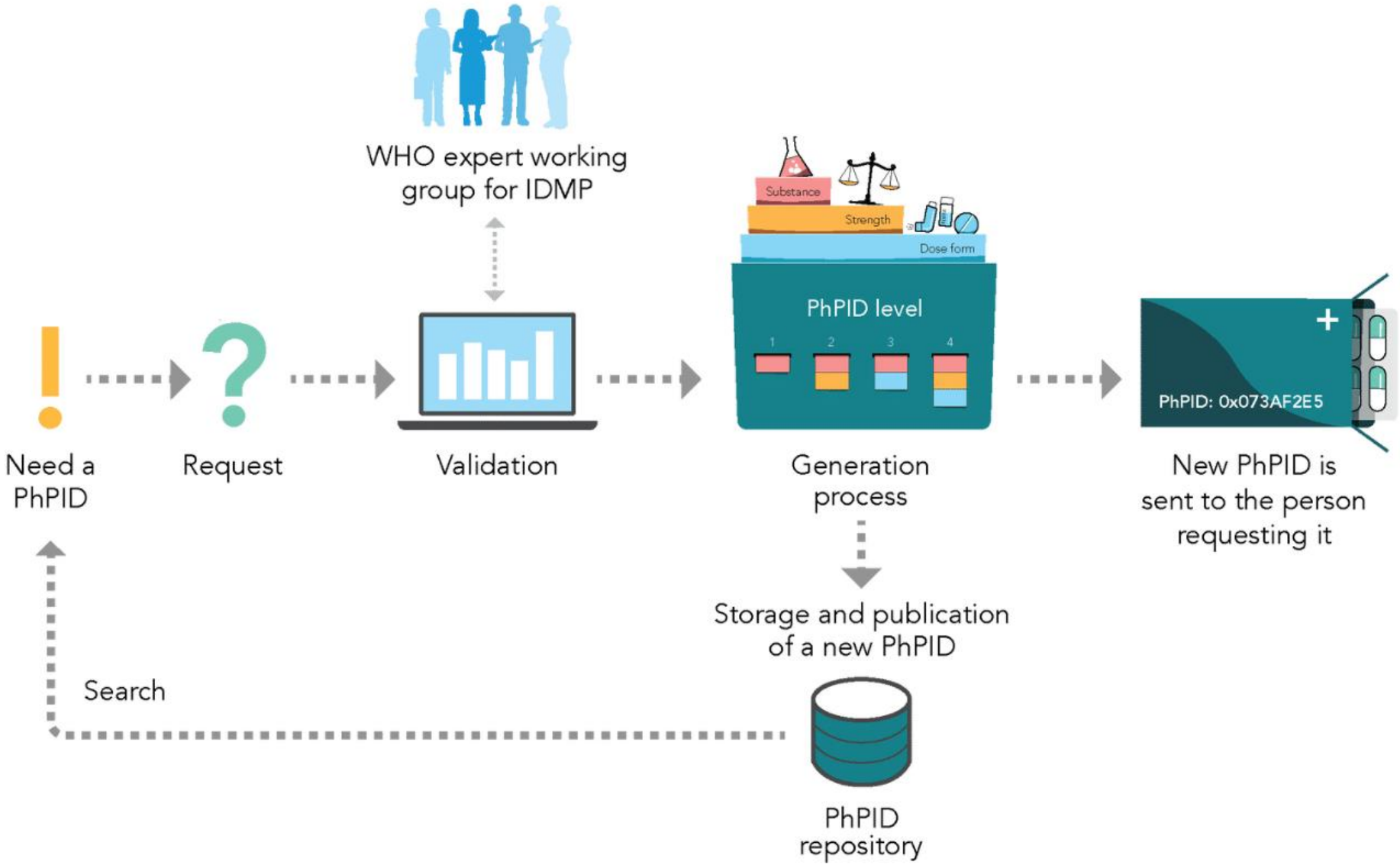
Leonardo Nascimento Santos (Anvisa)
Karin Hay (Health Canada)

Agenda

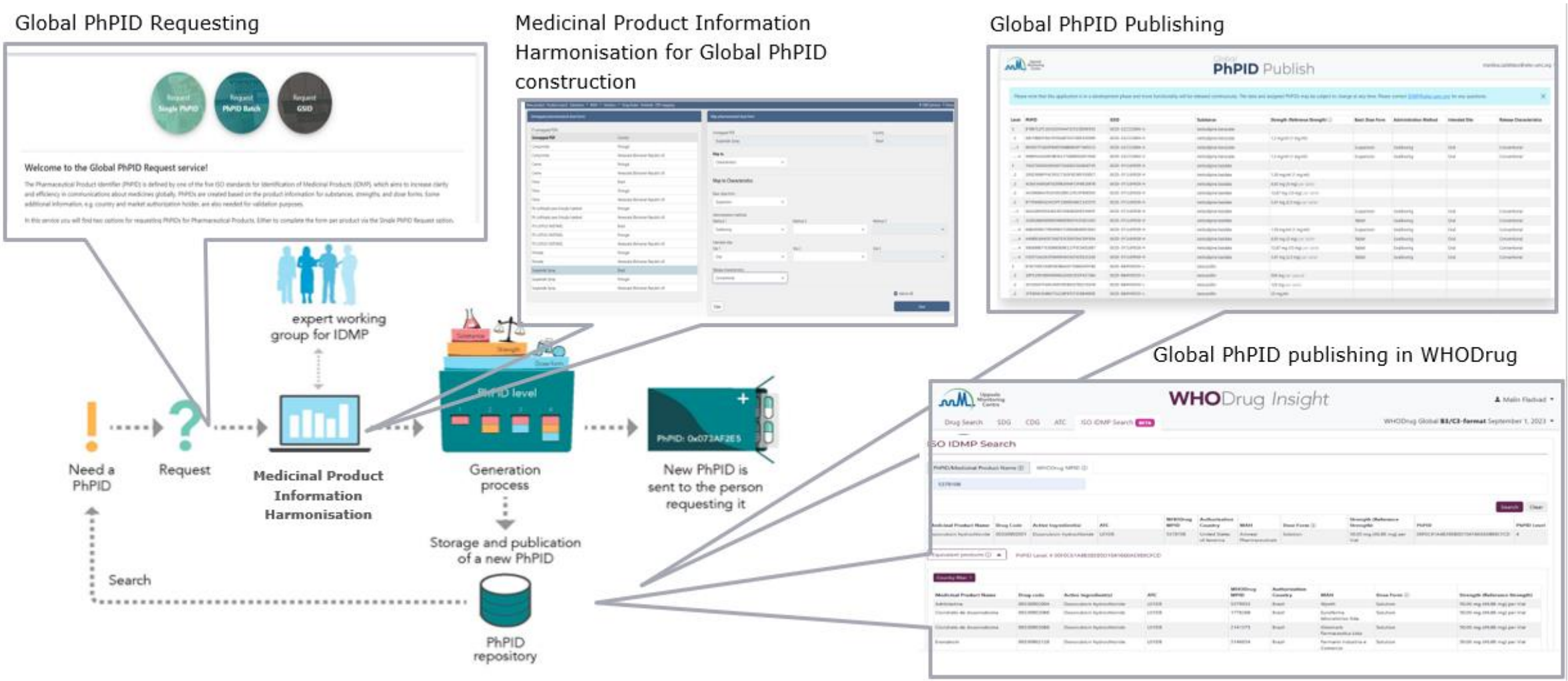
- PhPID End-to-End Testing
  - Operating Model for PhPID
  - Scope of End-to-End testing
  - Findings Overview
  - Next Steps

- Use Cases

IDMP PhPID Operations Model



Global PhPID Operating Model



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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:

•Harmonize medicinal product information and generate PhPIDs for medicinal products based on GIDWG Business Rules

• Selected Substances Dataset (150 substances: various degree of complexity on substances)

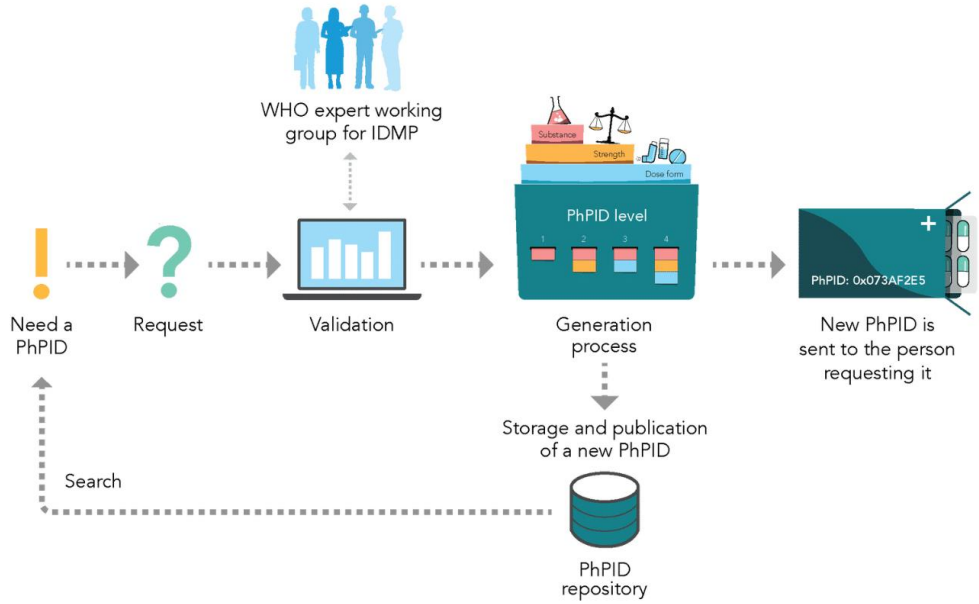
•EDQM + non-EDQM countries

•Similar products from different countries

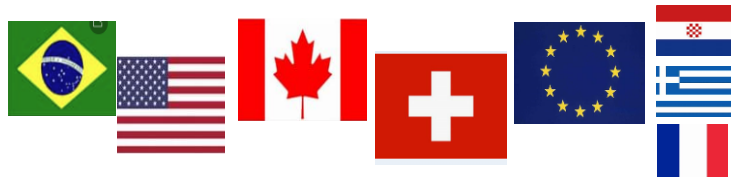
•Larger batches & smaller data sets for regulators

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

STATUS: concluded



countries:



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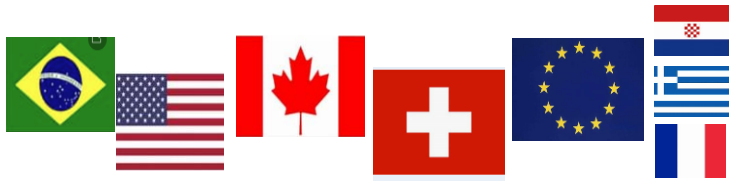
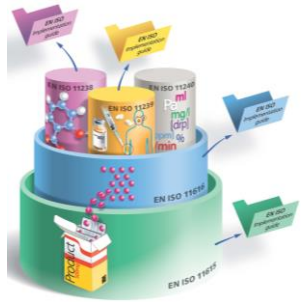
E2E: Data Validation Working Process

countries:



Medicinal product data

Selected data set

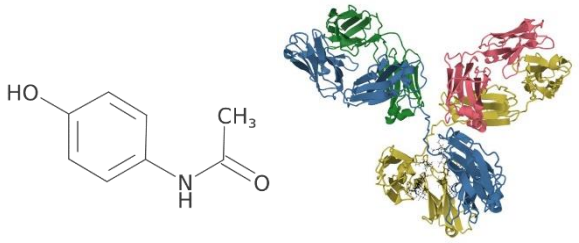


Substance

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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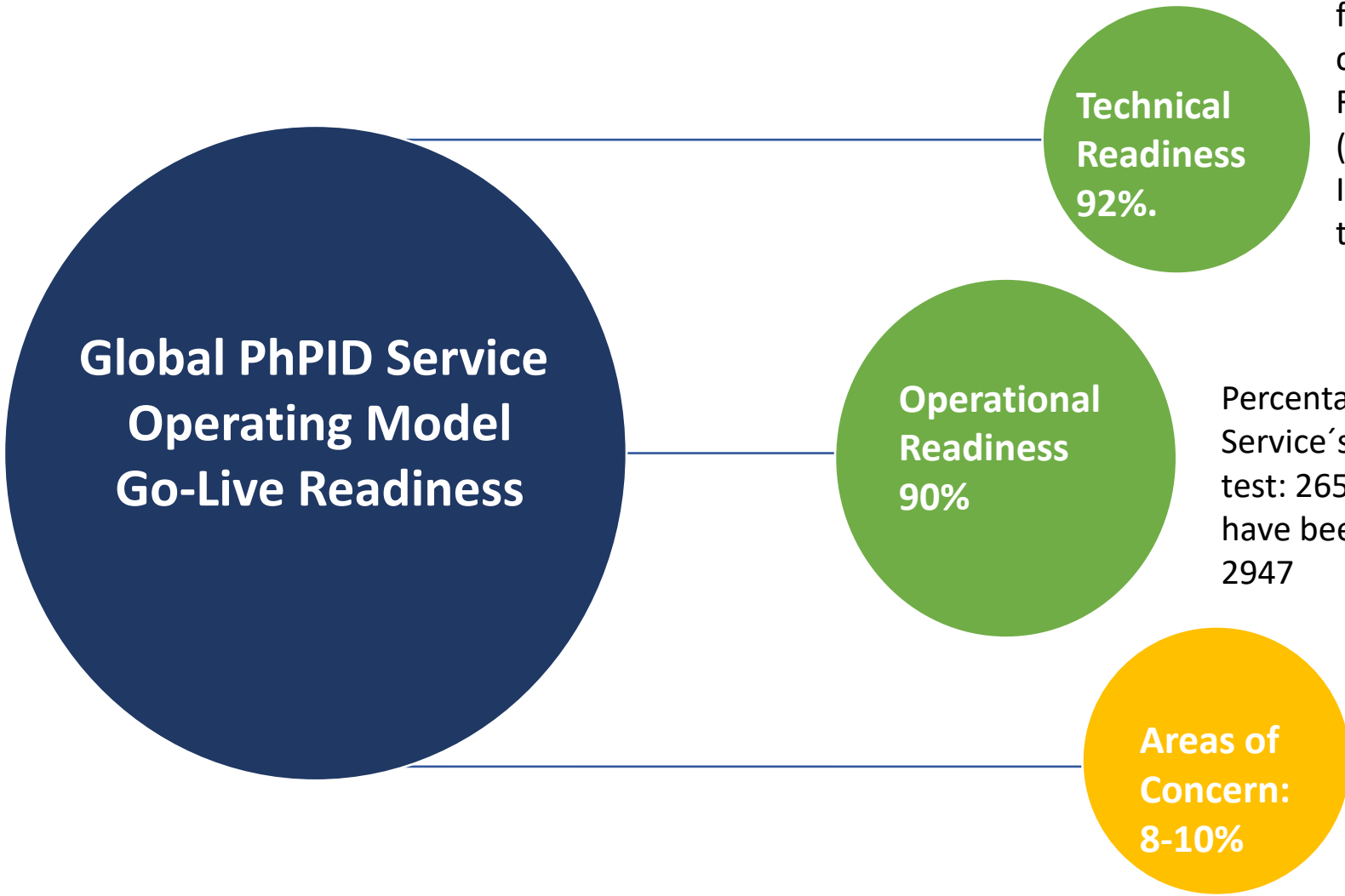
End-to-End Testing: Results



Percentage of the system's functionalities and processes covered by the test: PhPID Requestor, PhPID validating system (Drugstore), PhPID Publisher, and ISO IDMP Search in WHODrug have been tested successfully

Percentage of the Global PhPID Service´s processes covered by the test: 2655 Medicinal Products (90%) have been assigned PhPIDs out of 2947

Percentage of the system's and processes´ functionalities that are still under evaluation and covered under Findings

End-to-End Testing: Results

198 (87%) PhPIDs out of 230 products

456 (93%) PhPIDs out of 488 products

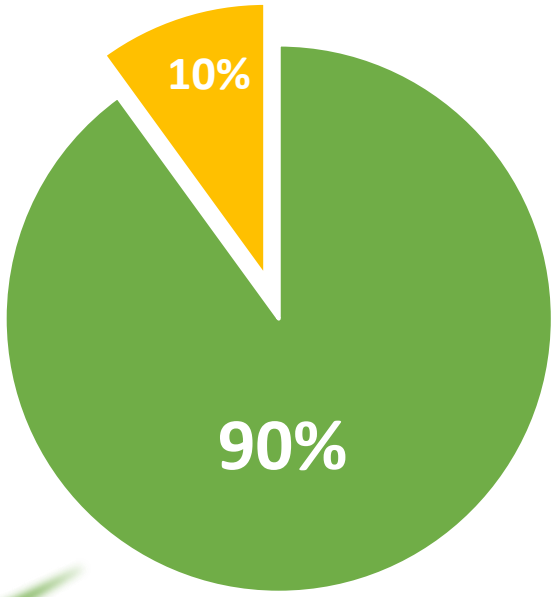
467 (89%) PhPIDs out of 525 products

678 (90 %) PhPIDs out of 752 products

856 (90 %) PhPIDs out of 952 products

PhPIDs for 2,657 (90%) out of 2,947 **Medicinal Products**

10% of Medicinal Products are part of E2E Findings and are under evaluation



90% of Medicinal Products have PhPID assigned

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End-to-End Testing: Ops Model Findings & Issues

Impact

Low | Medium | High

Operating Model & Processes Findings

PhPID Request

- PhPID Request process: data submission process was challenging

Impact

- PhPID request process needs further optimization

Risk/Issue

- Regulators/UMC spend excessive time on manual data processing

Strategy for Local IDs

- Local IDs were identified as important element both for PhPID use cases and for data validation.

Impact

- Increased product validation efficiency
- Easier to find SPC

Opportunity

- Improved aggregations and search functionalities for PhPID Service

Overarching PhPIDs

- Regulators have demonstrated an interest in having ´overarching´ PhPIDs that would group salts and bases

Impact

- Development needed
- Referred to ISO 116116 revision

Opportunity

- Improved aggregations and search functionalities for PhPID Service

SPC Challenges

- SPC has been requested to facilitate consistent identification, comparison and harmonization across medicinal products. In some of cases it has been challenging to find appropriate SPC or insufficient information on medicinal product in SPC to assign global identifiers.

Impact

- No PhPIDs

Issue

- No SPC verification

End-to-End Testing: Ops Model Findings & Issues

Impact

Low | Medium | High

Operating Model & Processes Findings

Harmonization Degree

- For PhPID generation involving substance, dose form, and strength, products with minor differences in SPCs were harmonized.

Five Region Verification

- The "Five Region Verification" was implemented and was intended to mitigate regional variations during end-to-end testing. It involved analyzing substances and products across five key regions: Asia, Europe, Latin America, North America, and Oceania, to understand how specific substances or products are described globally

Impact

- Increased process efficiency and data reliability

Opportunity

- Mitigation of differences between terminologies and different levels of granularity

End-to-End Testing: Automation Findings

Impact

Low | Medium | High

Automation Findings

Dose Form Characteristics (BDF, AME, ISI, and RCA)	Impact	Opportunity
• Medicinal product´s dose form mapped to specific EDQM Dose Form Characteristics (BDF, AME, ISI, and RCA) • Semi-automation Dose Form Characteristics assignment	• Increased product validation efficiency	• Automation • Interoperability

Substance	Impact	Opportunity
• Substance identification was performed in UMC-SRS using US data as a basis	• Manual substance mapping process	• Future automation using GSRS to connect UMC-SRS to US-SRS and EU-SRS

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End-to-End Testing: Substance Issues

Impact

Low | Medium | High

	No GSID	Impact	Issue	Mitigation
Substance & GSID related Issues	• Unable to assign GSID due to lack of public information (e.g. Octocog alfa) • Unable to assign GSID due to substance not described properly (e.g. ibuprofen resinate)	• Products on hold • Process gaps	• No PhPIDs	• Develop process for requesting non-public information from regulators and industry

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End-to-End Testing: Substance Findings

Impact

Low | Medium | High

Substance & GSID related Findings

Active Ingredient	Impact	Risk
• Base or salt? Variations and lack of clarity in Medicinal Product Information (e.g. Sildenafil products changed to Sildenafil citrate (Revatio), Sildenafil sandoz, Sildenax, Silvir, Viagra)	• Manual validation of every MP • Decreased validation process efficiency • Clarification on Business Rules	• Automation limitations • Creation of multiple PhPIDs, where products should be assigned to one PhPID

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End-to-End Testing: Dose Form Findings

Dose Form ID Findings

Variations in Dose Form Terminologies

- Differences between terminologies and different levels of granularity for dose forms submitted by countries.

Dose Form Characteristics Assignment

- RCA Dose Form characteristics are still challenging to assign due to that medicinal product dose form description is vague and/or twofold in Medicinal Product Information (Information on RCA is not always available and/or described unclear)

Impact

- Manual validation of every medicinal product
- Decreased validation process efficiency
- Clarification on Business Rules

Risk

- Automation limitations
- Several PhPIDs, where products should be harmonized and assign one PhPID

End-to-End Testing: Strength Issues

Impact

Low | Medium | High

Strength Definition ID Issues

Overfill	Impact	Issue
• Challenging to identify overfill. Almost impossible without validating different countries simultaneously	• Time-consuming validation process	• Several PhPIDs, where products should be harmonized and assign one PhPID

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End-to-End Testing: Strength Findings

Impact

Low | Medium | High

Strength Definition ID Findings

Medicinal Product Information

- Unclear in Medicinal Product Information on which strength to use? (e.g. when Medicinal Product Information has several strengths e.g., one for the base and one for the salt strength or different salt/ hydrate/ anhydrous strength

Impact

- Manual validation of every MP
- Decreased validation process efficiency
- Clarification on Business Rules

Risk

- Automation limitations
- Several PhPIDs, where products should be harmonized and assign one PhPID

Unit Conversion

- Unit harmonization to express the strength
  - mg/g vs mg/ml for semi-solids and liquids (e.g. Azithromycin hydrate)
  - mg/ml vs mmol/ml (e.g. Calcium chloride, or use different units for different product types)
- Units conversion (e.g. colecalciferol)

Impact

- Manual validation of every MP
- Decreased validation process efficiency
- Clarification on Business Rules

Risk

- Automation limitations
- Errors
- Several PhPIDs, where products should be harmonized and assign one PhPID

Specificity of Strength

- Different Medicinal Product Information display different number of value figures (e.g 10 mg patisiran base = 10.5 mg patisiran sodium. This does not match DS ratio wich would be 10 mg base = 10.66 mg salt).

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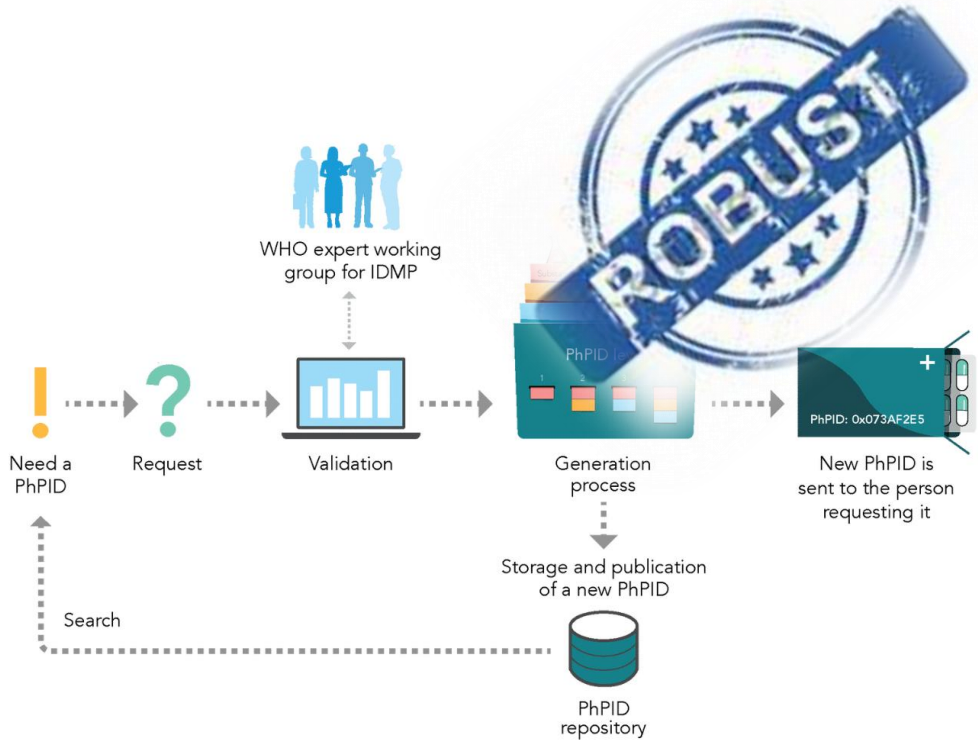
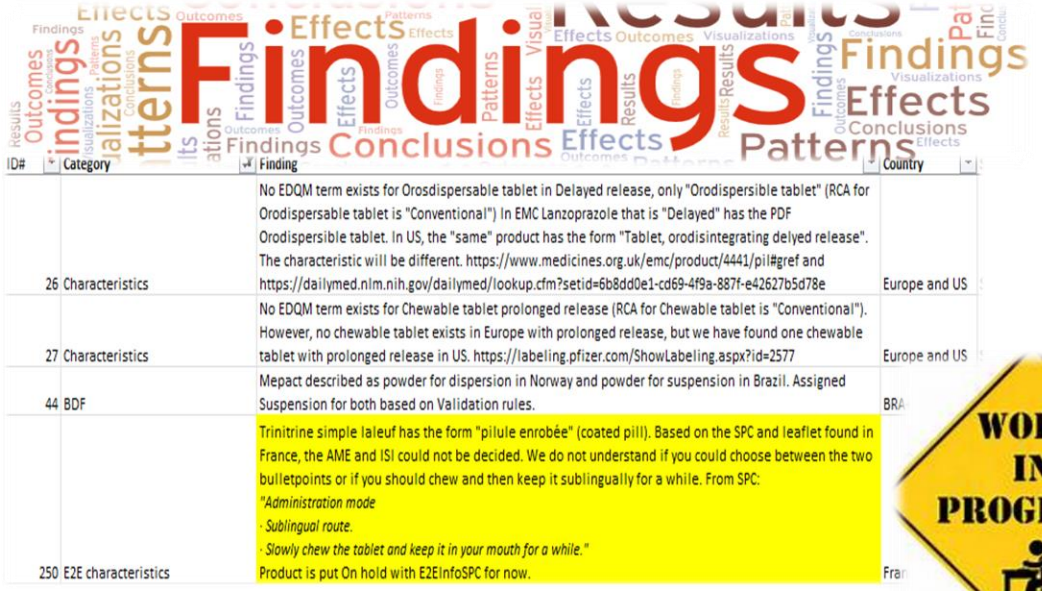
End-to-End Testing: Next Steps



90% success rate is commendable and reflects the robustness of our current operating model

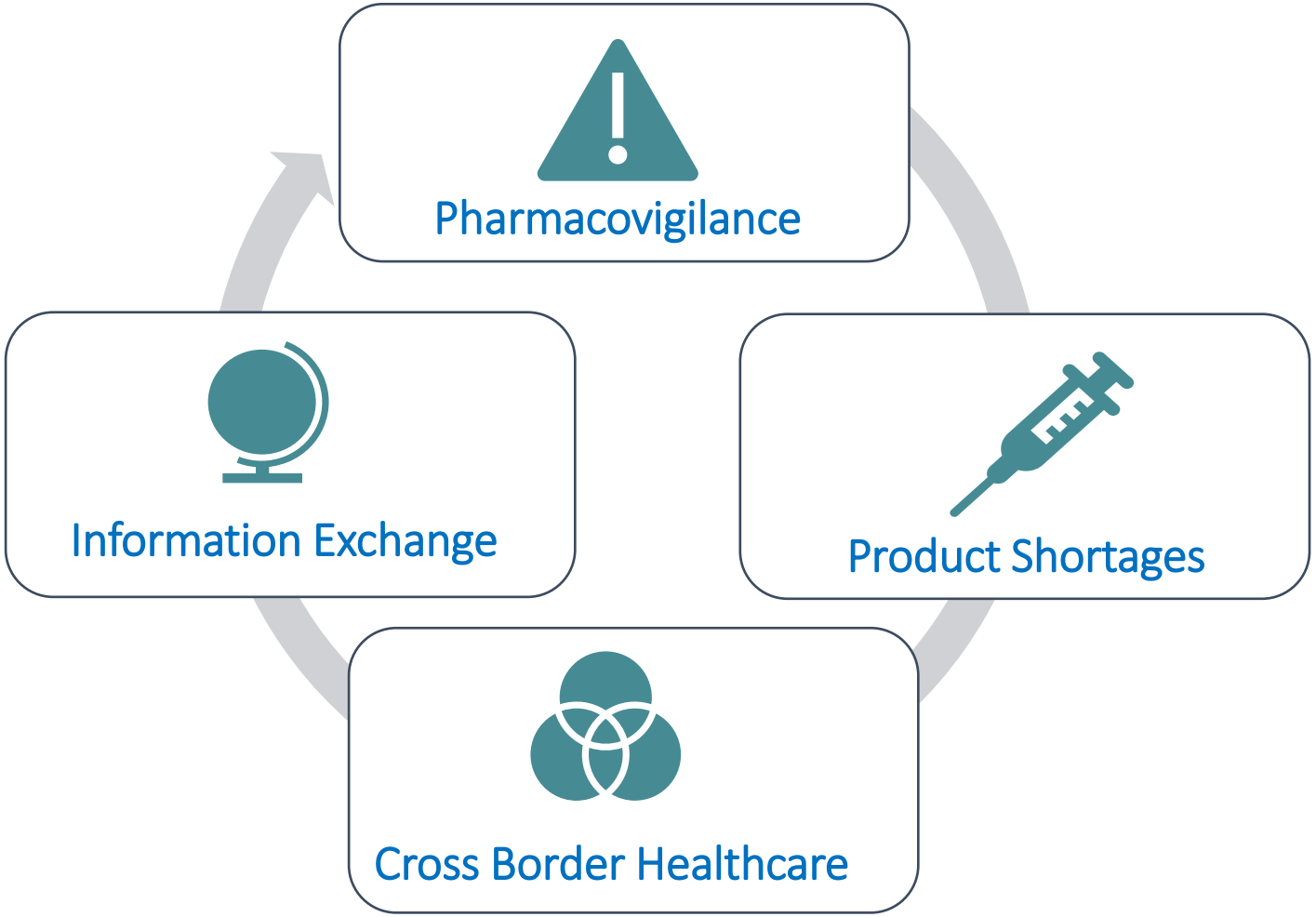


10% remaining represent an opportunity for improvement

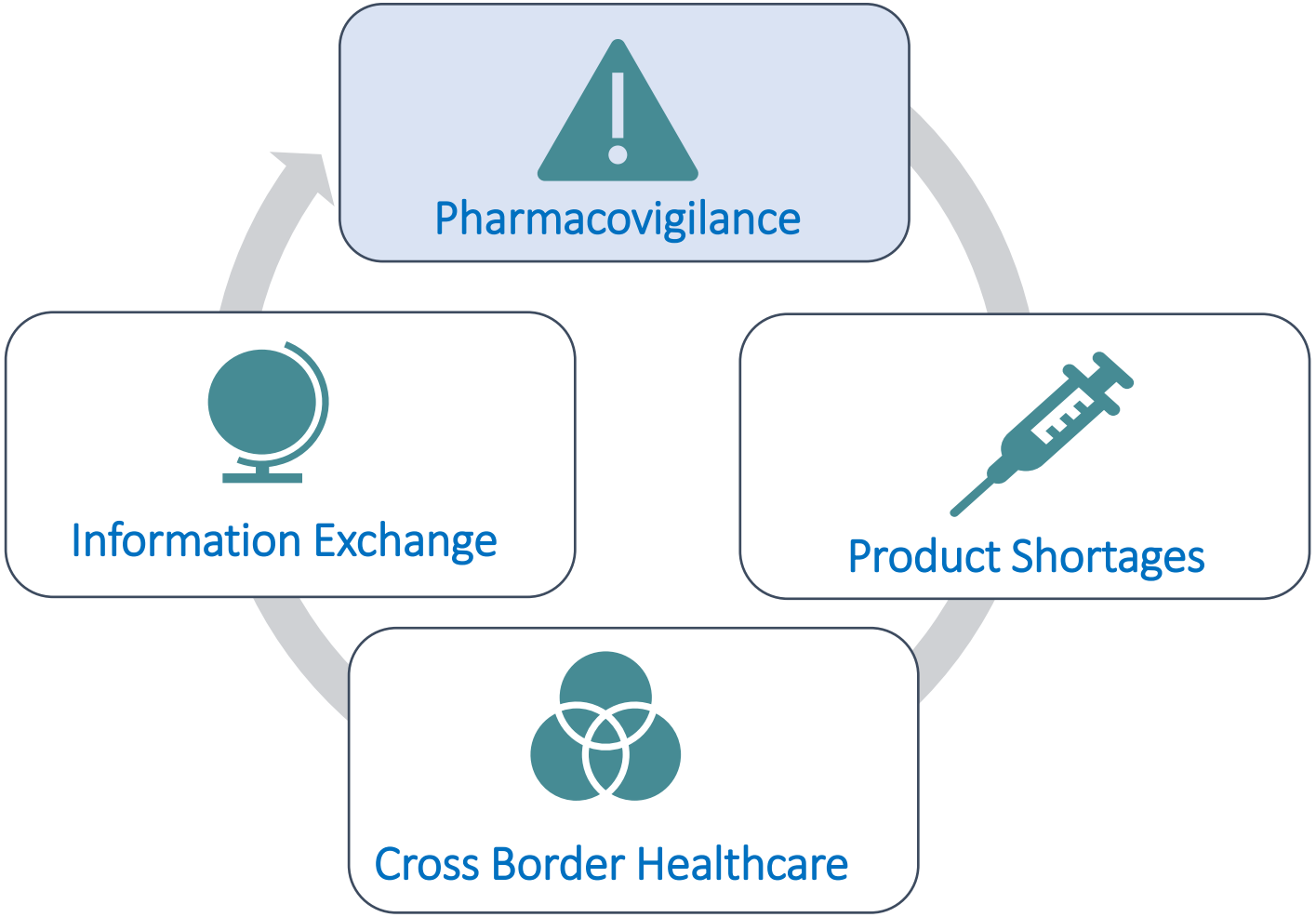
Additional testing may be required to focus on specific areas for PhPID implementation to **define the degree of medicinal product information harmonization** required for PhPID generation and even on testing Change Management model for PhPID maintenance.

Pharmacovigilance Use Case

Value of IDMP in the Medicinal Product Life Cycle

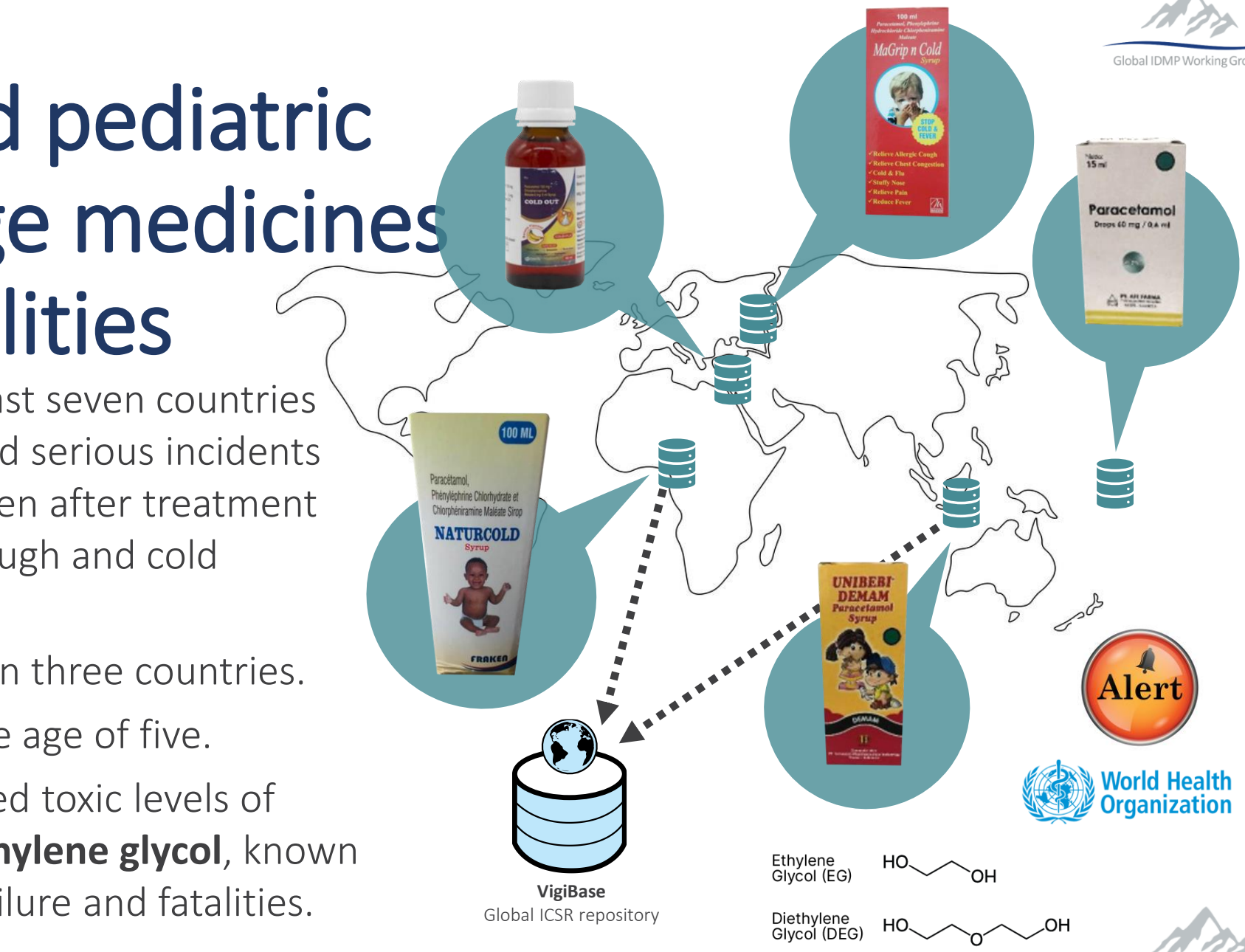


Value of IDMP in the Medicinal Product Life Cycle



Substandard pediatric liquid dosage medicines causing fatalities

- As of January 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.



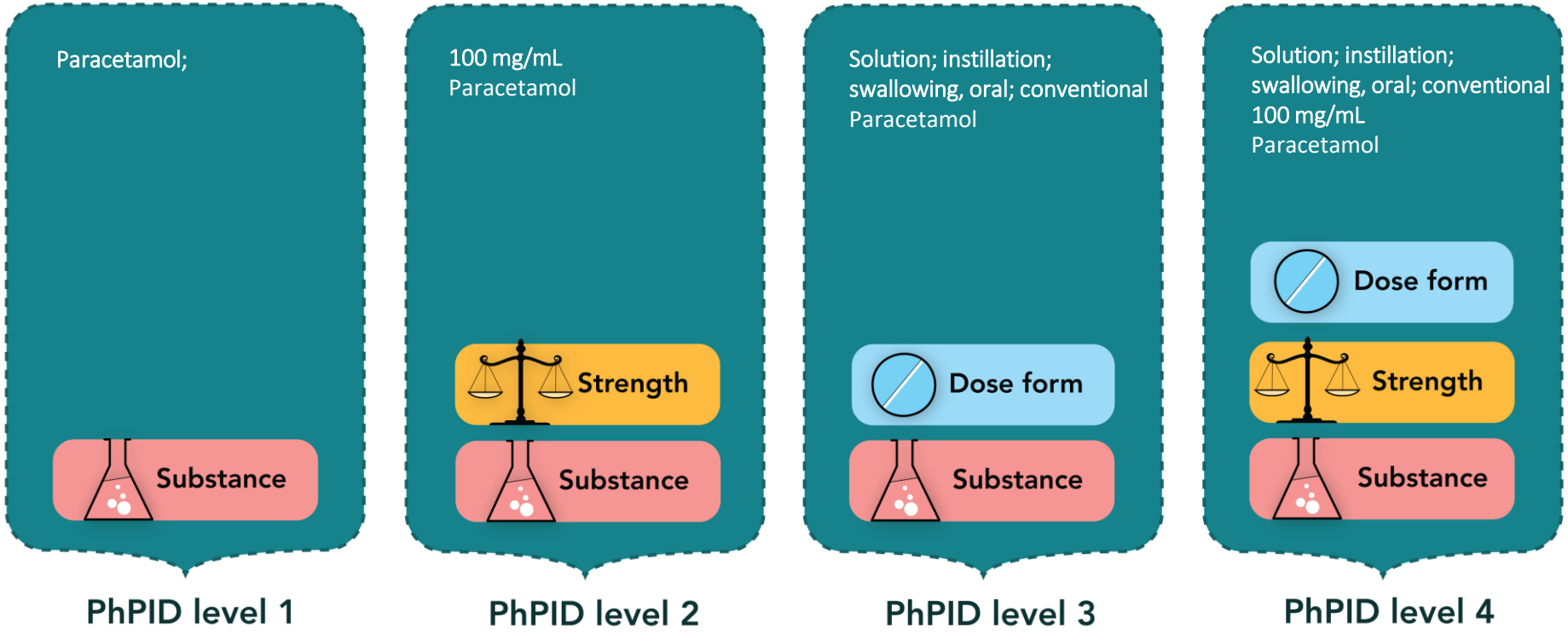
What Other Regions Could be Affected?

While WHO Medical Product Alerts refer to specific batches of substandard (contaminated) products Identified in a specific country, these products may have marketing authorisations in other countries or regions, or may have been distributed through informal markets to other countries.

VigiBase
Global ICSR repository

What if we had global PhPIDs?

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



Medicinal Products Containing Paracetamol- globally

Global IDMP Working Group

19,635

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

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Signalling with Global PhPID level 3

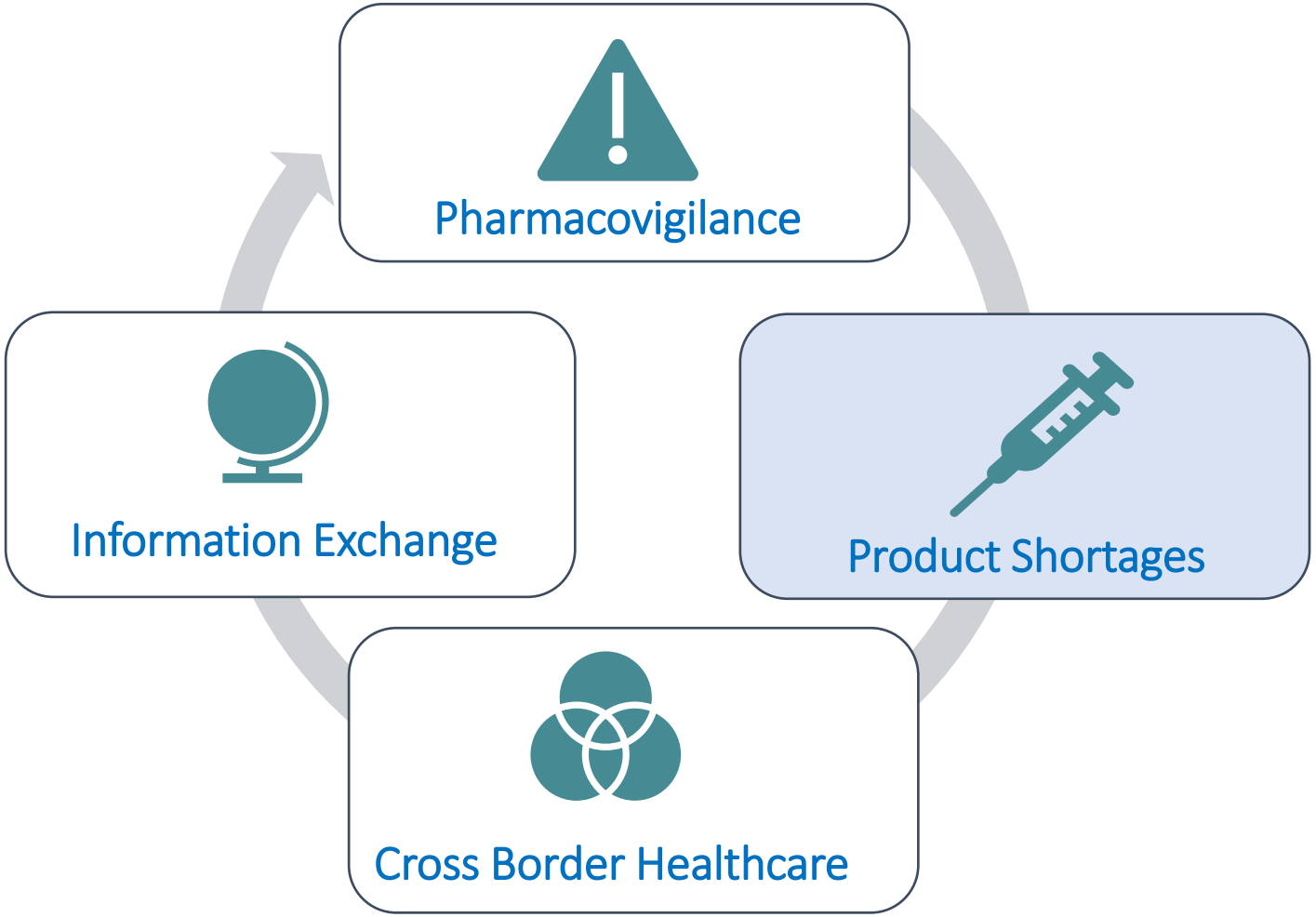
Global PhPID level 3 would enable identification of all medicinal products that share the same substance (paracetamol) and dose form (drops or syrup).

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

Global PhPID Take-Home Message

- Quicker and reliable signaling of rare adverse events
- Data analysis can be performed at different levels of granularity globally
- Real-time identification of unexpected serious adverse events/incidents in PV databases thanks to global standards
- **Effective alert communication to stakeholders**
- Immediate generation of accurate safety data for further investigation by regulators for evaluation and regulatory action

Value of IDMP in the Medicinal Product Life Cycle



Cisplatin

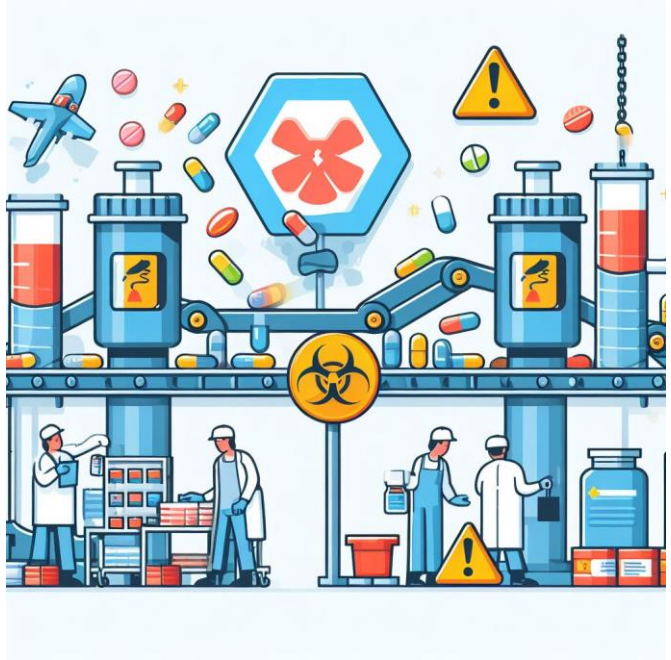
- To treat a wide range of cancers, including breast, ovarian, throat, lung, testicular, prostate and colorectal cancers.

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

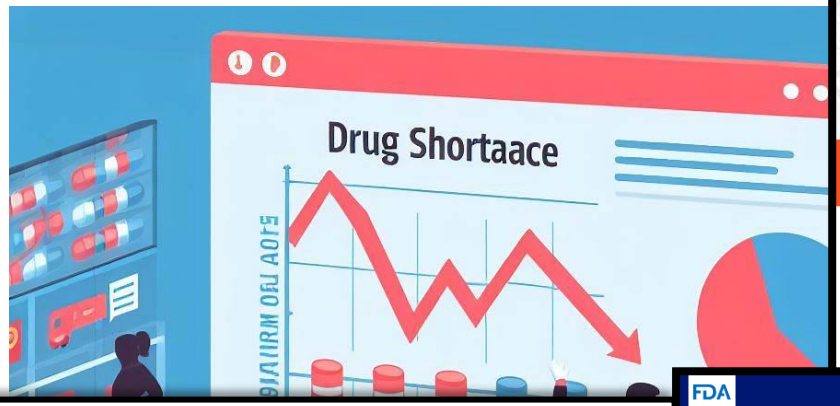
Healthcare Demand Outstrips the Supply of Cisplatin

In 2023, a quality-related manufacturing halt at one of the primary foreign production facilities for cisplatin with a US FDA approval causes a ripple effect.

Other approved marketing authorization holders (MAHs) are unable to meet the demand for this product.



Shortage Communicated to Stakeholders – February 2023



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

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DRUG SHORTAGES CANADA

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Search Products

Below you can search for drug products that are marketed for sale in Canada. The search results will show whether there has been a shortage and/or discontinuation report for the product.

...age.

...bsite overview for public users, found in the About & Resources page.

FDA

Search | Menu

Home / Drug Databases / Drug Shortages

FDA Drug Shortages

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THIS PAGE IS TEMPORARILY UNDER CONSTRUCTION WHILE ENHANCEMENTS ARE UNDERWAY. Drug shortage data continues to be updated while under construction.

Current and Resolved Drug Shortages and Discontinuations Reported to FDA

Report a Drug Shortage | Contact Us | FAQ | Background Info | Get Email Alerts | Download Current Drug Shortages

Search by Generic Name or Active Ingredient: Enter at least three characters Submit

Start Over

Results for: cisplatin

- Cisplatin Injection (*Currently in Shortage*)

Impact of Cisplatin Shortage

The cisplatin shortage potentially affects **100,000- 500,000 patients** annually.

Consequences may include treatment delays, dose adjustments, and transitions to alternative therapies. Such alterations increase the risk of medication errors and adverse events.

Drug Substitutes 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.

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

So, what if we had global PhPID?

Connected to a global resource of medicinal products, global PhPID level 4 could help to identify like medicinal products.

Potential 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

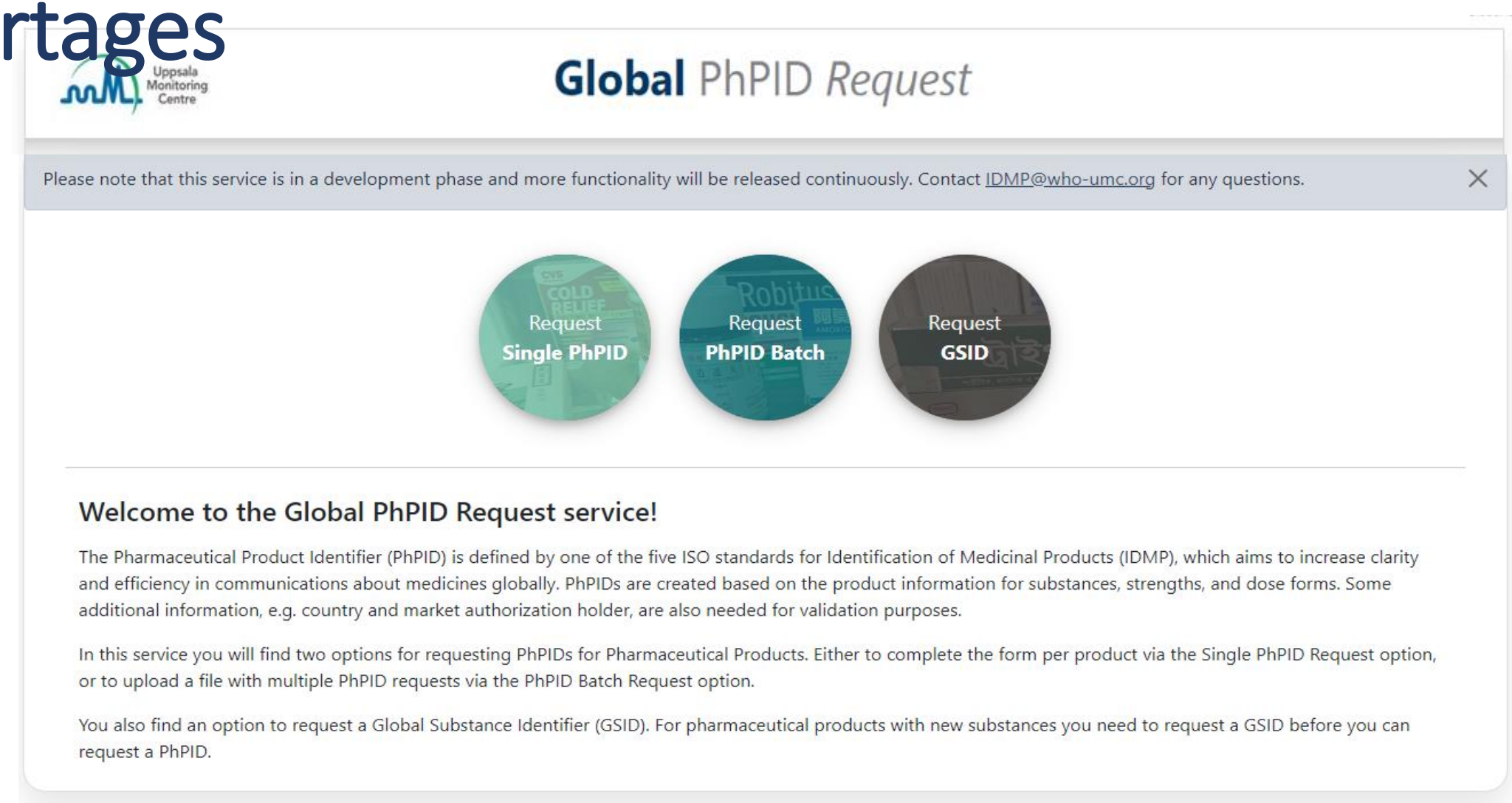
D934E701B1FF6B452828E1C6703B257E

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.

Use of Global PhPID for Early Mitigation of Drug Shortages



Use of Global PhPID for Mitigation of Drug Shortages

Global IDMP Working Group

Uppsala Monitoring Centre

Global PhPID Publish

marilina.castellano@who-umc.org

Medicinal Product Name	Drug Code	Active Ingredient(s)	ATC	WHODrug MPID	Authorization Country	MAH	Dose Form	Strength (Reference Strength)	PhPID	PhPID Level
Ach amlodipine	00972402A5R	Amlodipine besilate	C08CA, Dihydropyridine derivatives	5498368	Canada	Accord Healthcare	Tablet	6.93 mg (5 mg)	734116B72C5F6F9EB6DD5622C5210C19	4
Ach amlodipine	00972402A5R	Amlodipine besilate	C08CA, Dihydropyridine derivatives	5498373	Canada	Accord Healthcare	Tablet	13.87 mg (10 mg)	2E1557437501EF268CD8D06CC2990312	4
Alivpress	00972402776	Amlodipine besilate	C08CA, Dihydropyridine derivatives	3003845	Brazil	Cimed	Tablet	13.87 mg (10 mg)	2E1557437501EF268CD8D06CC2990312	4
Amlodil	00972402A1I	Amlodipine besilate	C08CA, Dihydropyridine derivatives	5153435	Brazil	Vitamedic industria farmaceutica ltda	Tablet	6.93 mg (5 mg)	734116B72C5F6F9EB6DD5622C5210C19	4
Amlodipin sandoz eco	00972402318	Amlodipine besilate	C08CA, Dihydropyridine derivatives	2731053	Switzerland	Sandoz pharmaceuticals	Tablet	6.93 mg (5 mg)	734116B72C5F6F9EB6DD5622C5210C19	4
Amlodipin viatris	00972402A5T	Amlodipine besilate	C08CA, Dihydropyridine derivatives	5507073	Switzerland	Viatris pharma	Tablet	6.93 mg (5 mg)	734116B72C5F6F9EB6DD5622C5210C19	4
Amlodipine besylate	00972402020	Amlodipine besilate	C08CA, Dihydropyridine derivatives	1612113	United States of America	Zydus Pharmaceuticals	Tablet	6.93 mg (5 mg)	734116B72C5F6F9EB6DD5622C5210C19	4
Amlodipine besylate	00972402020	Amlodipine besilate	C08CA, Dihydropyridine derivatives	5534784	United States of America	Viatris	Tablet	13.87 mg (10 mg)	2E1557437501EF268CD8D06CC2990312	4
Anlo	00972402068	Amlodipine besilate	C08CA, Dihydropyridine derivatives	5498366	Brazil	Ems sigma pharma	Tablet	13.87 mg (10 mg)	2E1557437501EF268CD8D06CC2990312	4
Norliqva	00972402A4E	Amlodipine besilate	C08CA, Dihydropyridine derivatives	5073818	United States of America	CMP Pharma	Solution	1.39 mg/mL (1 mg/mL)	D088EF02B6CA65640D8C62A51B09EB6C	4
Norvasc	00972402004	Amlodipine besilate	C08CA, Dihydropyridine derivatives	5511058	Switzerland	Viatris GmbH	Tablet	13.87 mg (10 mg)	2E1557437501EF268CD8D06CC2990312	4
Norvasc	00972402004	Amlodipine besilate	C08CA, Dihydropyridine derivatives	5532315	United States of America	Pfizer	Tablet	3.47 mg (2.5 mg)	A6EBB6A6AAE6E58410EDA2093A8C9F6C	4

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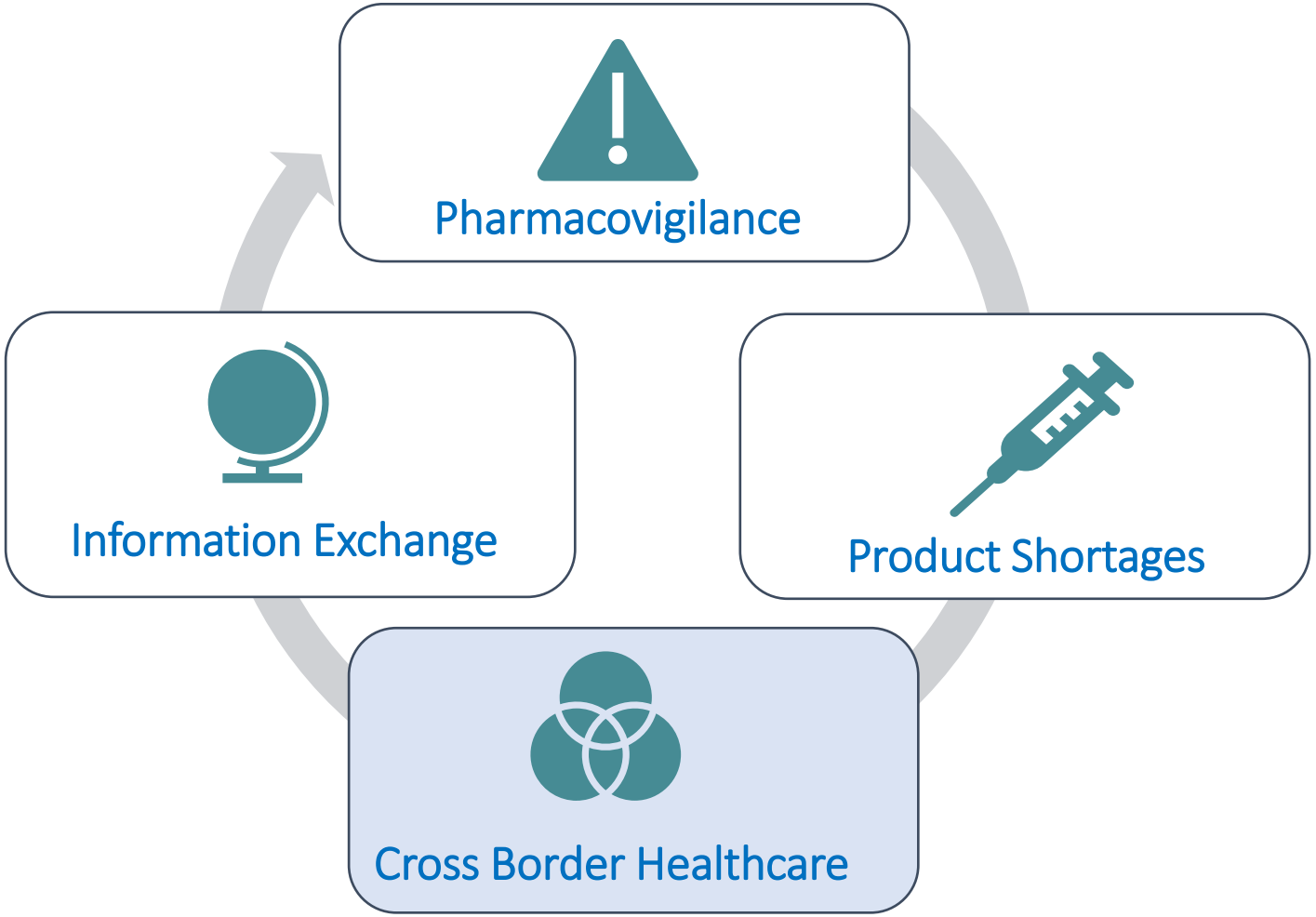
Value of IDMP in the Medicinal Product Life Cycle

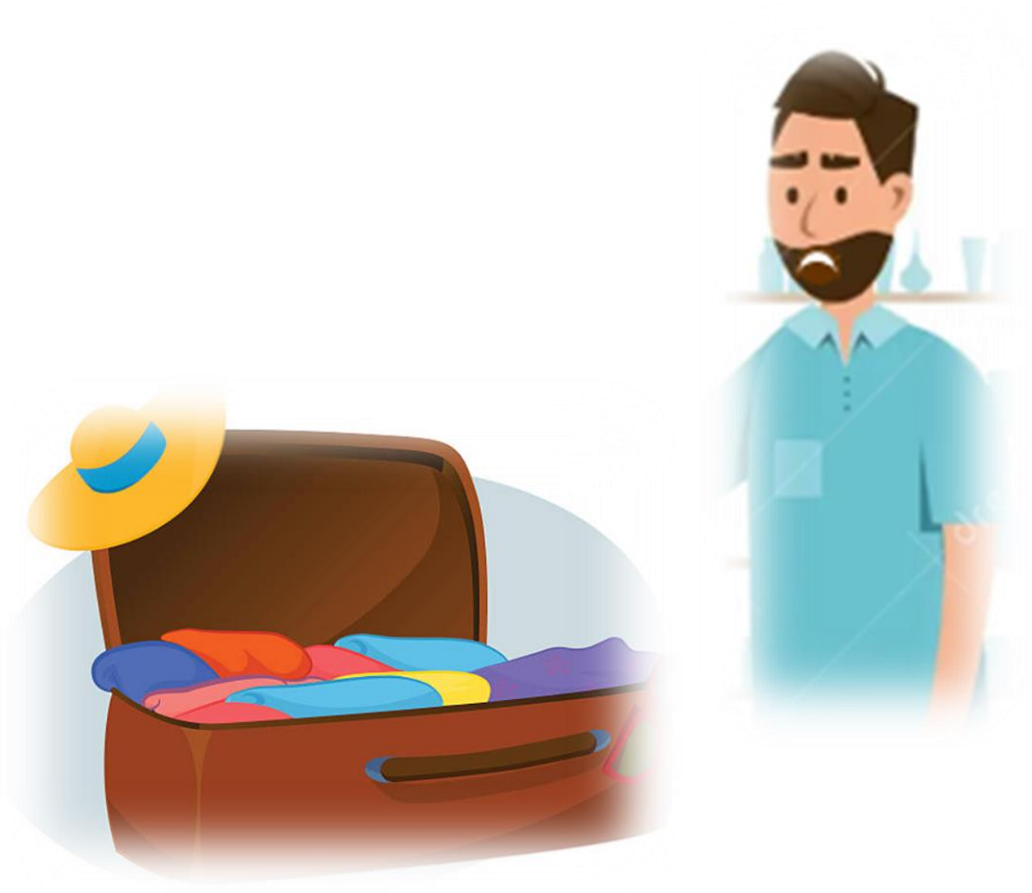


Cross Border Health Care Use Case

Travel from Saudi Arabia to Brazil

Ahmed embarks on an international journey from Japan to Brazil, poised for his anticipated vacation.

Forgotten Medication



Ahmed inadvertently forgets to carry an adequate medication supply for his three-week vacation in Brazil.

ePrescription

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

Challenge: Dispensing a foreign prescription

Travel to a foreign country and not having adequate amount of medicine for various reasons (lost/delay luggage, forgot/misplace, …)
Challenge: The local pharmacist cannot read or type foreign brand name in his system to look for like product and concerning potential misinterpretation and erroneous medication dispensation.

What if we had a global PhPID?

The pharmacist can now search his system for medicinal products that share the same Global PhPID.
Dispenses a regional medicinal product to preserve patient's health.

Global PhPID connecting Medicinal Product Across Regions

Global PhPID level 4, connected to a federated resource of medicinal products can help to identify “like” products across regions with various languages

The PhPID becomes the medicinal product’s “common denominator” from country-to-country

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GIDWG
Status Global IDMP Identifiers

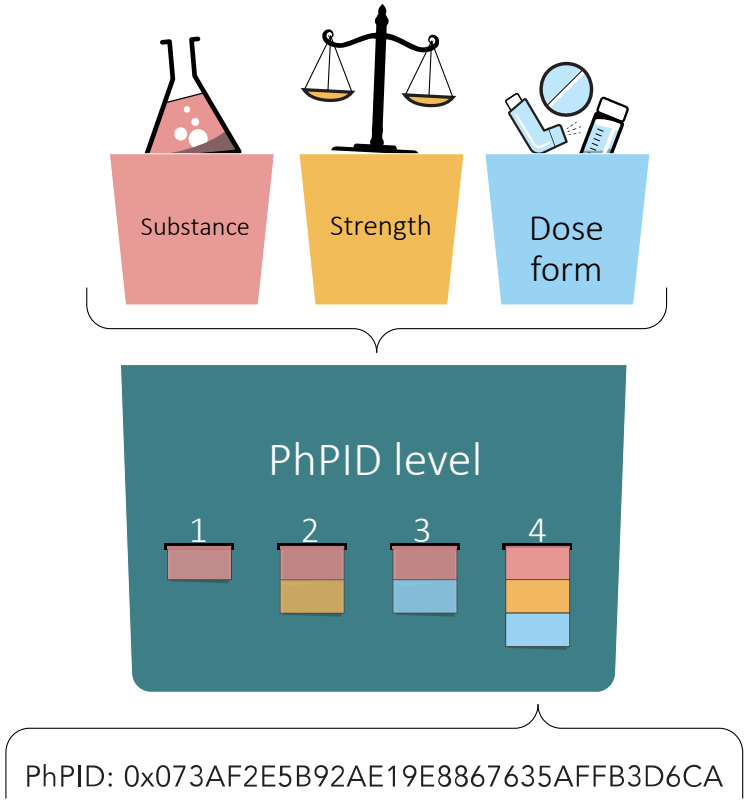
Olof Lagerlund (UMC)

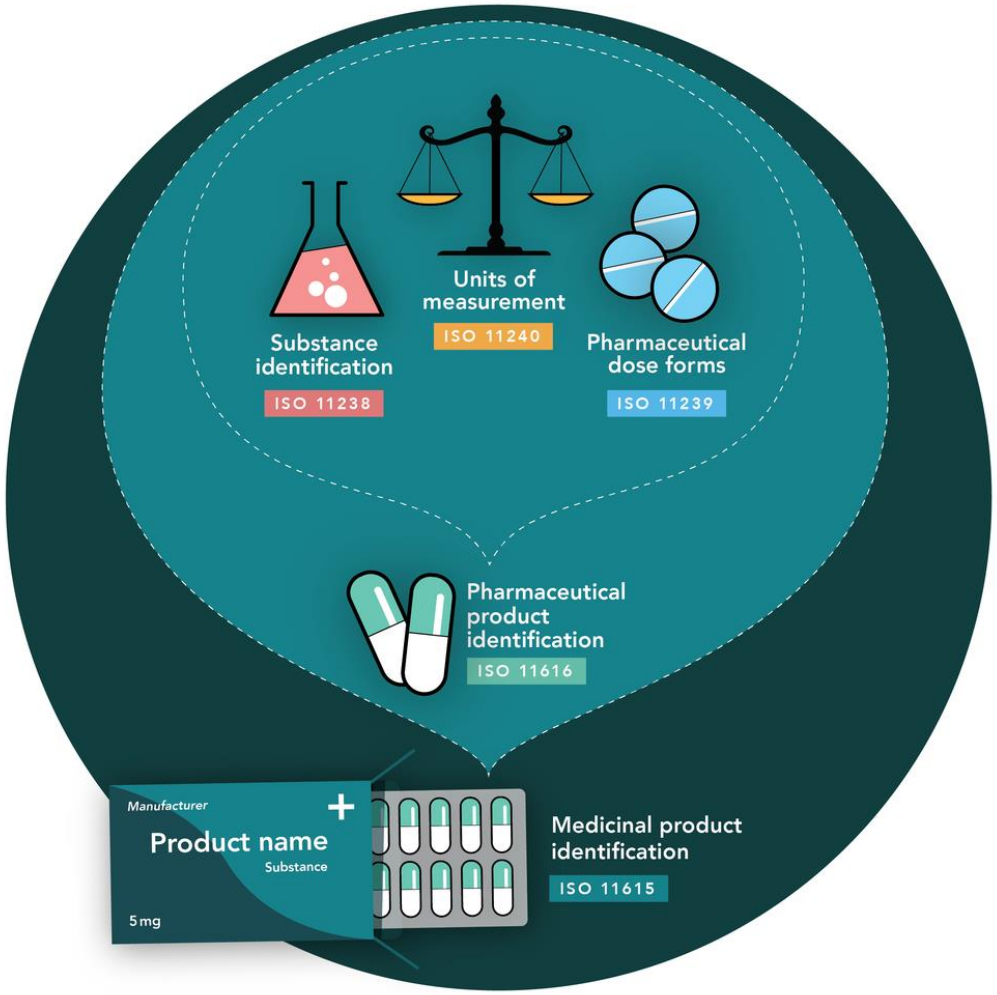
Global IDMP Working Group

Pharmaceutical product ID

PhPID

PhPID





ISO IDMP suits of standards
ISO 11238, 11240, 11239, 11616 and 11615

Creating catalogues of IDs for the generation of PhPID

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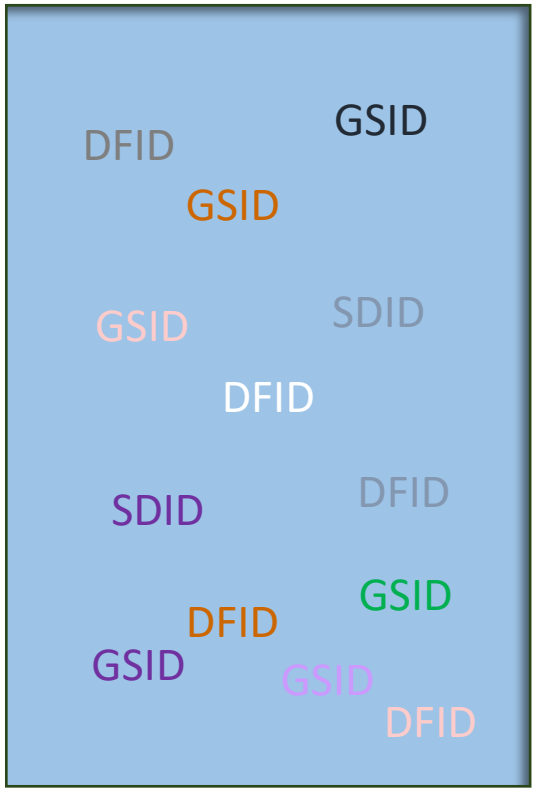
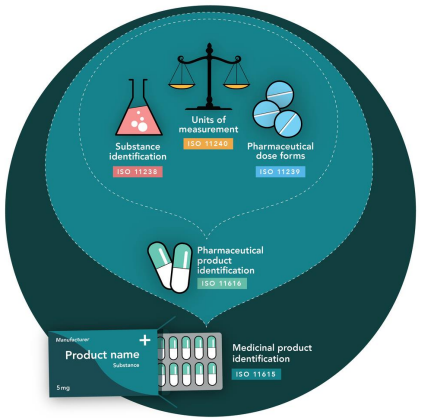
ID Catalogues



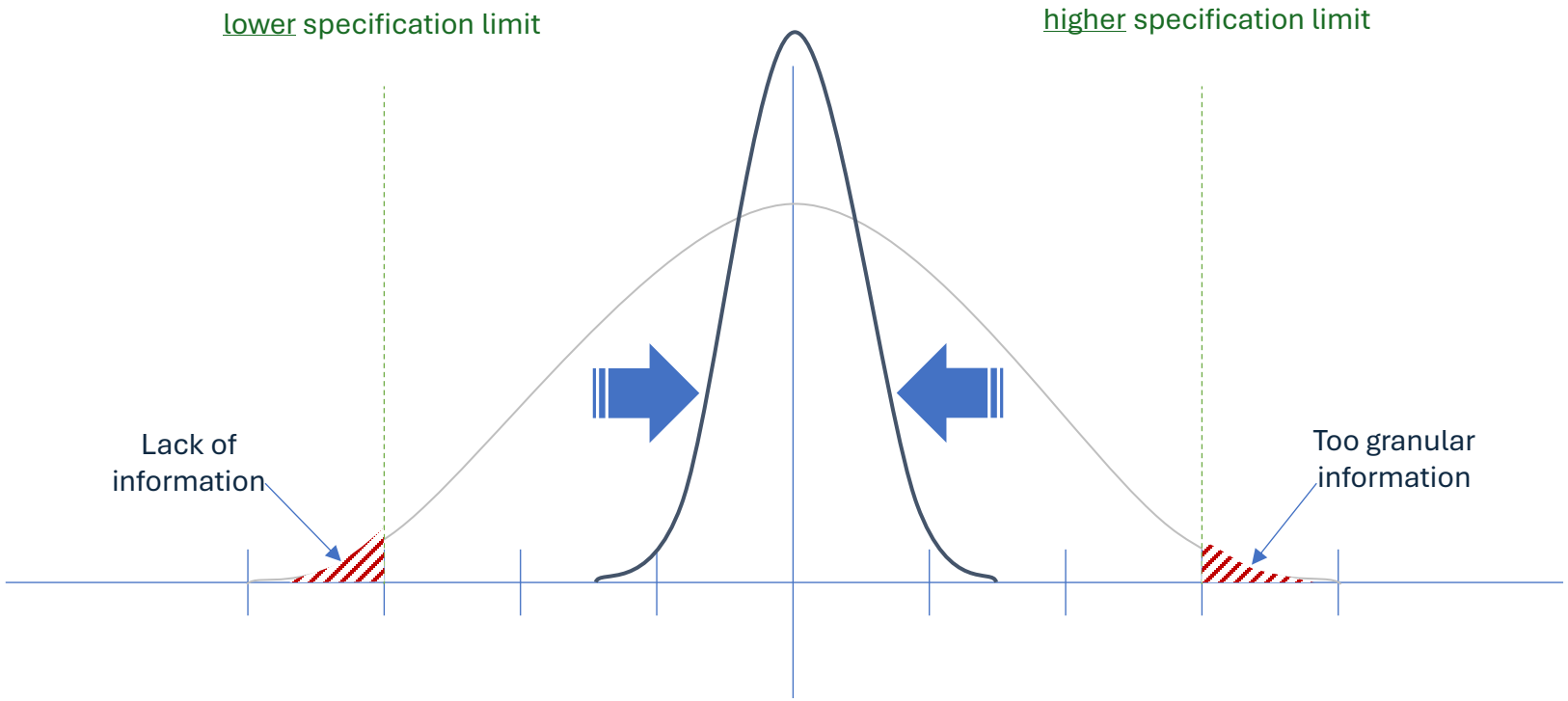
ISO Standards and GIDWG BR

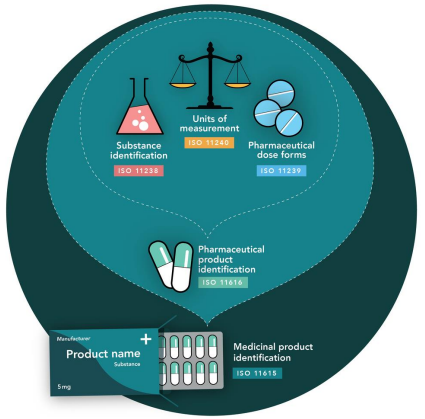
PhPID product (GSID, SDID, DFID)



Harmonization

During global ID assignment, information in SPCs for each product was reviewed individually. For the Global PhPID, products with minor differences in SPCs were harmonized.





Harmonization Degree

Finding

The extent of medicinal product information harmonization was evaluated across three use-cases: pharmacovigilance, drug shortage, and cross-border healthcare during end-to-end testing. Products with minor differences in SPCs were harmonized.

Recommendation

Ensure involvement of SMEs with competence within the different use cases for global PhPID to safeguard quality and efficiency in assignment of PhPID as well as to mitigate issues unclear or too granular information.

Five regions verification

Finding

Analyzing substances and products across five key regions to understand how specific substances or products are described globally and intended to mitigate challenges in harmonization.

Recommendation

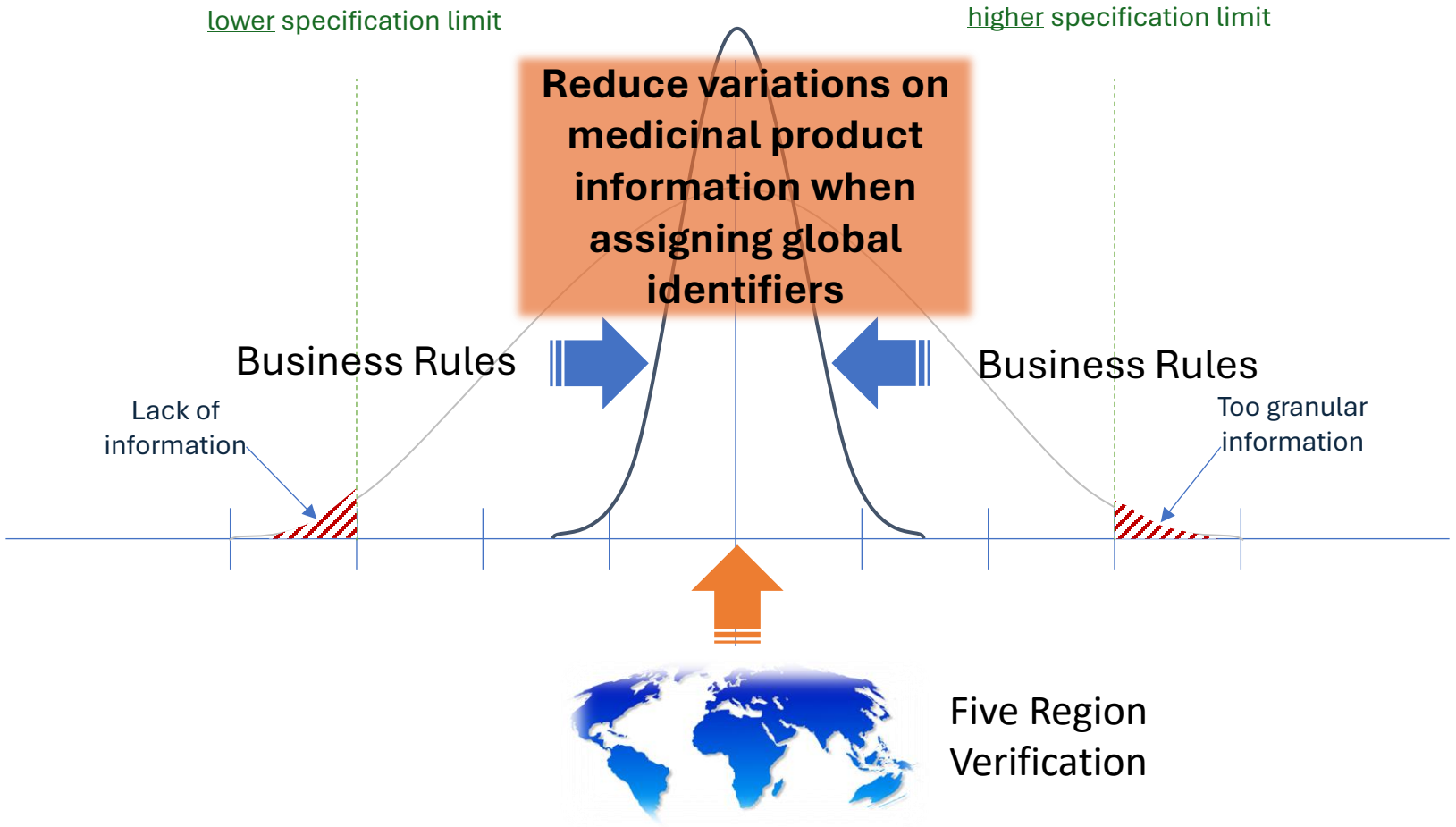
- Pro: Valuable method when validating additional products with the same substance variant and pharmaceutical form.
- Con: time consuming, should only be applied when relevant.

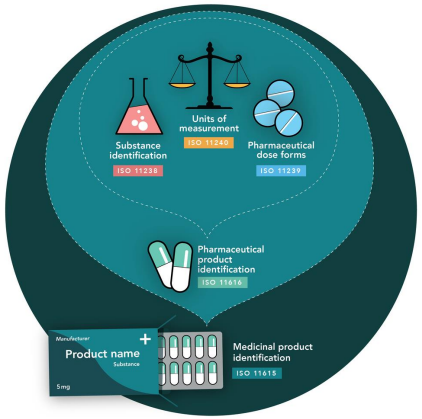
Harmonization

Global IDMP Working Group

LAGOM:
Not too little, not too much. Just right.

During global ID assignment, information in SPCs for each product was reviewed individually. For the Global PhPID, products with minor differences in SPCs were harmonized.





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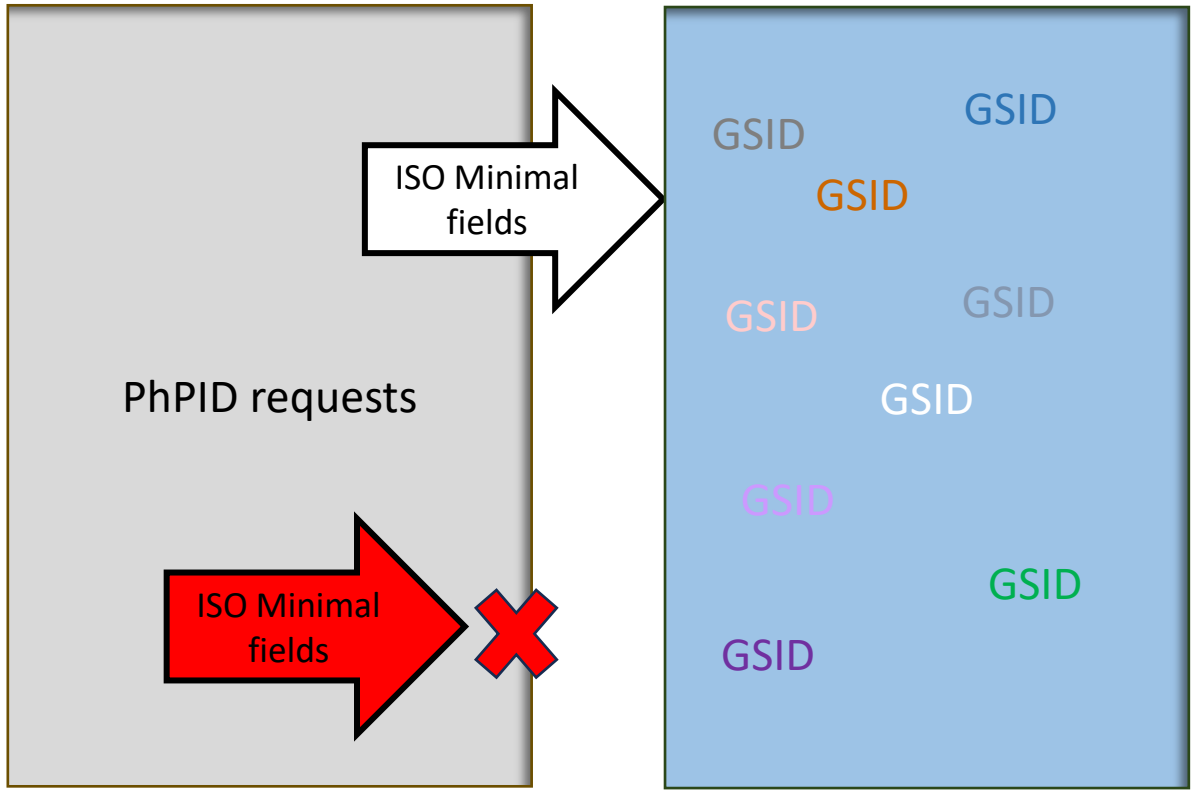
Global substance ID

GSID

GSID assignment

GSID assignment in end-to-end



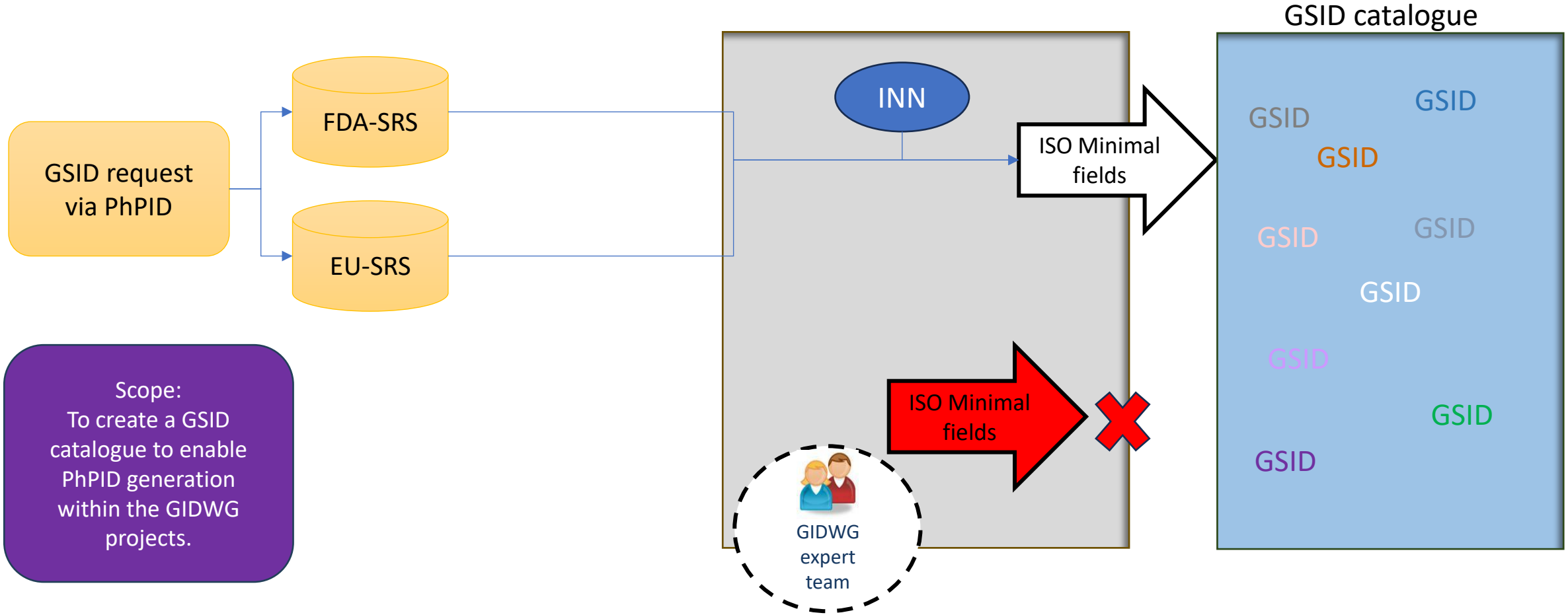
Substances types represented in the end-to-end:

- Chemicals
- Proteins
- Polymers
- Nucleic acids
- Structural Diverse

Scope:
To create a GSID catalogue to enable PhPID generation within the GIDWG projects.

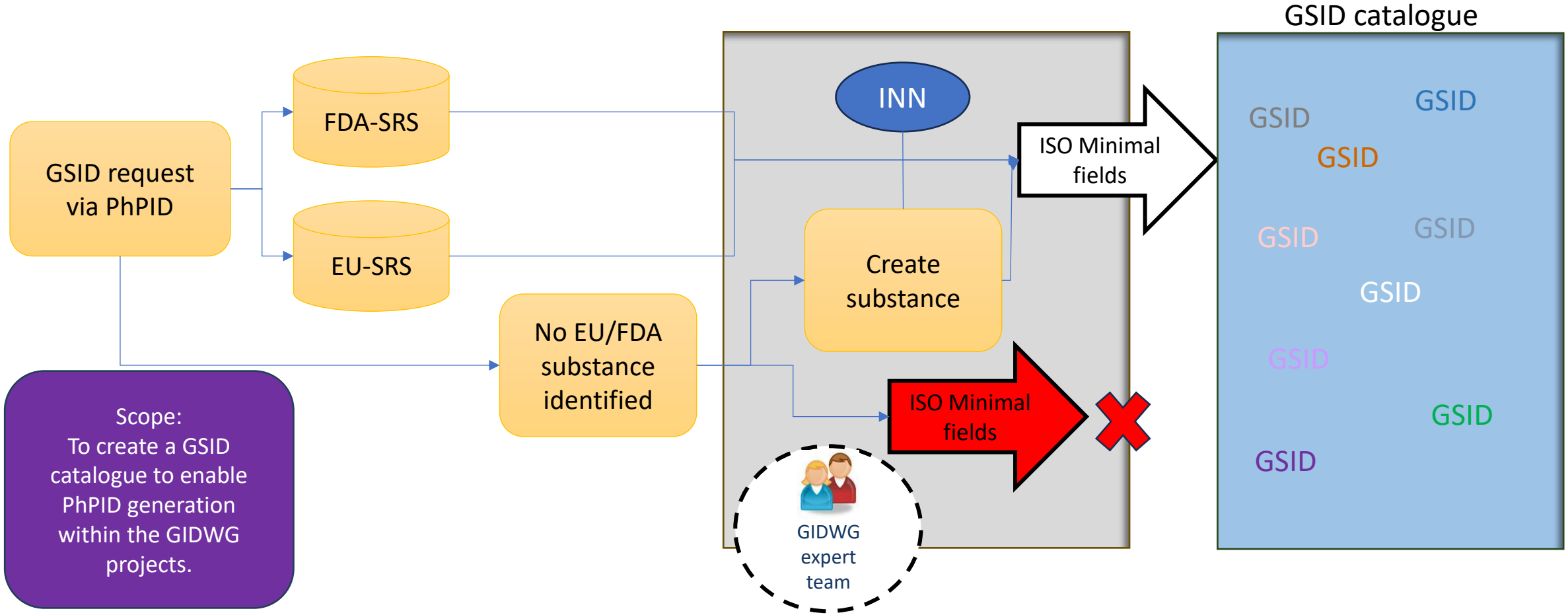
GSID assignment and creating a GSID catalogue

GSID assignment process for new substances

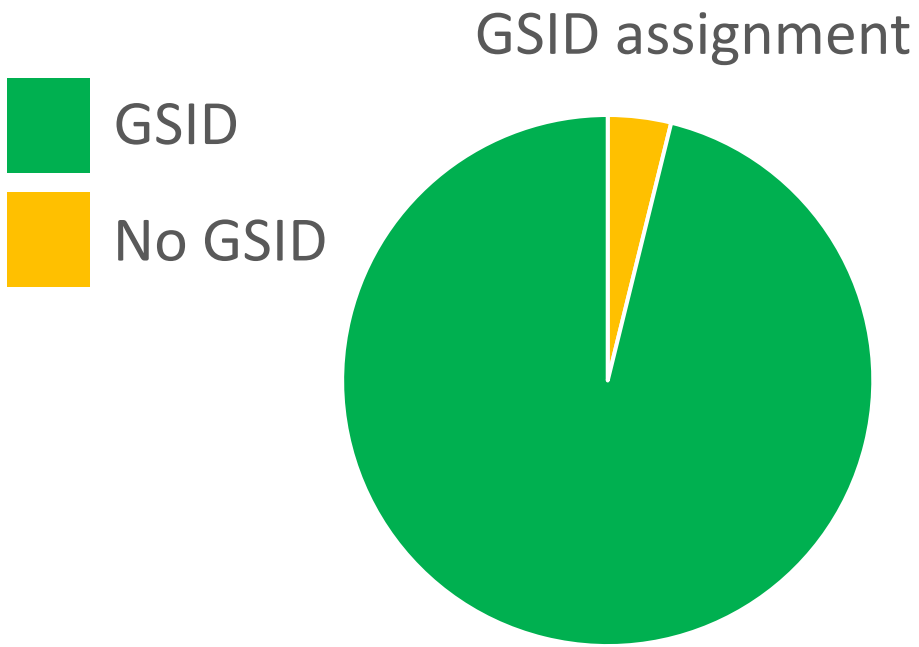


GSID assignment and creating a GSID catalogue

GSID assignment process for new substances



GSID assignment in the end-to-end



- 96% of the substances where successfully assigned a GSID
- The 4% not assigned was due to lack of or conflicting information
- Mitigation: Case-by-case

Selection of GSID for PhPID generation - harmonization

Finding

For rare cases, selecting GSID to ensure harmonization is difficult due to differences between how regulators describe the active ingredient.

For instance, the active ingredient is a base in one country and a salt in another, however they have the same MAH and similar trade name and dose form.

Selection of GSID for PhPID generation - harmonization

Global IDMP Working Group

1. NAME OF THE MEDICINAL PRODUCT

DEXAMETHASONE PANPHARMA 4 mg/mL, solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Dexamethasone phosphate..... 4, 0 mg

For one ampoule of 1 mL of solution for injection.

1 mL of solution for injection contains 4.0 mg dexamethasone phosphate.

1.8 mL of solution for injection contains 7.27 mg dexamethasone phosphate (6 mg dexamethasone base).

2 mL of solution for injection contains 8.0 mg dexamethasone phosphate (6.6 mg dexamethasone base).

Excipient with notable effect : each 1 mL ampoule of DEXAMETHASONE PANPHARMA 4 mg/mL contains 0.119 mmol (2.35 mg) sodium.

Each 1.8 mL ampoule of DEXAMETHASONE PANPHARMA 4 mg/mL contains 0.214 mmol (4.23 m

Each 2 mL ampoule of DEXAMETHASONE PANPHARMA 4 mg/mL contains 0.238 mmol (4.7 mg) s

For the full list of excipients, see section 6.1.

6.1. List of excipients

Creatinine, sodium citrate, hydrated citric acid, sodium hydroxide (for pH adjustment), water fo

A majority (20/21) of products were described with dexamethasone sodium phosphate.

Dexamethasone 3.3 mg/ml Solution for Injection

Summary of Product Characteristics Updated 26-Jan-2021 | Panpharma UK Ltd

1. Name of the medicinal product

DEXAMETHASONE 3.3 mg/ml, solution for injection

2. Qualitative and quantitative composition

Each ml of solution contains 3.3 mg dexamethasone (as sodium phosphate) which is equivalent to 4 mg dexamethasone phosphate or 4.37 mg dexamethasone sodium phosphate.

Selection of GSID for PhPID generation - harmonization

Finding

For rare cases, selecting GSID to ensure harmonization is difficult due to differences between how regulators describe the active ingredient.

For instance, the active ingredient is a base in one country and a salt in another, however they have the same MAH and similar trade name and dose form.

Recommendation

Harmonize based on the active ingredient in the majority of the products.

Global IDMP Working Group

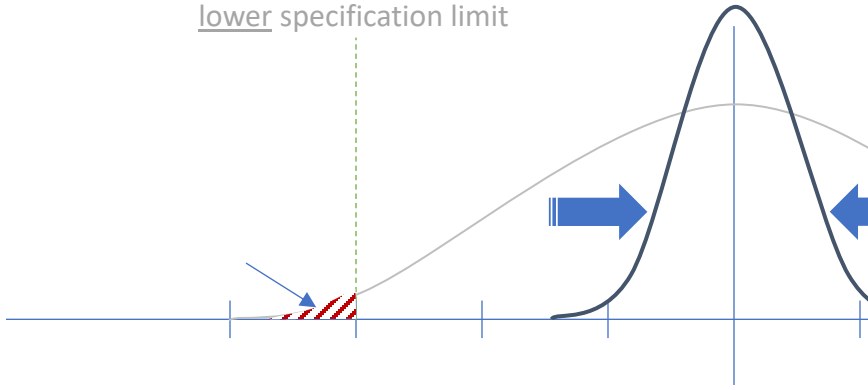
Global Dose Form Attributes

DFID

Dose form Attributes

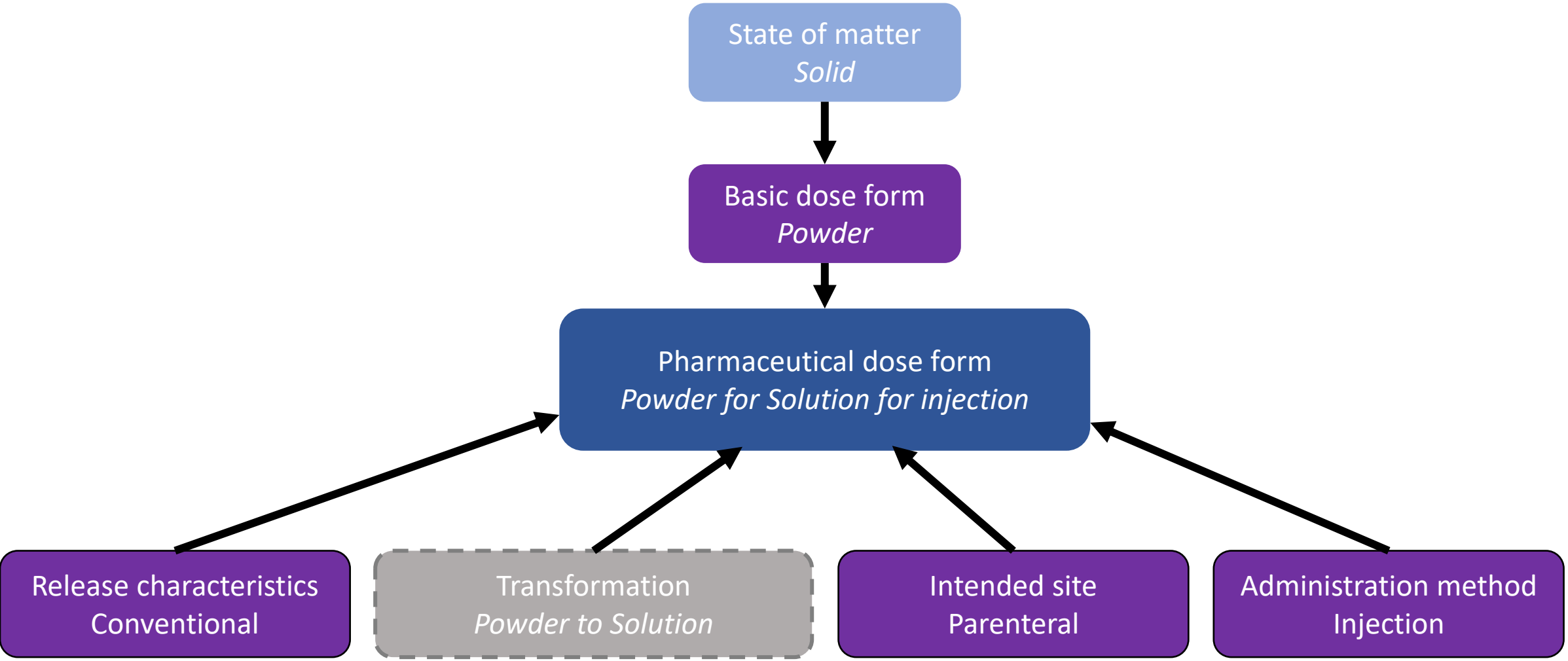
- No centralized/common terminology for Dose Form
  - Different granularity
    - Capsule vs Soft or Hard Capsule
    - Tablet, Coated Tablet, Film coated Tablet
  - Regulators approve different terms
    - Pellet vs granule

- Mitigation
  - Dose Form attributes
  - Business Rules

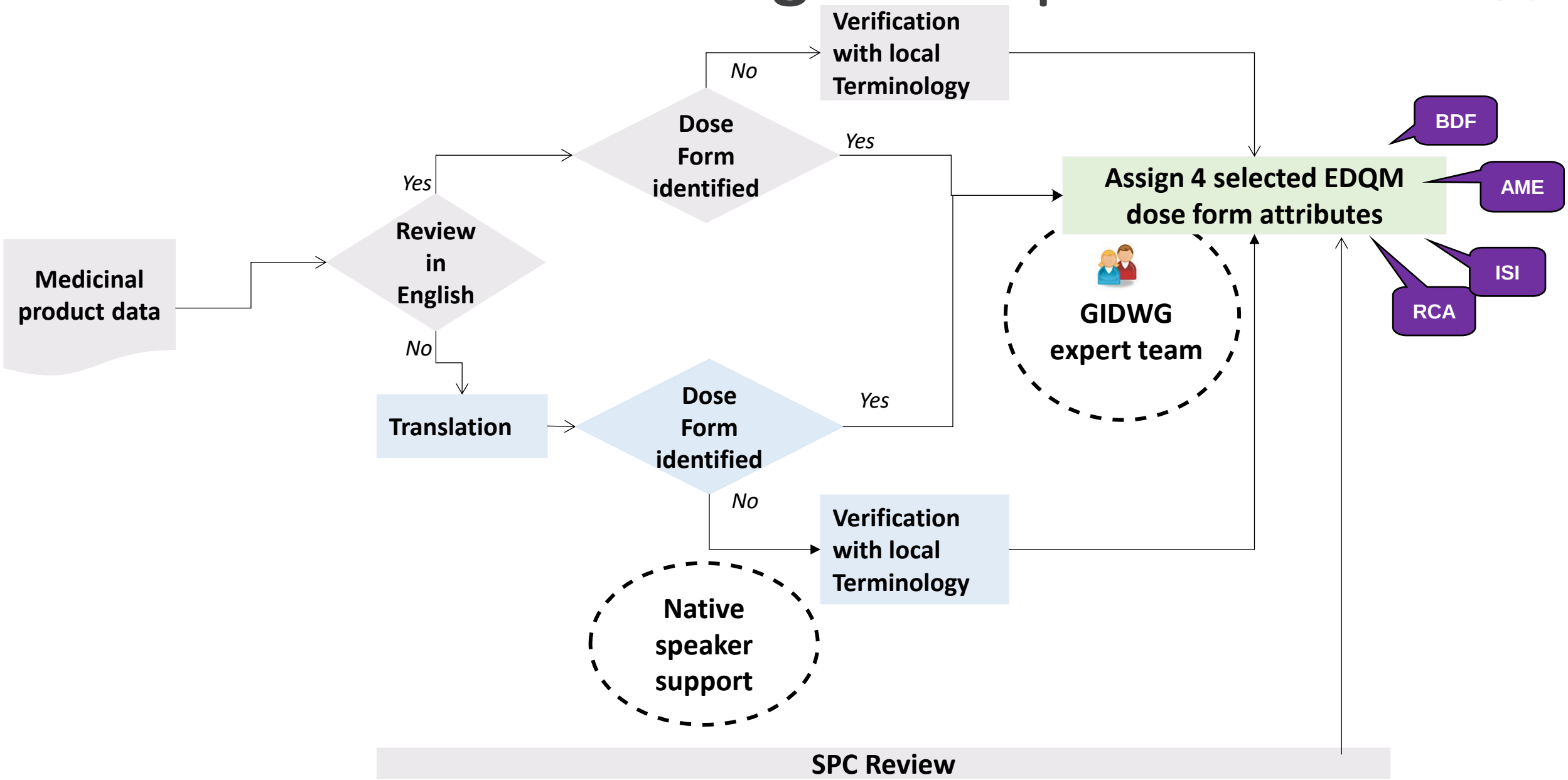


Assigning Dose form attributes

ISO 11239:2023



Dose form attributes assignment process



Dose form attributes selection Release characteristics (RCA)

Finding

The dose form are differently labeled, for example “delayed release tablet” in one country and a “modified-release tablet” in another.

Information about how the active substance is released is not always available in SPCs.

Terms such as ´controlled release´ and ´modified release´ indicate some special form of release, but not exactly which RCA.

Dose form attributes selection Release characteristics (RCA)

Global IDMP Working Group

Example of advanced formulations of Mesalazine

Formulations	Proprietary names	Mode of delivery	Site of drug release	Corresponding RCA for PhPID
pH dependent	Asacol®; Mesren®	Eudragit-S coating (dissolves at pH ≥ 7)	Terminal ileum, colon	**Delayed**
	Salofalk®; Mesasal®; Claversal®	Eudragit-L coating (dissolves at pH ≥ 6)	Mid ileum to colon	**Delayed**
	Salofalk Granules®	Eudragit-L coating and matrix core	Mid ileum to colon	Delayed + Prolonged → **Prolonged**
Time dependent	Pentasa®, Pentasa® granules	Microspheres encapsulated within an ethycellulose semi-permeable membrane	Duodenum to colon	**Prolonged**
MMX	Lialda®; Mezavant XL®; Mezavant®	Enteric coating (dissolves at pH ≥ 7). MMX of lipophilic and hydrophilic excipients	Terminal ileum and entire colon	Delayed + Prolonged → **Prolonged**

Table source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4635154/

Dose form attributes selection Release characteristics (RCA)

Finding

The dose form are differently labeled, for example “delayed release tablet” in one country and a “modified-release tablet” in another.

Information about how the active substance is released is not always available in SPCs.

Terms such as ´controlled release´ and ´modified release´ indicate some special form of release, but not exactly which RCA.

Recommendation

Only one RCA is used for one PhPID.

Formulations combining different release characteristics will be assigned one RCA.

Global IDMP Working Group

Global Strength Definitions

SDID

Global Strength Definitions

Global IDMP Working Group

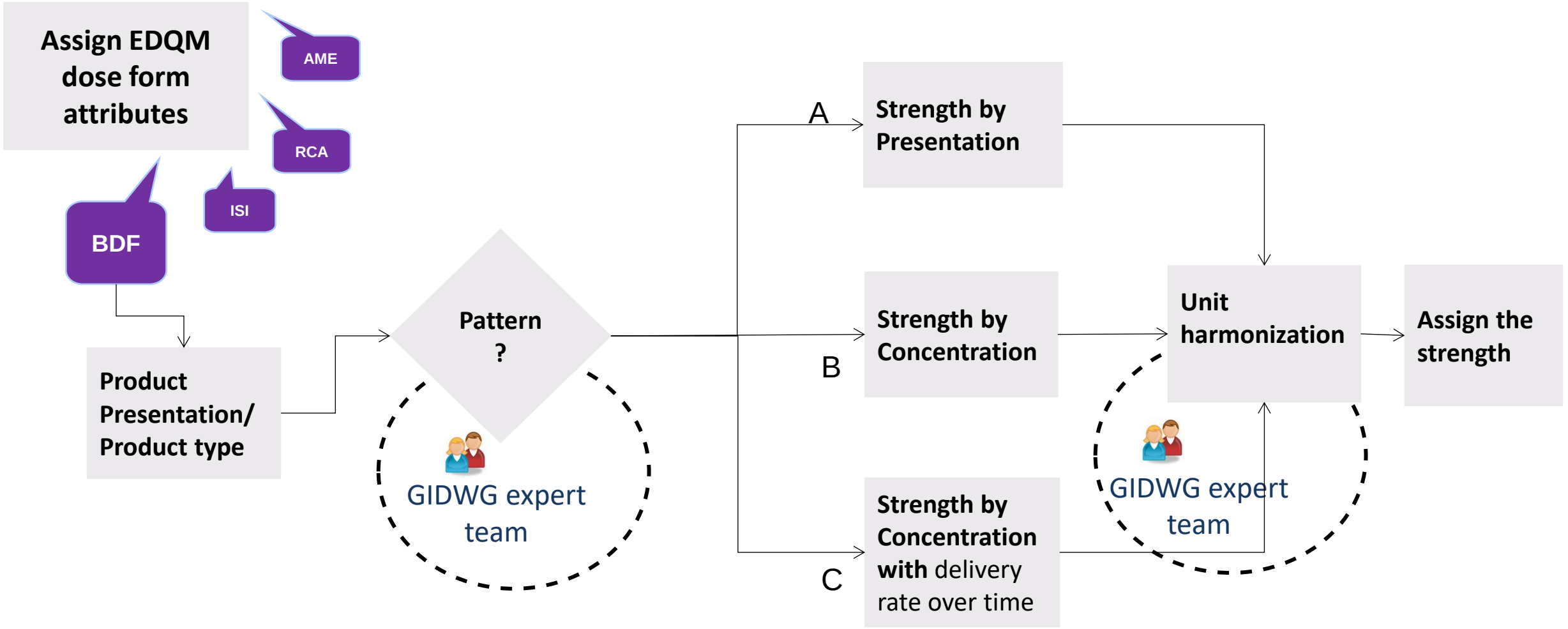
No common approach to strength and unit

- Different unit expression
  - IU, %, mg/mL, or mg/g
- Different precision of strength
  - 18 mg vs 18.06 mg
- Concentration strength vs presentation strength for liquids
  - 500 mg or 500 mg/ml

Mitigation

- Business Rules
- Patterns
- Conversion tables
- UCUM units

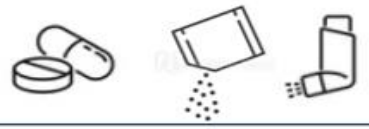
Global Strength Definitions



Strength Pattern framework

Finding

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	

Recommendation

A: The presentation strength ‘Pattern A’, is the strength of a substance described as a quantitative term describing the discrete unit in which a Pharmaceutical Product is presented, such as weight per tablet.

B: The concentration strength ‘Pattern B’, is the strength of a substance expressed as the amount of substance per unit of measurement, such as milliliter or gram.

C: The concentration strength ‘Pattern C´, is when the strength of a substance is expressed as a delivery rate over time.

Global Strength Definitions

Global IDMP Working Group

Some examples of Unit Conversions During End-to-End Testing				
Substance	**From unit**	**To PhPID unit**	**Conversion factor (Source)**	**Reason for decision**
Alteplase	IU	mg	10 mg = 5.8 MIU (SPCs)	mg more common (5 region verification)
Lenograstim	IU	mcg	150 mcg = 19.2 MIU (Martindale)	IU and mg equally common (5 region verification). The SPCs expressing strength in MIU also mention mcg, therefore mcg is used for PhPID.
Somatropin	IU/units	mg	3 units = 1 mg (Martindale)	mg more common (5 region verification)

Strength Unit Conversion

Finding

The absence of a globally approved unit conversion framework presents challenges in handling unit conversions (e.g., mg to IU).

Recommendation

To minimize the number of unit conversions, a five-region verification has been performed to identify the most common unit which is used for PhPID generation.

Key message Global Identifiers

The assignment of Global Identifiers and selection for PhPID are based on the ISO IDMP suite of standards and GIDWG business rules.

Separate catalogues for substance, dose form and units was created and maintained.

Global IDMP Working Group

Thank you!

Global IDMP Working Group

Report: HL7 FHIR

Panagiotis Telonis (EMA)

GIDWG – Global use cases E2E testing & HL7/FHIR

4th Global Identification Working Group (GIDWG) Public Stakeholders Meeting,
Sheraton Sao Paulo WTC Hotel, Sao Paulo, Brazil, 12 September 2024

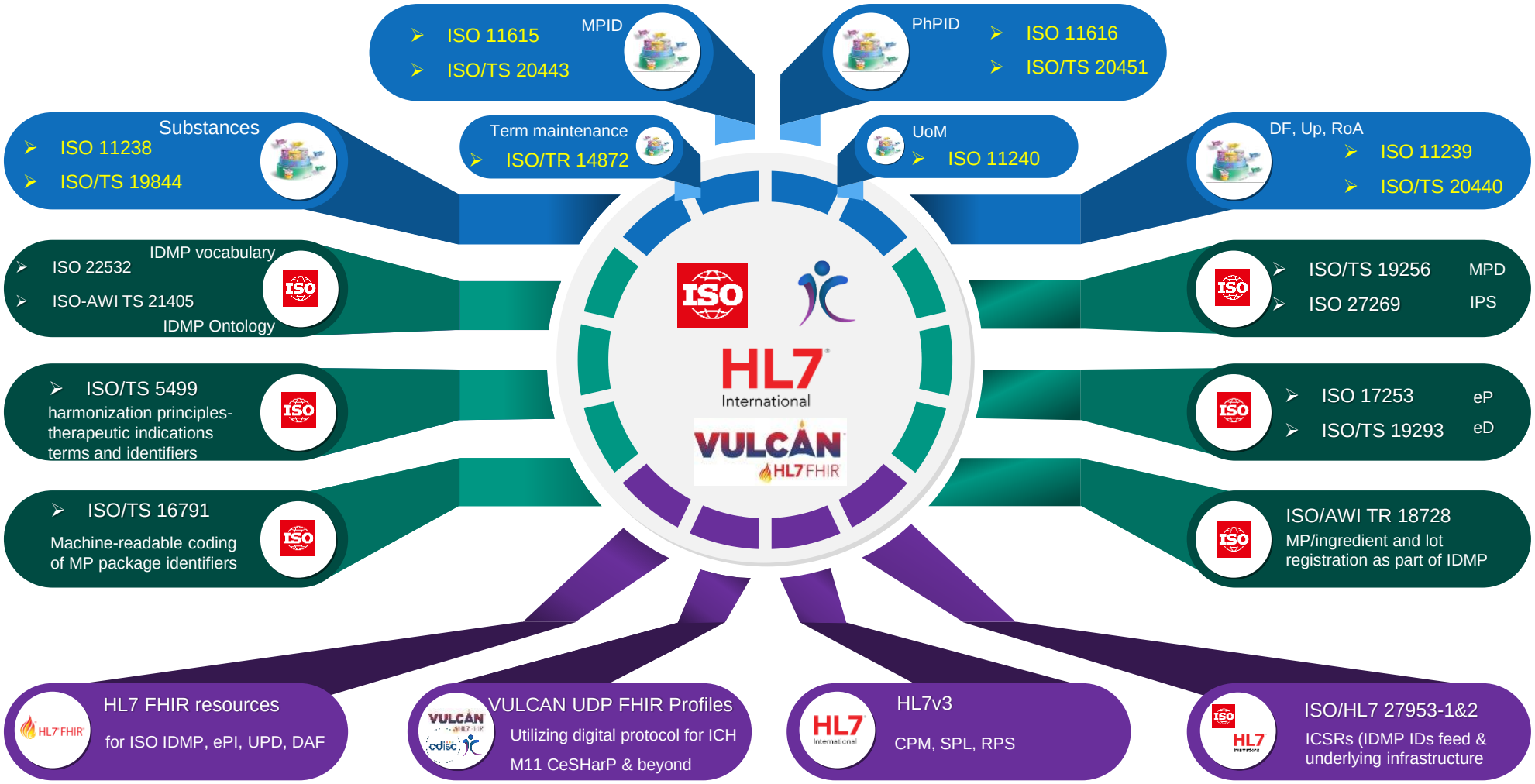
Panagiotis Telonis (EMA)
João Almeida (HL7 Europe)
Magnus Wallberg (UMC)
Åsa Pärnaste (UMC)

The IDMP use case and beyond

ISO IDMP Standards & their Technical Specifications

ISO Standards, Technical Specifications and Reports consuming or complement IDMP

HL7 messaging standards



Source: P. Telonis, I. Chicharo, International data standardisation activities, I-Division all staff meeting, European Medicines Agency, 13 March 2024

GIDWG journey up to now…

ISO IDMP

WHO workshop

GIDWG

GIDWG 5 pilot projects

(DF, Strength ID, Substance ID, Operation Model, FHIR)

Use cases

- Global PhV
- Shortages
- Cross-boarder healthcare
- FHIR

End to End Testing

GIDWG* - PhPIDs for supporting Global use cases

EUROPEAN MEDICINES AGENCY

Global IDs - Approaching Global Target Operating Models

We plan to 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) and mapped globally by UMC.
- Medicinal products: according to regulatory frameworks, they will be managed regionally (*e.g.* FDA, EMA) and provided to UMC.
- PHPIDs – Will be managed by UMC.

* Global Identification Working Group founded by EMA, FDA, and UMC

Source: P. Telonis, I. Chicharo, International data standardisation activities, I-Division all staff meeting, European Medicines Agency, 13 March 2024

Early IDMP Message exchange representations (snippets)

Example case: ISO 11238:2018, ISO/TS 19844:2018, FDA SRS/GSRS

Built-in GSRS message

```
{
  "uuid": "1a370770-a810-4b49-9336-083d53a0cb46",
  "created": 1471036247000,
  "createdBy": "admin",
  "lastEdited": 1471036247000,
  "lastEditedBy": "admin",
  "deprecated": false,
  "definitionType": "PRIMARY",
  "definitionLevel": "COMPLETE",
  "substanceClass": "chemical",
  "status": "approved",
  "version": "1",
  "approvedBy": "FDA_SRS",
  "approved": 1470433349000,
  "names": [
    {
      "uuid": "52c967d2-a27b-4aee-acbf-a3ed037ad46e",
      "created": 1471036247000,
      "createdBy": "admin",
      "lastEdited": 1471036247000,
      "lastEditedBy": "admin",
      "deprecated": false,
      "name": "AP-24534 HCL",
```

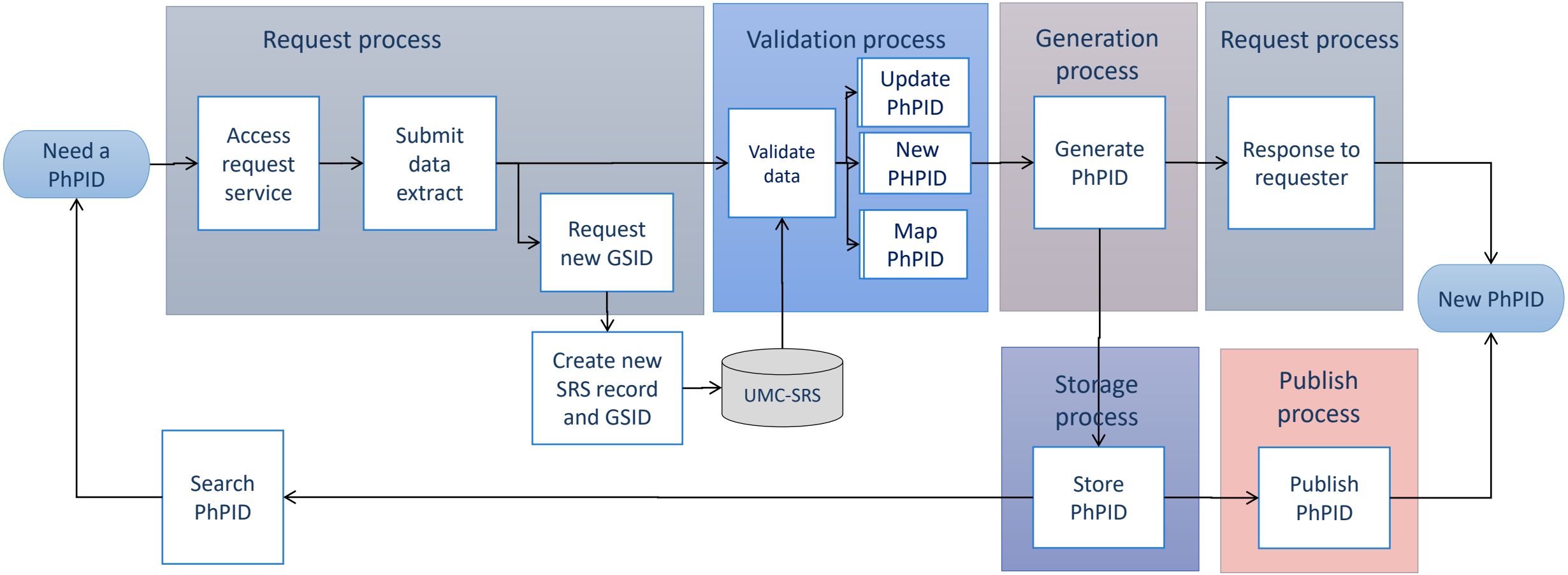
HL7 v3 SPL/CPM

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Chemical: AP-24534 HCL -->
<document xmlns="urn:hl7-org:v3"
        xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
        xsi:schemaLocation="urn:hl7-org:v3 ../../xml/schemas/spl-r8-draft/schemasR2b/SPL.xsd"
        classCode="DOC"
        moodCode="EVN">
  <id/>
  <code/>
  <effectiveTime/>
  <component typeCode="COMP">
    <structuredBody classCode="DOCBODY" moodCode="EVN">
      <component typeCode="COMP">
        <section classCode="DOCSECT" moodCode="EVN">
          <id root="exampleId" extension="exampleSectionId"/>
          <subject typeCode="SBJ">
            <identifiedSubstance>
              <id root="substanceOID" extension="96R6PU3D8J"/>
              <code code="chemical" codeSystem="substanceTypeOID"/>
              <identifiedSubstance>
                <code code="chemical" codeSystem="substanceTypeOID"/>
                <asNamedEntity>
                  <name xml:lang="en">AP-24534 HCL</name>
                </asNamedEntity>
```

FHIR

```
<?xml version="1.0" encoding="UTF-8"?>
<SubstanceSpecification xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="http://hl7.org/fhir ../../generated/diagramHTML/FHIR/schema/fhir-all.xsd"
xmlns="http://hl7.org/fhir">
    <substanceId>
        <system value="substanceOID"/>
        <value value="96R6PU3D8J"/>
    </substanceId>
    <substanceType>
        <coding>
            <system value="http://substanceTypeOID"/>
            <code value="chemical"/>
        </coding>
    </substanceType>
    <structure>
        <stereochemistry>
            <coding>
                <system value="http://stereochemistryOID"/>
                <code value="Achiral"/>
            </coding>
        </stereochemistry>
        <opticalActivity>
            <coding>
                <system value="http://opticalactivityOID"/>
                <code value="N/A"/>
            </coding>
```

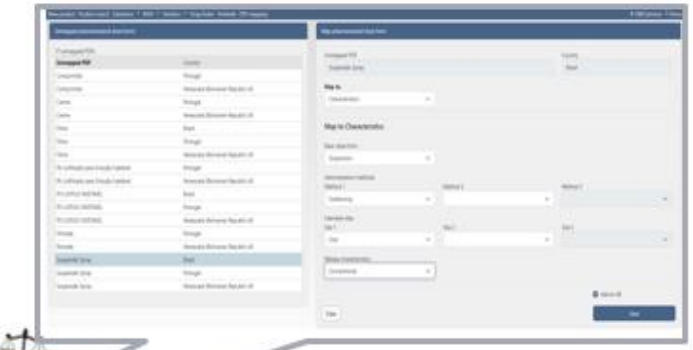
PhPID Operating Model including GSID request



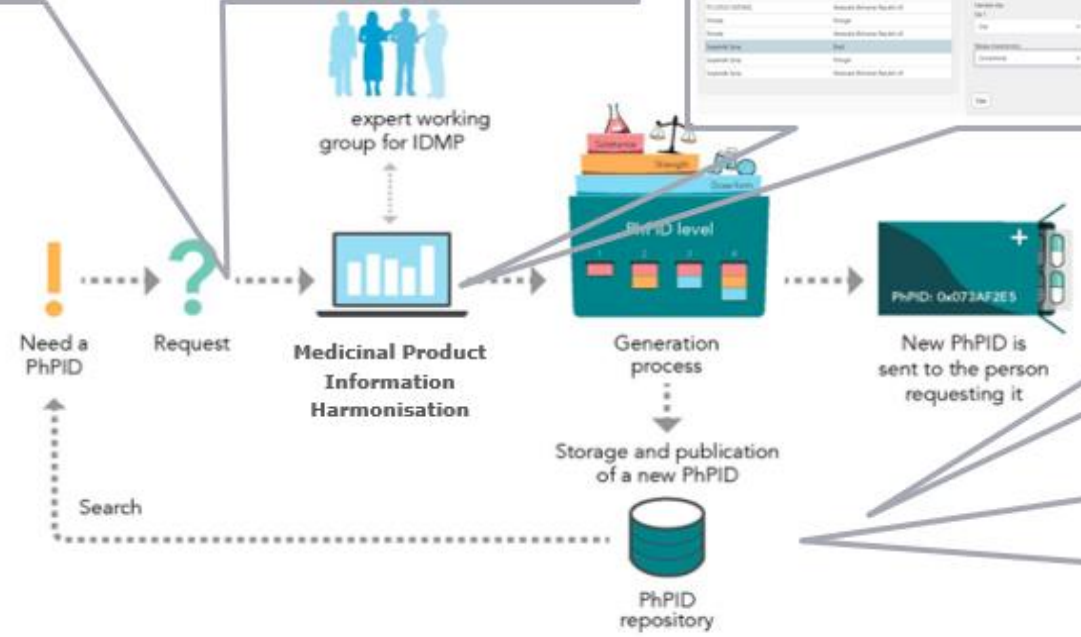
Services supporting the operating model

Global PhPID Requesting

Medicinal Product Information Harmonisation for Global PhPID construction

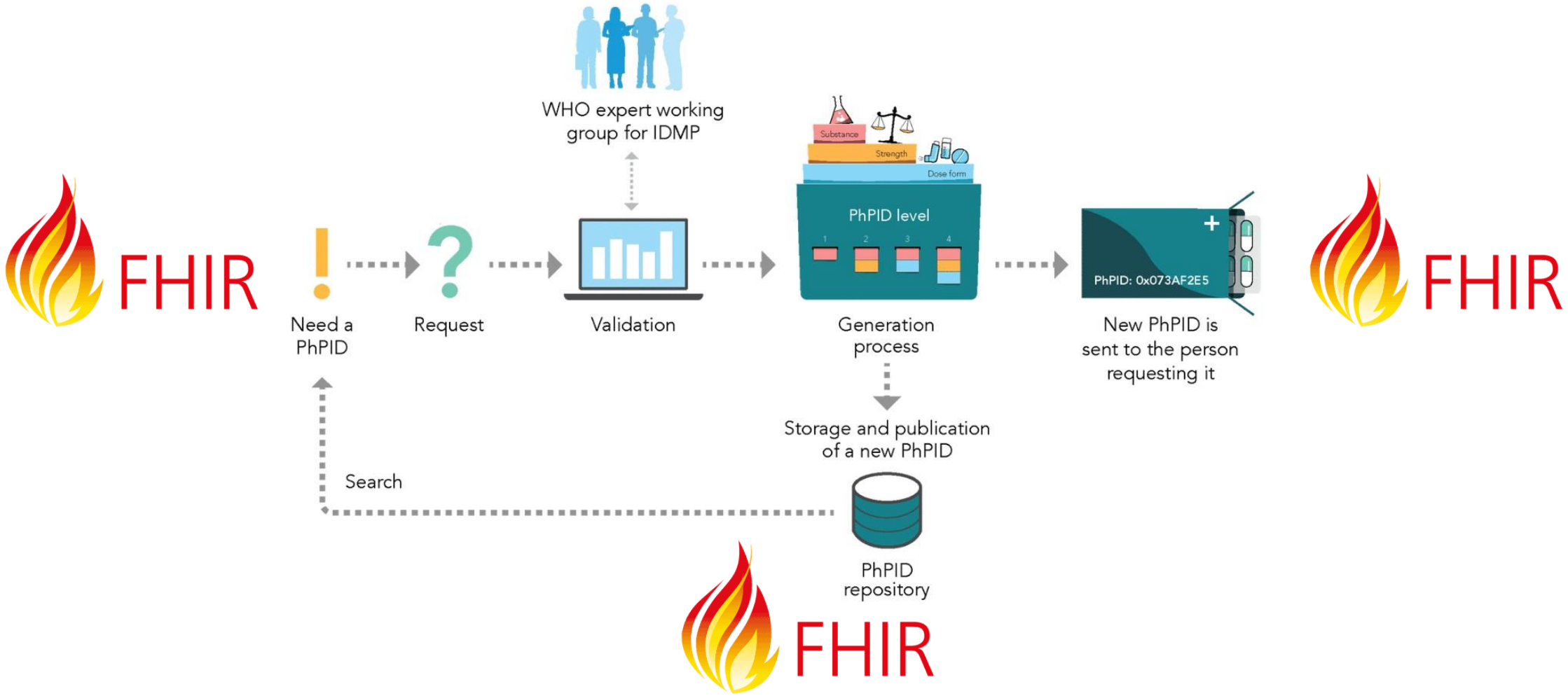


Global PhPID Publishing



Global PhPID publishing in WHODrug

PhPID operating model on FHIR



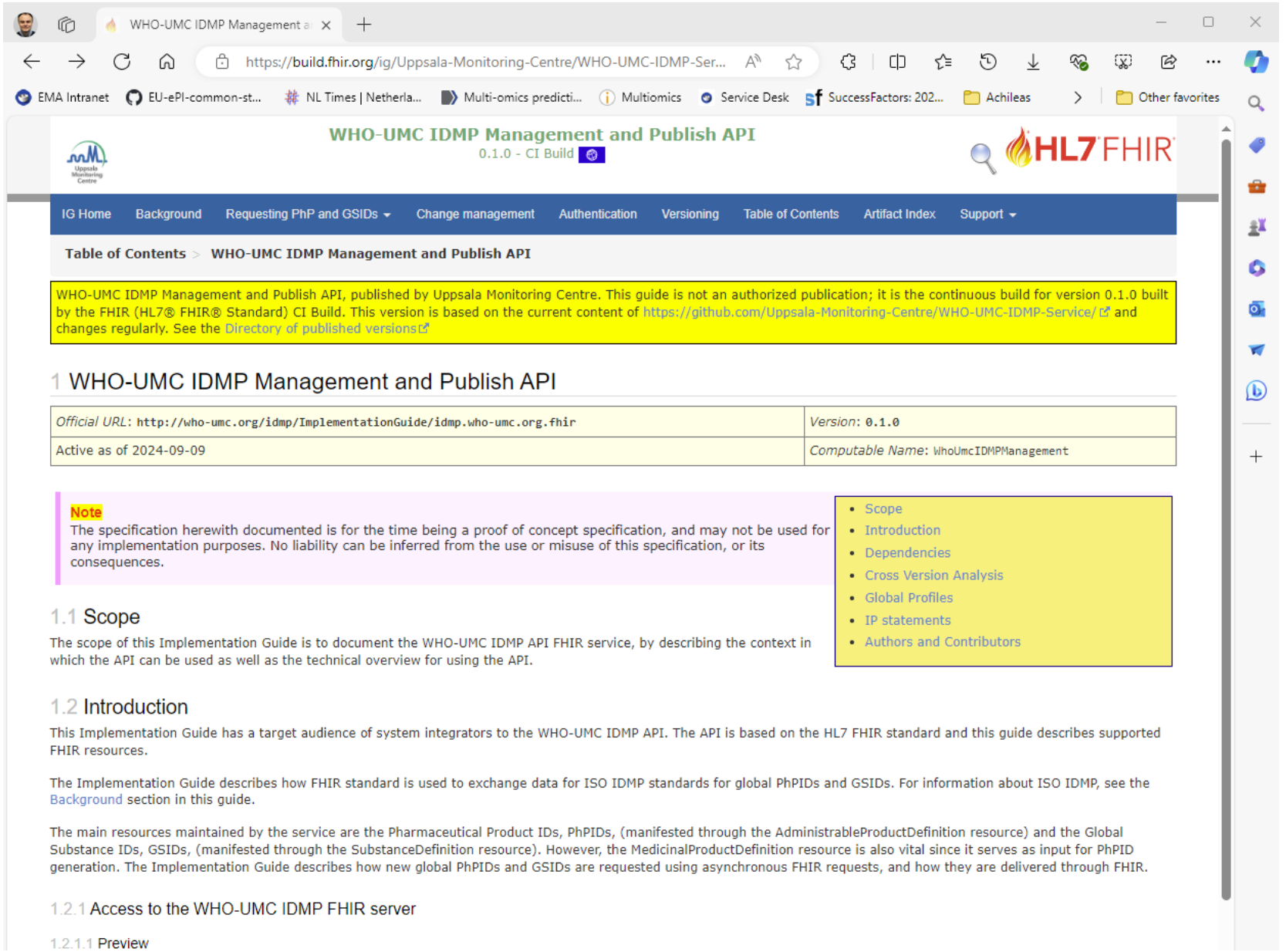
WHO-UMC IDMP Management and Publish API

Global IDMP Working Group

- This implementation Guide (IG) documents the developed IDMP API FHIR service, by describing the context in which the API can be used, as well as the technical overview for using the API (*work in progress*)

→ In simple language: This IG describes how FHIR standard is used to exchange data based on the ISO IDMP standards for global PhPIDs and GSIDs.

- Available at: https://build.fhir.org/ig/Uppsala-Monitoring-Centre/WHO-UMC-IDMP-Service/index.html



Resources used for various PhPID scenario's testing

Global IDMP Working Group

MedicinalProductDefinition

AdministrableProductDefinition

Ingredient

SubstanceDefinition

Organization

Task

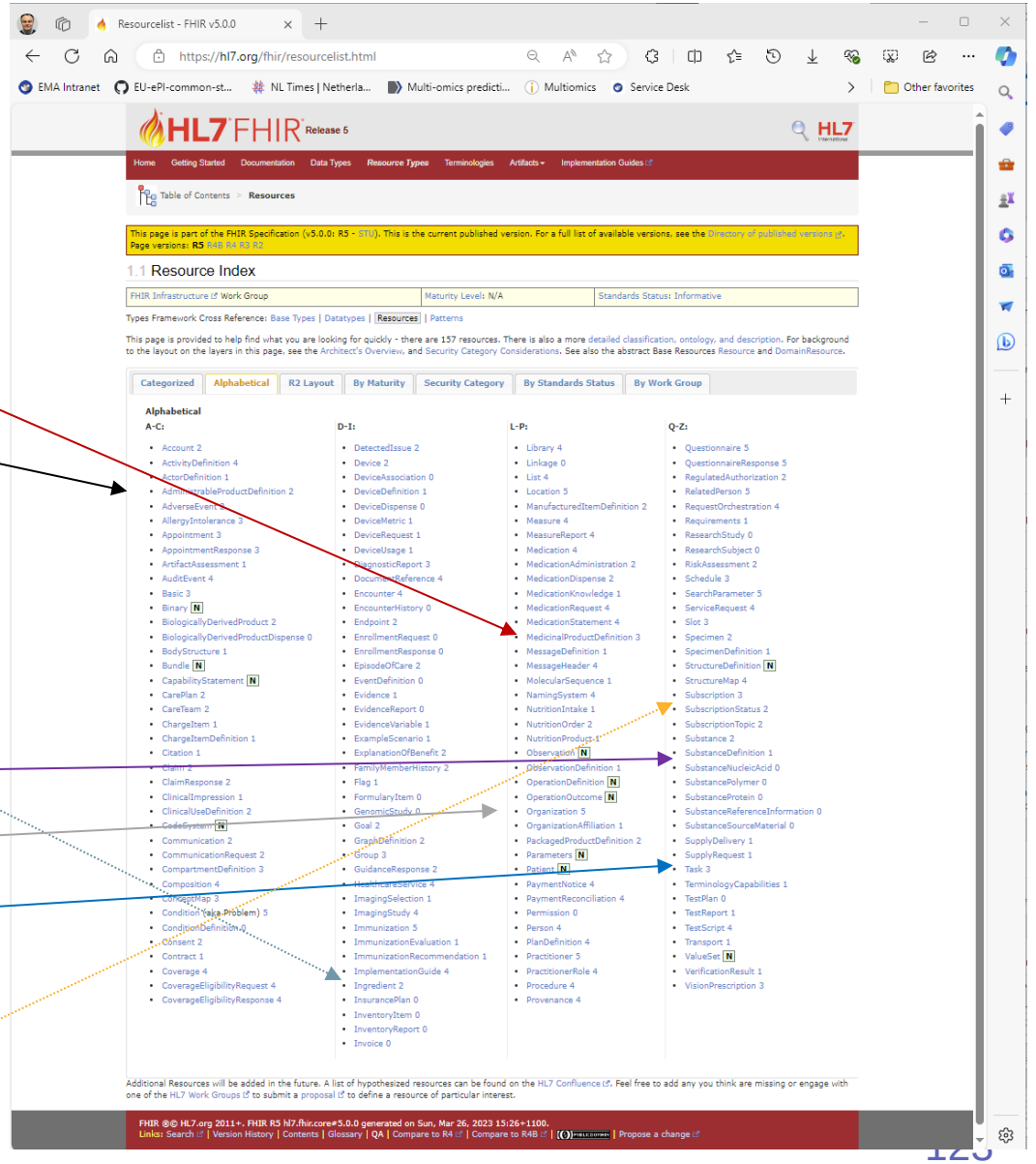
Subscription

Products from organisational, national, or jurisdictional datasets or/and WHODrug products

(PhPIDs)

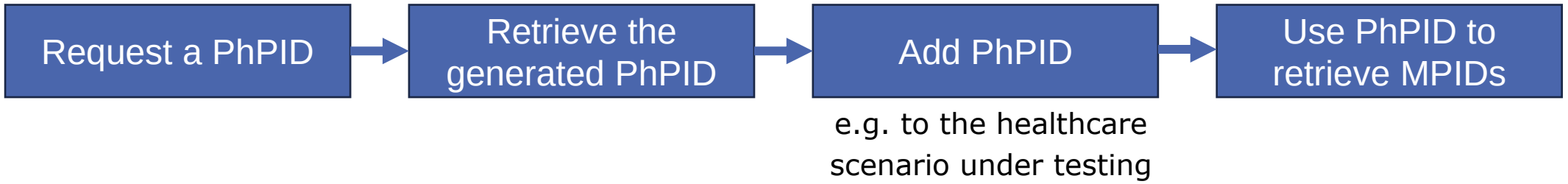
FHIR

(GSIDs)



FHIR API and Use Cases (1/5)

Example: Request PhPIDs and Cross border prescriptions

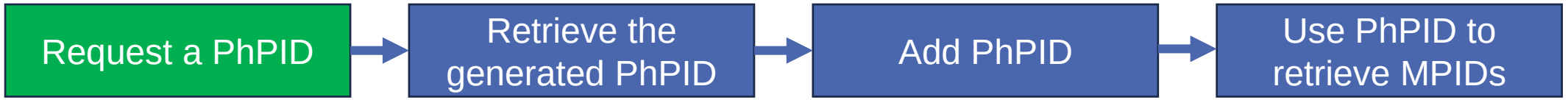


FHIR API and Use Cases (2/5)

Global IDMP Working Group

Example: Request PhPIDs and Cross border prescriptions

e.g. to the healthcare scenario under testing




```
Content
-----------------------------------------------
{
  "resourceType": "Task",
  "id": "template-generated-by-server-phpid-req",
  "meta": {
    "profile": [
      "http://who-umc.org/idmp/StructureDefinition/Task-who-php-phpid"
    ]
  },
  "contained": [
    {
      "resourceType": "MedicinalProductDefinition",
      "id": "702011b3-e5f3-4d21-beb3-29e1cbc8fbc4",
      "meta": {
        "profile": [
          "http://who-umc.org/idm...
-----------------------------------------------
```

FHIR API and Use Cases (3/5)

Global IDMP Working Group

Example: Request PhPIDs and Cross border prescriptions

e.g. to the healthcare scenario under testing

Request a PhPID → Retrieve the generated PhPID → Add PhPID → Use PhPID to retrieve MPIDs

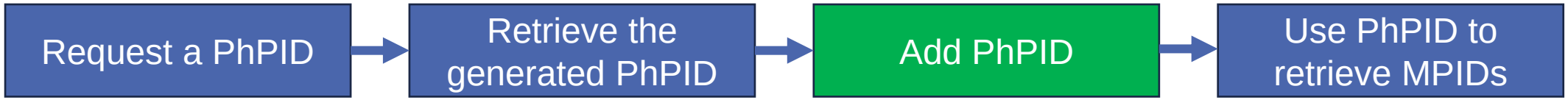
```
Output
-----------------------------------------------
PhPID: 10DD499443FAE493691301348AFDDDF3
Calling https://idmp.who-umc.org/fhir/AdministrableProductDefinition/10DD499443FAE493691301348AFDDDF3

Content
-----------------------------------------------
{
  "resourceType": "AdministrableProductDefinition",
  "id": "10DD499443FAE493691301348AFDDDF3",
  "meta": {
    "versionId": "1",
    "lastUpdated": "2018-01-30T07:47:49.7711852+00:00",
    "source": "http://idmp.who-umc.org/fhir",
    "profile": [
      "http://who-umc.org/idmp/StructureDefinition/AdministrableProductDefinition-who-php"
    ]
  },
  "text": {
    "status": "generated",
    "div...
-----------------------------------------------
```

FHIR API and Use Cases (4/5)

Global IDMP Working Group

Example: Request PhPIDs and Cross border prescriptions

e.g. to the healthcare scenario under testing



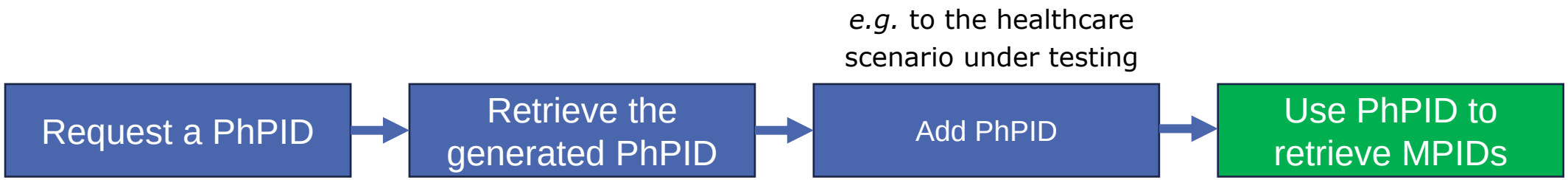

```
"classification": [
  {
    "coding": [
      {
        "system": "http://who-umc.org/idmp/level4-phpid",
        "code": "10DD499443FAE493691301348AFDDDF3"
      }
    ]
  }
],
```

Note that this is only an example of how to reference the PhPID in a test healthcare scenario (*e.g.* MPD resource, in this example within an ePI).

FHIR API and Use Cases (5/5)

Global IDMP Working Group

Example: Request PhPIDs and Cross border prescriptions



https://idmp.who-umc.org/fhir/
MedicinalProductDefinition
?product-classification=
http://who-umc.org/idmp/level4-phpid|10DD499443FAE493691301348AFDDDF3
&name-country=SE

FHIR Connectathon 34

Sheraton Phoenix Downtown, September, 2024

Track: 2023 - 09 Vulcan/Gravitate Health - ePI/IPS and SPL-FHIR, GIDWG

HL7 FHIR Connectathon 34

Global IDMP Working Group

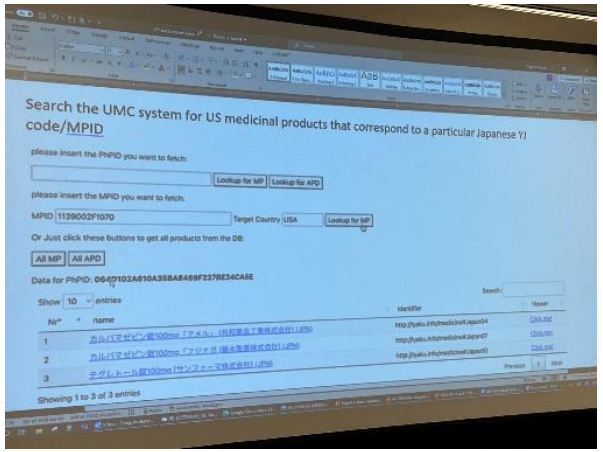
Connectathon (What)

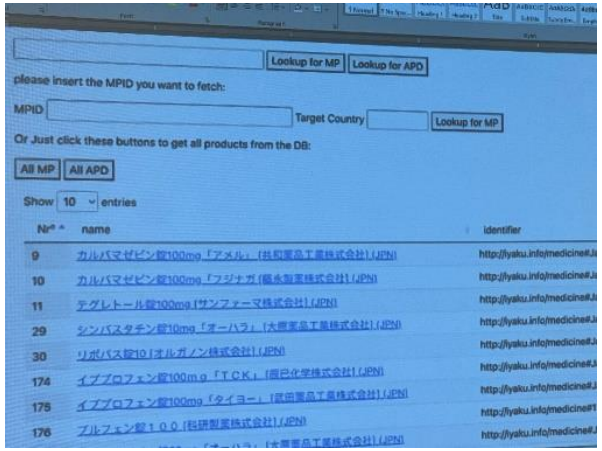
- HL7 FHIR Connectathons feature hands-on FHIR development and testing.
- Implementers and developers come together to hold technical discussions that advance the FHIR specification, develop FHIR-based solutions, and exchange data with other FHIR interfaces.
- Connectathons are a great opportunity to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

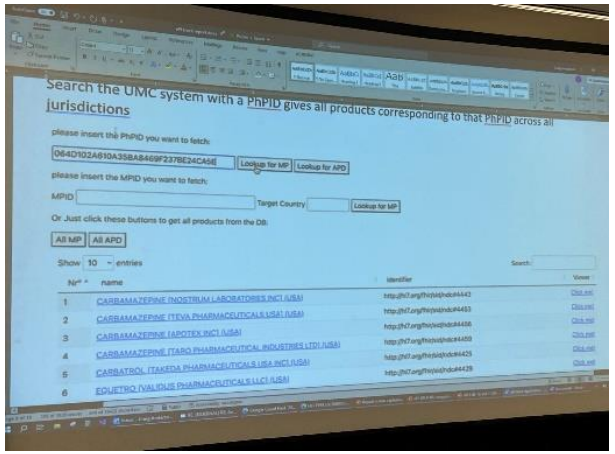
Track Objective

- 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.







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

FHIR Connectathon 35

Track: 2024 - 01 Vulcan/Gravitate Health - ePI/IPS, UNICOM, GIDWG

Athens, Greece, January 2024

Track Participants

Datapharm

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FELLESKATALOGEN

Glemser

Global IDMP Working Group

HL7 Europe

UNICOM

UiO : University of Oslo

Uppsala Monitoring Centre

Pfizer

FHIR C35 & Athens Hakathon, Jan 2024 (test scenarios)

Test Scenario		Brief Description
1	Cross-border travel	Japanese patient needs a Japanese ePI after being dispensed a medication in Europe. European patient needs a Norwegian ePI/patient information leaflet (or Swedish, Danish, English) after medication is dispensed in Japan
2	Pharmacovigilance	Local pharmacovigilance center receives report on a specific medication and needs to find other similar reports from other centers/databases.
3	Drug shortage	A shortage of a medicinal product is looming in Croatia. There is a need to find the products that could be used to address this shortage from neighboring countries to resolve the shortage.
4	Cross-border ePrescription substitution	Test FHIR interactions in cross-border dispensation, with prescribing and dispensing systems, with a substitution component (generic).
5	PhPID operating model	Test PhPID Operating model (search, generation, publishing) as part of an ePI workflows with central maintenance authority (UMC).
6	Pharmacy system and GTIN	Explore use of GTINs in ePIs in pharmacy system look up for cross-border medication, prescribing or dispensing.
7	ePI Validation and Nordic+1	Demonstrate validation of EMA ePIs Pilot against the specification and in alignment the Nordic Compedia +1 project.

- See testing scenarios available at: https://confluence.hl7.org/pages/viewpage.action?pageId=204276603

FHIR Connectathon 36

Dallas, TX, May 18-24, 2024

Track: 2024 - 05 Vulcan/Gravitate Health - ePI/IPS, UNICOM, GIDWG

FHIR C36 - Vulcan/Gravitate Health (content)

ePI Governance: Define joint profiles and governance model between EMA, Gravitate Health and Vulcan

ePI style sheet: Create and test a final draft of a default style sheet for ePIs

ePI Capability: Define basic API functionality requirements

Connectathon Roadmap: Define objectives for the next 4 connectathons (including IDMP testing)

PhPID IG: Test and clarify API capability, profiles and resources to support the GIDWG end-to-end request process

Global IDMP Working Group

FHIR Connectathon 37 (coming soon…)

Atlanta, GA, USA, September 21-27, 2024

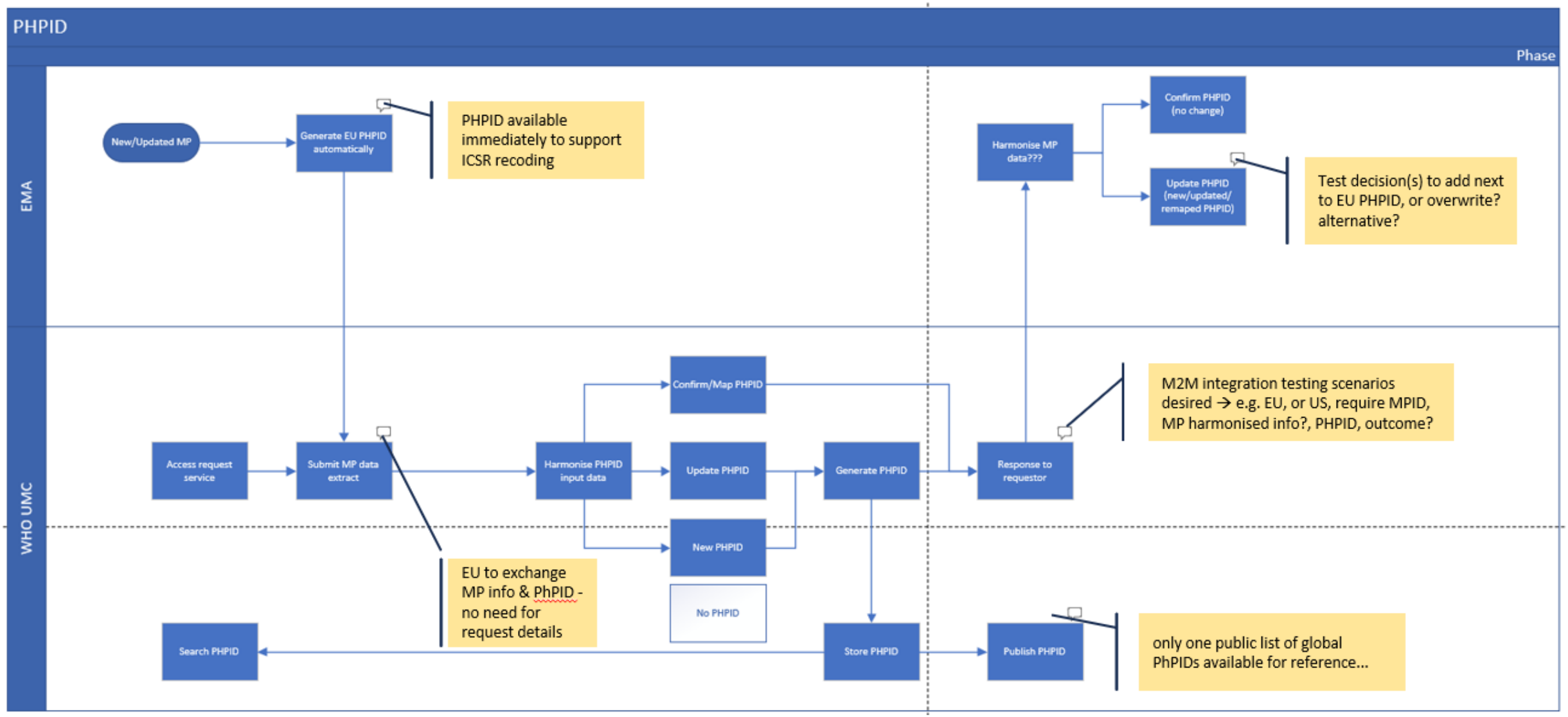
ePI variation lifecycle

- Technical validation rules
- API exchange capabilities
- Best practice for business versioning and FHIR server versions
- ePI terminology server

IG Comparison and harmonization to maintain alignment between the ePI-Core IG and its related national IGs (Nordic, UK, US, EU)

IDMP's PhPID workflow details

Example of preparing draft testing scenarios for FHIR Connecthathons



Tools: HL7 Europe Sandbox

open source

free for everyone to use

free to create your own instalments

making FHIR projects and specification more approachable

test real world scenarios

tool focused in sustainability

HL7 Europe Sandbox

HL7 Europe Sandbox

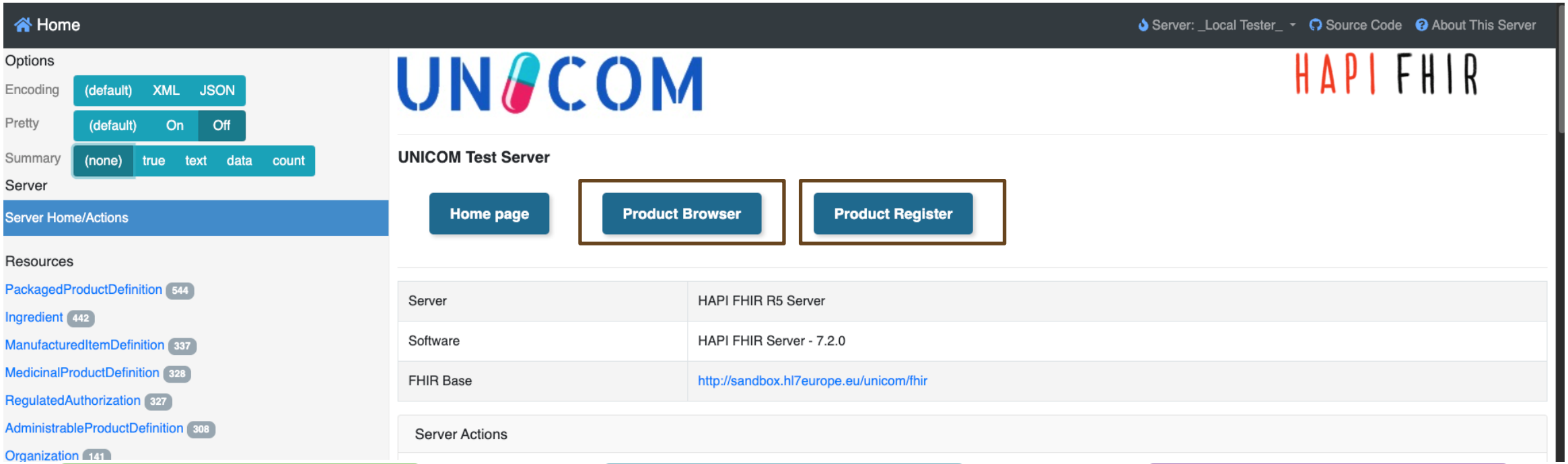
Link	Description
HL7 Europe Sandbox for Laboratory	A platform for laboratory-related HL7 activities and resources.
HL7 Europe Sandbox for UNICOM	A sandbox environment for UNICOM-related projects and tools.
HL7 Europe Sandbox FHIR Server	Access the HL7 FHIR server for testing and development purposes.
ePI Creator for Gravitate-Health	Create and manage ePI documents for the Gravitate-Health initiative.
HL7eu Gravitate-Health ePI Server	Server dedicated to the Gravitate-Health ePI services.
FLUTE Server	Access the FLUTE server for FHIR-related operations.
IG Uploader	Upload and manage Implementation Guides (IGs) using this API.
FHIR Questionnaire Viewer	View and interact with FHIR Questionnaires.
FHIR IG Dependency Checker	Check dependencies for FHIR Implementation Guides.
IDEA4RC FHIR Server	Play and test with IDEA4RC resources.
Infrastrucuture checker	Monitoring servers health.

https://sandbox.hl7europe.eu/

HL7 Europe Sandbox

https://github.com/hl7-eu/unicom-ig

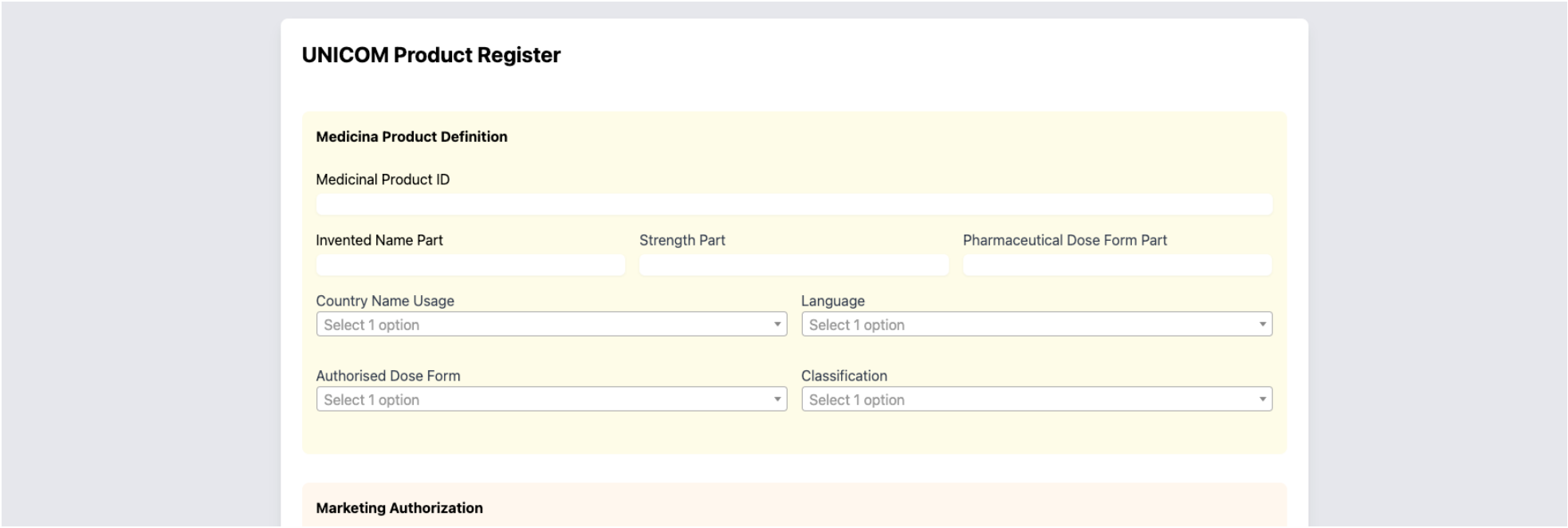
https://github.com/unicom-project-eu/UNICOM-test-lab



FHIR Server → IDMP-based product browser → Product Register

https://sandbox.hl7europe.eu/unicom

HL7 Europe Sandbox

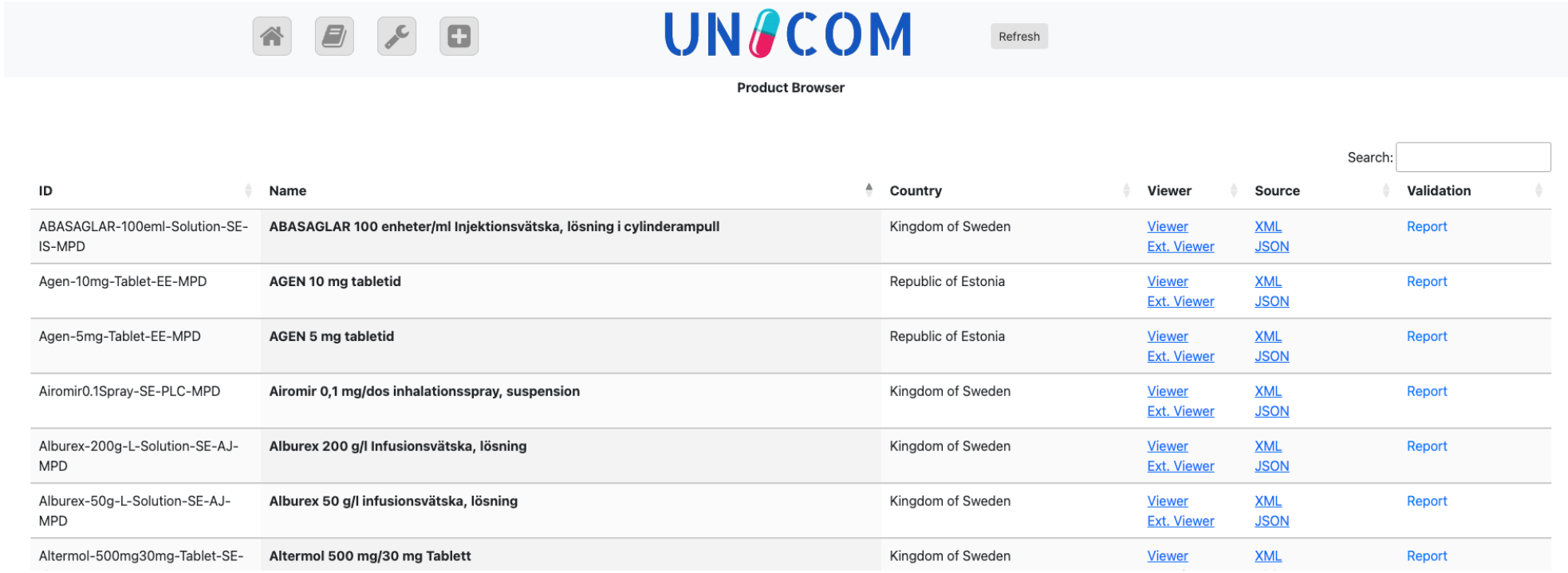


easy to use

compliance with unicom under the hood

automatic resource creation at the push of a button

HL7 Europe Sandbox



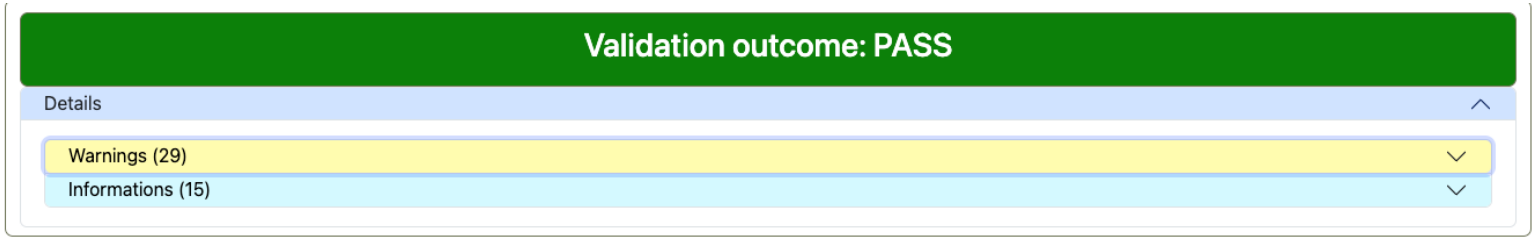
ID	Name	Country	Viewer	Source	Validation
ABASAGLAR-100eml-Solution-SE-IS-MPD	**ABASAGLAR 100 enheter/ml Injektionsvätska, lösning i cylinderampull**	Kingdom of Sweden	Viewer Ext. Viewer	XML JSON	Report
Agen-10mg-Tablet-EE-MPD	**AGEN 10 mg tabletid**	Republic of Estonia	Viewer Ext. Viewer	XML JSON	Report
Agen-5mg-Tablet-EE-MPD	**AGEN 5 mg tabletid**	Republic of Estonia	Viewer Ext. Viewer	XML JSON	Report
Airomir0.1Spray-SE-PLC-MPD	**Airomir 0,1 mg/dos inhalationsspray, suspension**	Kingdom of Sweden	Viewer Ext. Viewer	XML JSON	Report
Alburex-200g-L-Solution-SE-AJ-MPD	**Alburex 200 g/l Infusionsvätska, lösning**	Kingdom of Sweden	Viewer Ext. Viewer	XML JSON	Report
Alburex-50g-L-Solution-SE-AJ-MPD	**Alburex 50 g/l infusionsvätska, lösning**	Kingdom of Sweden	Viewer Ext. Viewer	XML JSON	Report
Altermol-500mg30mg-Tablet-SE-	**Altermol 500 mg/30 mg Tablett**	Kingdom of Sweden	Viewer	XML	Report

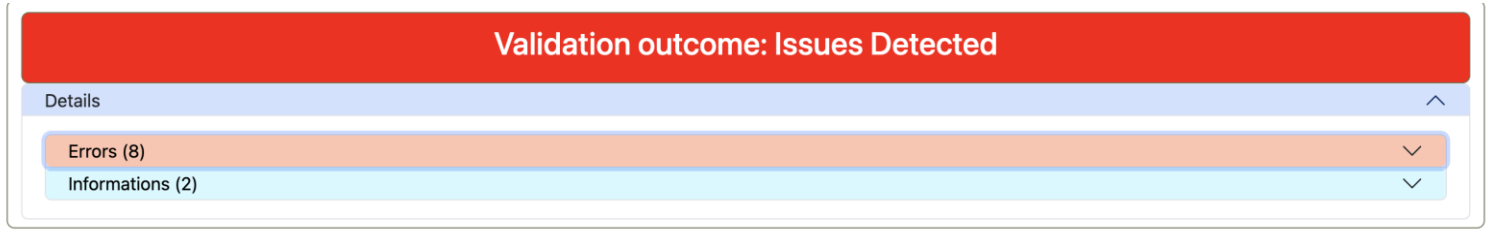
human-friendly browser

automatic testing for products in the server

search and ordering

HL7 Europe Sandbox





automatic testing for tens/hundreds of rules instantly

levels of errors

description of error or warnings in human-friendly

Next steps on FHIR testing and ISO/IDMP developments

Global IDMP Working Group

Q1 2025 - Berlin

10-11 May - Madrid

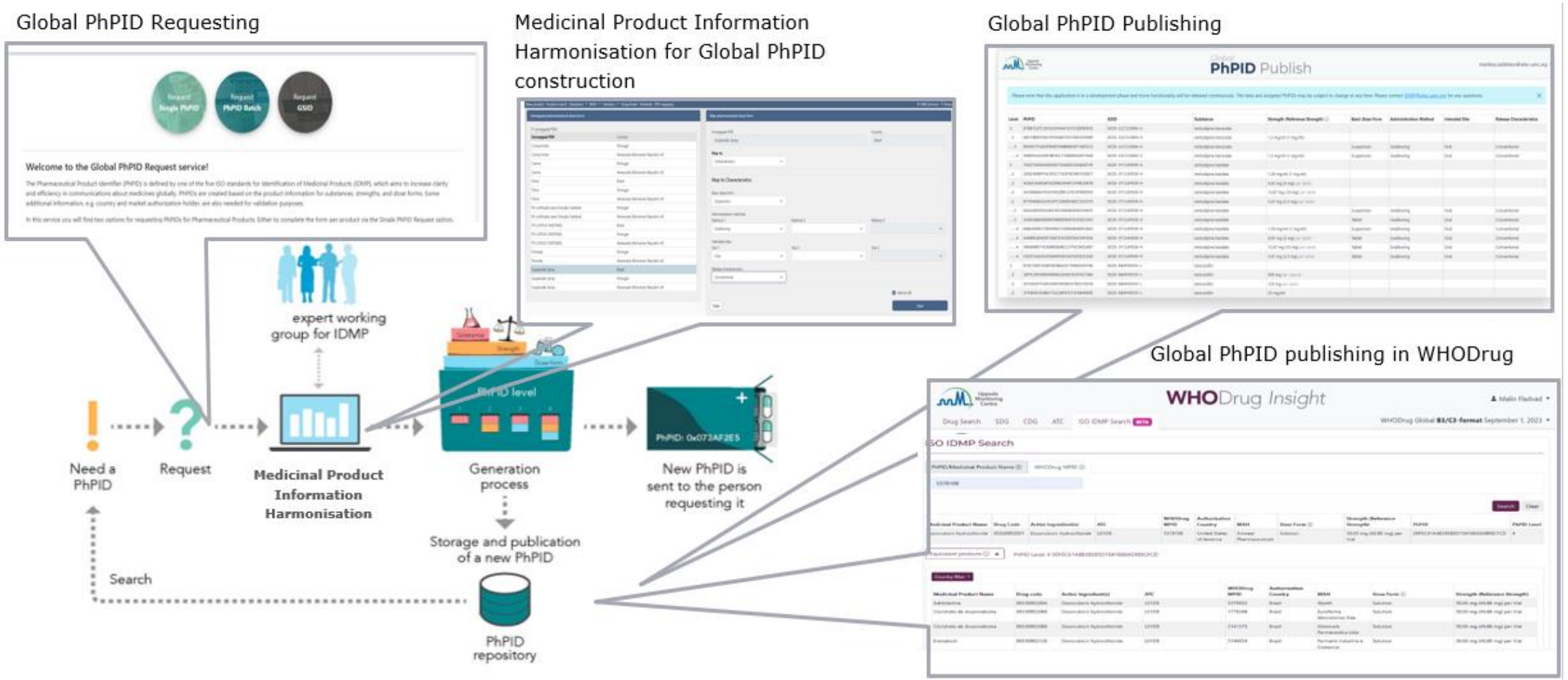
September

Join Us!

Report: Global Framework IDMP Implementation & Maintenance of global identifiers

Malin Fladvad (UMC)

Operating model for Global PhPID



Demo of the global PhPID operating model

Methotrexate orion

Name specifier

Country: Sweden

MAH: Orion

Orion pharma

Reference: Company reference

Version: 2024

Comments

Old form

Delete | Put on hold | Save draft

TABLETS

PhPID (4/4)

Ingredient (1)	a.	+
Methotrexate	2.5 mg	

Ingredient

Add | Clear ing

G02CX
L01BA
L04AX

Add

Spc
https://www.lakemedelsverket.se/sv/sok-lakemedelsfakta/lakemedel/20150711000012/lakemedel-%7C-lakemedelsverket

Approve

8 Similar approved products

Refresh

Filter by:

Trade name Methotrexate orion	NS	Ingredient Methotrexate	Country Sweden	MAH Orion pharma	Form TABLETS	Strength 2.5 mg	PhPID Strength	ATC	Changed
Methotrexate orion		Methotrexate sodium	Hungary	Orion	TABLETS	2.5 mg		L04AX	2019-12-17
Methotrexate orion		Methotrexate sodium	Hungary	Orion	TABLETS	10 mg		L04AX	2019-12-17
Methotrexate Orion	*old form*	Methotrexate	Sweden	Orion pharma	TABLETS	2.5 mg	2.50 mg	L01BA, L04AX	2023-12-13
Methotrexate Orion	*old form*	Methotrexate	Estonia	Orion	TABLETS	10 mg		L04AX	2023-12-13
Methotrexate orion pharma		Methotrexate sodium	Spain	Orion Corporation	TABLETS	2.5 mg		L01BA, L04AX	2023-04-17
Methotrexate orion pharma		Methotrexate sodium	Spain	Orion Corporation	TABLETS	10 mg		L01BA, L04AX	2023-04-17
Methotrexate orion pharma		Methotrexate sodium	Sweden	Orion pharma	TABLETS	2.5 mg	2.74 mg	L01BA, L04AX	2023-12-13
Methotrexate orion pharma		Methotrexate sodium	Sweden	Orion pharma	TABLETS	10 mg	10.97 mg	L01BA, L04AX	2023-12-13

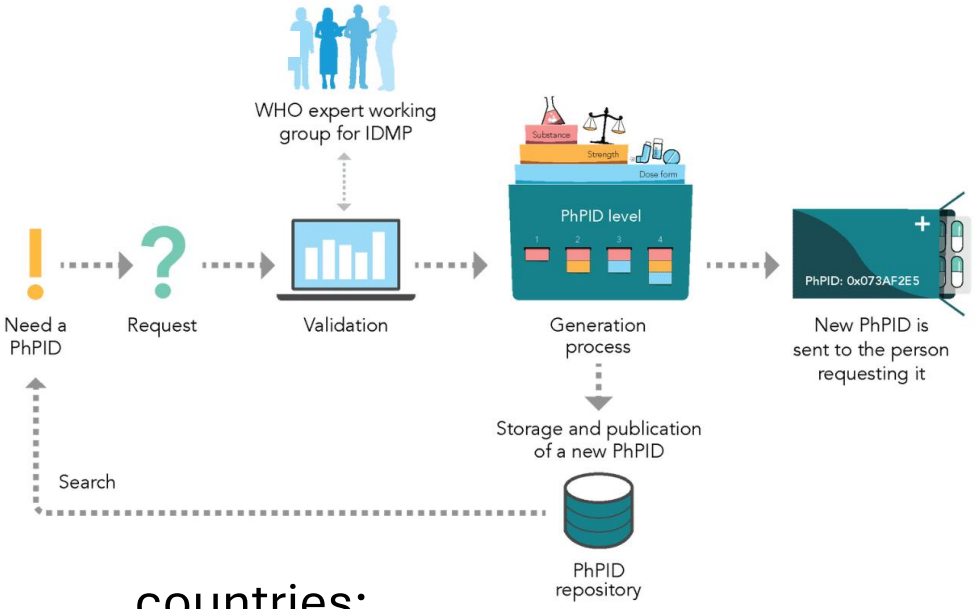
3 Similar approved characteristics

Refresh

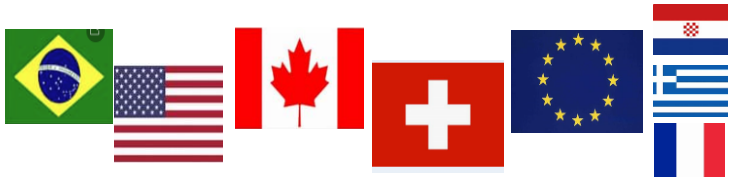
Filter by:

Pharmaceutical dose form Tablet	Basic dose form Tablet	Administration methods Swallowing	Intended sites Oral	Release characteristics Conventional	Products
	Tablet	Swallowing	Oral	Conventional	21
Tablet	Tablet	Swallowing	Oral	Conventional	4
	Capsule	Swallowing	Oral	Conventional	1

Global IDMP PhPID End-to-End Testing Report



countries:



To be published in Q4 2024

Business rules for PhPID generation

Business rules for PhPID construction

Global IDMP Working Group

Public Version 1.0

1 May 2024

The flow chart in Figure 10 illustrates strength pattern assignment for different parenteral preparations:

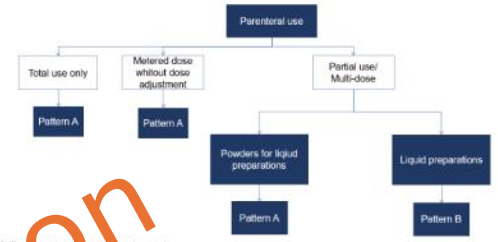


Figure 10. Illustrates strength pattern assignment

2. When the ManDF is different from the AdmDF, the BDF is manually changed from the ManBDF to the AdmBDF (examples in Table 10). For a product example of how dose forms can differ between regions as well change from ManBDF to AdmBDF, see Table 11.

Table 10. Examples of business rules for PDFs with different AdmDF and ManDF

Medicinal product name	ManDF	AdmDF	ManBDF	AdmBDF	Harmonised AdmBDF for PhPID
Hyaluronidase	Powder for solution for infusion	Solution for infusion	Powder	Solution	Solution
Deferasirox®	Dispersible tablet	Oral suspension	Tablet	Suspension	Suspension For tablets that are always dispersed before being taken, the BDF will be 'Suspension'
Lamictal® (Lamotrigine)	Chewable/ dispersible tablet	Chewable tablet Oral suspension	Tablet	Tablet Suspension	Tablet For tablets that can be swallowed and taken as a solution/suspension, the BDF will be 'Tablet'
Berocca®	Effervescent (soluble) tablet	Oral solution	Tablet	Solution	Solution

Table 11. Examples of business rules for PDFs with different AdmDF and ManDF, and same product expressed differently in different regions

Medicinal product name	Country	ManDF	AdmDF	ManBDF	AdmBDF	Harmonised AdmBDF for PhPID
Zithromax® (azithromycin)	UK	Powder for oral suspension	Oral suspension	Powder	Suspension	Suspension
	Korea	Dry syrup	Syrup	Powder	Syrup	
	USA	For oral suspension	Oral suspension	Powder	Suspension	

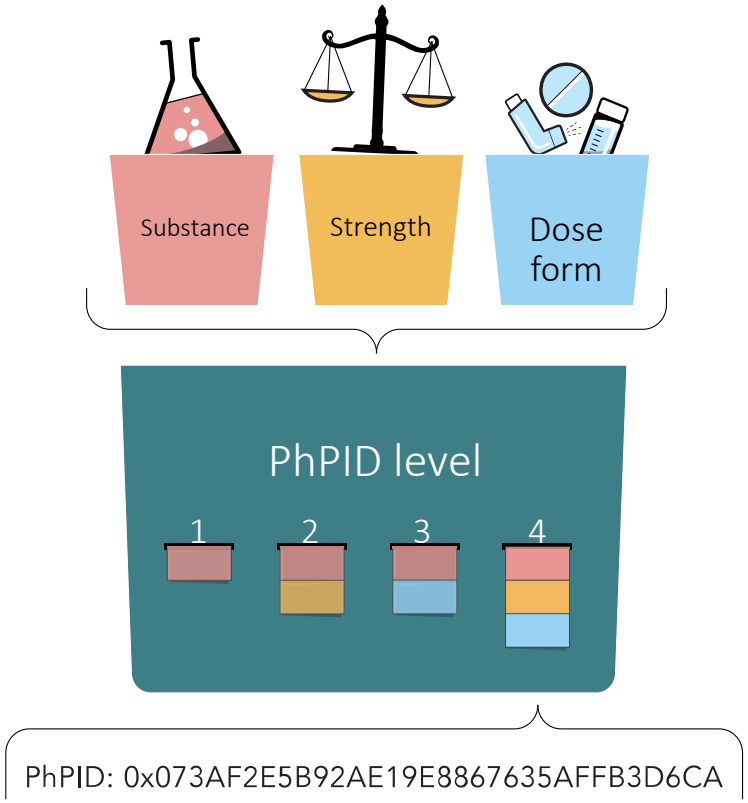
Public version

Published by Q3 on https://gidwg.org/

Example of business rule for global PhPID generation

The GSID for PhPID is generated based on the anhydrous form of the substance

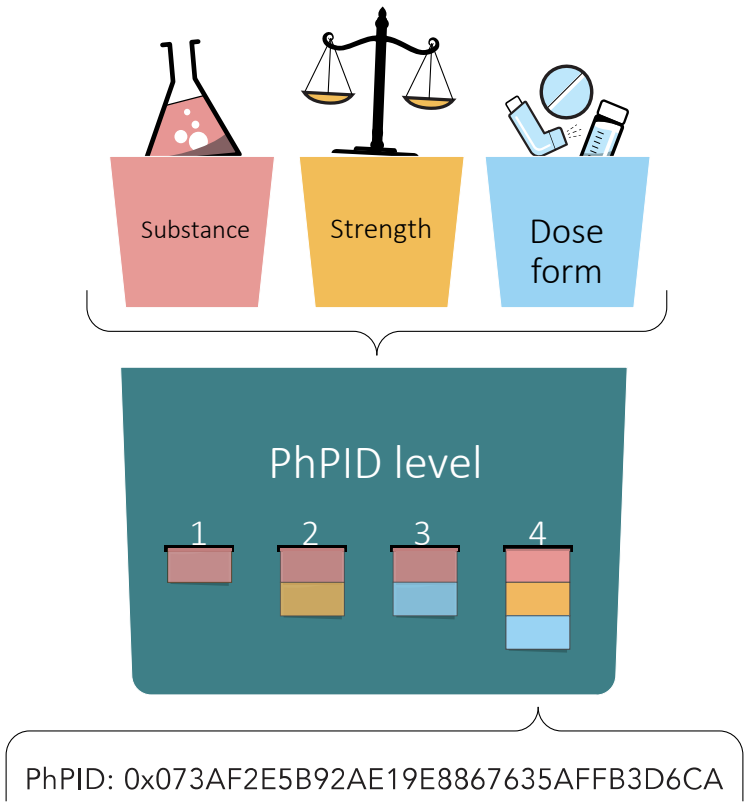
Lidocaine HCl monohydrate
→Lidocaine HCl



Examples Business rules for strength expression for global PhPID generation

The value number for PhPID denominator should generally be 1 except for patches and vaginal rings. Strength is hence recalculated for PhPID to match the business rule.

100 mg/5 ml is expressed as 20 mg/ml

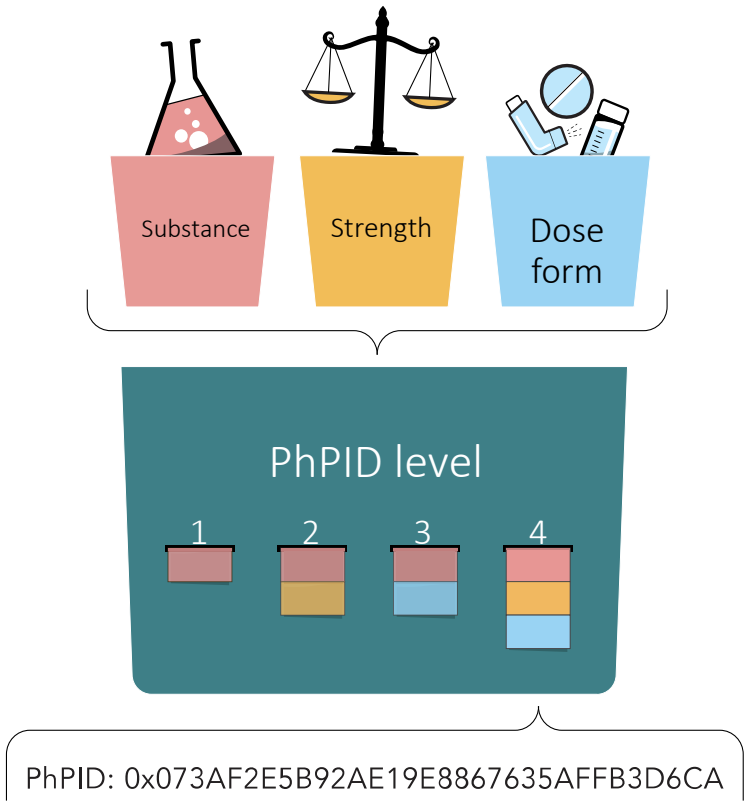


Examples Business rules for global PhPID generation

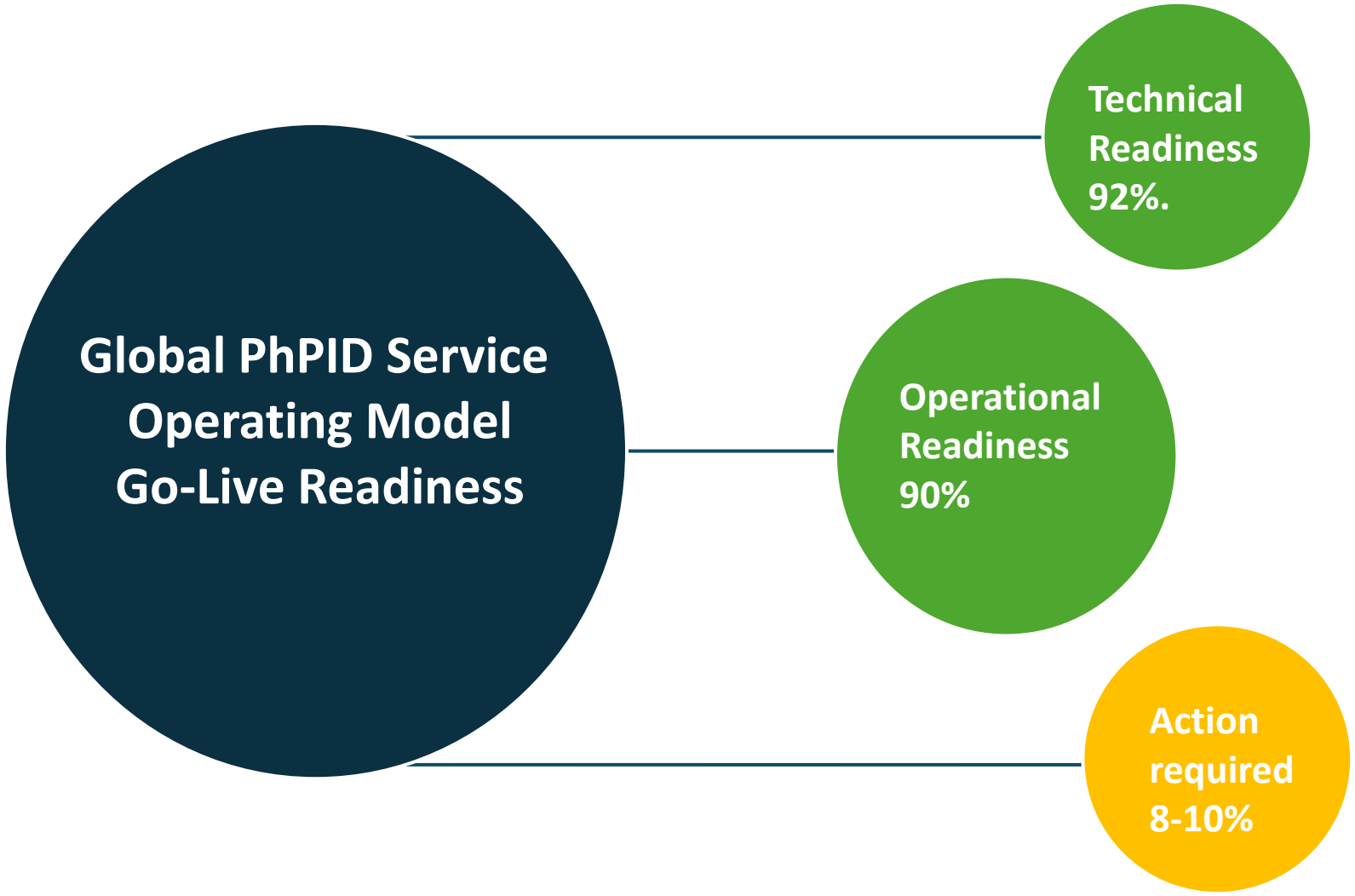
The intended site is generally assigned based on primary use. One or several intended sites can be assigned to a medicinal product.

Eye/ear drops

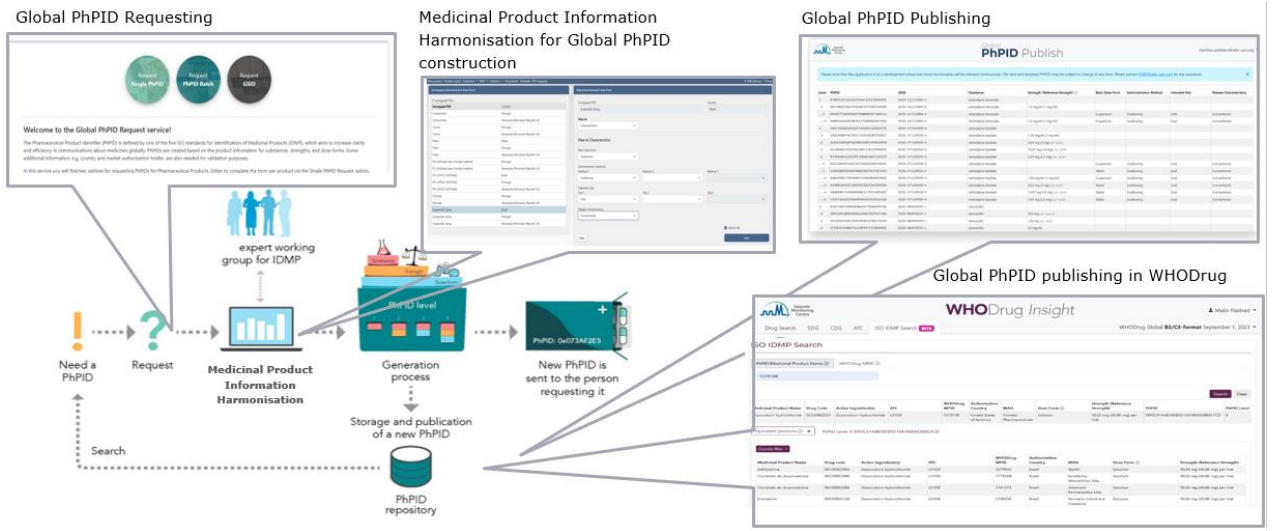
Cutaneous/ transdermal



Readiness after End-to-End Testing



Technical readiness



SYSTEM TESTING: ALL FUNCTIONAL, INTEGRATION, USER ACCEPTANCE, AND REGRESSION TESTING HAVE BEEN COMPLETED.

BACKUP AND RECOVERY: BACKUP AND DISASTER RECOVERY PROCESSES ARE IN PLACE.

INFRASTRUCTURE: HARDWARE, NETWORKING, AND OTHER INFRASTRUCTURE COMPONENTS ARE CORRECTLY CONFIGURED.

SECURITY AND MONITORING: SECURITY ASSESSMENTS, AND TESTING COMPLETED. MONITORING IN PLACE

CONFIGURATION MANAGEMENT: ALL SYSTEM CONFIGURATIONS ARE DOCUMENTED AND VERSION-CONTROLLED.

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

Operational Readiness

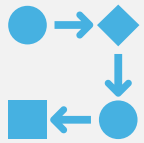
User Training and documentation

Help Desk/Customer Support

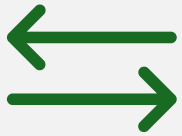
SLA Agreements

Communication Plan

Operational Readiness

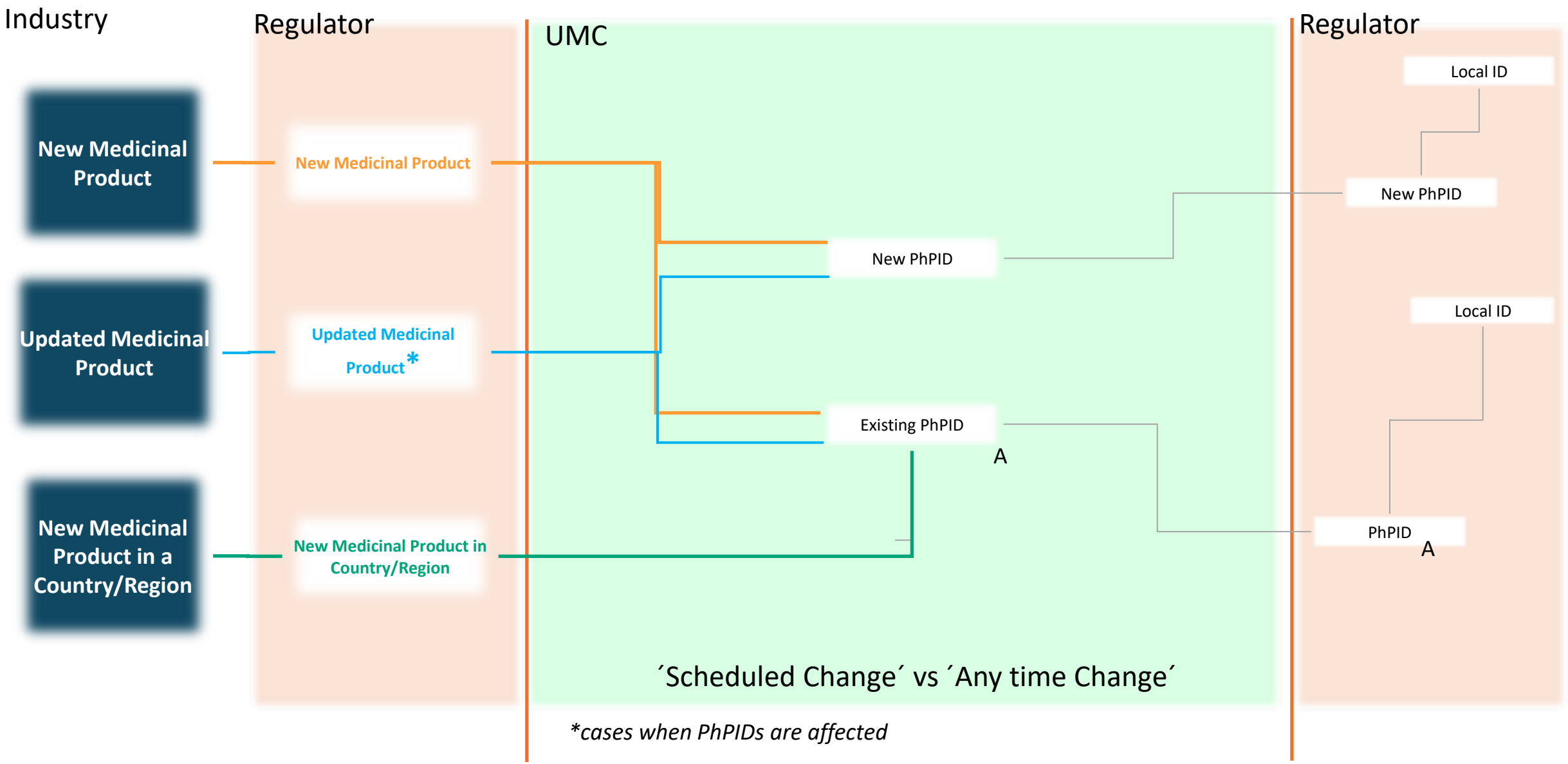


Process readiness



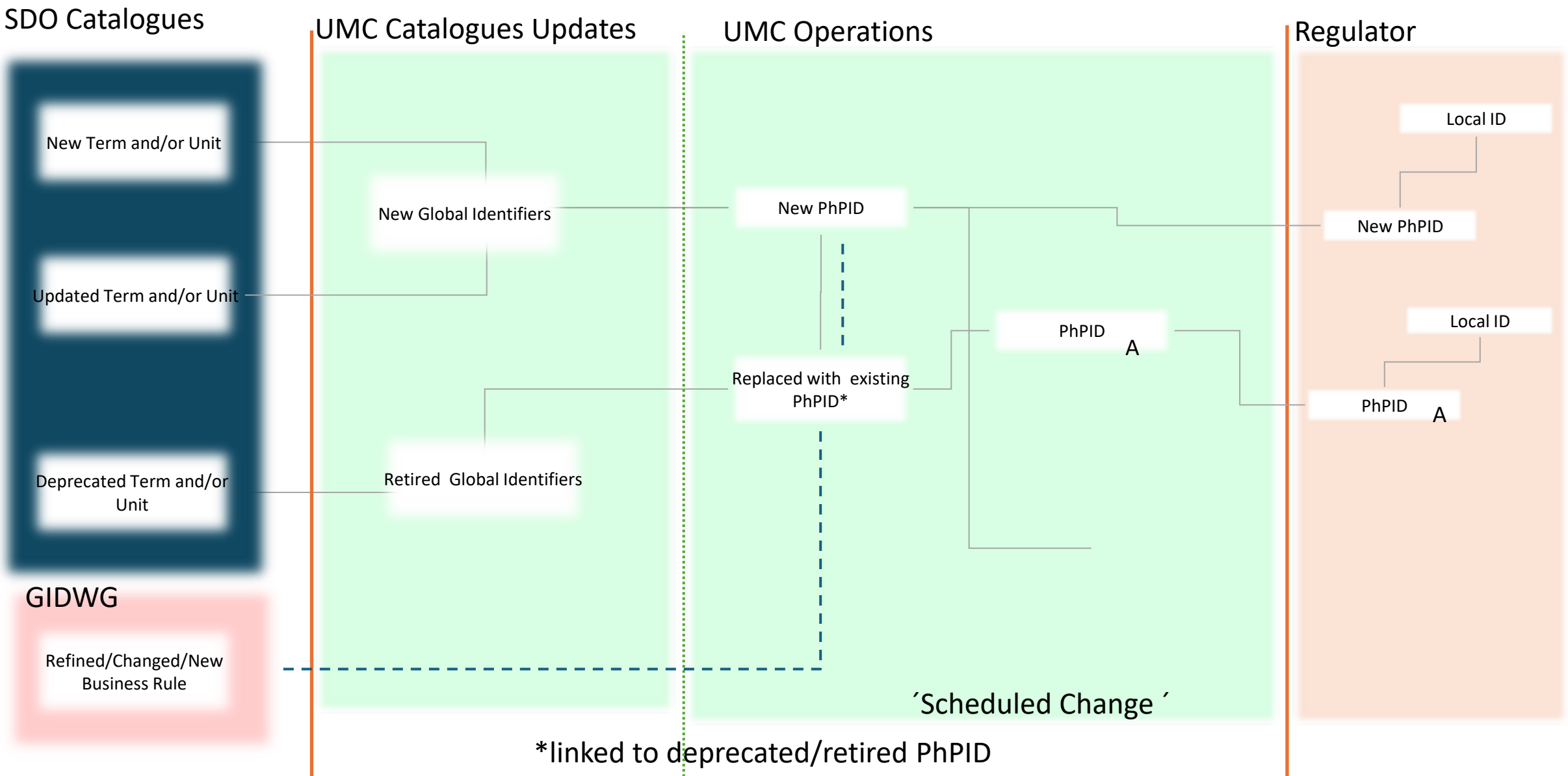
Change management

Proposed change management of PhPID on MP level



Proposed change management of PhPID

Changes in substance, dose form or strength/unit



Highlighted findings and recommendations from End-to-End testing

Strategy for Local IDs

(MPID, local dose form, local strength expression, units)

Finding

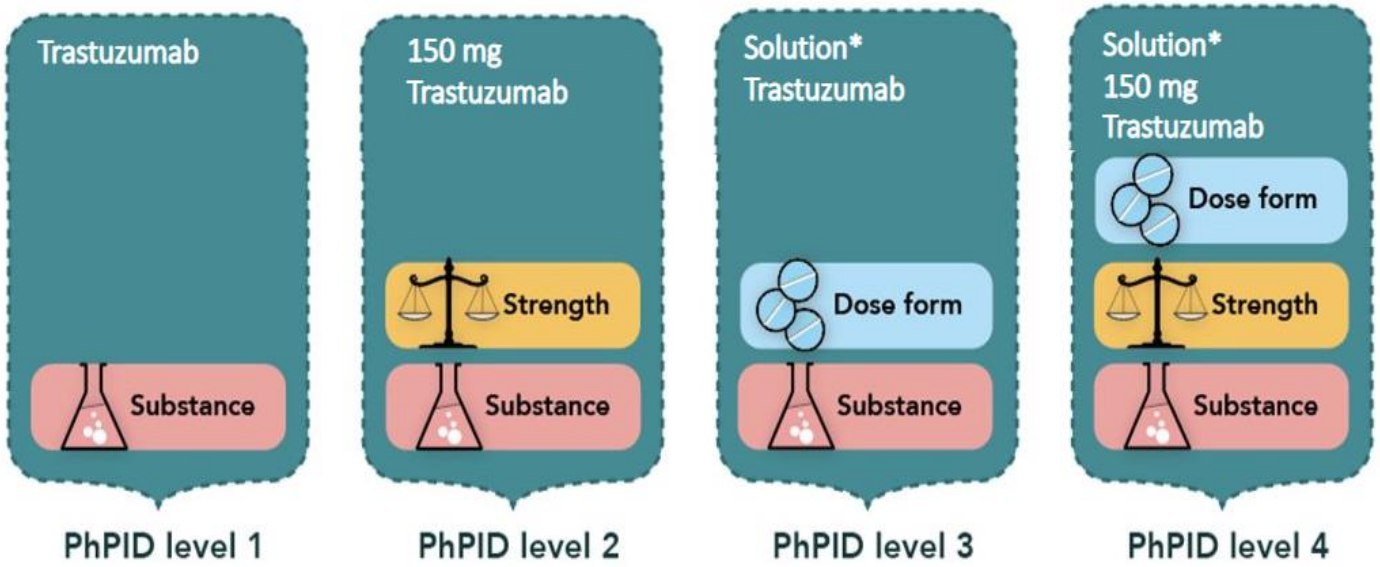
- End to end testing identified the need to collect and provide local IDs with global PhPID to facilitate interpretation of the data

Recommendation

- Local IDs can be included in the request both through API and PhPID Request Tool

Global PhPID linked to Medicinal product dictionaries

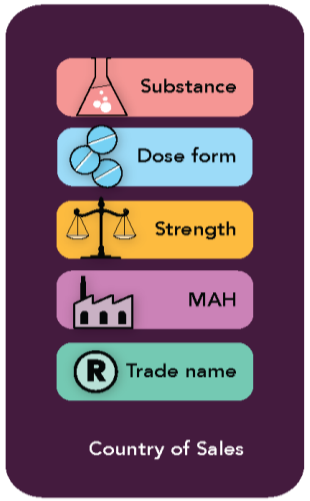
Pharmaceutical products



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

Medicinal products

National IDs:
MPID
Dose form ID
Substance ID



WHODrug

Overarching PhPID

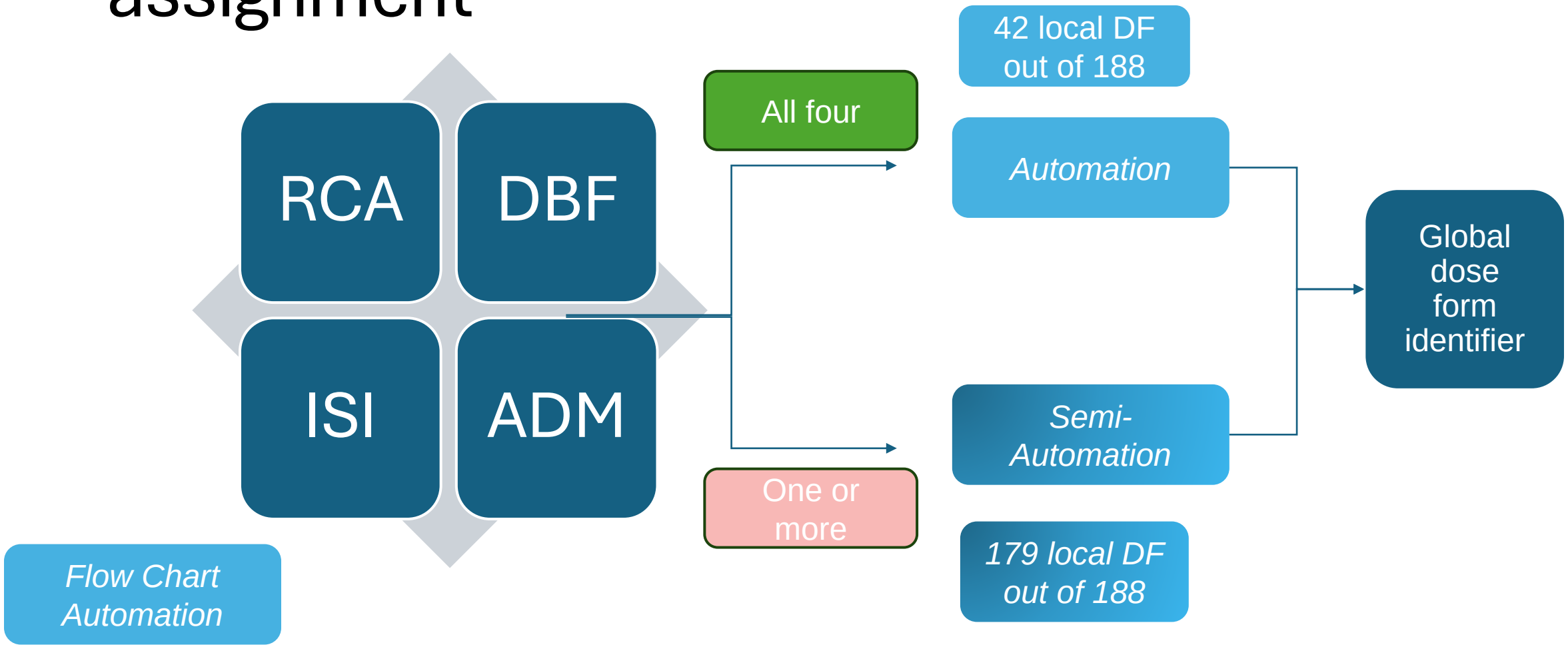
Finding

- There is a need to group related chemical substances, such as bases and their corresponding salts, to improve aggregation and search functionalities

Recommendation

- Development of an overarching PhPID
- Recommendations for non-normative amendments to ISO 11616/TS 20451

Automation of dose form attributes assignment



Implementation of automation findings

8 Similar approved products

Refresh

Filte

Trade name Methotrexate orion	NS	Ingredient Methotrexate	Country Sweden	MAH Orion pharma	Form TABLETS	Strength 2.5 mg	PhPID Strength
Methotrexate orion		Methotrexate sodium	Hungary	Orion	TABLETS	2.5 mg	
Methotrexate orion		Methotrexate sodium	Hungary	Orion	TABLETS	10 mg	
Methotrexate Orion	*old form*	Methotrexate	Sweden	Orion pharma	TABLETS	2.5 mg	2.50 mg
Methotrexate Orion	*old form*	Methotrexate	Estonia	Orion	TABLETS	10 mg	
Methotrexate orion pharma		Methotrexate sodium	Spain	Orion Corporation	TABLETS	2.5 mg	
Methotrexate orion pharma		Methotrexate sodium	Spain	Orion Corporation	TABLETS	10 mg	
Methotrexate orion pharma		Methotrexate sodium	Sweden	Orion pharma	TABLETS	2.5 mg	2.74 mg
Methotrexate orion pharma		Methotrexate sodium	Sweden	Orion pharma	TABLETS	10 mg	10.97 mg

3 Similar approved characteristics

Refresh

Similar approved dose form attributes list

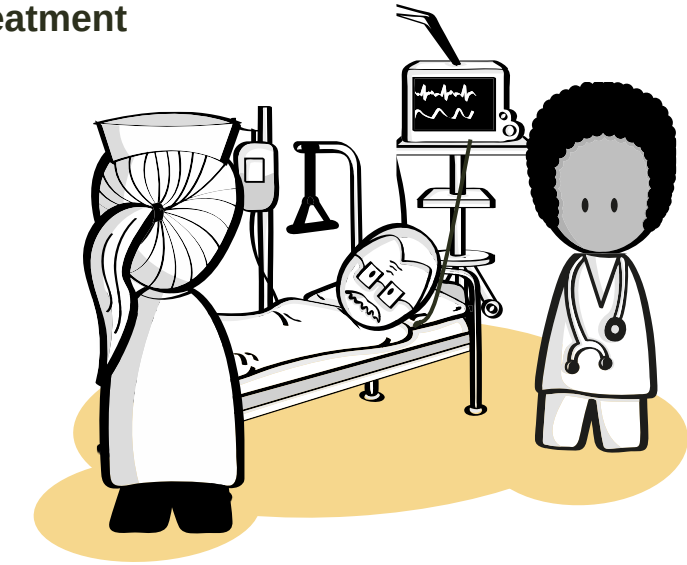
Filte

Pharmaceutical dose form Tablet	Basic dose form Tablet	Administration methods Swallowing	Intended sites Oral	Release characteristics Conventional
	Tablet	Swallowing	Oral	Conventional
Tablet	Tablet	Swallowing	Oral	Conventional
	Capsule	Swallowing	Oral	Conventional

New Use Case from Norway: The value of PhPID in hospital healthcare

1 **Patient admission, anamnesis and medication reconciliation**

2 **Plan and complete medical treatment**



3 **Finish treatment and discharge**

Prescription based on….

Package / PhPID level 4	PhPID level 3	PhPID level 4
substance + dose form + strength	substance + dose form	substance + dose form + strength

Key message

All of the work presented today has provided confidence of the establishment of the global PhPID framework

Thank you!

Closing Remarks
Public Meeting Adjourned

Ron Fitzmartin (US FDA)

Global IDMP Working Group

Thank You for your work on IDMP!