4th Global IDMP Working Group (GIDWG) Stakeholders Meeting

Regulator and Industry Forums

11 September 2024

Meeting Location

Sheraton Sao Paulo WTC Hotel,

São Paulo, Brazil

Global IDMP Working Group

Day 3

AGENDA

09:00 – 09:30	**Regulatory and Industry Forums** Welcome, Introductions, Opening Remarks IDMP Introduction	Nelio Aquino (Anvisa) Ron Fitzmartin (FDA) Ta-Jen (TJ) Chen (FDA)
09:30 – 10:00	**LATAM Regulators (Part 1)** US FDA IDMP Readiness, Opportunities, Challenges	Ta-Jen (TJ) Chen (FDA)
10:00 – 10:15	**LATAM Regulators (Part 1)** EMA IDMP Readiness, Opportunities, Challenges	Isabel Chicharo (EMA)
10:15 – 10:30	**LATAM Regulators (Part 1)** ANVISA IDMP Readiness, Opportunities, Challenges	Leonardo N Santos (ANVISA)
	BREAK (11:00-11:15)	
11:15 – 11:30	**LATAM Regulators (Part 2)** Swissmedic IDMP Readiness, Opportunities, Challenges	Philipp Weyermann (Swissmedic)
11:30 – 12:00	**LATAM Regulators (Part 2)** NOMA IDMP Readiness, Opportunities, Challenges	Kristine Aasen, Elin May Merry & Bernd Moeske (NOMA)

AGENDA

	Lunch (12:00 – 13:00)	
13:00–13:15	**LATAM Regulators (Part 2)** Health Canada IDMP Readiness, Opportunities, Challenges	Karin Hay (Health Canada)
13:15 – 13:50	**LATAM Regulators (Part 3)** Questions and Discussion	All
	Industry & Regulators Joint Forum	
13:50 – 14:00	**Opening and Introductions**	Nelio Aquino (ANVISA) & Janis Bernat (IFPMA)
14:00 – 14:45	**Outcomes from Regulatory Forum** IDMP Readiness, Opportunities, Challenges	Isabel Chicharo (EMA) & Ron Fitzmartin (US FDA)
	BREAK	
15:15 – 16:00	**Outcomes from Industry Forum** IDMP Readiness, Opportunities, Challenges	Sheila Inada (AstraZeneca) & Rodrigo Palacios (Roche)
16:00 – 16:45	**Joint Discussion on Outcomes & Action Planning**	Nelio Aquino (ANVISA) & Joerg Stueben (Boehringer- Ingelheim)

Regulator and Industry Forums
Welcome, Introductions, Opening Remarks

Nelio Aquino (Anvisa) &
Ron Fitzmartin (US FDA)

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LATAM Regulators (Part 1)
US FDA
IDMP Introduction & Readiness, Opportunities, Challenges

Ta-Jen (TJ) Chen
Office of Strategic Programs, CDER,
US FDA

Global IDMP Working Group

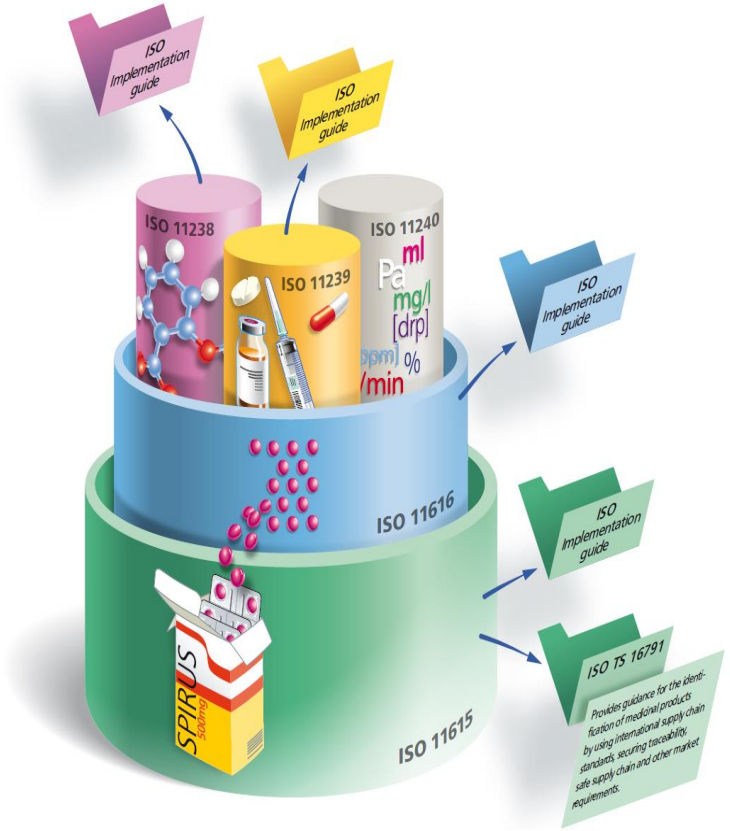
Agenda

- IDMP Introduction
- IDMP Benefits
- Challenges with Global/Cross-Regions Implementation
- FDA IDMP Implementation
  - Readiness
  - Challenges
  - Opportunities

What is ISO IDMP

The Identification of Medicinal Product (IDMP) is a suite of five ISO standards that:

- Data elements and structure to **uniquely** and **unambiguously** identify medicinal product, Pharmaceutical Product, and substance
- **common vocabularies** for improved people communication



- ISO 11615 – Medicinal Product Identification
- ISO 11616 – Pharmaceutical Product Identification
- ISO 11238 – Substance Identification
- ISO 11239 – Pharmaceutical dose forms, units of presentation and routes of administration
- ISO 11240 – Units of measurement

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ISO 11615: Medicinal Product ID

Primary Identification of Medicinal Products

- **MPID** – Medicinal Product Identifier
  - **Country Code + Marketing Authorization Holder + Product Code**
- **PCID** – Medicinal Product Package Identifier
  - MPID + **Package Description Code**
- **BAID_1** – Medicinal Product Batch Identifier (*Outer Packaging*)
  - PCID + **Batch Number + Expiration Date (ISO 8601 date format)**
- **BAID_2** - Medicinal Product Package Batch Identifier (*Immediate Packaging*)
  - PCID + **Batch Number + Expiration Date (ISO 8601 date format)**

ISO 11238: Substances/Specified Substances

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Substance:

- Is defined based on its main, general characteristics
  - ***What the material is*** not how it is made or used
  - Independent of physical form or grade
  - Can be a single molecular or mixtures either synthesized or isolated together
  - Be defined using one or more of the following groups:
    - Chemical, Protein, Nucleic acid, Polymer, Structurally diverse, Mixture

Specified Substance: More granular, specific description of a substance

- Group-1 Multiple substance materials (Coatings, Colorants, Flavorants); Physical Form; Extracts
- Group-2 Manufacturer and minimal manufacturing information
- Group-3 Grade of material (USP, EP, technical, standardized etc.)
- Group-4 Detailed Manufacturing information, Specification

ISO 11240: Units of Measurement

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ISO 11240 - Data elements and structures for unique identification and exchange of units of measurement

Specifies rules for the usage and coded representation of units of measurement for the purpose of exchanging information about quantitative medicinal product characteristics (e.g.strength)

The Unified Code for Units of Measure (**UCUM**) is a code system intended to include all units of measures being contemporarily used in international science, engineering, and business.

UCUM_CODE	Description of the Unit (using UCUM descriptions where they exist)
mg/mL	milligram per minilitter
mg/kg/(8.h)	milligram per kilogram per 8 hour
nmol/min/mg{prot}	nanomole per minute per milligram of protein

ISO IDMP Global Harmonisation

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apomedifot.de

ISO 11616: Pharmaceutical Product Identification

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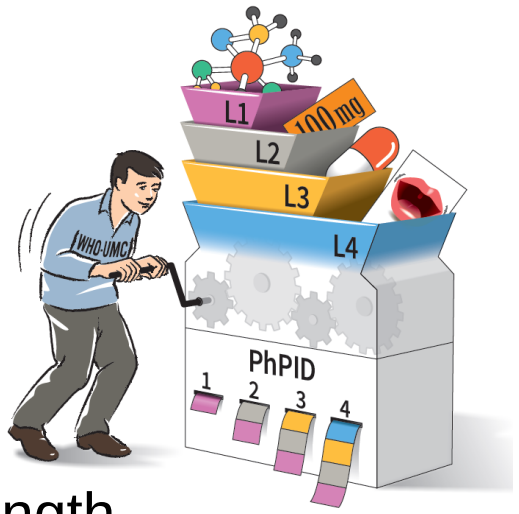
- Derived ID based on the following subset of elements:
  - Substance(s)/Specified Substance(s)
  - Strength(s) & Strength units
  - Administrable Dose Form(s)



- PhPID Set
  - PhPID Level_L1 → Substance(s) Term
  - PhPID Level_L2 → Substance Term(s) +Strength+ reference strength
  - PhPID Level_L3 → Substance Term(s) + ***Administrable Dose Form***
  - PhPID Level_L4 → Substance(s) Term+ Strength + reference strength + ***Administrable Dose Form***

- Substance is the key for all PhPIDs

Connecting Medicinal Products

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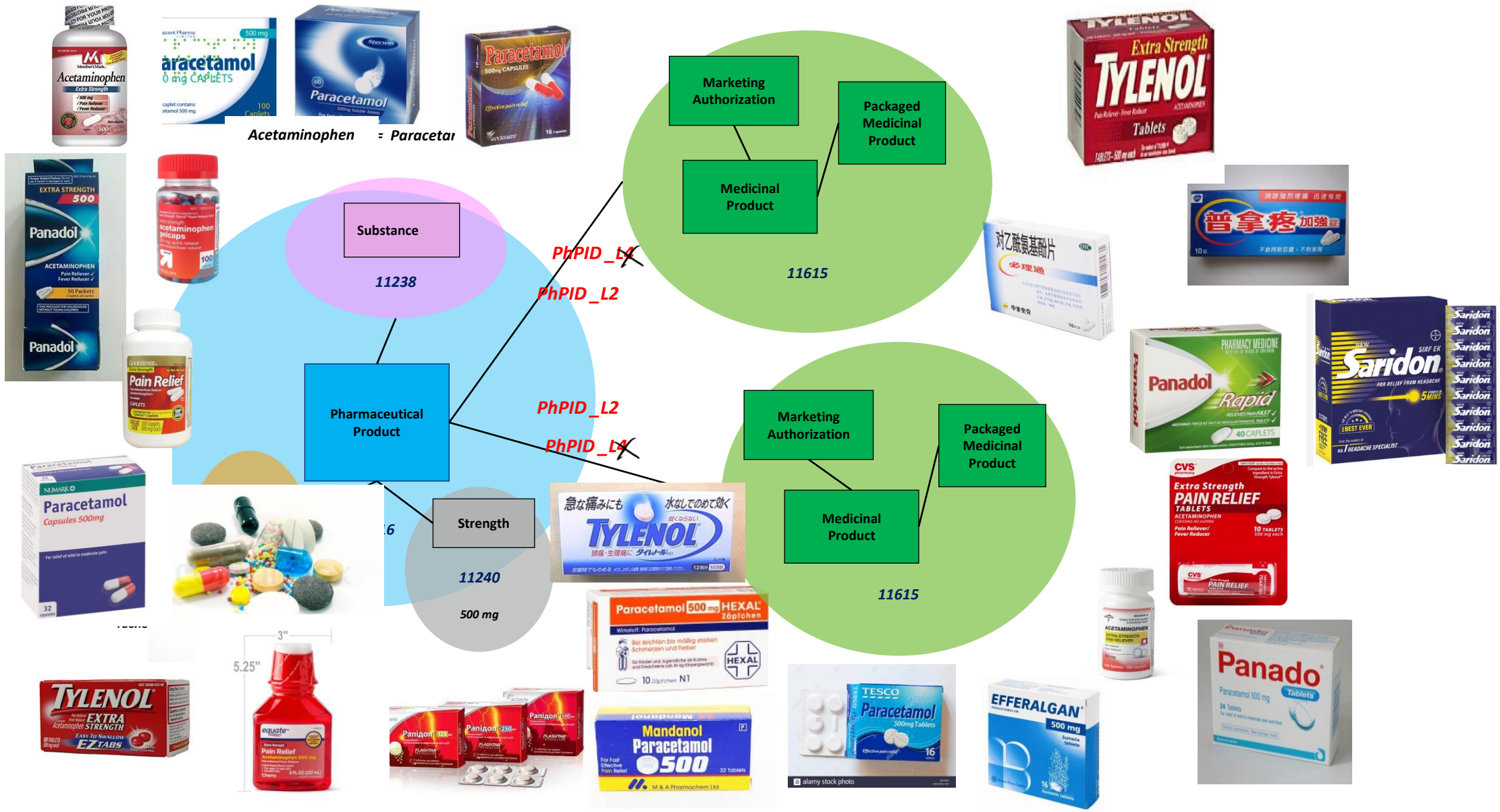

Key Benefits of IDMP

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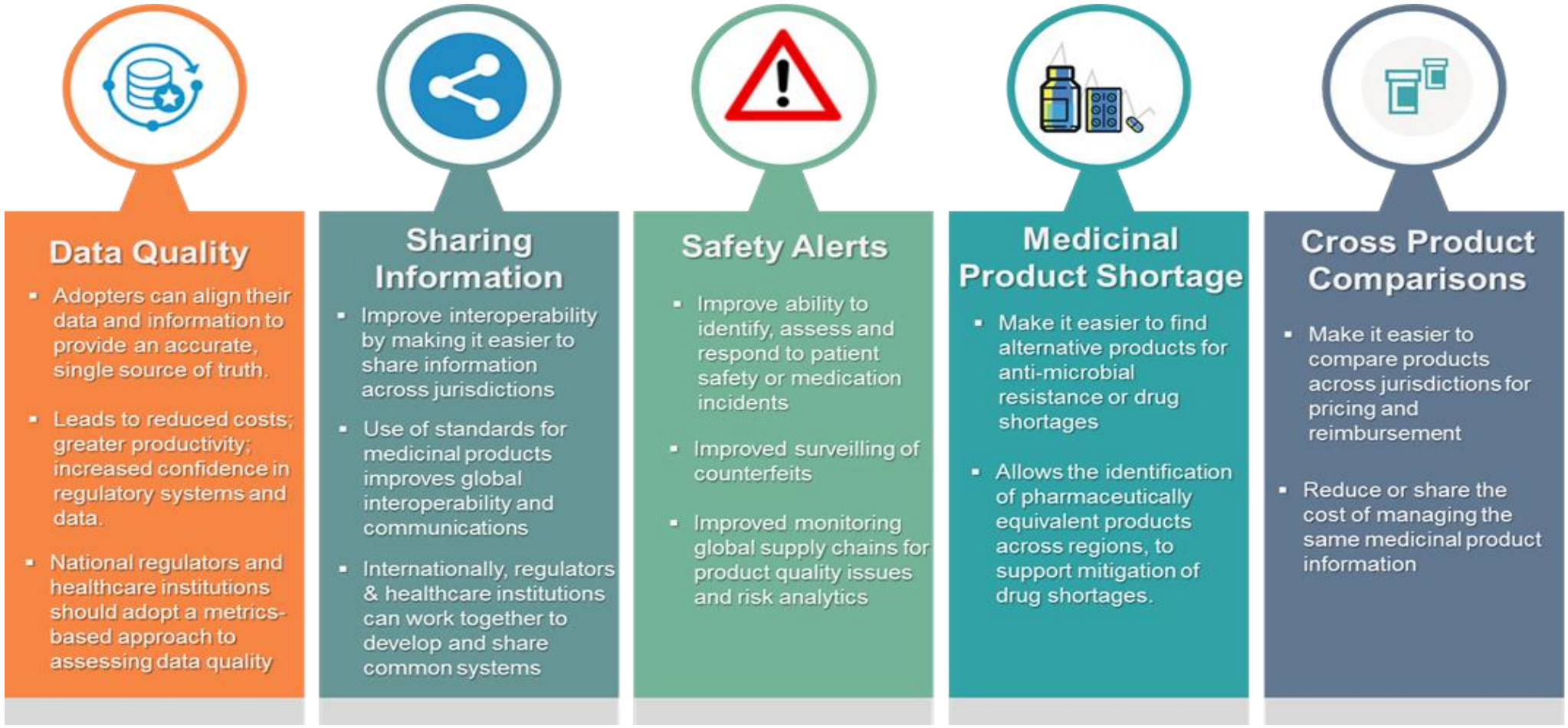

- Cross-regions or global agreement to harmonize on substance ID, representation of dose form, and strength is needed to maximize the benefits

Global Implementation Challenge - Dose Form

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- 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

- Remedy
  - Use DF characteristics (attribute) in place of various DF terminology
  - Aided by Harmonization Business Rules

Dose Form	***BDF***	***Relase***	***Admin***	***Intended Site***
Capsule	*Capsule*	*Conventional*	*Swallowing*	*Oral*
Soft Capsule	*Capsule*	*Conventional*	*Swallowing*	*Oral*
Hard Capsule	*Capsule*	*Conventional*	*Swallowing*	*Oral*

Global Implementation Challenge - Strength

- Concentration Strength vs Presentation Strength

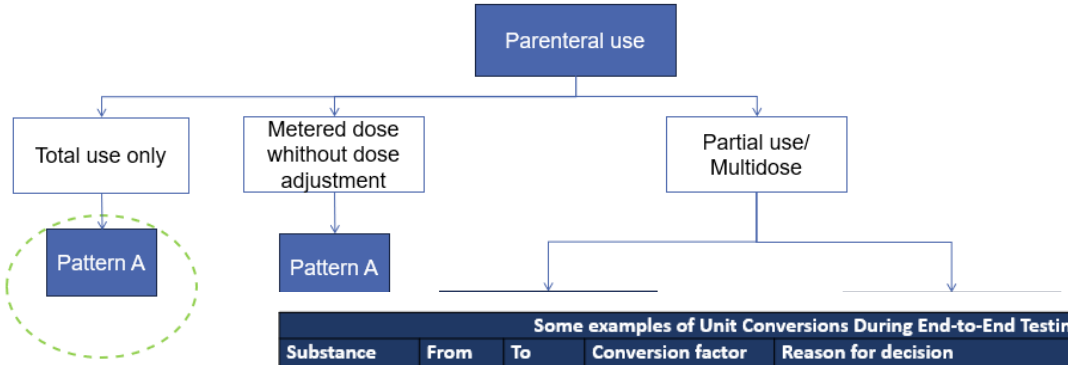
----------DOSAGE FORMS AND STRENGTHS----------

100 mg/mL concentration (3.1):

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

Global Implementation Challenge - Strength

- No common approach to strength and unit
  - Different unit expression
    - IU, %, mg/mL, or mg/g
  - Different precision of strength
    - Selincro - 18 mg vs 18.06 mg
- Remedy
  - Harmonization Business Rules
  - Aided by Conversion table



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 check)
Colistin/ colistimethate sodium	mg	IU	150 mg base = 360 mg salt = 4.5 MIU (EMA)	IU and mg equally common (5 region check). Substance is a mixture, meaning correct ration between salt and base in not possible to decide (see MW for colistin). Choosing IU ensures we get correct strength, since activity is not dependent on base/salt.
Lenograstim	IU	mcg	150 mcg = 19.2 MIU (Martindale)	IU and mg equally common (5 region check). 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 check)

FDA IDMP Roadmap to Implementation - 2012-2024

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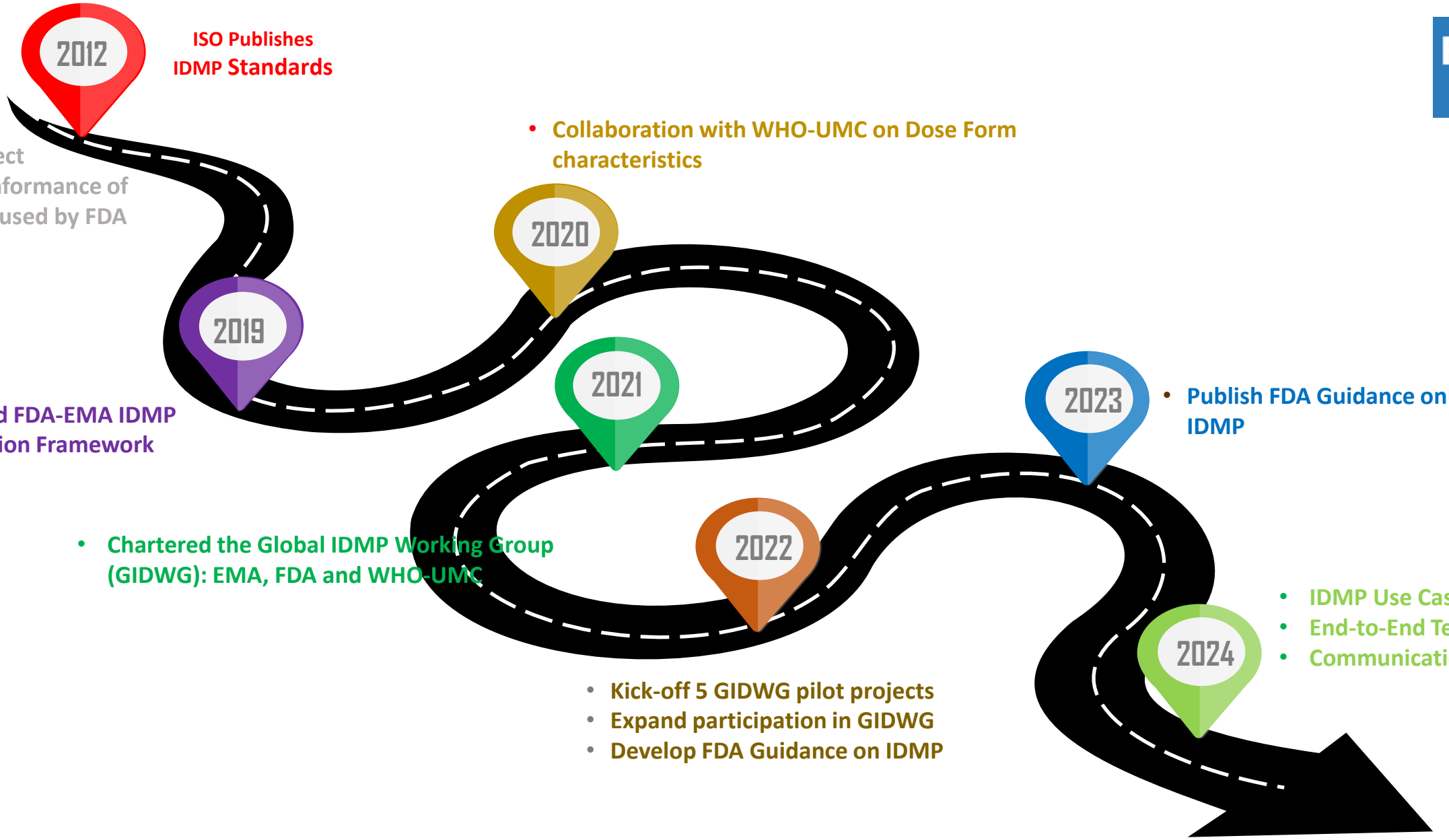
FDA



Readiness

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- 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

Readiness

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- GSRS – Substance
  - Based on ISO 11238/TS 19844, FDA, NIH's National Center for Advancing Translational Sciences (NCATS), the EMA, and experts from research organization and industry have collaborated to create a Global Substance Registration System (GSRS) to enable the efficient and accurate exchange of substance information.
  - FDA has established a production GSRS and will include GSIDs once available
- CDER Integrity – Product
  - Built based on ISO 11616, has placeholder for Global PhPIDs
- FAERS - PV
  - Has placeholder in Product Dictionary for Global PhPIDs
- SPL – medicinal product exchange standard
  - Based on Hl7 v3
  - SPL on FHIR – convert SPL to and from HL7 MPID FHIR based message

Challenges

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- Existing standards
  - Regulatory requirements
  - Inter-Agency activities
  - Communication to industry

Opportunities

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

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LATAM Regulators (Part 1): EMA

IDMP Readiness, Opportunities, Challenges

Isabel Chicharo
(EMA)

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?

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Substance ID

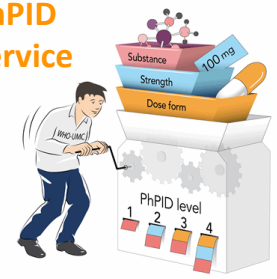
Strength

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.

How ESMP uses IDMP/PMS data for managing shortages

EUROPEAN MEDICINES AGENCY

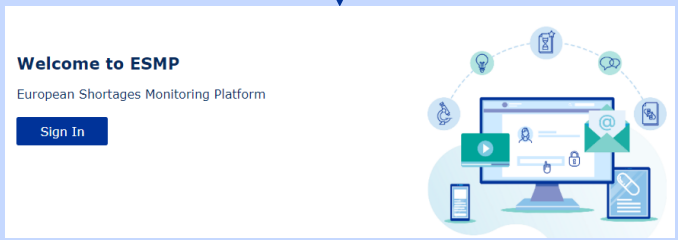
Member State data systems

NCAs report critical national shortages and provide data on demand for medicinal products in crisis and in preparedness situations

Industry data systems

MAHs perform routine shortage reporting and provide data on supply of medicinal products in crisis and in preparedness situations

ESMP



Users access ESMP and download reporting templates or submit data through machine-to-machine interface

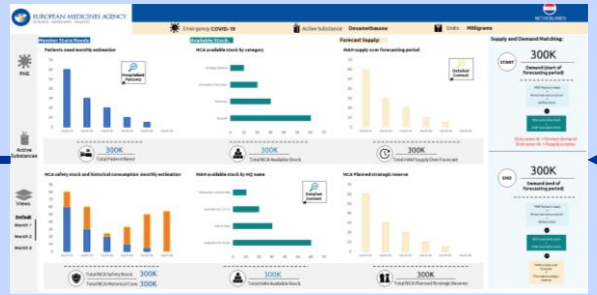
Packaged medicinal product data (PMS)

Prefilled in ESMP templates/Machine-to-Machine

	A	B	C	D	E	F	G	H	I	J	K
1	Packaged	Medicinal product - (Full medicinal	Medicinal product	Active Substance	Strength	Pharmaceutical form	Pack Size	Packaging	PCID	Country of authorisation	Marketing Status
2	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		AT	Temporarily unavailable
3	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		BG	Marketed
4	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		IS	Marketed
5	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		LI	Temporarily unavailable
6	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		NO	Marketed
7	55878	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	98 x 1 tablets (unit dose)	Blister		BG	Marketed
8											

Users **complete ESMP templates** with availability information per product

ESMP Data Analytics platform



Matching of supply and demand data

Regulatory coordination

SPOC WP, MSSG, and EC

Measures to prevent, manage and mitigate shortages in EU/EEA, such as exploring MAHs supply capacity and possibility to increase production, regulatory support, etc.

Prevent, monitor and manage shortages

Shortages and PHPID

Why?

- Allow a **deeper understanding** of the supply and demand on a **more granular level**
- Allow the formulation of recommendations on medicinal product level
- Starting point for discussion with industry

How?

- Aggregation, analysis and visualisation of supply and demand data taking into account different types of classes of medicinal products
- For every product, **6 different combinations** are created based on product and related substance information. This information is used during product recoding.

Shortages and PHPID

Level 1 (PhPID1) *Active substance(s)*

- level 1 we have implemented as PHPID level 1

Level 2 (PhPID2) *Active substance(s) - Strength(s) - Strength unit(s)*

- level 2 we have implemented but we do not use it for shortages → pharmaceutical form is always relevant

Level 3 (PhPID3) *Active substance(s) - Pharmaceutical Dose Form*

- level 3 is not implemented and has been adjusted to level 3.1 → using pharmaceutical form groups
- ***Level 3.1**: Active substance + Pharmaceutical form **group***
- *Pharmaceutical form **group**. Manual grouping of interchangeable pharmaceutical dose forms based on the business needs. Use of Dose Forms Characteristics did not yet provide a solution to all business needs so it is to be further considered in the future.*

Level 4 (PhPID4) *Active substance(s) - Strength(s) - Strength unit(s) - Pharmaceutical Dose Form*

- level 4 is not implemented and has been adjusted to level 4.1 → used for MSSG led preparedness and PHE
- ***Level 4.1**: Active Substance + Strength + Pharmaceutical form **group***

Level 5 (*New*) *Active substance + pharm group + strength + container size*

- Level 5 support analysis of multidose oral liquids → For example: to be able to differentiate between Amoxicillin 250mg/5ml, oral suspension 15ml bottle and 35 ml bottle, PHPID level 4 is insufficient, so a 5th level is designed including bottle size (15 ml and 35ml) → This grouping is not needed for other pharmaceutical form groups (tablets, capsules,…)

Level 6 (*New*) *For vaccine sonly - Grouping on ATC code*

- **For vaccines only** the active substance is not relevant as long as indication is the same and they can be used interchangeably. This is a theoretical approach based on the experiences of the COVID-19 pandemic

Challenges & Opportunities

EUROPEAN MEDICINES AGENCY

Challenges

- Still early for EU to use GSID or generating the Hash.
- We identified Regional requirements not (yet?) covered by ISO IDMP.

Opportunities

- Early alignment possible!
- GIDWG/UMC work contains valuable business rules and lessons learnt – the timing is opportune to align!
- ISO IDMP standards up for review.
- HL7/Vulcan FHIR Connectathons for testing.

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LATAM Regulators (Part 1)
ANVISA
IDMP Readiness, Opportunities, Challenges

Leonardo N Santos
Advisor at the General Office of Medicines
Anvisa, Brazil

Agenda

- IDMP Readiness
- Challenges
- Opportunities

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Anvisa’s IDMP readiness

IDMP as a strategic project

PLANO ESTRATÉGICO ANVISA 2024-2027

Carteira de Projetos Estratégicos

Plano Estratégico Anvisa 2024-2027

P1. Reconhecimento do Brasil como autoridade reguladora de referência internacional - WHO Listed Authority (WLA) 2

P2. UDI - Identificação Unívoca de Dispositivos Médicos 7

P6. Registro eletrônico da dispensação de produtos controlados 35

P7. Regulação Ágil 42

P8. Modelo de consolidação de súmulas no âmbito da Anvisa 49

P9. Consolidação e integração de dados de VISA na RNDS para apoiar a tomada de decisão em saúde pública 55

P10. AvallA - Sistema de avaliação automática de documentação para funcionamento de empresas 62

P11. Transformação Digital do PAS 68

P12. Programa de Substâncias Químicas de Referência da Farmacopeia Brasileira 73

P13. Serviço Seguro - Projeto Nacional para a Melhoria da Segurança Sanitária dos serviços de saúde e de interesse para a saúde 80

P14. Estimando os riscos da ingestão de alimentos contendo múltiplos resíduos de agrotóxicos 87

P4. IDMP Implementation

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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

Anvisa’s readiness to the IDMP

Simplified process for regulations providing convergence to international standards:

- Regulatory encouragement

Tools required for IDMP implementation:

- Controlled Vocabularies
- Substance ID (DCB)

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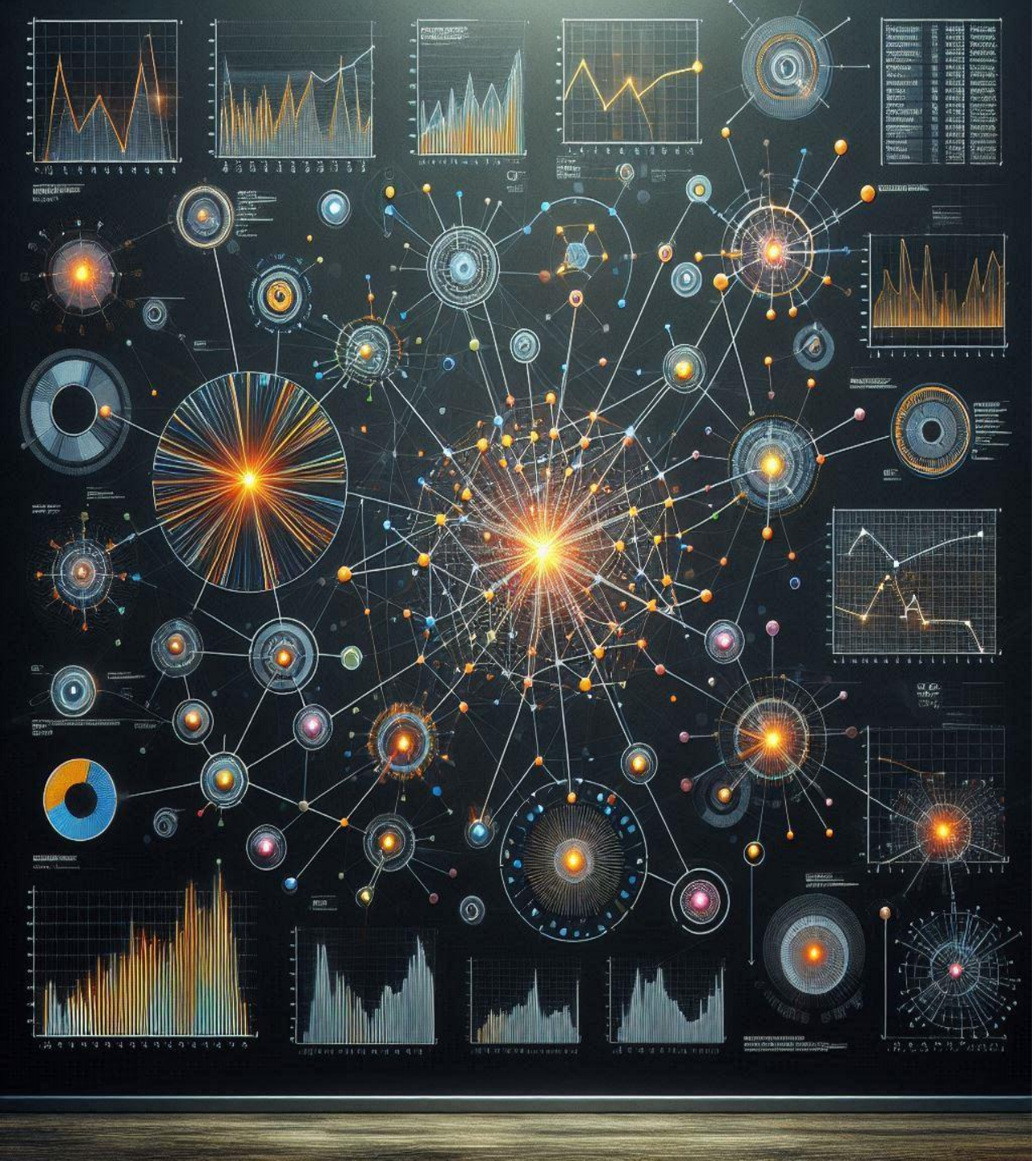
Implementation level

- ✓ ISO 11238 – Substance ID
- ✓ ISO 11239 - Dosage Form and Route of Administration
- ✓ ISO 11240 – Units of measurement
- ✓ ISO 11615 – Medicinal Product ID
- ✓ ISO 11616 – Pharmaceutical Product ID
  - PhPID End-to-End Testing (456/488)



Challenges

New submissions and Legacy

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

Tools required for IDMP implementation:

- Controlled Vocabularies
- Substance ID (DCB)
- Medicinal product ID

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Opportunities

Medicines regulation worldwide has adopted a data-driven approach in order to increase the efficiency of its work processes.

The data standardization and quality of data is essential for this to be successful.

Opportunities

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

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Agência Nacional de Vigilância Sanitária

Thank you

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www.gov.br/anvisa

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LATAM Regulators (Part 1): Swissmedic

IDMP Readiness, Opportunities, Challenges

Dr. Philipp Weyermann
Head of Unit Regulatory Assessment 2
Swissmedic

Swissmedic: About

- **Established** in **2002** as the first **Federal Authority** on **therapeutic products** along with the coming into force of the **Act** on **Therapeutic Products**
- **Public Institution** of the Swiss Federal Government
- **Independent** in organisation and management
- **Scope** of Products
  - **Medicinal products** for **human** and **veterinary** use
  - **Medical devices** (☞ Notified Bodies and CE-Marking)
- **Budget 2023:** 115,3 Mio. CHF
  - Federal contribution: ~ 16%
  - Fees: ~ 84%
- **Human resources 2023:**
  - Headcount: 580
  - Full-time equivalents: 493

Overview

IDMP Readiness

Opportunities

Challenges

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.

Digital Transformation at Swissmedic

Excerpt strategic objectives 2023 – 2026 Swissmedic

- **«Swissmedic uses state-of-the-art digital technologies»**
  - Swissmedic has the technological capabilities required to **collaborate** with the therapeutic products industry, other authorities and other countries **on a data-focused basis**. It operates a modern enterprise information management system. The working infrastructure consists of a sensible combination of private and public clouds. The open data architecture and structure are **compatible with national and international standards**. Artificial intelligence in the form of machine learning or natural-language processing is deployed wherever this is sensible. The implemented data protection and information security measures and business continuity management ensure the integrity, legal conformity and availability of data.

Strategic objectives (swissmedic.ch)

Digital Transformation at Swissmedic

Excerpt strategic objectives 2023 – 2026 Swissmedic

- **«Swissmedic is an agile and data-focused authority»**
  - Swissmedic is a knowledge-based organisation well-versed in the wide variety of scientific and regulatory disciplines found in the therapeutic products sector. A continuous exchange and processing of analogue and digital information form the basis of and are the precondition for Swissmedic's ability to perform. The use of new digital technologies means that far more data from a variety of sources are available and can be networked. Swissmedic supports the **interoperability of data and standards** in the Swiss healthcare system and in international collaboration with authorities and organisations. Work processes are digitally transformed and data-driven. Swissmedic promotes its employees' digital skills and assists them in working with innovative new business models and ways of thinking.

Strategic objectives (swissmedic.ch)

Swissmedic Data Strategy

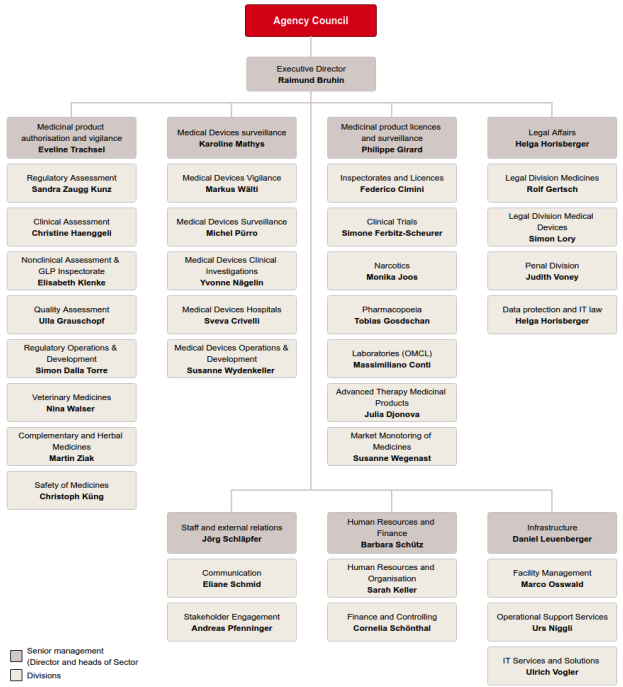
Our way to a data-centric agency

We want to be able to make well-founded decisions on the basis of our data and make the best possible use of supporting evaluations and analyses for our business case processing

We want to create the basis for working with our data securely and in compliance with data protection regulations

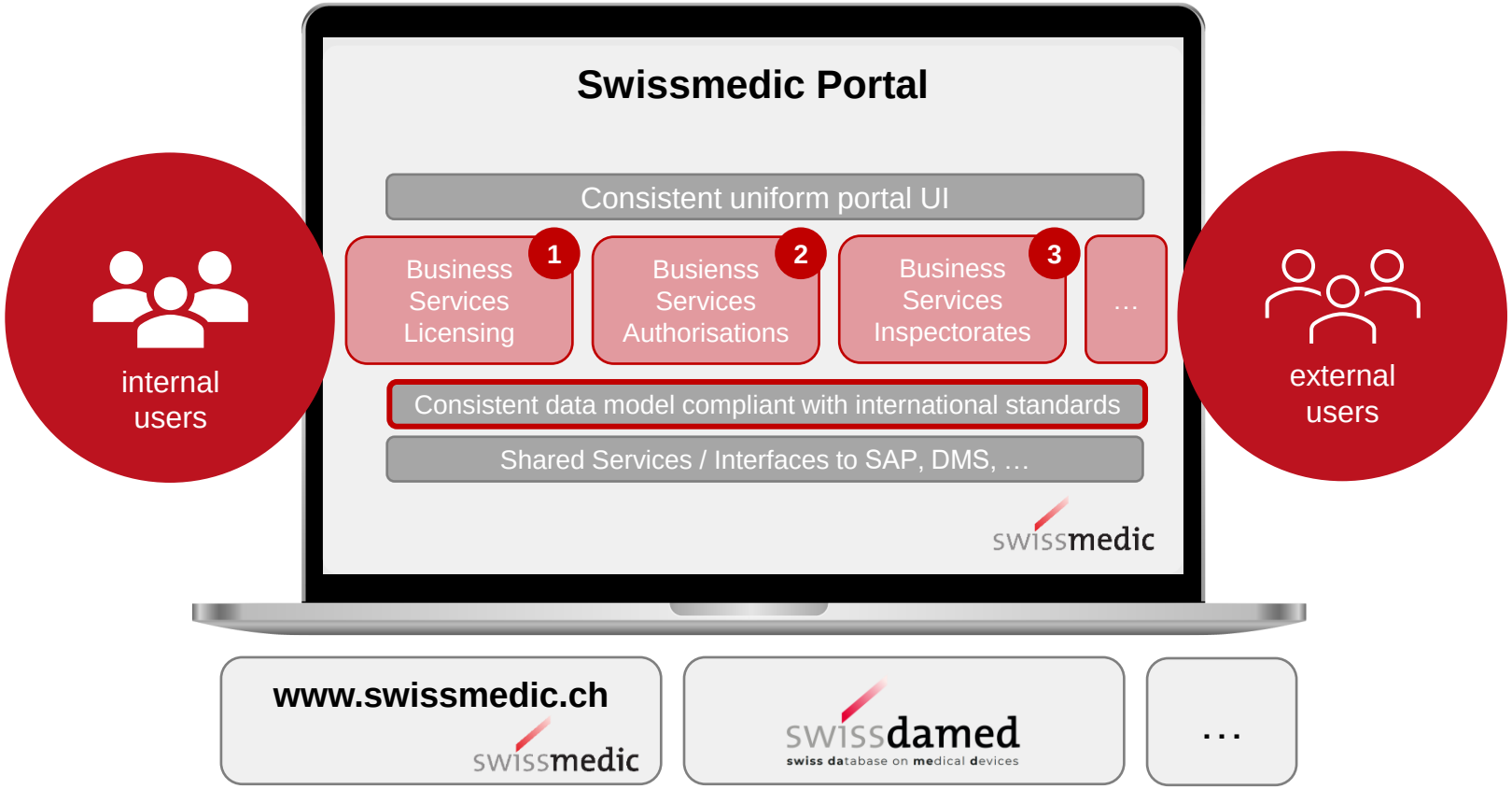
We operate between the poles of regulation, data protection, information security and innovation

New Swissmedic Portal: Architecture / High-level concept



Lifecycle of medicines

Lifecycle of medical devices

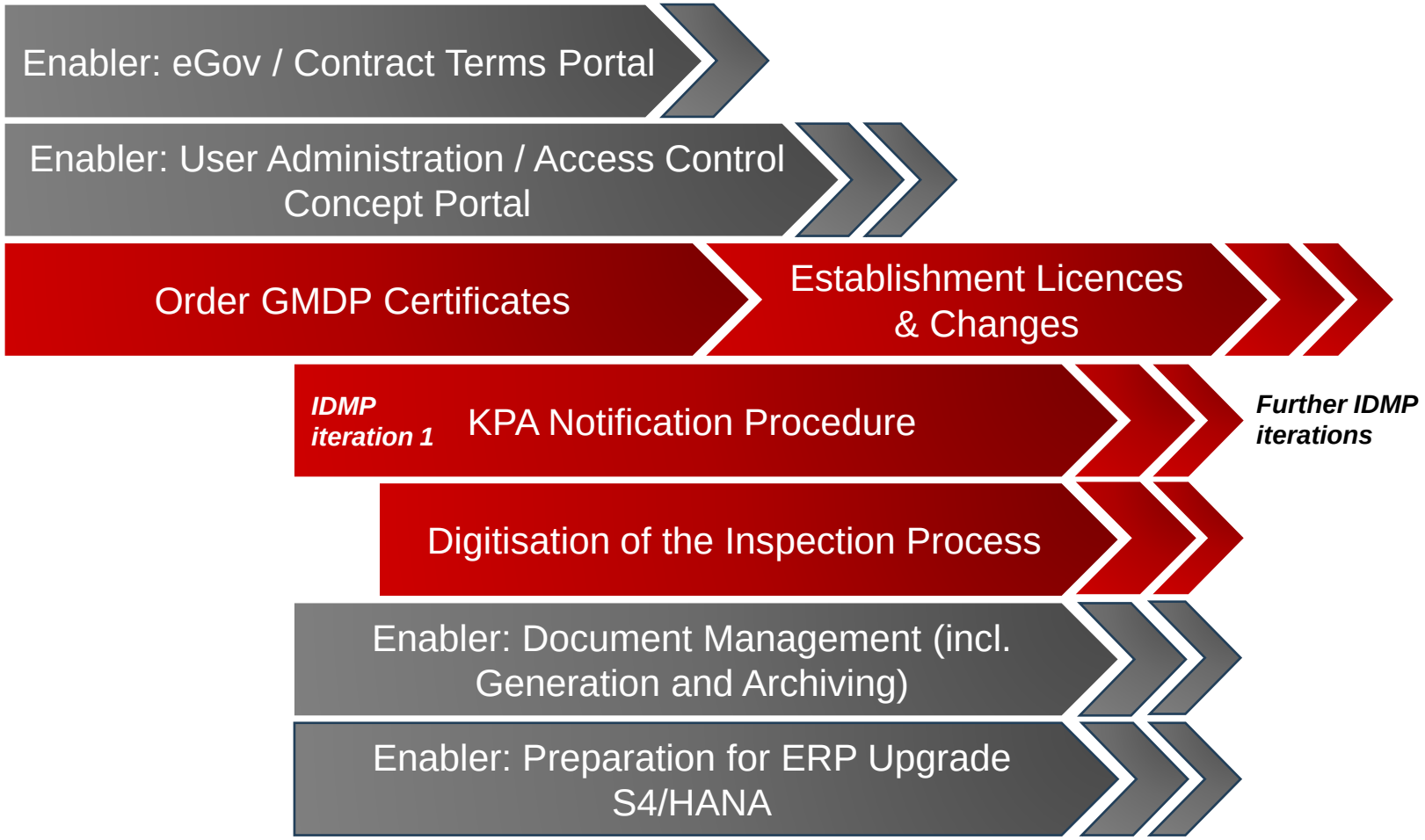


Harmonised coexistence of Swissmedic's platforms in the interaction with our external stakeholders / customers

Program Roadmap 2024

Business functions & features

Enabler for business functions and features



Further topics in 2024

- *User Interaction Concept*
- *Audit Trail*
- *Signatures*
- *Regulatory Data*
- *Business Partners*

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

Swissmedic’s approach to IDMP implementation

- There is no IDMP legislation in Switzerland.
  But (electronic) Application Forms will require IDMP-compliant data

- Only data used in day-to-day business will be required
- Introduction of the 1st iteration in coordination with an eAF
- The current scope of data is based on Swiss Module 1

- Intention to be as close to the EU implementation as possible

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

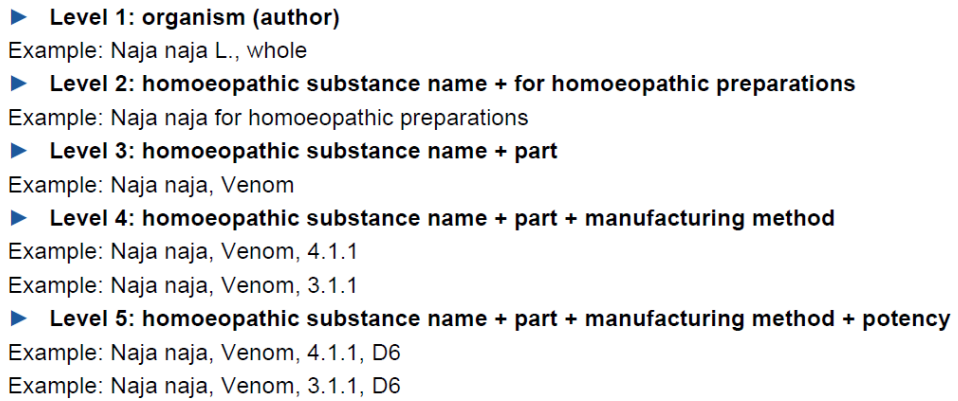
→ Representation and contribution in specific bodies

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

Swissmedic IDMP Advisory Group Meeting, 13.03.2024

Previous efforts towards implementing IDMP

- **Dose forms** – migrated to EDQM Standard Terms in 2013 (still ongoing)
- **Substances in general** – mapping to UNII since 2014 (ongoing, ca. 70% are mapped)
- **Homeopathic specified substances** – handling according to EU-SRS Homoeopathics guide, version 1.0



- OMS-ID's for Swiss organisations with an establishment license – since 2022
- Website on IDMP @Swissmedic: Identification of Medicinal Products (IDMP) (swissmedic.ch)

Current focus: Upgrading Swissmedic's Data Model to IDMP

Swissmedic IDMP Data Model:

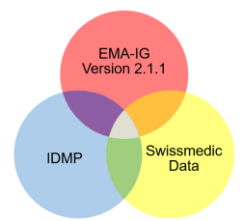
- Developed an internal SMC data model based on the 5 ISO IDMP-standards
- Challenged the current data model on internal and external business value
- Prioritised the interoperability of the data model and FHIR structure

Additional data fields (vs. EMA)*:

- Special Measures
- Physical Characteristics (Scoring)

Data fields not implemented*:

- Name Parts
- Risk of supply shortage



*subject to change, not exhaustive

Controlled vocabularies:

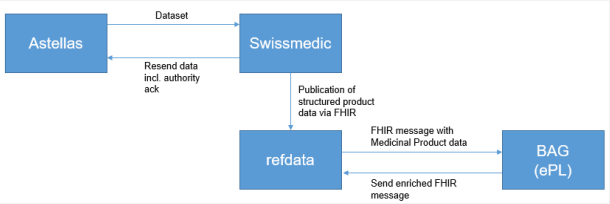
- 17 Swissmedic specific lists, e.g.:
  - *Medicinal Product Category* is more detailed than EMA
  - *Regulatory Authorisation Type* and *Procedure Type* have a different legal basis
  - *Scoring* is an additional list not used by EMA

By building the **new Swissmedic data model** on the basis of ISO IDMP, a **foundation for national and global interoperability** between health authorities and other institutions is formed.

Next steps: Data exchange pilot with key stakeholders, IG …

IDMP Pilot:

- Finalised data scope
- Align and define business processes with stakeholders
- Align on Swiss FHIR standards



Swissmedic IDMP Implementation Guide V1.0:

- Based on EMA IG Chapter 2 and focused on Pilot data scope
- Exchange with IDMP Advisory Group

(Homoeopathic) Substance database

- Implementation based on the Specified Substance structure
- Transfer of homoeopathic substance data from legacy system(s) into new database

Moving forward, we will focus on **scoping of the IDMP Pilot,** the **development of the Swissmedic Implementation Guide** and the development of the **substance database.**

Overview

IDMP Readiness

Opportunities

Challenges

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**

Overview

IDMP Readiness

Opportunities

Challenges

Challenges at Swissmedic

- **Migration of data in Swissmedic's IT system:**
  - Strengths of ingredients (currently not in line with IDMP standards)
  - Pharmaceutical product (concept currently missing)
  - Packaged medicinal product (current data not highly structured, mostly free text)
  - Indications (data not available in current database, neither as text nor coded)

- **Non-availability of a global identifier for organisations (foreign manufacturers)**

- **Building up technical know how regarding IDMP, including FHIR messaging**

Global IDMP Working Group

LATAM Regulators (Part 1): NOMA

IDMP Readiness, Opportunities, Challenges

Kristine Aasen, Elin May Merry
& Bernd Moeske
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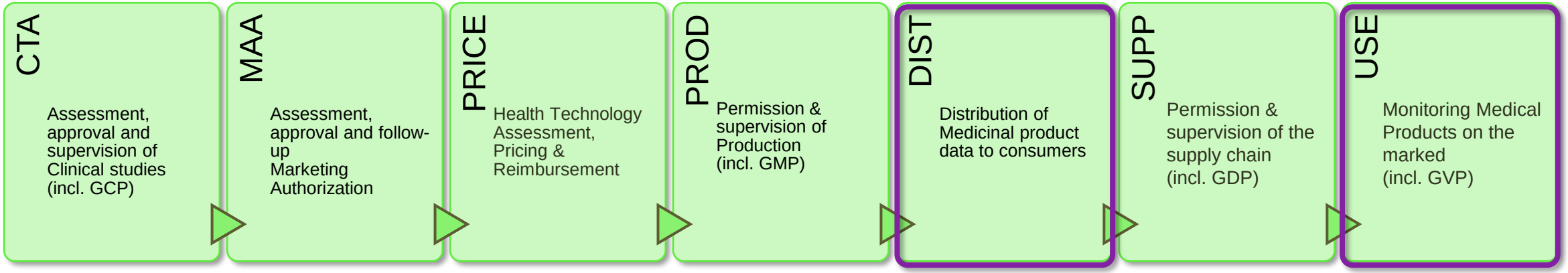
The Norwegian Medical product Agency (NOMA)

NOMA is the national competent authority of Norway

- 360 employees
- Located in Oslo
- Responsible for medicinal products, medical devices, blood, cells and tissues, narcotics and homeopathic
- Distributes data on 9000 medicinal products both with and without marketing authorisation
- The mission is ensuring that people have equitable and timely access to effective medicines of high quality to the lowest possible price

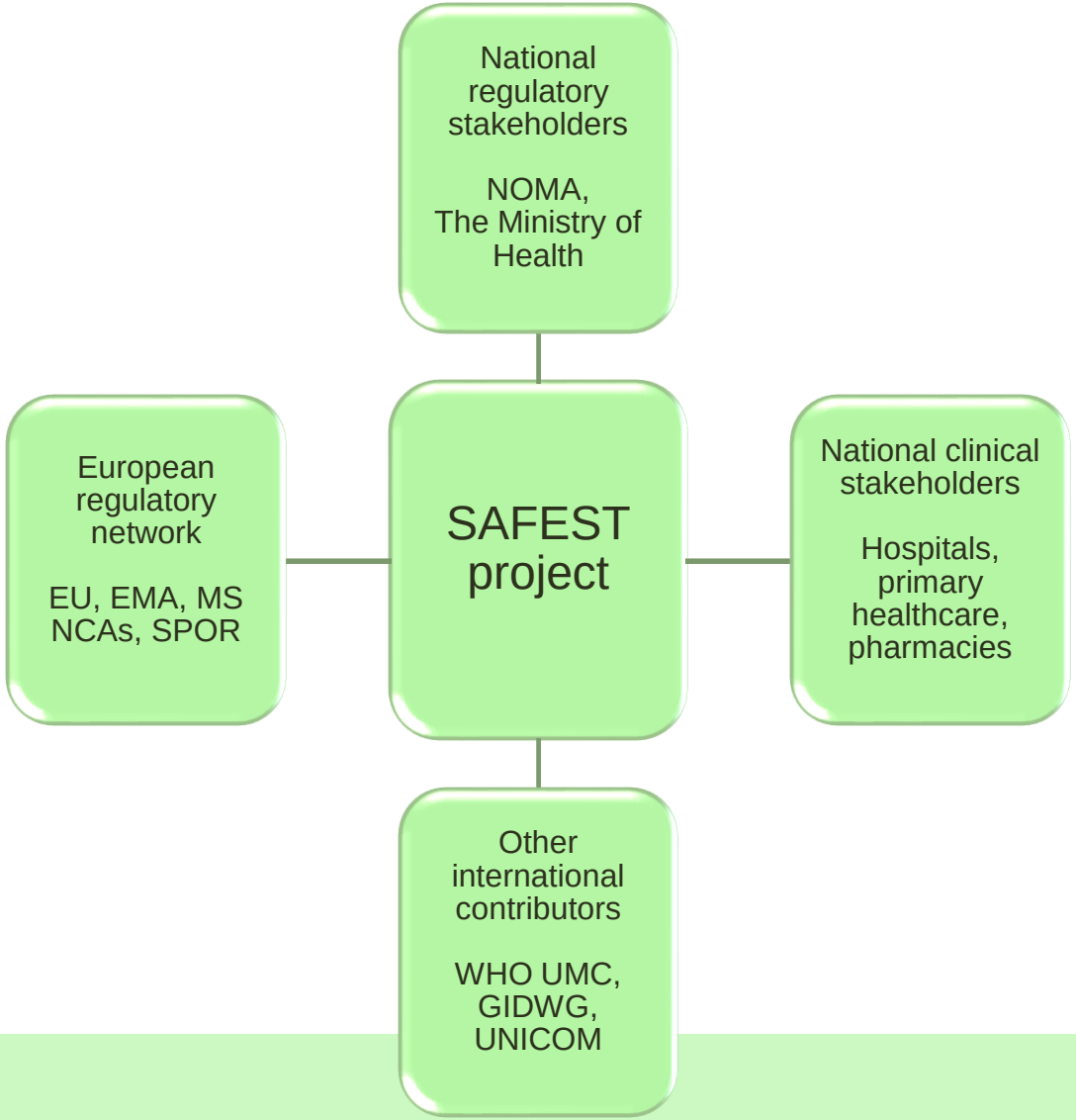
NOMA’s Value Chain



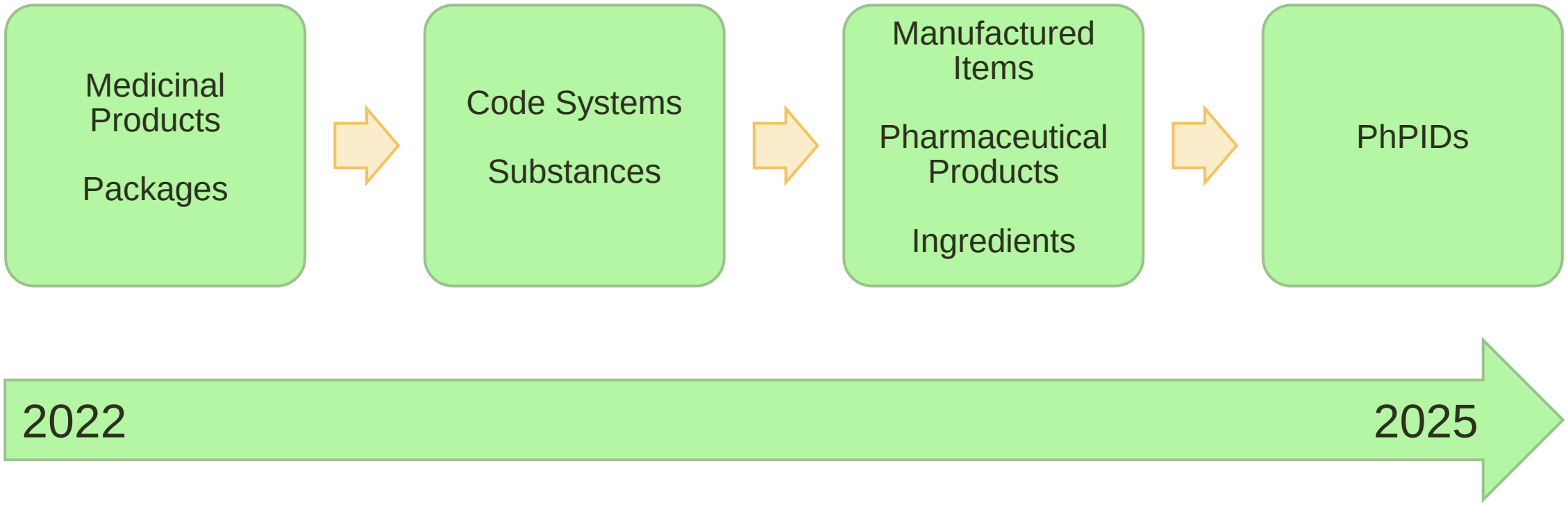
NOMA’s SAFEST project, - Getting to IDMP

Collaboration with different stakeholders

- National and international actors
- Regulatory and clinical domain



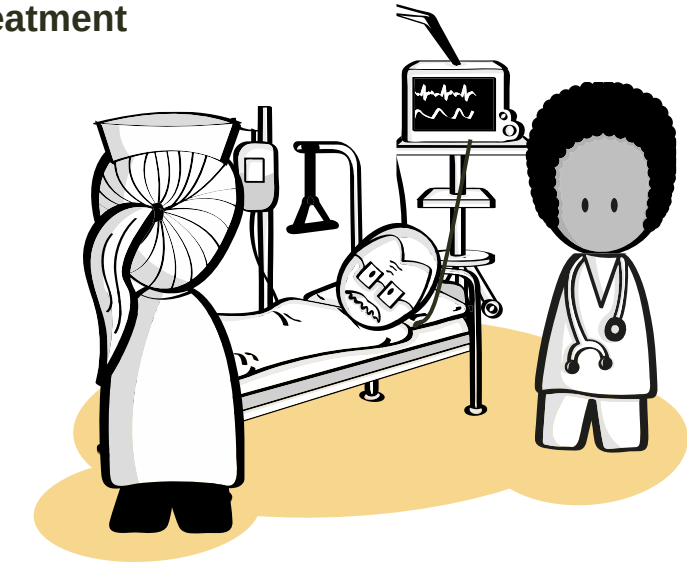
SAFEST deliverables timeline



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

Thomas arrives at hospital with chest pain

1 Patient admission, anamnesis and medication reconciliation

Thomas, aged 62, arrives at the hospital with increasing symptoms of known heart failure. He had a heart attack two years ago.

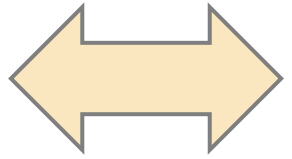
He has brought his current medication for heart failure prevention.

The doctor conducts a medication reconciliation

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

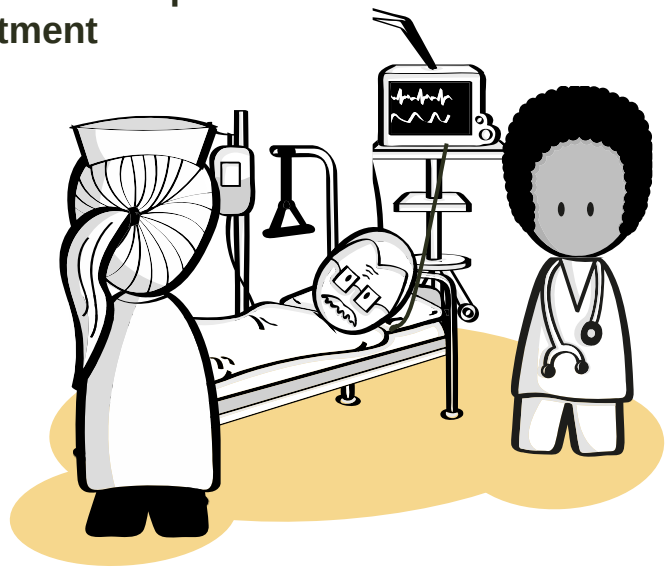
The doctor retrieves Thomas's medication record from the E-prescription system. He confirms the product details and reviews the PhPID level 4 specifying the substance, dose form and strength.

He then admits Thomas to the cardiology ward for further treatment



Thomas is admitted to the ward and his medication list is transferred to the electronic medical record system

2 Plan and complete medical treatment

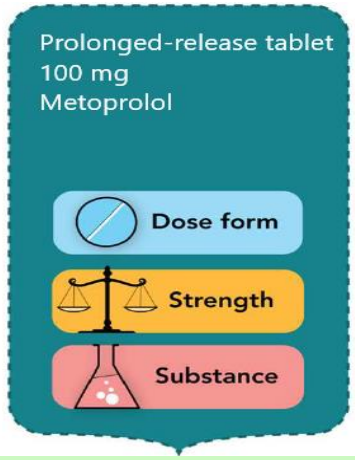


At the hospital ward Thomas will continue to receive his home medication.

His medication is converted to PhPID level 3 and transferred to the electronic medical record to monitor treatment during his stay.

Electronic Health Record system

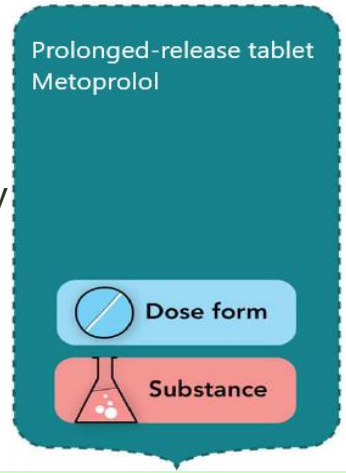
PhPID level 4



Dosage:
1 tablet,
1 x per day

converting

Dosage:
100 mg,
1 x per day

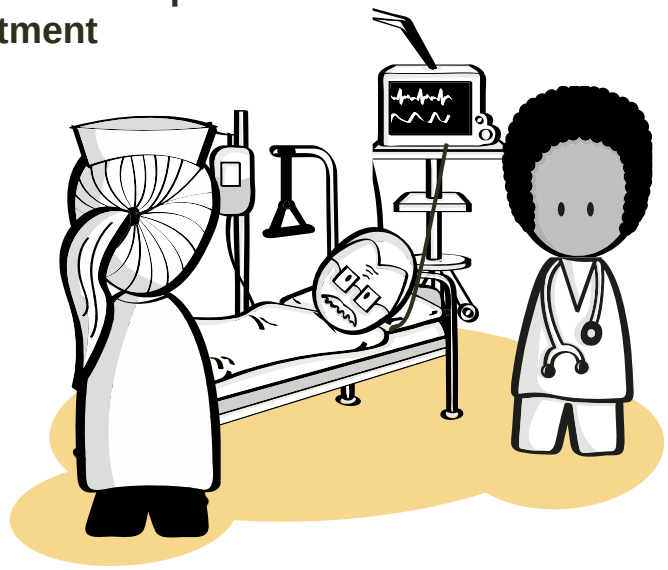


electronic medical record system

PhPID level 3

The nurse dispenses and administers the medication

2 Plan and complete medical treatment



The medicine room stocks only 50 mg prolonged-release tablets under the brand name Bloxazoc, a generic equivalent of Selo-Zok.

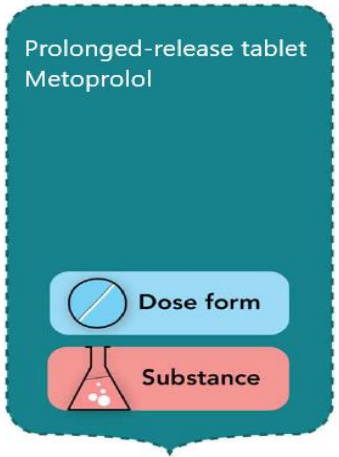
Bloxazoc shares the same PhPID level 3 as Selo-Zok, meeting the hospital's prescription requirements.

The nurse scans the 50 mg Bloxazoc package, and the system indicates that 2 tablets should be given to Thomas.

The nurse then administers the medication.

PhPID level 3

Dosage:
100 mg,
1 x per day



Both Selo-Zok 100 mg and Bloxazoc 50 mg can be used

Before hospital discharge, the doctor issues a new prescription with an increased strength

3 **Finish treatment and discharge**

The hospital doctor increases the medication dose from 100 mg to 200 mg.

To simplify administration for Thomas at home, the tablet strength is increased to 200 mg so that he can continue taking 1 tablet every morning.

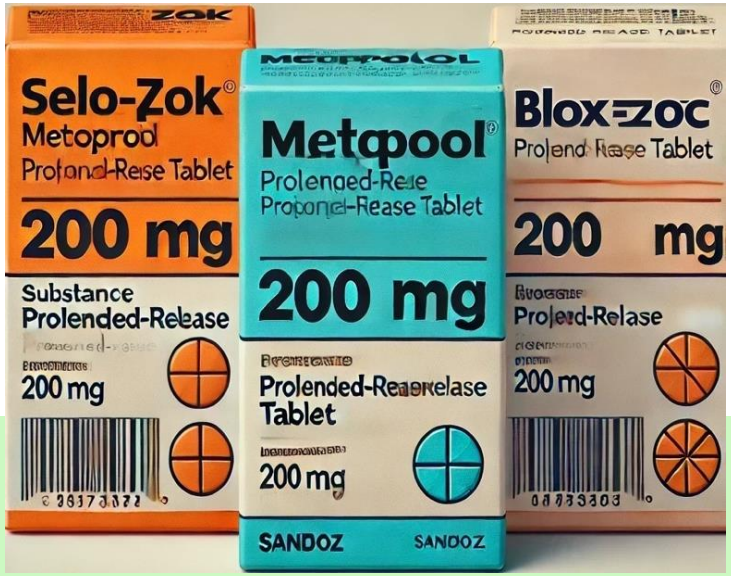
The doctor creates a new prescription based on PhPID level 4, detailing the substance, dose form, and strength.
The prescription is then transferred to the national E-prescription system.

Thomas picks up the medication at the pharmacy

3 **Finish treatment and discharge**

The pharmacist tells Thomas he can choose from three different brands with the same clinical effect.

According to the national reimbursement scheme, the cheapest brand is free, but he can pay extra for another brand. Thomas chooses the free option.



The benefits of using PhPID in hospital healthcare

- The national goal is to increase the use of substance-based prescriptions, based on PhPID, to **improve flexibility and reduce medication costs** at pharmacies
- PhPID level 3 in hospitals **improves flexibility and saves nurses time** by allowing them to dispense available medicines with the same clinical effect
- **Improves efficiency for doctors** by reducing the need to change prescriptions when certain strengths are out of stock
- **Patient safety is ensured** through the hierarchical structure of PhPID levels 3 and 4.
- Standardization with PhPID as the national and global identifier for substance-based prescriptions **increases safety and system interoperability**

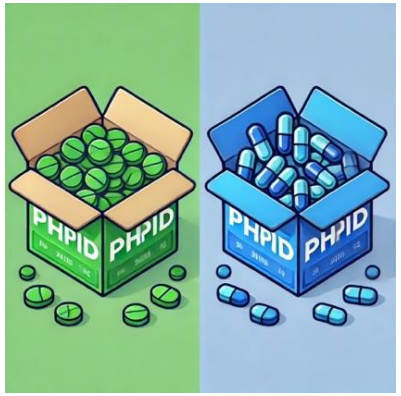
Medicinal Product Dictionary at NOMA: From Proprietary to IDMP and PhPID

- Our “Recipe” for getting to IDMP and PhPIDs
- Spotlight:
  Harmonizing Pharmaceutical Products
- Collaboration with UMC:
  Global and National PhPIDs
- Status and Roadmap

Getting to IDMP: A Gradual, Step-by-Step Process

Our “recipe” for transitioning from a proprietary product database to an IDMP-based Medicinal Product Dictionary and PhPID

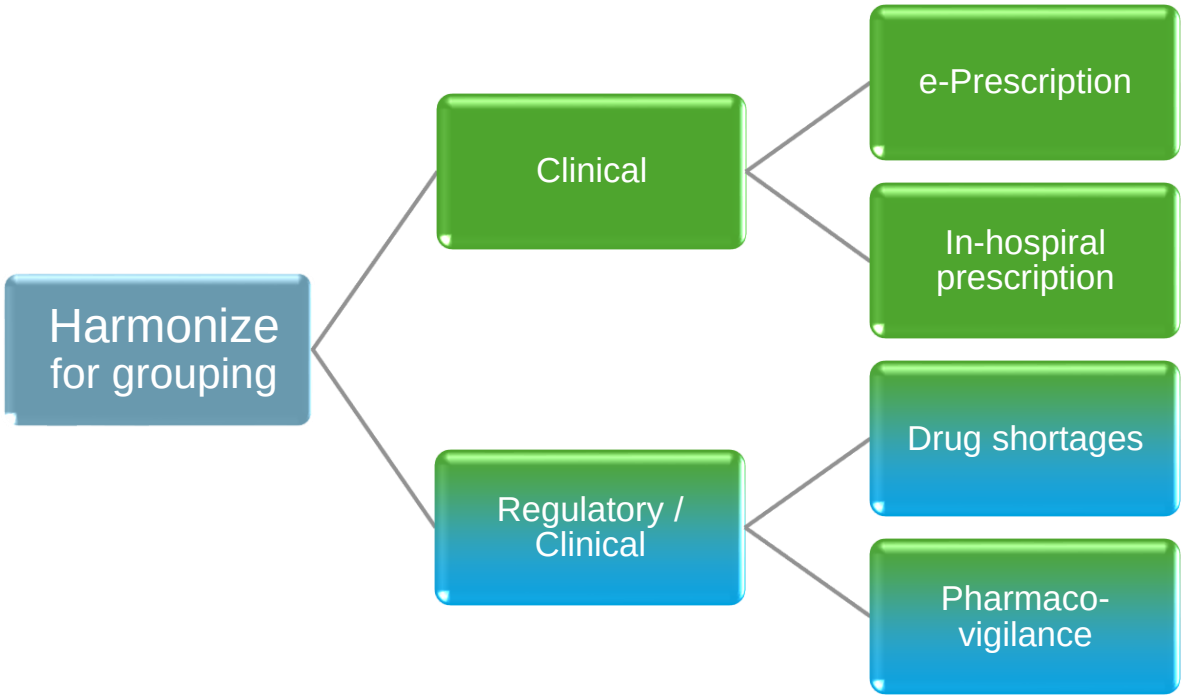
Centralize data on Medicinal Products → Transform into IDMP format → Harmonize for grouping → Design and generate PhPID

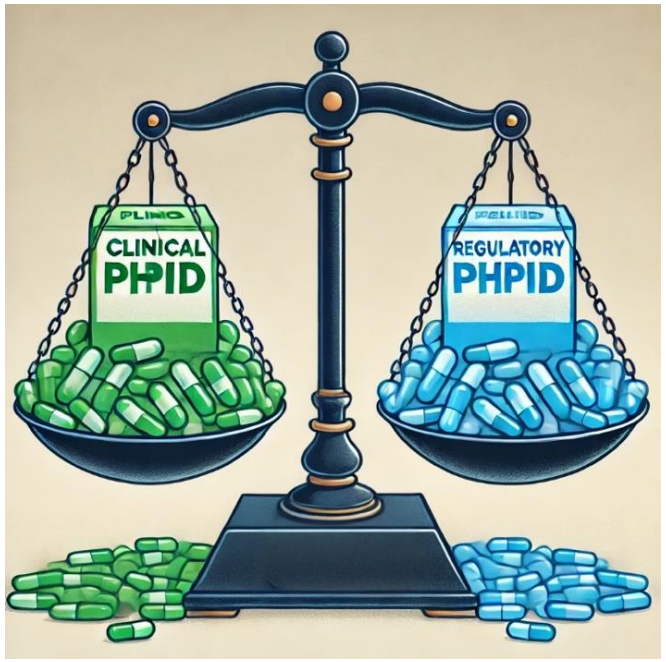


Harmonizing is Essential

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.





Collaboration with WHO UMC

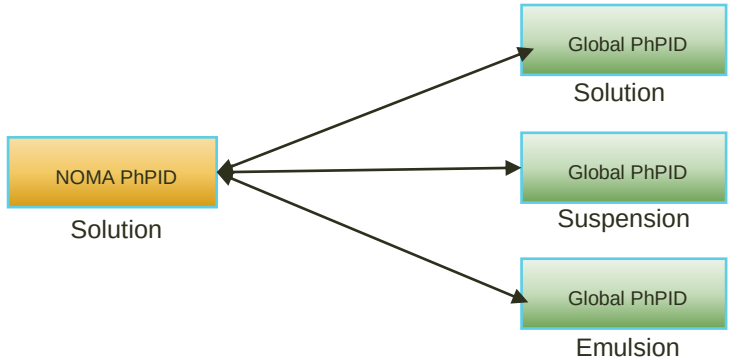
Tight collaboration with UMC has been a key success factor in our journey.

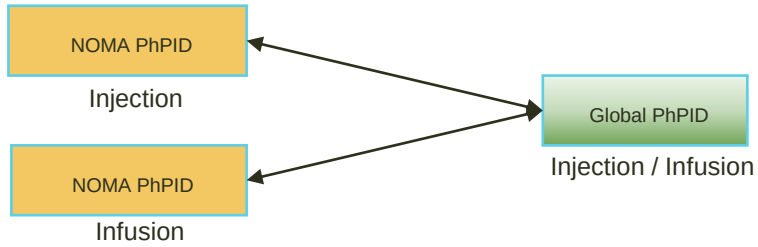
UMC and NOMA expect and accept that national and global PhPIDs may differ in some instances.

However, we do not anticipate that these differences will significantly impact the value of the PhPIDs for their respective use cases.

National and Global PhPIDs at NOMA

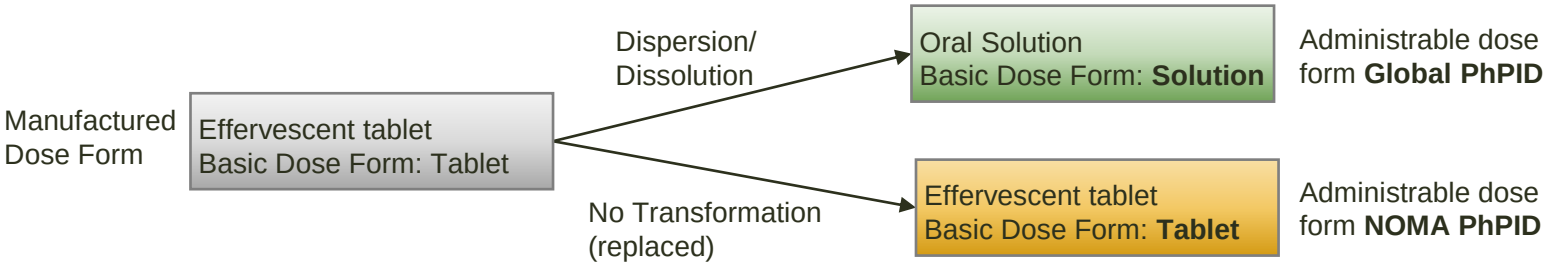
- NOMA has established business rules for PhPID generation and developed a PhPID generation tool to validate the results.
- We are currently testing UMCs global PhPID service API and a gap analysis is planned for Q4 2024.
- Our medicinal product dictionary will contain both national and global PhPIDs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





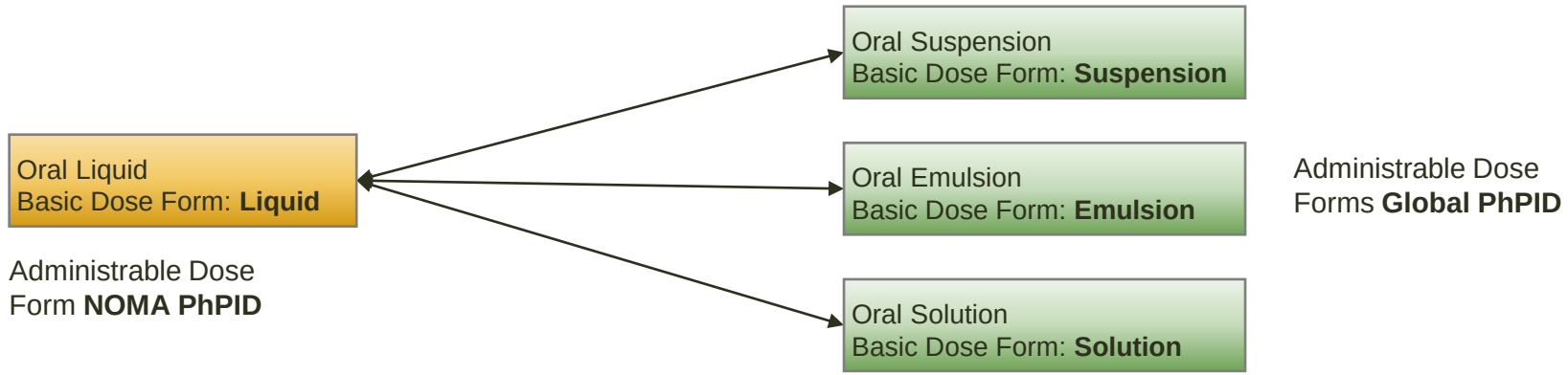
Clinical Need for National Adaption of PhPIDs Example 1: Effervescent Tablets are Tablets.

- Effervescent tablets are generally dispersed in water before administration. The intended (RMS/SPOR) administrable dose form is 'Oral Solution' or 'Oral Suspension'
- In clinical practice, prescribing an oral solution should not result in administering effervescent tablets. Therefore, 'Tablet' is used when prescribing this medication.
- These tablets have an equivalent clinical effect and should be grouped with other general tablets, sharing the same PhPIDs at levels 3 and 4.
- NOMA has adapted the PhPID generation by using the basic dose form 'tablet' instead of 'Solution' or 'Suspension'



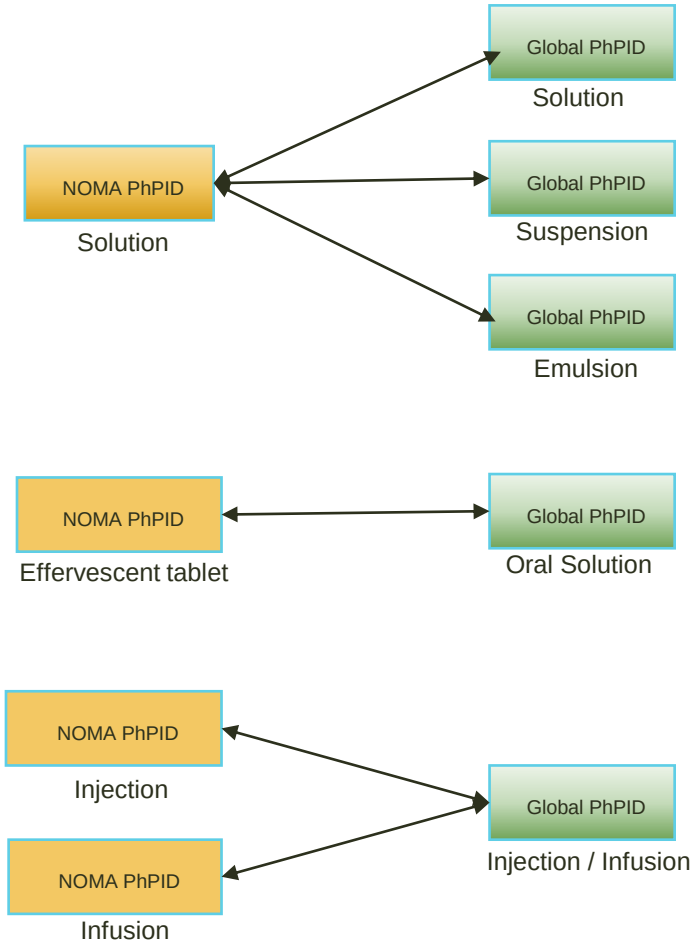
Clinical Need for National Adaption of PhPIDs Example 2: Harmonize Dose Forms for Liquids

- EDQM dose forms vary between Oral Solution, Oral Suspension, and Oral Emulsion
- Clinical practice prefers not to choose between different dose form variants and requires all variants to be harmonized into a single dose form and PhPID
- These variants have equivalent clinical effects and are interchangeable. It is crucial to allow hospitals to use all variants during stock shortages



Using both National and Global PhPIDs at NOMA

- NOMAs focus has been on supporting clinical use cases
- The global PhPIDs do not fully support our national clinical processes and needs.
- Therefore, we will include the global PhPIDs in our MPD and enable mapping from and to global PhPIDs without compromizing patient safety
- Future international collaboration on clinical use cases might result in convergence between national and global PhPIDs



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.

Global IDMP Working Group

LATAM Regulators (Part 1): Health Canada

IDMP Readiness, Opportunities, Challenges

Karin Hay
Health Canada

Context | Overview of the Health Products and Food Branch

Our mandate

We work to protect and promote the health and safety of Canadians by being **a trusted scientific and regulatory authority for health products** and food in Canada and internationally.

The Health Products and Food Branch's (HPFB) mandate is to manage the health-related risks and benefits of health products and food by:

- minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food,
- providing information to Canadians so they can make healthy, informed decisions about their health

Health Product Business Lines

- Biologic and Radiopharmaceutical Drugs
- Pharmaceutical Drugs
- Medical Devices
- Natural and Non-prescription Health Products
- Marketed Health Products
- Veterinary Drugs Directorate

Open Health Product Datasets

Drug Product Database (DPD)
13,000 Drugs 19,500 Ingredients

Natural Health Products Ingredients Database (NHPID)
Licensed Natural Health Products Database (LNHPD)
7,000 Ingredients, 82,000 Licensed Products

Adverse Reaction Reports
1.1 M Drugs Reports 40k Medical Device Reports

Clinical Information Portal
+200 Products, +11,700 documents, 5M pages

New Health Product Approvals

	New Drugs: 80 /yr	Generic / Biosimilar: 150 /yr
	Class IV: 50 /yr	Class III: 270 /yr
	New Substances: 500 /yr	Product Licenses: 8,100 /yr
	New Drugs: 5 /yr	Generic / Biosimilar: 15 /yr

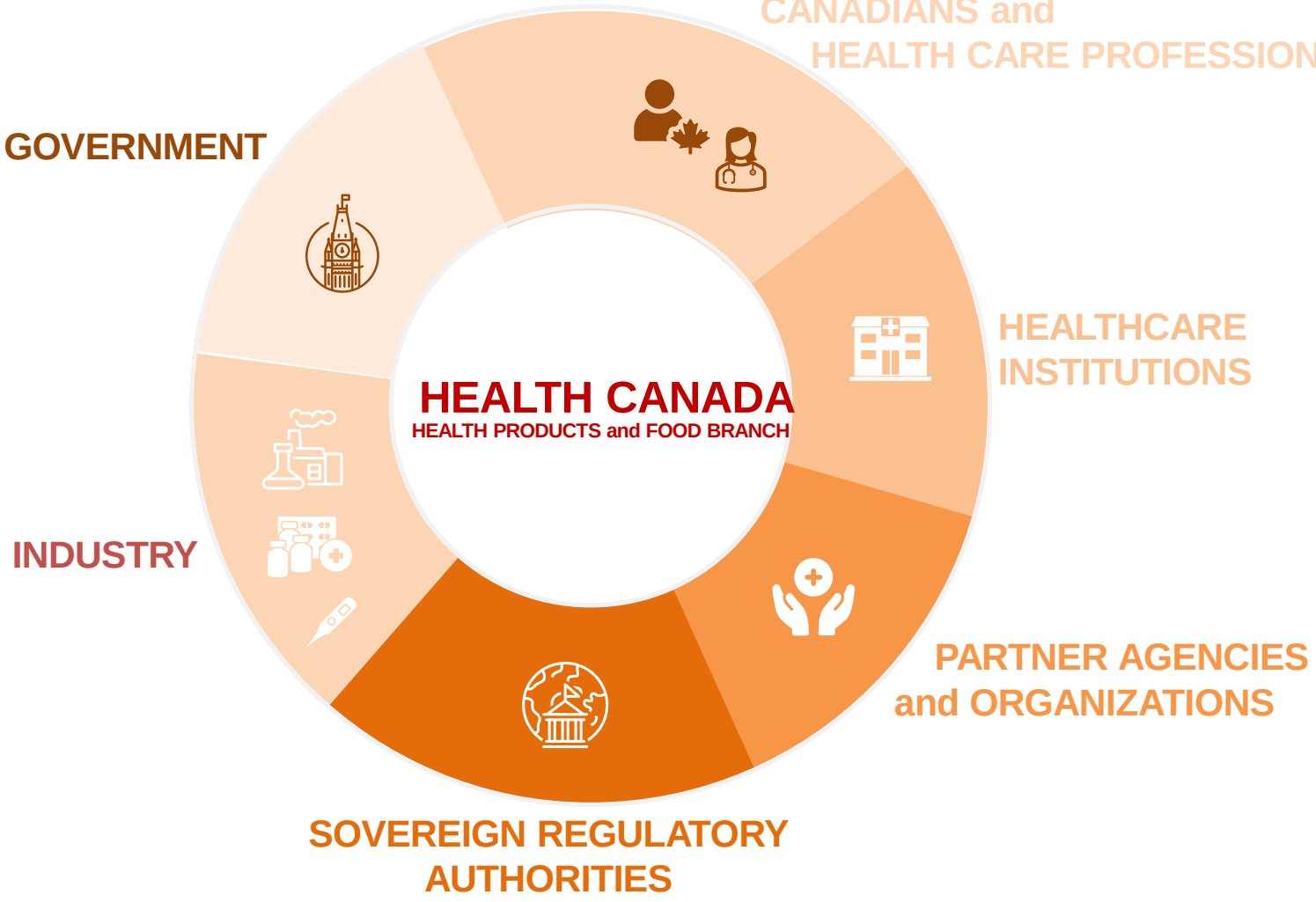
Clinical Trials Approved

1,200 /yr | 140 /yr

Special Access Authorizations

12,500 /yr | 3,100 /yr

Operating Context | Supporting our Internal and External Stakeholder's needs

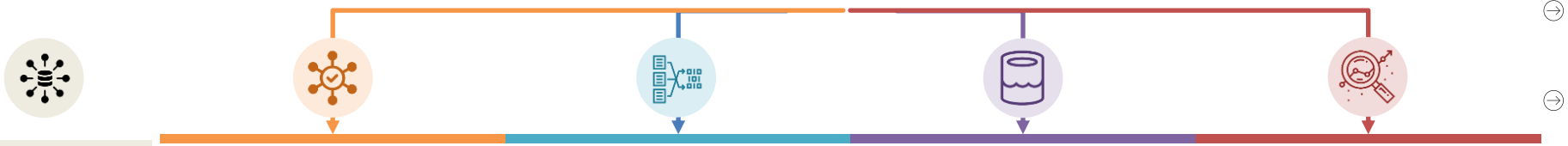


A varied and complex portfolio of stakeholder needs

+ Increasing number of Health Products
+ Increasing complexity, novelty of Health Products and size of datasets
+ Demand for timely sharing of evidence-based data

Data Modernization: Improving Evidence-Based Decision Making and Transparency

Supporting regulatory modernization agenda through improved transparency, increased domestic and international collaboration and better operational efficiencies



	STANDARDS	MODELLING & TRANSFORMATION	INFORMATION AT SCALE AGGREGATION	HOLISTIC ANALYTICS AT SCALE
DATA				
Key Activities	**Define standardized data**: ▪ Identifiers ▪ Definitions ▪ Formats Accelerate adoption of internal and international standards in key areas	**Create aligned meta data model** and relationships between datasets with extensions for what we know, don't know, expect and observe; operational support	Combine (newly standardized) source data sets into a **centralized repository** (data lake), enabling 'whole of business' analytics Build platform and ingest source datasets	Research and **prototype novel techniques and technologies** for holistic **predicative analytics and signal detection** (e.g. machine learning predictive analytics against centralized repository/data lake)
	Develop Policy Frameworks for data standard requirements, establish master data sets inventory and scorecards to measure inherent risks.	**Transform source datasets and update line of business applications** to support data standards, readiness (e.g. intake updates)	Create data linkages and extend ingestion routines to **external trusted sources and partner datasets**	**Implement** successful tools, techniques and operational support for regulatory decisions, surveillance and reassessment decisions.
Enabling regulatory and IT modernization	**Develop and adopt data standards , create a master data set list and scorecards of inherent risks**	**Transform processes and systems to support new standards and enable data aggregation**	**Combine enhanced data sets into a centralized repository creating a holistic information asset**	**Introduce new tools that support large dataset analysis**

FOCUS OF ACTIVITIES: DUE DILIGENCE & POLICY → PEOPLE & PROCESSES → TOOLS & TECHNOLOGY

KEY OUTCOMES + ALIGNMENTS

- **Improves transparency**
- **Deeper insights to support decision making**
- **Reduces manual workloads in data gathering / supports greater focus on assessment & evaluation**
- **Improves services levels**
- **Increases ability for regulatory collaboration, industry and health systems engagement**
- **Uphold data stewardship accountabilities**
- **Play leadership role in Canada's adoption of data standards and analytics for health products and food**

Benefits will accrue iteratively overtime as polices are implemented and mature across different product lines and key enterprise platforms.

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

Highlights | Industry and Health Products

Projects and Initiatives Highlights

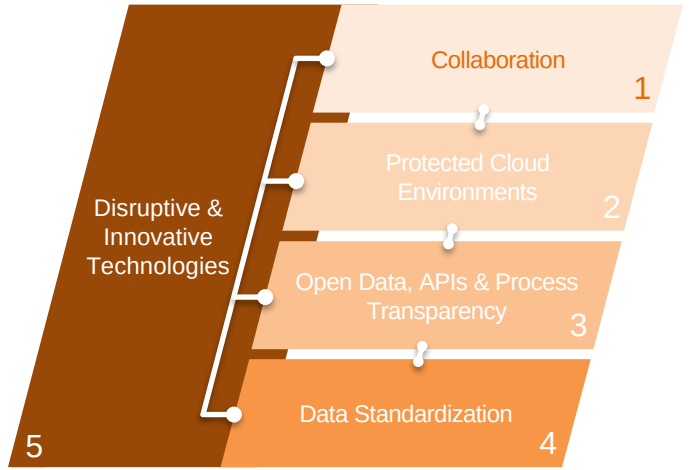
RECENT

- 3 4 ○ XML Product Monographs
- 3 4 ○ Submission eValidator
- 3 4 5 ○ CVP Elastic Search
- 3 ○ PRCI (Public Release of Clinical Information) Portal
- 3 ○ COVID-19 Vaccines & Treatments Portal

FUTURE

- 3 4 5 ○ Clinical Trial Modernization – IT Transparency
- 2 3 4 ○ DHPR v2 Portal
- 2 3 4 5 ○ AI Enable Incident Report Filing & Data Bridging
- 1 2 4 ○ International Regulator Submission Collaboration Space
- 1 2 3 4 5 ○ AI/ML/PA - Signal Detection Adverse Incidents
- 3 4 ○ Special Access Program – Mobile

Technology Synergy Model



1 2 3 4 5

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

Data Governance at HPFB

Guiding Principles

- Optimize the capture, analysis, and display of data to be meaningful to Canadians.
- Prioritize transformation to structured data for all product lines to make our data more open and interoperable.
- Support modernization efforts that enable HPFB to be a modern, agile regulator.
- Maximize the use of key tools that create efficiencies for HPFB and stakeholders.

- ✓ **People:** Individuals and bodies who advise on or undertake data governance and stewardship activities across different levels of HPFB driving 'data governance by default' from policy development to implementation.
- ✓ **Data Leadership and Strategy:** One voice to articulate, disseminate, and promote of the vision and plan of action for data in the branch.

- ✓ **Roles, Responsibilities, and Accountabilities:** Clear duties and obligations undertaken by individuals and bodies to support data governance across the branch.

- ✓ **Capacity and Skills:** Technical, policy and science skills, competencies, and tools that enable HPFB employees to govern data.
- ✓ **Community:** Groups and individuals involved or interested in data governance and stewardship including the federal, provincial, territorial, or other level of government in Canada; private sector; academia; civil society; international organizations; or public sectors in other jurisdictions.

Community and Change Management

Awareness raising and broad dissemination of data governance priorities and best practices across HPFB, supported by plans to drive organizational change.

IDMP| Opportunities

Improving Data Quality

A 360° view of HPFB's information assets to help determine where data can be improved. The scorecard is an important tool to help improve HPFB's data quality and lead to the development of improved technology solutions and the early identification of risks in our data.

Data Quality Health Check Score
Validity and Completeness
Accuracy and Conformity
Uniqueness and Consistency
Accessibility and Timeliness
Policy and Governance
Total (/156)

IDMP| Challenges

- Confidence building and communication to encourage change takes time
- Change management, and moving from a paper-based to digital environment in the regulatory context requires a high effort to implement and, in some cases, can overshadow the realized benefits of standardization.
- Transparency and confidentiality of data can often act as a barrier to building high quality data sets
- Complexity of the domain combined with resourcing can slow down growth

Global IDMP Working Group

Outcomes from Regulatory Forum
IDMP Readiness, Opportunities, Challenges

Isabel Chicharo (EMA) & Ron Fitzmartin (US FDA)

Note: The summary of outcomes from Regulatory Forum are the part of meeting minutes

IFPMA

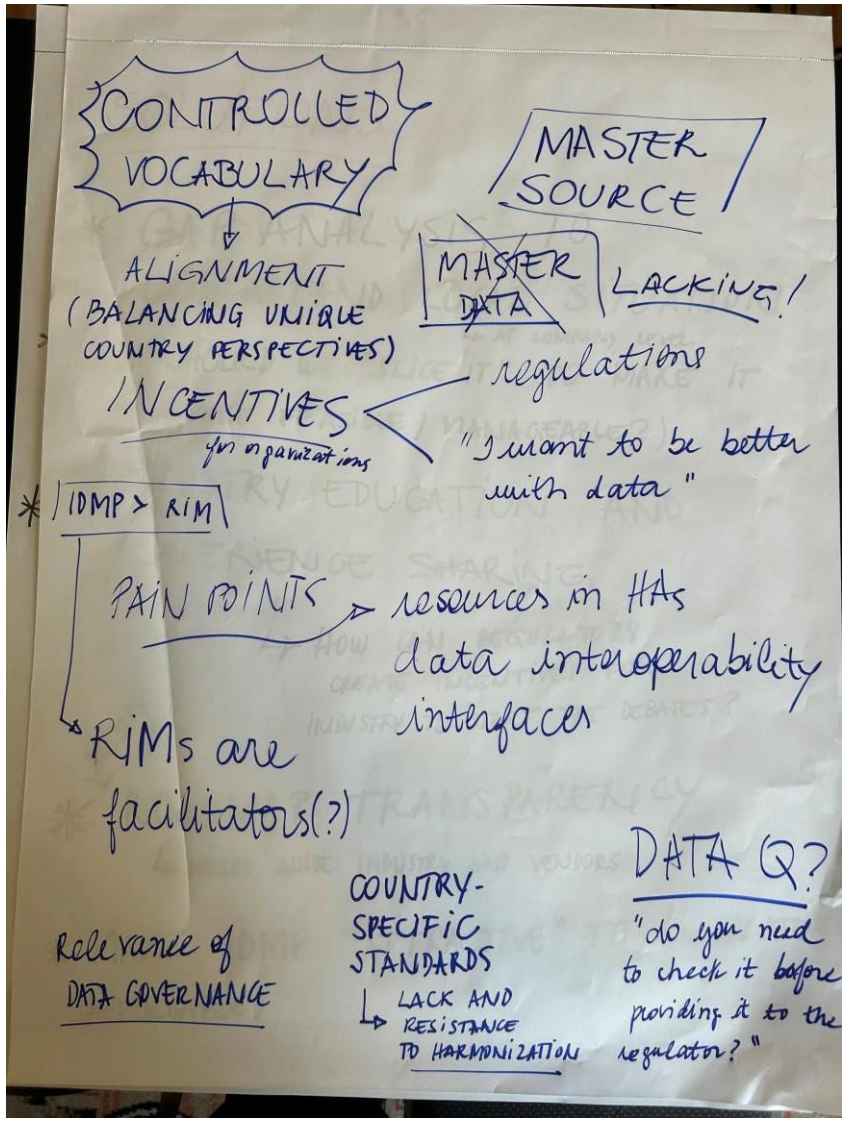
Mini-Workshop: IDMP in LATAM Region

Industry Outcome

11 Sept 2024

IDMP Status and Challenges

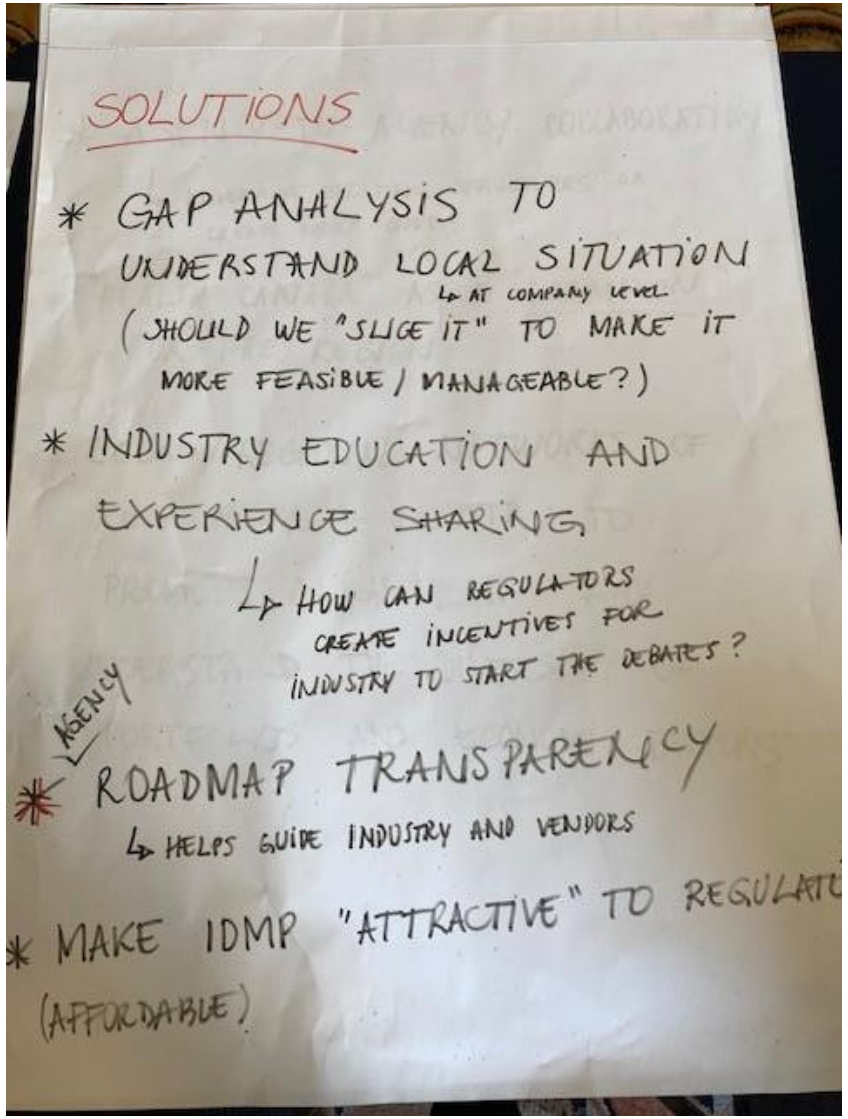
- **Initial Information Sessions:** Held last year by IFPMA, Interfarma, Anvisa, and Sindusfarma for the industry in Latin America.
- **Lack of Understanding:** There is not a clear understanding of the IDMP standards.
- **Data Quality Issues:** Local data is not fully under control or at the right quality 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.



IFPMA

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

Joint Discussion on Outcomes & Action Planning

Nelio Aquino (ANVISA)
& Joerg Stueben (Boehringer-Ingelheim)

Note: The summary of outcomes from Action Planning are the part of meeting minutes

Thank you for your work on IDMP!