Global IDMP Implementation: Getting Closer to the Goal

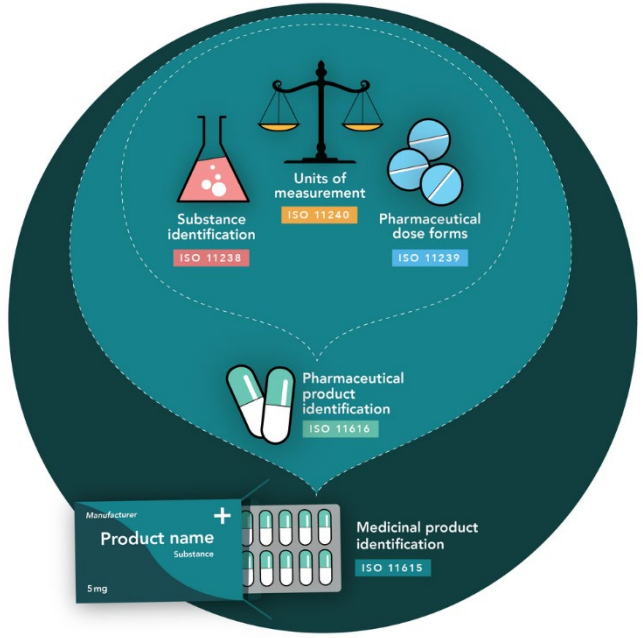
Ron Fitzmartin, PhD, MBA
Sr. Advisor
Office of Regulatory Operations
Center for Biologics Evaluation & Research
U.S. Food & Drug Administration

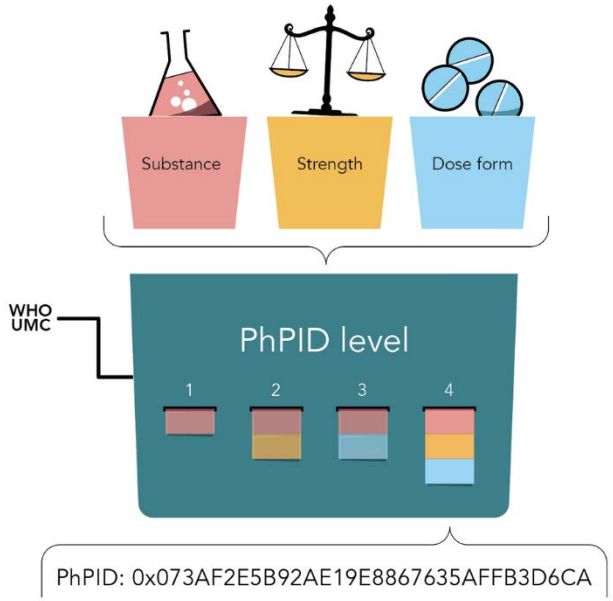
Ta-Jen (TJ) Chen
Project Management Officer
Office of Strategic Programs,
Center for Drug Evaluation & Research
US Food & Drug Administration

Olof Lagerlund, PhD
Substance Expert
Uppsala Monitoring Centre
WHO Collaborating Centre for
International Drug Monitoring

What is IDMP?

- **A set of five ISO standards that:**
  - Establishes a framework to uniquely identify and describe medicinal products with consistent documentation and terminologies.
  - Uses substance, dose form and strength information for global identification.
  - Products share the same *pharmaceutical product identifier or* PhPID, regardless of e.g., brand name & packaging.





Global IDMP Working Group

Benefits of Global IDMP

Safety & Pharmacovigilance

- Uniquely identifying & consistently exchanging medicinal product and substance identifiers, e.g., ICSRs, SUSARs.
- Signal management can access more accurate reports / data that can be integrated globally.

Medicinal Product Shortage

- Leads to improved traceability and supply chain integrity
- Improved monitoring of global supply chains for product quality issues and risk analytics
- Improved surveilling of falsified / counterfeit products

Cross-Border Healthcare

- Allows healthcare providers (HPs) to compare drug information across different regional / country medicinal products databases.
- Helps HPs fill a prescriptions across regions and countries or fill it with safe alternatives

Interoperability

- Improved interoperability by making it easier to share product and substance information across jurisdictions
- Internationally, allows regulators to share information on medicinal products and re-used across different purposes

Global IDMP Working Group (GIDWG)

- GIDWG was chartered in 2021 following a WHO IDMP Workshop in 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 and sustain a regulatory framework, including business rules, best practices and operating model, for global IDMP implementation and maintenance of global identifiers for marketed products.

Current GIDWG Member Organizations

FDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Uppsala Monitoring Centre

swissmedic

Health Canada
Santé Canada

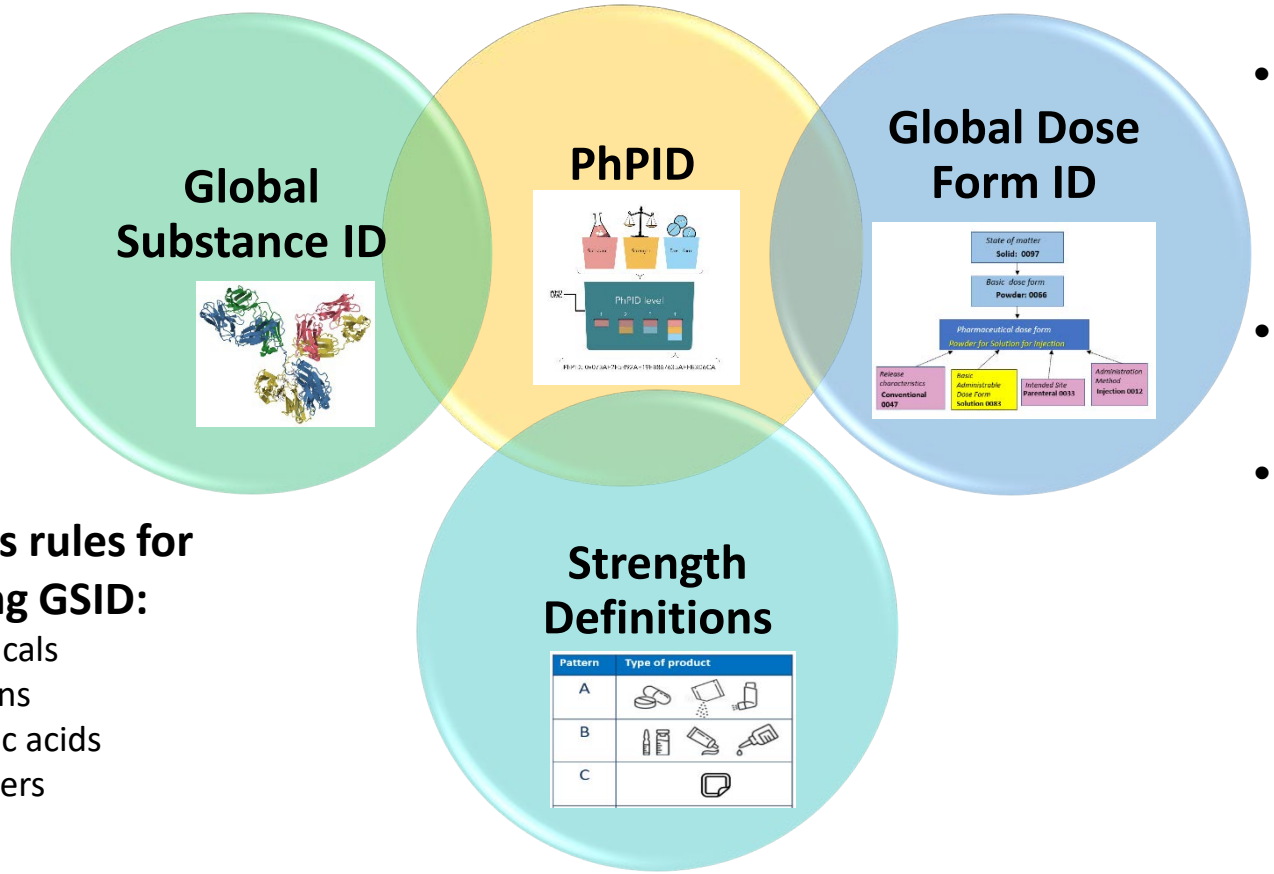
Agência Nacional de Vigilância Sanitária

SFDA

Norwegian Medical Products Agency

IFPMA

GIDWG Projects – Making the Standards "fit" for Global Use



Business rules for assigning GSID:

- Chemicals
- Proteins
- Nucleic acids
- Polymers

- **Use of four EDQM dose form characteristics to describe dose form.**
- **Confirmed for input to global PhPID.**
- **Confirmed semi-automated process**

Utilizing a pattern framework determines how the strength should be expressed.

www.gidwg.org

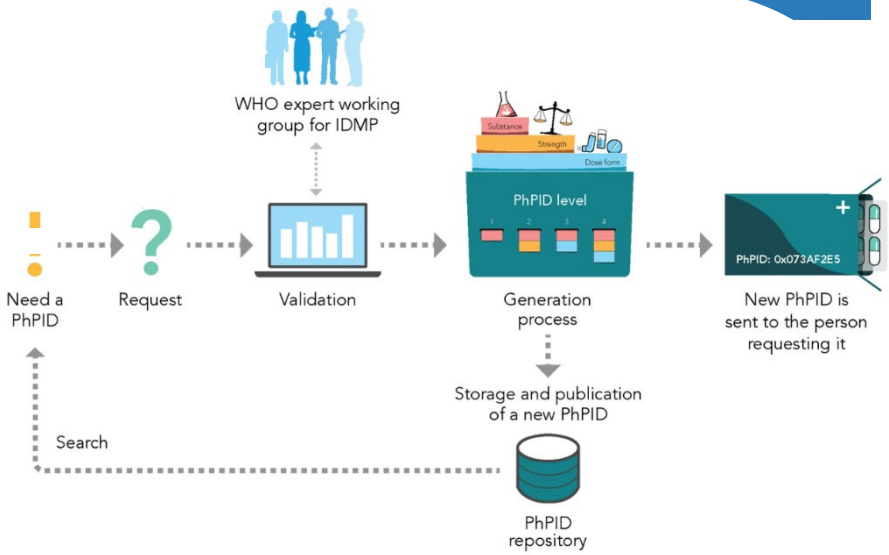
SMEs From

FDA
EMA
HMA-SVG
ANVISA
Health Canada
Swissmedic
UMC
WHO PVG
WHO INN
EDQM
USP
ISO/CEN
HL7
U.S. NCI / EVS
IFPMA

End-to-End Testing

Purpose:

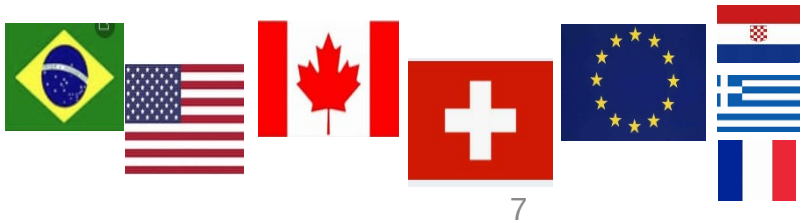
Testing framework, including business rules, best practices, software and operating model, for the global IDMP implementation and maintenance of global identifiers for marketed products.



Scope:

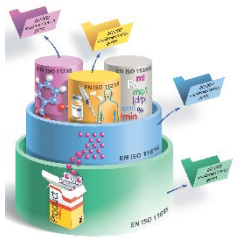
- Selected substances dataset - 150 substances which were represented in ~2,000 medicinal products.
- Harmonize medicinal product information and generate PhPIDs for medicinal products based on GIDWG Business Rules
- Evaluated the value of gPhPIDs in Pharmacovigilance, Drug Shortages and Cross-border Healthcare

Countries:

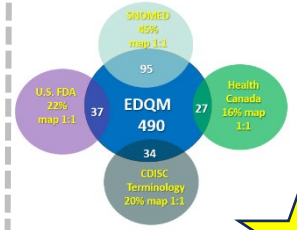


GIDWG's Journey so far…

2012 — ISO IDMP



2018 — ISO 11239 - Global implementation

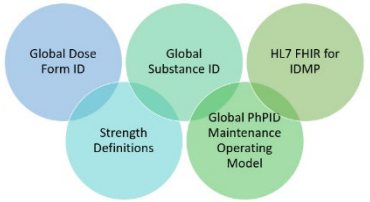


2019 — WHO Workshop

2021 — GIDWG

Global IDMP Working Group

2022 — GIDWG Projects



Q4 2023 — GIDWG E2E Testing & Report

2024