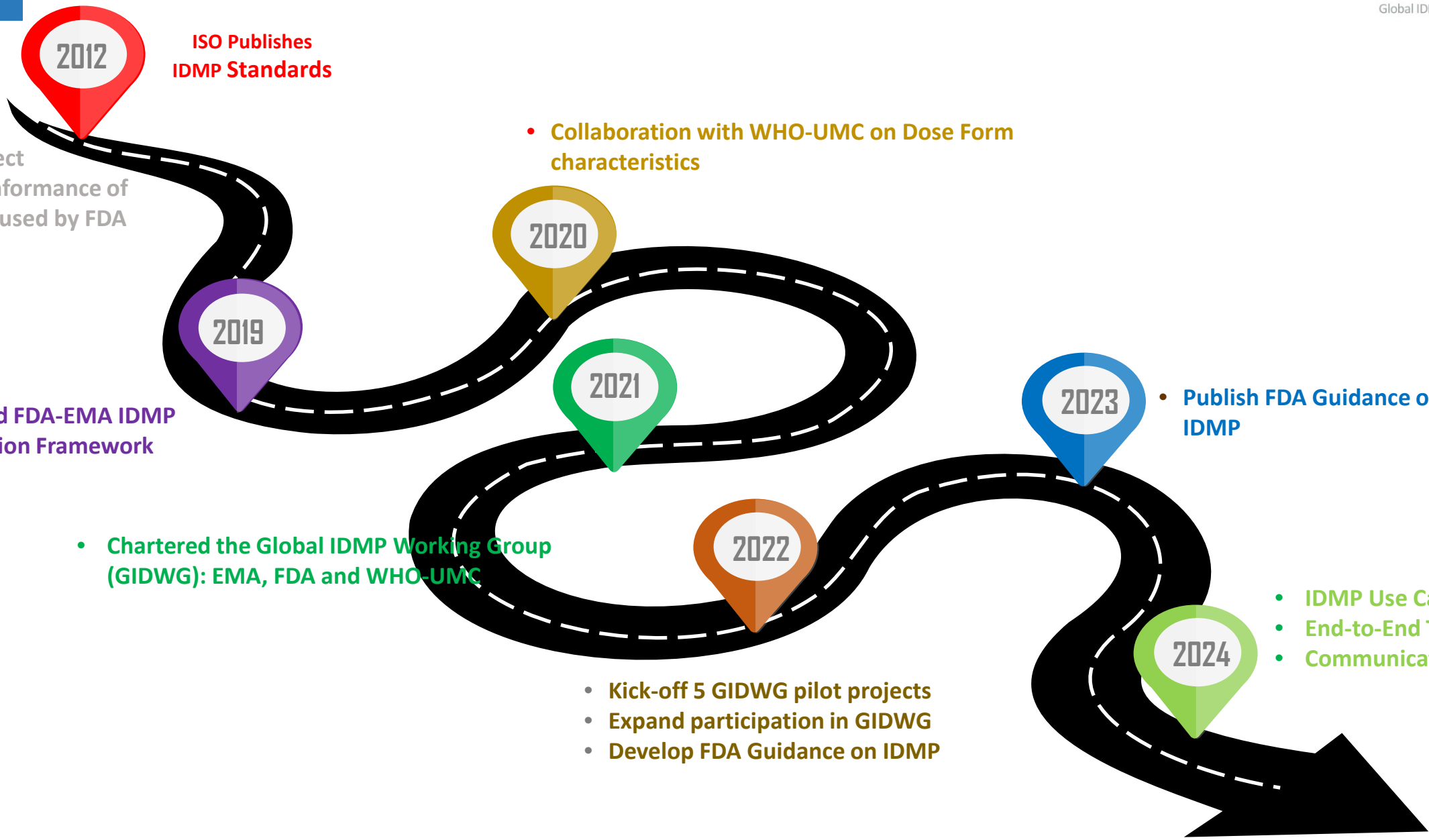
Global IDMP Working Group

Global IDMP Implementation:

Readiness

FDA IDMP Roadmap to Implementation - 2012-2024



Readiness

- FDA has used, for many years, standards that are in conformance to IDMP
  - *National Drug Code (Medicinal Product ID)*
  - *Unique Ingredient Identifier (Substance ID)*
  - *Unified Code for Units of Measure (Strength)*

- FDA's goal is the harmonization of the standards for the international exchange of medicinal product data
  - FDA will continue to work with international partners (e.g., WHO-UMC, HL7, ISO, GIDWG, ICH) to ensure the standards can be implemented for the key use cases
  - FDA supports the establishment of a framework for the maintenance of the global IDMP identifiers

Opportunities

- Global collaboration
  - Faster response and broader alternative products to address drug shortage
  - Faster response to AE, even “proactive” PV
  - Life saving and Cost saving

IDMP implementation readiness in EU

EUROPEAN MEDICINES AGENCY

ISO 11239
Pharmaceutical dose forms, units of presentation and routes of administration

- **RMS implemented ISO 11239** in 2017

ISO 11240
Units of Measurement

- **RMS implemented ISO 11240** in 2017

ISO 11238
Substance

- SMS phase 1 delivered in 2019 with limited functionality, not ISO 11238 compliant.
- **ISO 11238 compliant** European substance reference system (**EU-SRS**) hosting handed over to EMA in Dec 22
- **Substance data cleansing ongoing**, review by Substance Validation Group
- Integration of **SMS** with **EU-SRS taken up in Research & development Value stream, prioritisation ongoing**

ISO 11615
Medicinal Product

- PMS covers the **authorised medicinal product** part from ISO 11615.
- **Future PMS iterations** to cover other data elements of the authorised medicinal product and investigational medicinal products.
- **ISO 11615 compatibility/format** implemented by data migration/transformation in 2024 - **CAP & NAP data already available in ISO 11615 compatible** format
- **ISO 11615 compliance/business rules –** planned enrichment/correction by Industry starting with Manufacturers for critical medicines

ISO 11616
Pharmaceutical Product

- **RISK: EU implementation at early stages** - Substance cleansing ongoing, although product migration/transformation completed enrichment/correction still needed by MAH/NCAs
- **APPROACH: Iterative/piloting** approach taken! - A**utomatic PHPID generation** is **ongoing** for EU critical medicines to support **Shortages**
- **Closer alignment with GIDWG/UMC** in recent times to ensure best practices are exchanged

Completed In progress Not started

For EU... Why PHPID?

EUROPEAN MEDICINES AGENCY

Substance ID

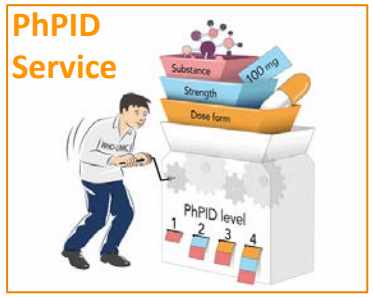
Strength

AdmDF
Dose form

or

ManDF
Dose form

PhPID Service



Pharmacovigilance

Safety Alerts

- Improve ability to identify, assess and respond to patient safety medication incidents.
- Improved surveilling of counterfeits
- Improved monitoring global supply chains for product quality issues and risk analytics

Drug Shortages

Medicinal Product Shortages

- Make it easier to find alternative products in microbial resistance or drug shortages.
- Allows the identification of pharmaceutically equivalent across regions to support mitigation of drug shortages

Cross-border prescription

Cross Product Comparisons

- Make it easier to compare products across jurisdictions for cross-border healthcare
- Reduce or share the cost of managing the same medicinal product information.

IDMP as a strategic project

PLANO ESTRATÉGICO ANVISA 2024-2027

Carteira de Projetos Estratégicos

Plano Estratégico Anvisa 2024-2027

P4. IDMP Implementation

ANVISA
Agência Nacional de Vigilância Sanitária

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

Opportunities

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

ANVISA
Agência Nacional de Vigilância Sanitária

Strategic Goals of Swissmedic 2023 – 2026

#	Strategische Ziele
GA2	Swissmedic has intensified its supervisory and monitoring activities in the therapeutic products market.
S1	Swissmedic is known to the public as a trustworthy authority.
S2	Swissmedic works together with other authorities and medical experts in a targeted manner.
S3	Swissmedic supports the development of novel therapeutic products and contributes to rapid access to innovative therapies.
P1	Swissmedic implements Swiss medical device regulation in an international network.
P2	Swissmedic uses state-of-the-art digital technologies.
M1	Swissmedic is an agile and data-centered authority.

IDMP as part of the digital transformation of Swissmedic

- Implications of the IDMP implementation at Swissmedic
  - External and internal interface for medicinal product data
  - Marketing authorisation holders will be able to view their data in the future
  - Exchange/synchronisation with international databases (e.g. for substances, referentials)
- No “isolated” implementation of IDMP at Swissmedic
  - Exchange of data via portal as part of the application process
  - Electronic application forms for capturing IDMP data
  - Electronic patient and professional information as a later use case

Networking & Collaboration

- Swissmedic is active in both international and national bodies

- Our intentions:
  - High compatibility, harmonised implementation
  - Connection to international databases
  - Building our solution on existing experience

→ Representation and contribution in specific bodies

→ Formation of a dedicated IDMP body for the specific needs of Swissmedic and its stakeholders (Swissmedic IDMP Advisory Group)

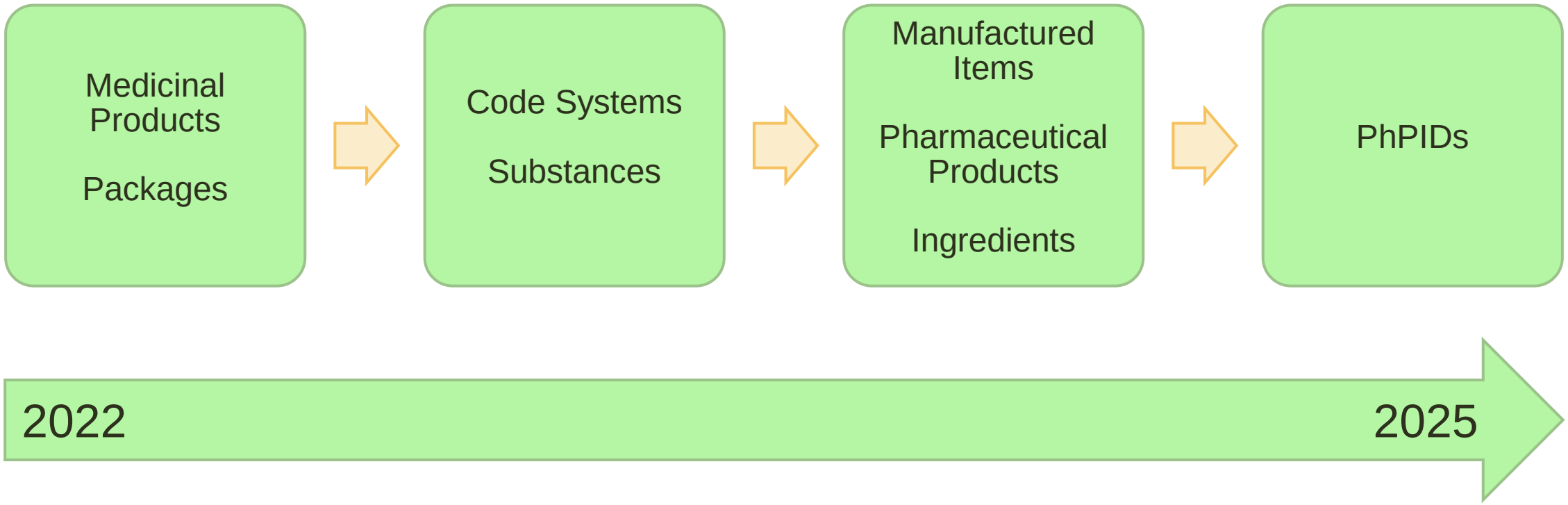
Opportunities for Swissmedic

- **Eliminate manual data entry to a large extent**
  - IDMP standards are a key enabler for electronic application forms
  - Improving data quality with data-centric processes
  - Industry acceptance due to global re-usability of data

- **Increase transparency for MAH’s by making (almost) all data available for them**

- **Streamlining heterogenous an complicated publication processes**

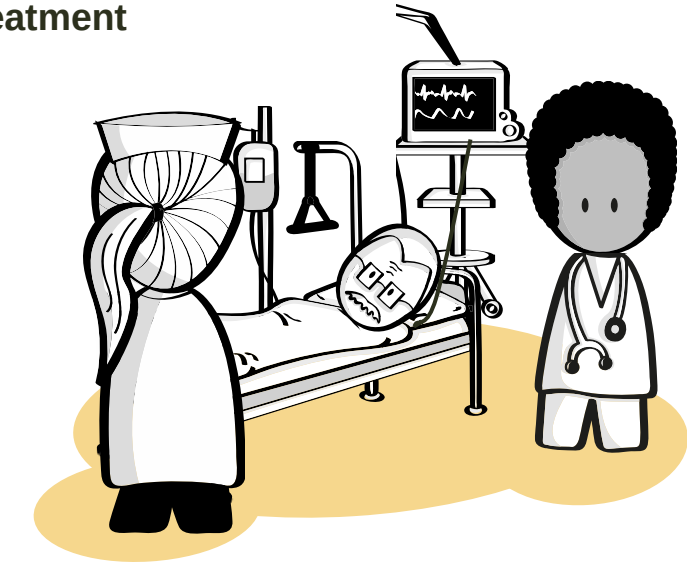
SAFEST deliverables timeline



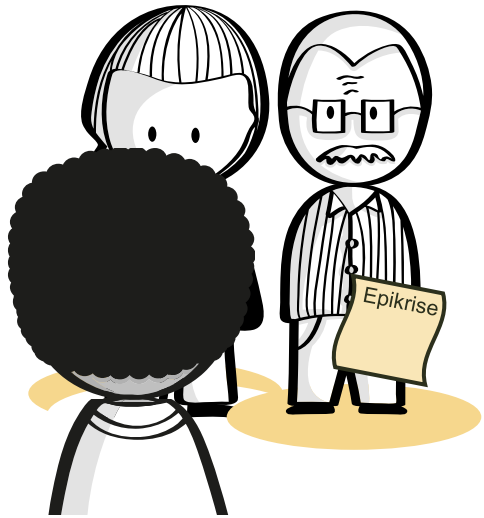
Use Case: The value of PhPID in hospital healthcare

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

2 **Plan and complete medical treatment**



3 **Finish treatment and discharge**



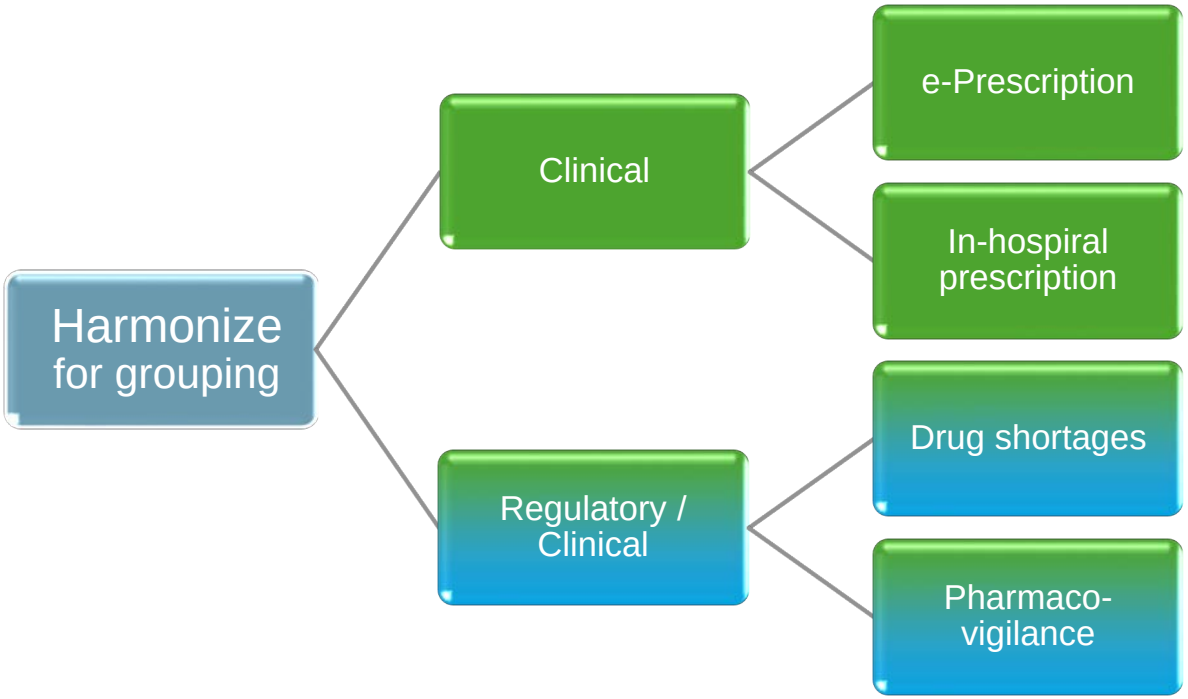
Prescription based on….

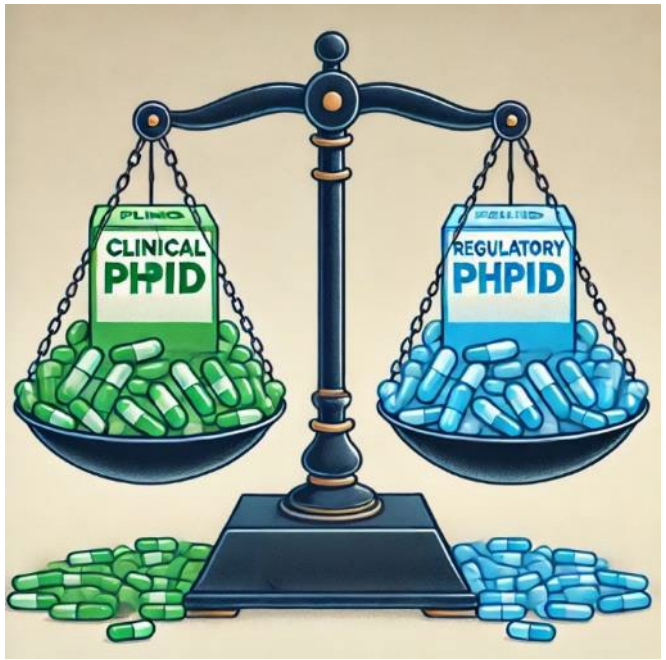
Package / PhPID level 4	PhPID level 3	PhPID level 4
substance + dose form + strength	substance + dose form	substance + dose form + strength

Harmonizing is Essential

Different use cases may require varying strategies for making the pharmaceutical products comparable, potentially resulting in (slightly) different PhPID sets for different use cases.

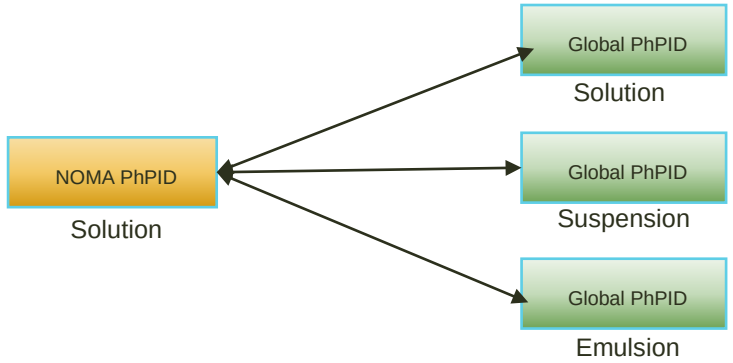
Continuous testing and verification is important part of the process.

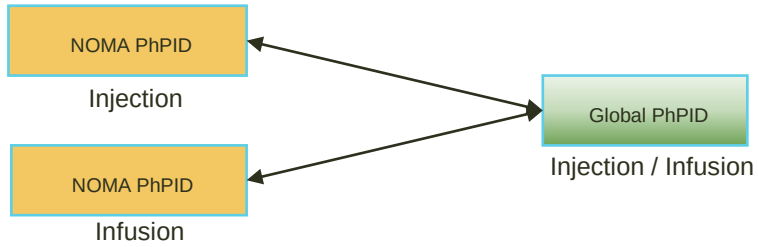




National and Global PhPIDs at NOMA

- NOMA has established business rules for PhPID generation and developed a PhPID generation tool to validate the results.
- We are currently testing UMCs global PhPID service API and a gap analysis is planned for Q4 2024.
- Our medicinal product dictionary will contain both national and global PhPIDs which will be mapped according to the specific use cases and scope.





Roadmap: Transitioning to IDMP/FHIR in Norway

Publishing National MPD (2022- 2025)

Distribute ISO IDMP-compatible national master data on medicinal and nutrition products.

Including national and global PhPID sets.

National transisitoning to IDMP and FHIR

Gradually transitioning from proprietary MPD and transaction data to ISO IDMP, FHIR and national PhPIDs

Enabling international data exchange using IDMP

Enabling the exchange of medication-related data with international stakeholders, based on ISO IDMP, FHIR and global PhPIDs.

IDMP| Readiness

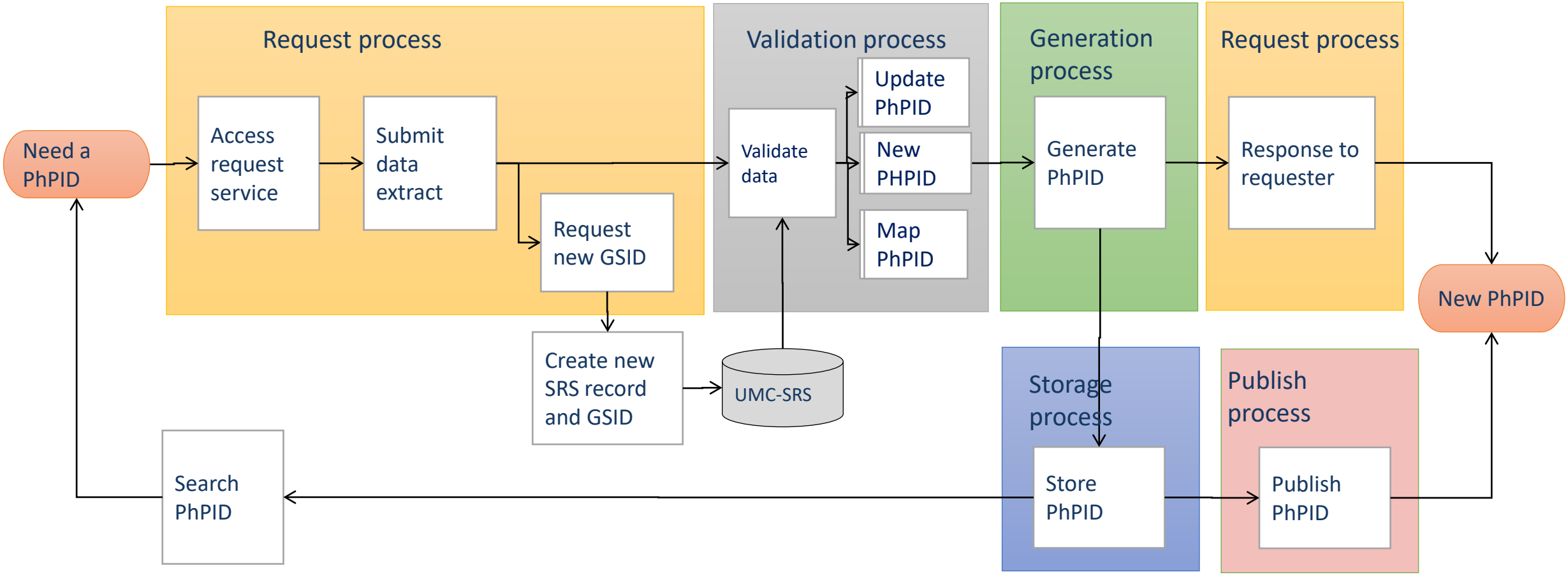
- IDMP is an essential to model, aggregate and analyze data at scale
- Gradual implementation and integration into automated platforms and business tools
- Establish policies and procedures to support master data management

IDMP| Opportunities

- A common language when describing health products across regulatory documents can provide benefits to regulators, industry and the healthcare system
- Creation of meaningful information sources that provide better value stakeholders
- Improve traceability of information making information more transparent as to decision making and ownership

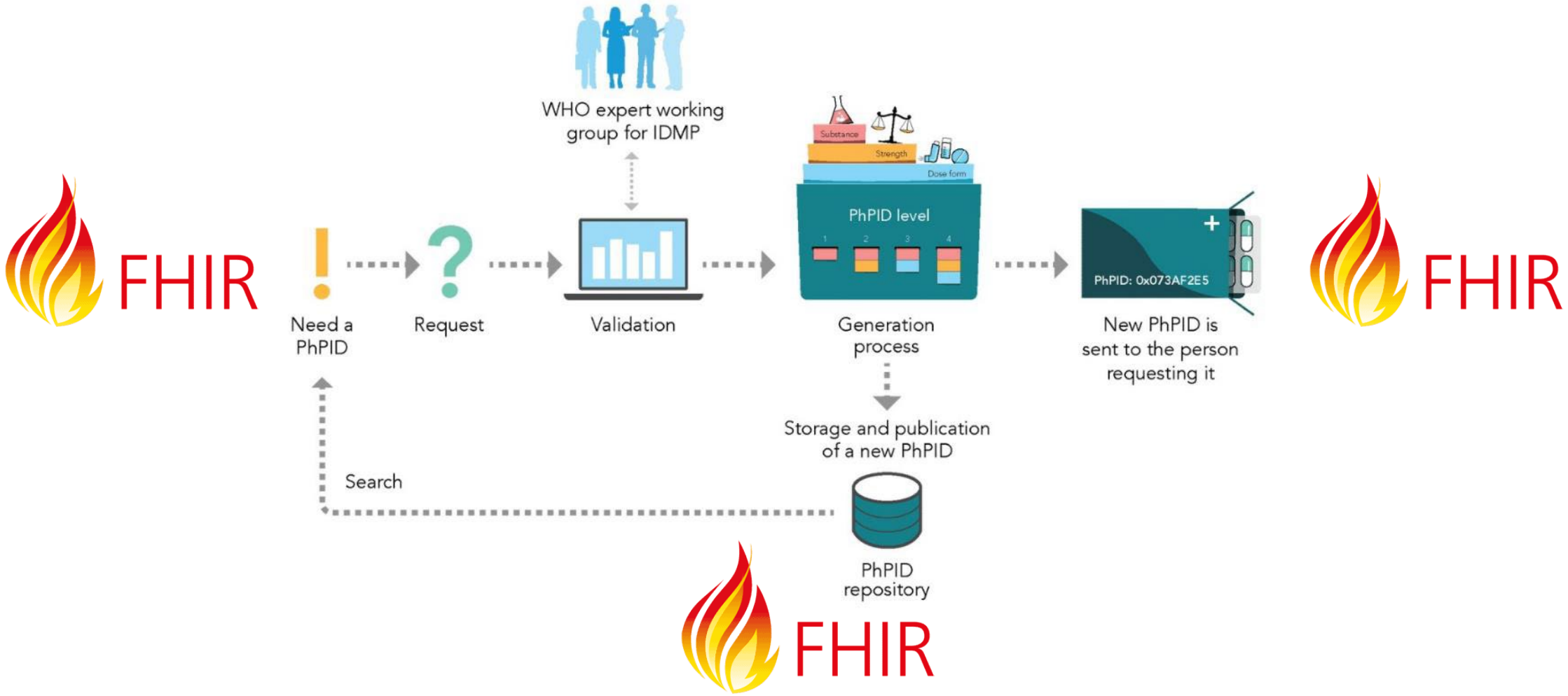
PhPID Operating Model including GSID request

A high-level representation



PhPID operating model in the context of FHIR

A high-level representation



Resources used for various PhPID scenarios' testing

Global IDMP Working Group

MedicinalProductDefinition

AdministrableProductDefinition

Ingredient

SubstanceDefinition

Organization

Task

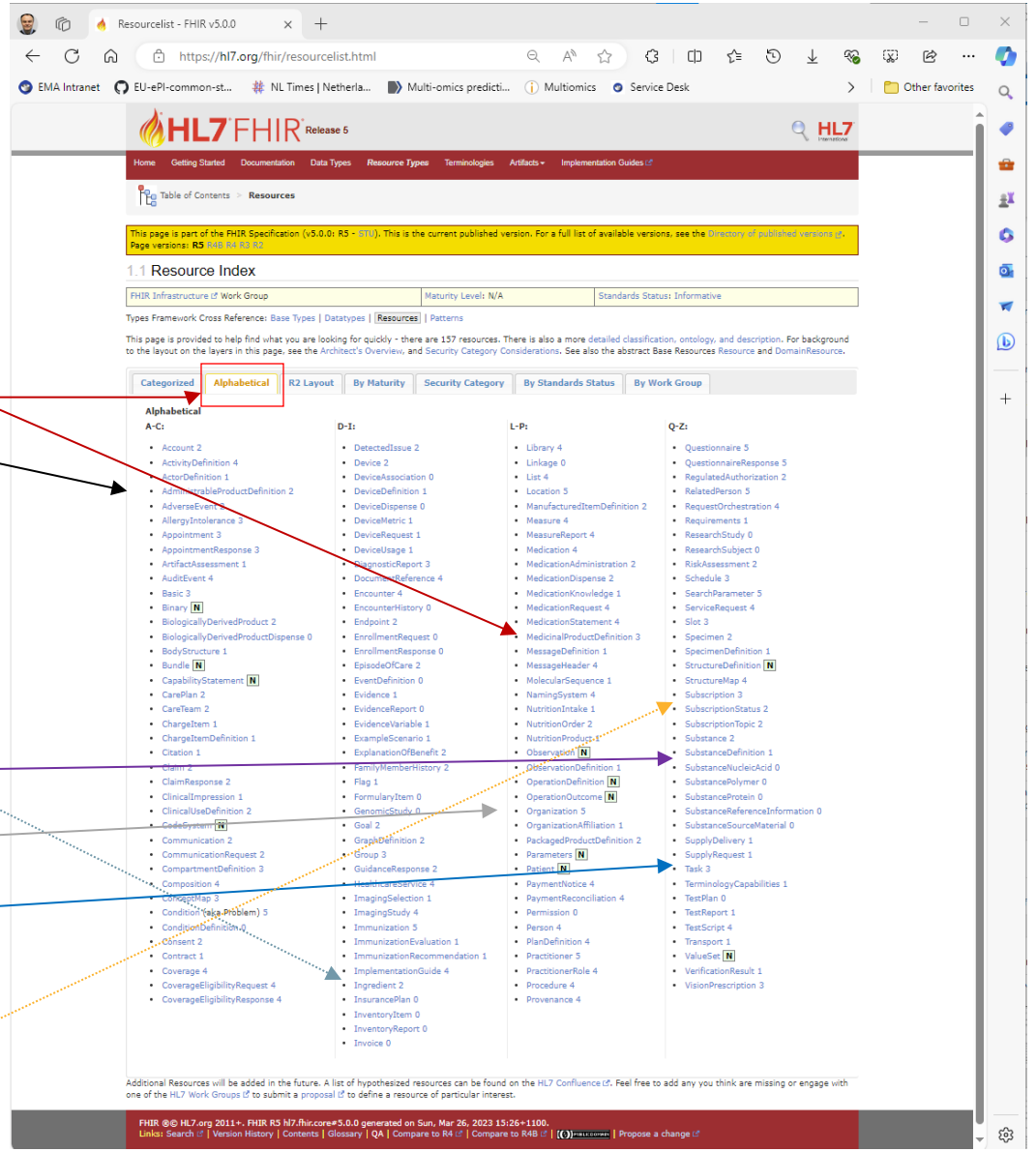
Products from organisational, national, or jurisdictional datasets or/and WHODrug products

(PhPIDs)

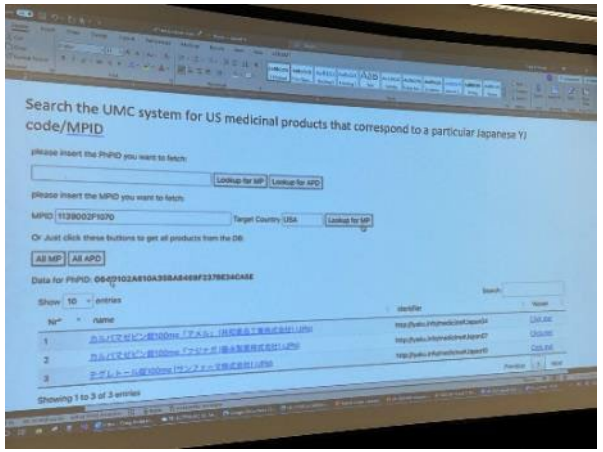
FHIR

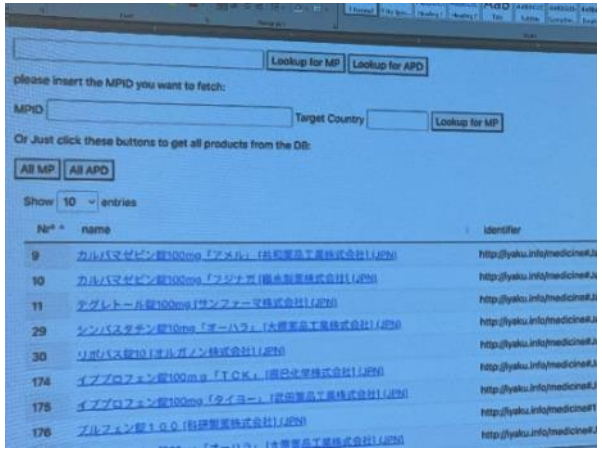
(GSIDs)

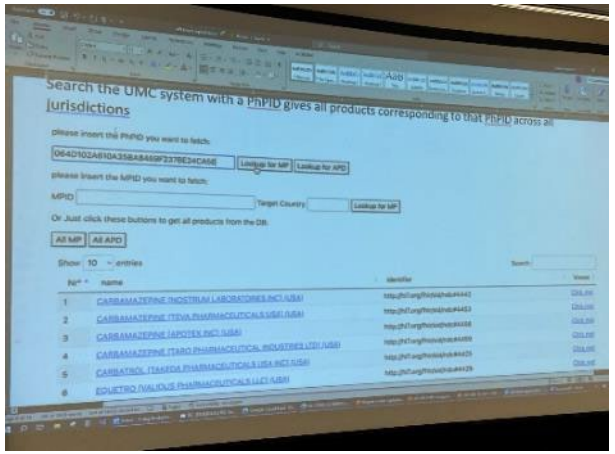
Subscription



https://www.hl7.org/fhir/resourcelist.html (select the alphabetical representation to view all)







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

Global IDMP Working Group

Key message FHIR

- **FHIR resources can support PhPIDs for global use cases as per submitted scenarios.**
- FHIR can support ISO IDMP but it not there only for IDMP; it supports the wider healthcare domain including regulatory use cases.
- The “80-20 rule of thumb”: to complement the 80% “coverage” within the FHIR core specification, FHIR defines an inherent extension mechanism to allow for requirements beyond those developed and formalized.
- A draft Implemetation Guide has been developed to show how FHIR is used to exchange data based on the ISO IDMP standards for global PhPIDs and GSIDs (work in progress).
- **Further work and testing scenarios related to GIDWG operational model workflows will take place at public HL7 Vulcan FHIR accelerator events (on average, 3 a year).**
- Specific GIDWG substance related use cases (*e.g.*, definitional fields for global cases as per current ISO 11238/19844 revisions) will be scheduled for next year and will be built upon the FHIR profiles that are currently under development by EMA, FDA, and UMC.

Contributors

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Thank You!