DCI Network and UNICOM presents

Unlocking the Potential of IDMP: Global Strategies for Enhanced Pharmacovigilance and Data Management

Wednesday, 05/22/2024 - 12:00 EDT

Robert Stegwee, PhD
Work package leader EU UNICOM project on behalf of Nictiz - CEN/TC 251
Strategic Consultant for Health IT, focusing on meHealth for citizens and professionals in health and care

Robert Vander Stichele, PhD
Work Package Task Leader EU UNICOM project at I-HD
Professor, Ghent University, Ghent, Belgium

Ron Fitzmartin, PhD, MBA
Senior Advisor, Office of Regulatory Operations, Data Standards Branch, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration

Yuri Quintana, PhD
Chief of Division of Clinical Informatics, Beth Israel Deaconess Medical Center
Assistant Professor of Medicine, Harvard Medical School

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Co-organized by DCI and UNICOM

UNICOM

The UNICOM project is financed by the European Commission within the framework of the Research and Innovation Program "Horizon 2020", this action has a budget of 21 million euros, with an EC funding of 19 million euros. The consortium is composed of 70 organizations that includes 18 European countries and the United States, either as beneficiaries or as observers. UNICOM will focus on the development of the IDMP set of standards (Identification of medicinal and pharmaceutical products) of the International Organization for Standardization (ISO), its testing, implementation and dissemination for regulatory purposes by the National Pharmaceutical Agencies, for global pharmacovigilance and for the advancement of European cross-border dispensing. Learn more at https://unicom-project.eu

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The Division of Clinical Informatics (DCI) at Beth Israel Deaconess Medical Center (BIDMC) is a leading center for scalable informatics research and policymaking. The DCI Network accelerates solutions to complex healthcare problems through multi-stakeholder alliances and strategic roadmaps, focusing on harmonizing data, improving patient engagement, and building trust in AI. Learn more about DCI at https://research.bidmc.org/dci
Learn more about DCI Network at https://www.dcinetwork.org

DCI NETWORK

Mission and Approach

- DCI Network Mission: Accelerate solutions to complex healthcare problems requiring multi stakeholder collaborations.
- Create new consortia and roadmaps to develop breakthrough initiatives.
- Provide a safe harbor for stakeholders to develop strategic alliances.
- Ensure wider inputs from patients and the public.
- Working Groups:
  - 1. Standardized Data Models for Patient Journey and Real-World Evidence
  - 2: Innovative Patient Engagement Strategies
  - 3: Innovative Applications of Artificial Intelligence in Healthcare
- For more information on DCI Network https://www.dcinetwork.org

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- If you are comfortable having your webcam on, please do.
- Please utilize the Zoom functions like raise hand and reactions to engage during the webinar.
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Unlocking the Potential of IDMP: Global Strategies for Enhanced Pharmacovigilance and Data Management

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DCI Network and UNICOM Webinar

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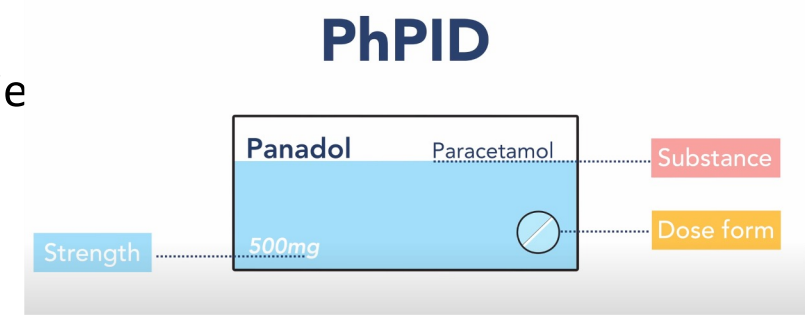
Introducing the Identification of Medicinal Products (IDMP)

A Universal Language for Medications

- Many medicines have different names and come in different forms even though they have the same active ingredients.
- IDMP is a set of five international standards developed by the International Organization for Standardization (ISO).
- These standards provide a common language for uniquely identifying and describing medicinal products.
- It is like a universal barcode system for medications, ensuring everyone can indetify the exact product being referred to.
- IDMP covers the entire lifecycle of a medicinal product, from development to post-marketing surveillance.
- A key output if the creation of a universal Pharmaceutical Product Identifie



More on IDMP: ISO - International Organization for Standardization https://www.iso.org

FDA and IDMP https://www.fda.gov/industry/fda-data-standards-advisory-board/identification-medicinal-products-idmp

Image Source: https://www.youtube.com/watch?v=UtZTjueEeQ0

Use Case 1: Pharmacovigilance and Regulatory Oversight

Scenario:
Pharmaceutical companies and regulatory bodies need a reliable and standardized way to track adverse drug reactions (ADRs) and ensure medication safety across different regions and healthcare systems.

Need for IDMP:

- The implementation of IDMP standards allows for the consistent identification and reporting of medicinal products involved in ADRs.
- By providing a universal framework for coding and describing medicinal products, IDMP facilitates the aggregation and analysis of pharmacovigilance data from multiple sources.
- This standardization ensures that data submitted from various regions are interoperable, accurate, and can be effectively used for regulatory decision-making and public health monitoring.

Benefits:

- Improved data accuracy and consistency in pharmacovigilance reporting.
- Enhanced ability to detect and respond to safety signals across borders.
- Streamlined regulatory processes and improved communication between regulatory authorities globally.

Use Case 2: Cross-Border Prescription and Healthcare Interoperability

Scenario:
Patients frequently travel across borders within regions such as the European Union, requiring their medications to be recognized and dispensed accurately in different countries.

Need for IDMP:

- The harmonization and standardization of medicinal product information through IDMP enable seamless cross-border prescription and medication dispensing.
- IDMP standards ensure that healthcare providers in different countries can accurately identify the prescribed medications and understand their composition, dosage, and regulatory status.
- This interoperability is critical for maintaining continuity of care, especially for patients with chronic conditions who rely on consistent medication management while traveling.

Benefits:

- Enhanced patient safety and continuity of care across borders.
- Reduction in medication errors due to standardized product identification.
- Increased efficiency in healthcare delivery and pharmacy operations in a multi-country context.

In collaboration with Gravitate Health on user interface design adaptations to health literacy.

Image Source: https://www.socialistsanddemocrats.eu/newsroom/sds-demand-more-investment-and-better-access-cross-border-healthcare

Use Case 3: Global Healthcare Standards and Research

Scenario:

Researchers and healthcare providers require comprehensive and standardized medicinal product information to conduct global health studies and improve public health outcomes.

Need for IDMP:

Adopting IDMP standards globally ensures that medicinal products are uniformly identified and described, which is crucial for conducting multi-country research studies and meta-analyses. This standardization supports the collection of high-quality data, enabling researchers to compare and combine data from different healthcare systems reliably. Additionally, standardized medicinal product information enhances the ability to track medication use and outcomes in diverse populations, facilitating better public health interventions.

Benefits:

- Enhanced quality and comparability of data in international research studies.
- Improved ability to conduct global public health surveillance and interventions.
- Facilitation of collaborative research efforts and sharing of medicinal product information across borders.

Robert Stegwee, PhD

Work package leader EU UNICOM project on behalf of Nictiz - CEN/TC 251

Strategic Consultant for Health IT, focusing on meHealth for citizens and professionals in health and care

Dr. Robert Stegwee is a consultant for Health Informatics, based in the Netherlands. He is passionate about meHealth: improving the healthcare experience from a healthcare consumer and professional perspective. He has been involved in healthcare IT in different capacities since 1993, starting in a hospital environment and consulting in different sectors of healthcare.

Dr. Stegwee believes that aligning the technological achievements with the organizational dynamics within healthcare is an especially rewarding challenge, as improving the efficiency and effectiveness of healthcare benefits us all. His work in healthcare has focused on the use of high level architectures to achieve an evolving integrated health information environment.

Dr. Stegwee has participated in the development of the Health Level 7 standards and currently serves as member of the board of HL7 The Netherlands, member of the board of HL7 Europe, chair of CEN/TC 251 on Health Informatics, and member of Joint Initiative Council on Global Health Informatics Standardization. His current project involvement includes UNICOM, XpanDH and xShare, all financed by the European Union but all with an outlook to the adoption and use of international standards.

Dr. Stegwee has co-authored a large number of both scientific and professional publications, including a book on Strategies for Healthcare Information Systems and a chapter on Standards in Healthcare Data. As a professor at the University of Twente, he has supervised numerous MSc and PhD projects, some of them directly related to standards in healthcare.

Robert Vander Stichele, PhD

Workpackage Task Leader EU UNICOM project at I-HD

Professor, Ghent University, Ghent, Belgium

Dr. Robert Vander Stichele is a certified clinical pharmacologist, and pharmaco-epidemiological researcher.

He retired as a family physician in Ghent, Belgium in 2019, after 41 years of clinical practice, combined with research projects, since 1982. He obtained his PhD (in medical sciences) in 2004, and was appointed as teaching professor in the department of Pharmacology in the University of Ghent. He became a certified clinical pharmacologist in 2009.

Dr. Vander Stichele's interests are on information on and use of medicines. He is member of the Special Interest Group on Drug Utilization in the International Society for Pharmaco-epidemiology (ISPE). He is a senior-researcher in the research alliance on “End-of-Life Care”, a consortium of the University of Ghent, Brussels, Amsterdam and Rotterdam.

Dr. Vander Stichele is a member of the Board of the International Society of Phthirapterists (ISOP), and of the European Society for the study of Patient Adherence and Compliance (ESPACOMP). He is founding member of the Board of the Belgian Centre for Evidence-Based -Medicine (CEBAM). Currently, he works as an expert in European projects for the European Institute for Innovation through Health Data (I-HD), and in the spinoff Ramit of the Department of Medical Informatics of the University of Ghent. He has been appointed as work package leader for the UNICOM project on Identification of Medicinal Products, working on applications of the new ISO IDMP standards to clinical practice and medical clinical research.

Ron Fitzmartin, PhD, MBA

Senior Advisor, Office of Regulatory Operations, Data Standards Branch, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration

Dr. Ron Fitzmartin serves as a Senior Advisor in the Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA). In this capacity, Dr. Fitzmartin contributes to the development and implementation of strategy and guidance related to electronic submissions and standardized data in support of the regulatory review of medical products. In addition, Dr. Fitzmartin has led the FDA's policy to implement the ISO Identification of Medicinal Products (IDMP) for global use for post market pharmacovigilance, drug shortage and cross-border healthcare. Dr. Fitzmartin, along with Dr. Malin Fladvad (WHO/UMC), chartered the Global IDMP Working Group in 2021 to focus on the development of global identifiers. In addition to global IDMP standards, Ron is Rapporteur of the ICH M11 Clinical electronic Structured Harmonized Protocol Expert Working Group with a goal to have an endorsed Clinical Protocol Guideline, Template, and Technical Specification in 2025.

Prior to FDA, Dr. Fitzmartin held roles as the VP of Informatics & Knowledge Management at Daiichi Sankyo, Inc., VP of Biostatistics, Data Management and Informatics at Daiichi Medical Research, Inc., and Group Executive Director of Biostatistics & Clinical Operations at Purdue Pharma.

Over many years Dr. Fitzmartin has been a regular speaker, session chair, and meeting chair at numerous professional meetings. In 2006, Ron was elected DIA's President-elect and served as President in 2007-2008. During Dr. Fitzmartin' s tenure as President, DIA established offices in India and China.

Thank you for joining us today!

Here are the Links to the Upcoming Conference and Recordings of Previous DCI Network Webinars

https://www.dcinetwork.org/events

June 27, 2024
8 am - 6 pm EDT
Attend Online: The Future of Patient Engagement: Insights, Innovations, and Implementations

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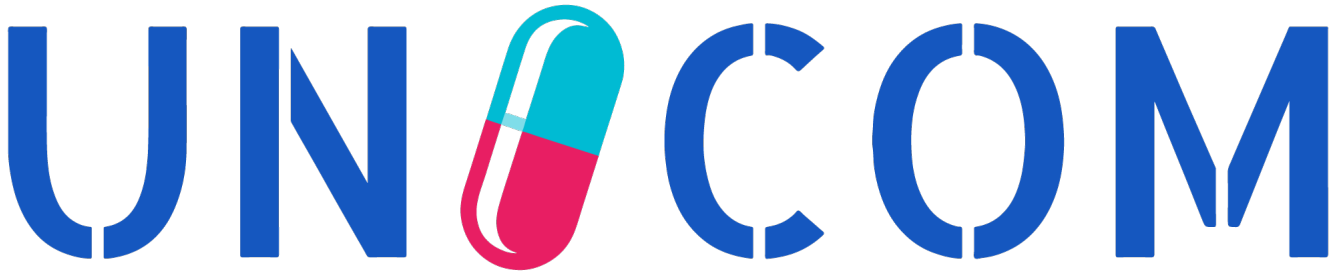
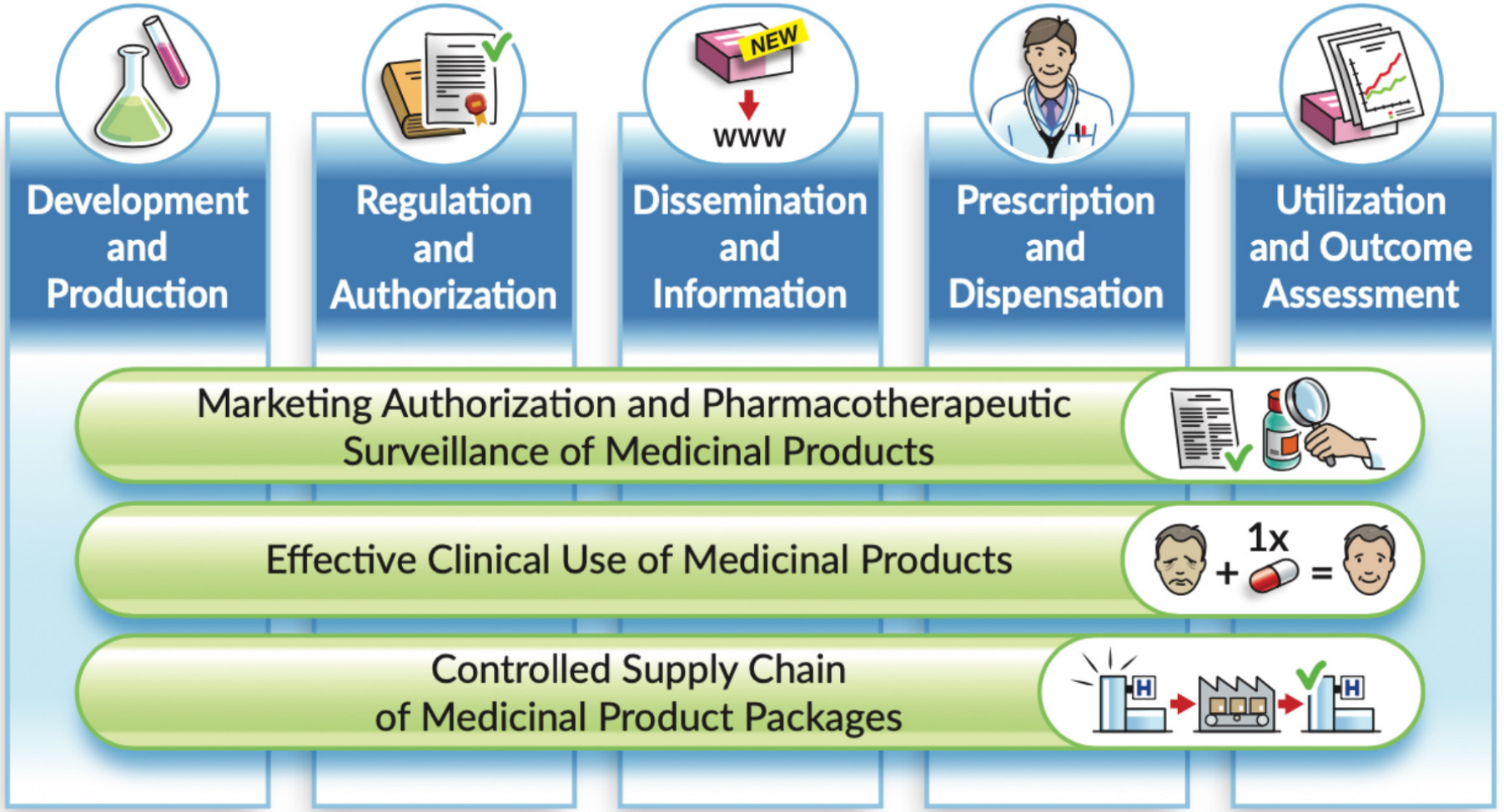


Standards for Safe Medication Data

Work Package 1 on IDMP-related Standards and Terminologies

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

We need standards to connect the data across five domains and within three main processes



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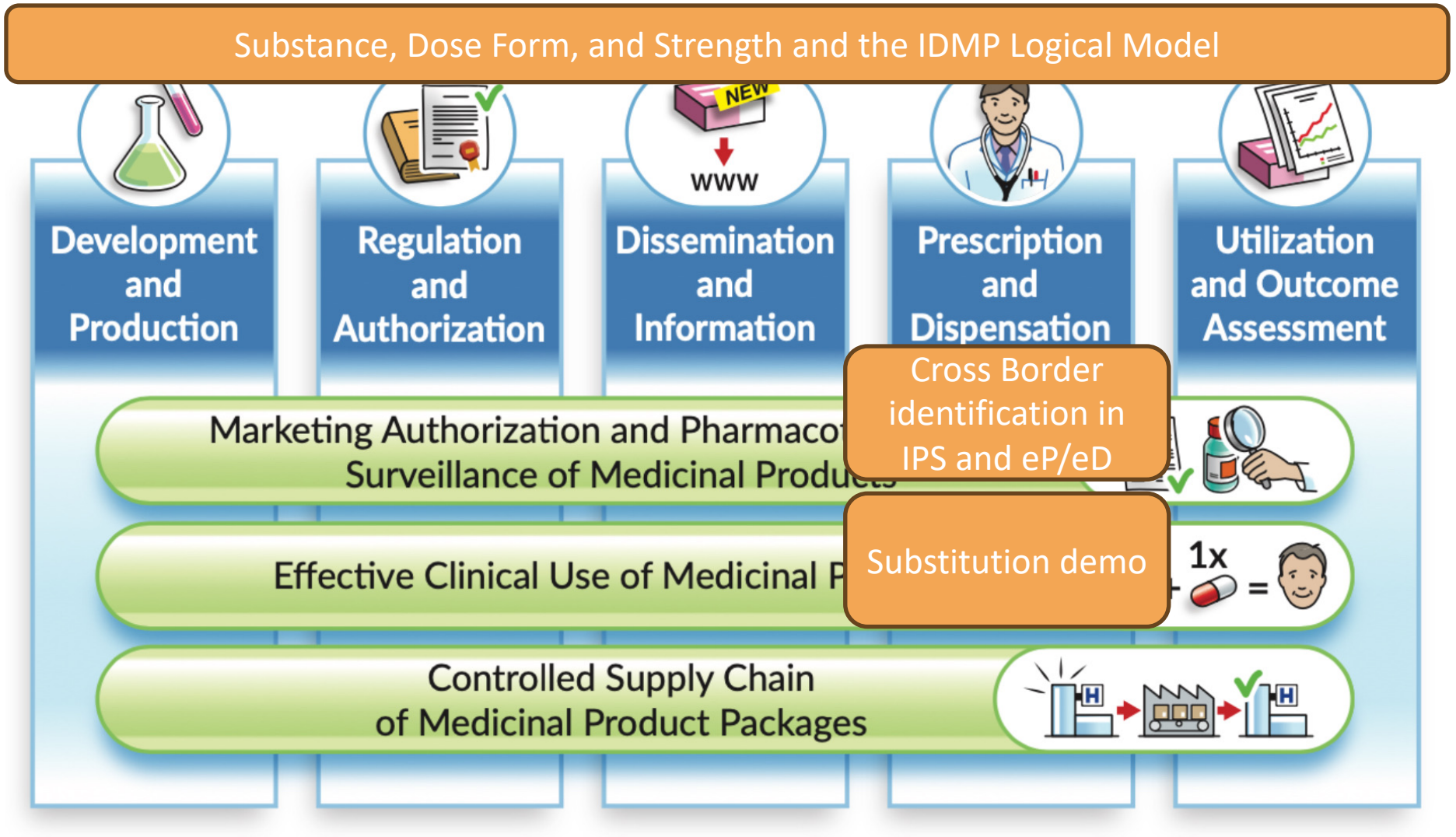
Ensure that any medicine and what it contains can be identified across borders



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Cross-border identification of medicinal products in the IPS and ePrescribing/eDispensing

describe each medicinal product

Reason	O	Label Concept
Medicinal product	R	Label Concept
Product code	O	Coded Element
Product common name (and strength)	RK	String
Pharmaceutical dose form	R	Coded Element
Brand name	O	String
Active ingredients	R	List
Active ingredient	R	Label Concept
Substance code	R	Coded Element
Strength	R	Ratio

- Product Code permits current usage rather than the unique identifiers (PhPIDs, MPID, PCID) allocated to a medicinal product for medicinal products worldwide [ISO 11615], which have not yet been realized.
- For Europe we now have standardized on EDQM for dose form, EMA Substance code, and UCUM Strength

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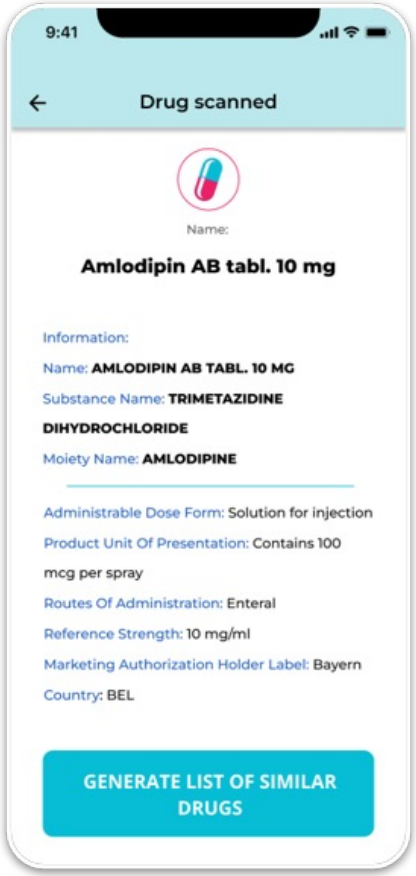
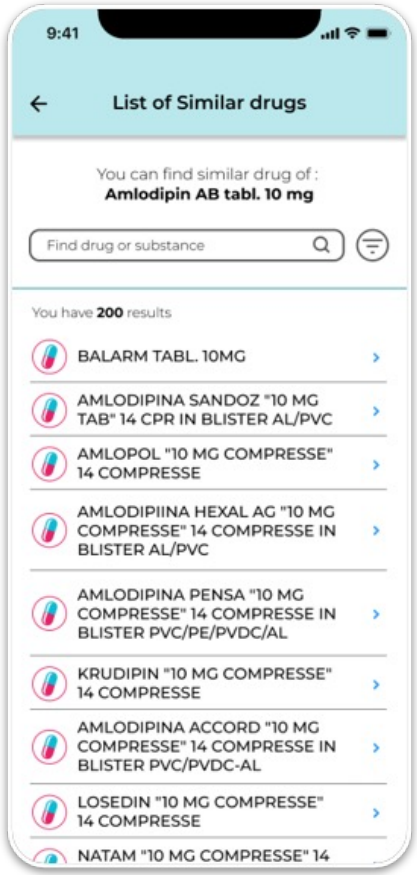
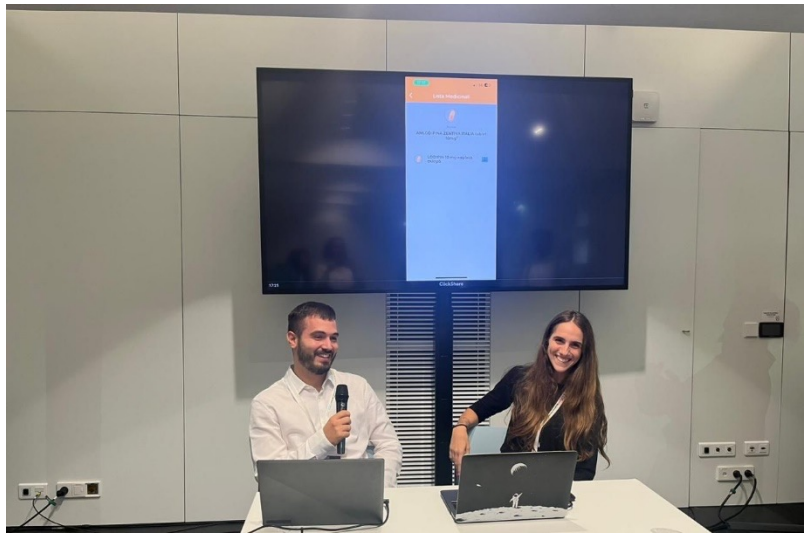
Substitution demo developed as part of the UNICOM Test Lab







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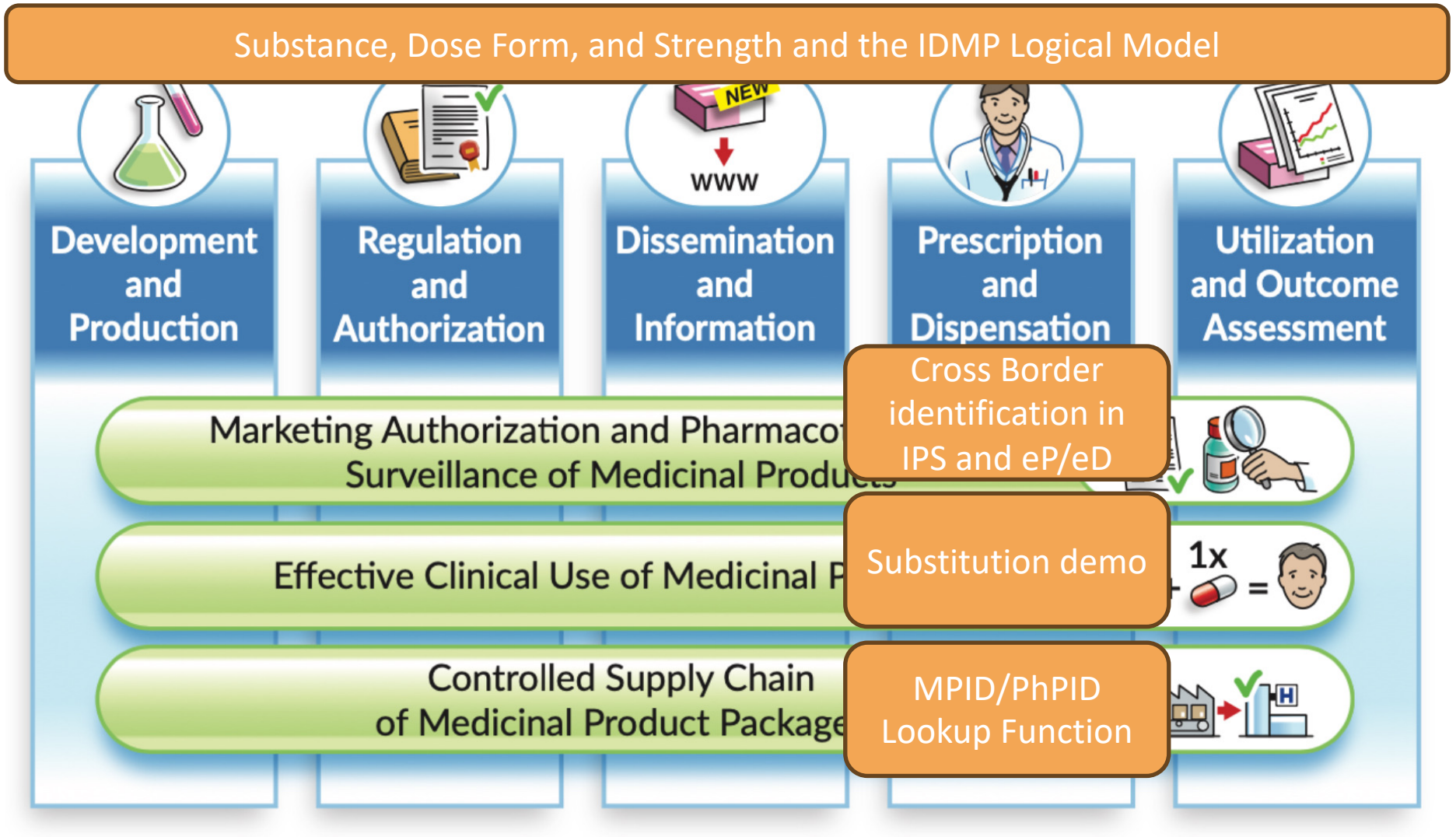
Ensure that any medicine and what it contains can be identified anywhere in the world



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MPID and PhPID lookup at the January 2024 HL7 FHIR Connectathon – Athens / virtual

UNICOM

Global IDMP Working Group

Pharmacovigilance

Drug Shortages

Cross border healthcare

Datapharm

FELLESKATALOGEN

Glemser

HL7 Europe

UNICOM

UiO : University of Oslo

Uppsala Monitoring Centre

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pfizer

MPID 1849D6A2F100

UMC FHIR demo

PhPID L4
891F49AAEFF401136F39525064C91540

PhPID L4
891F49AAEFF401136F39525064C91540

UMC FHIR demo

List of matching MPIDs

VULCAN
HL7 FHIR

Gravitate Health

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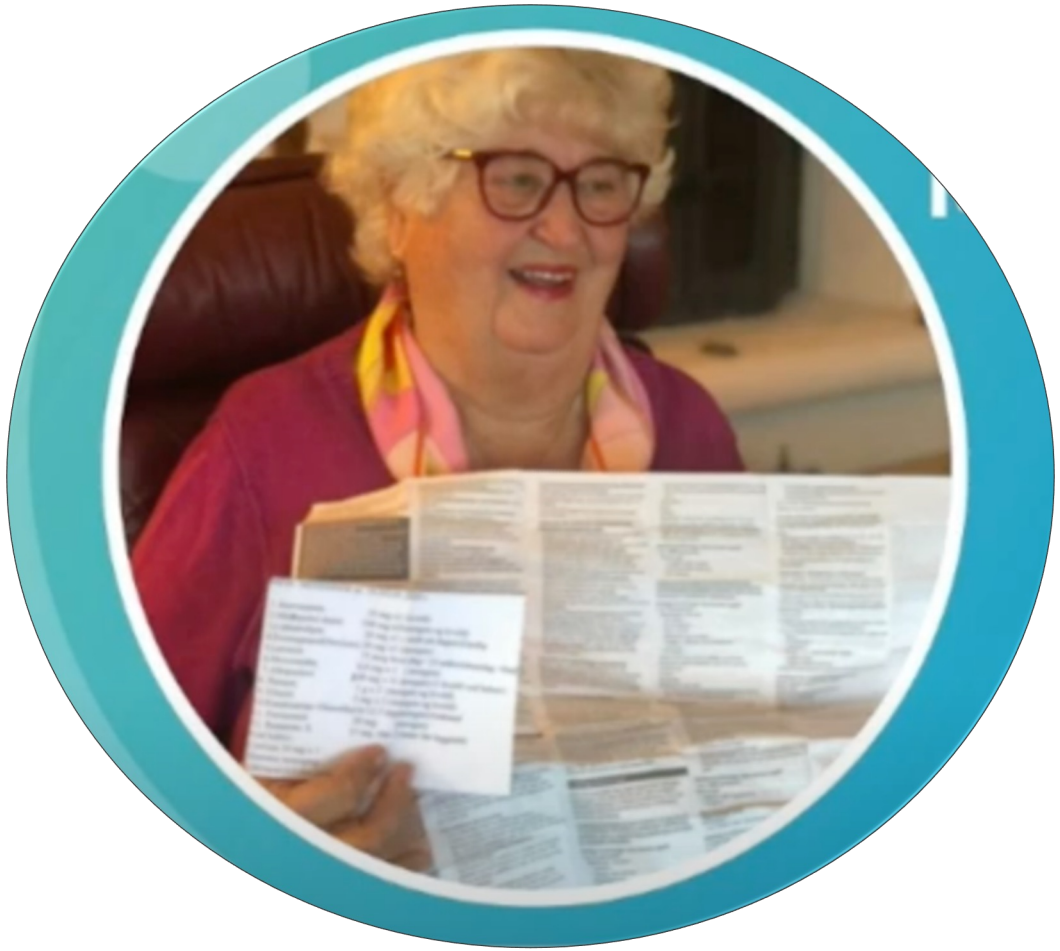
Maria from the GravitateHealth project



The Gravitate Lens (G-lens®) focuses (but does not conceal or filter) approved electronic product information (ePI) content, and offers a route for patients to access trustworthy, up-to-date information that better meets their individual needs, preferably in their own language.

https://www.gravitatehealth.eu/

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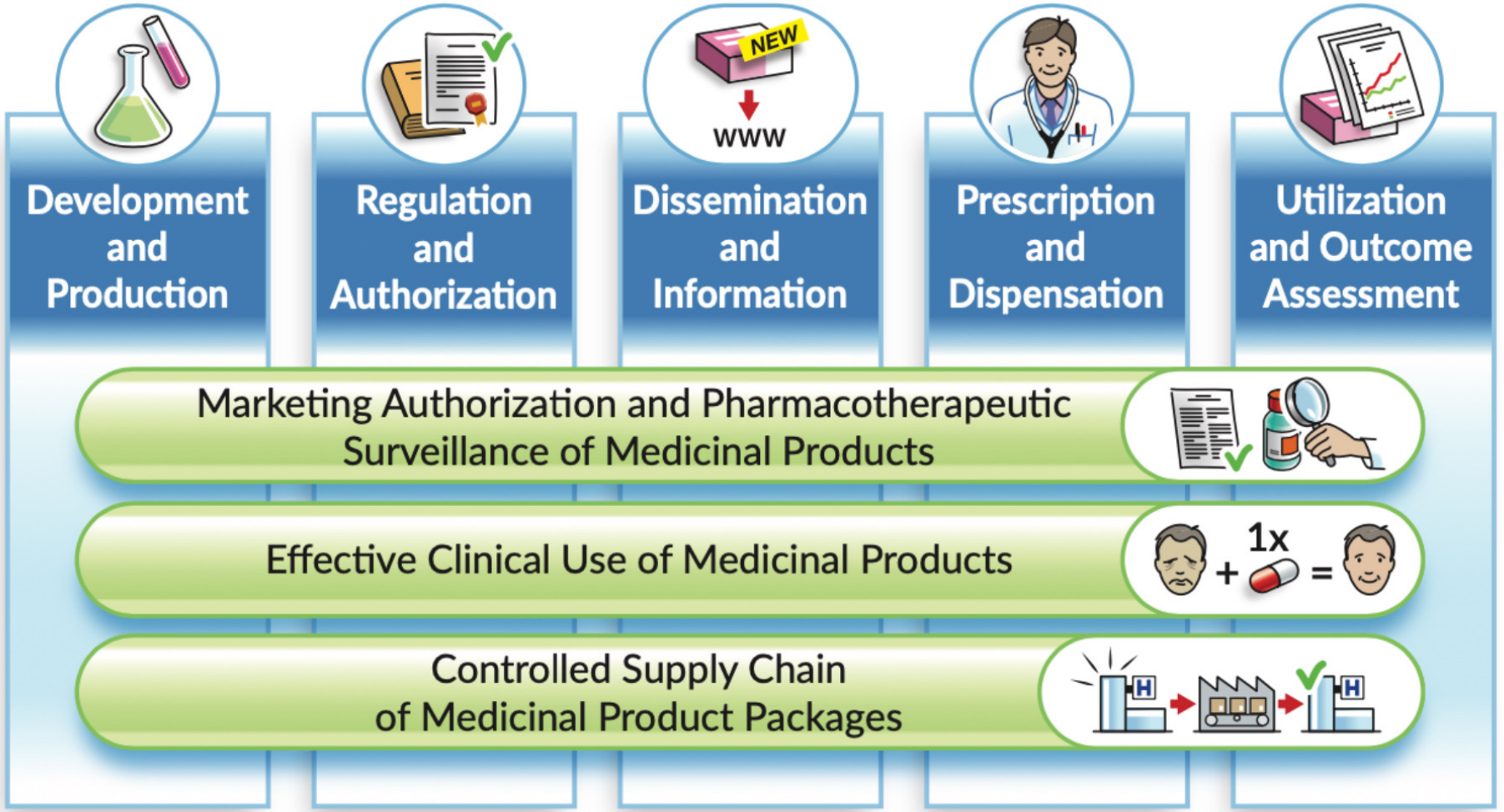
Medication Safety supported by Safe Medication Data, realised through standards



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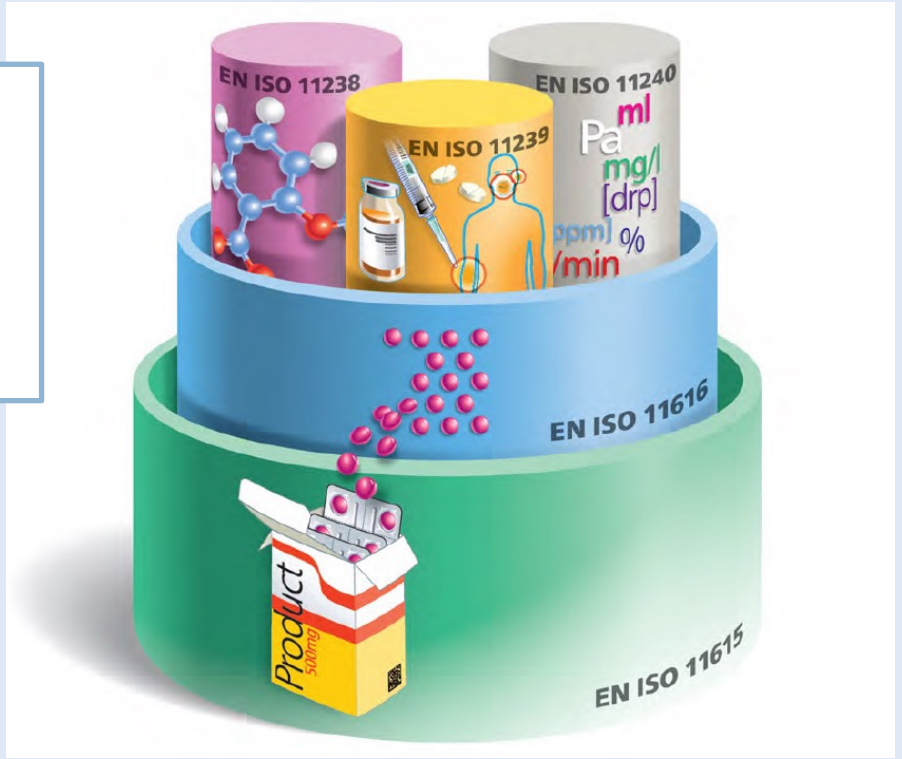

Thanks to all contributors to UNICOM Work Package 1

Challenges in implementation of IS0/CEN standards for Identification of Medicinal Products in the USA

Robert Vander Stichele, MD, PhD

May 22, 2024

Disclosure

No conflict of interest to declare

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Overview

- What is IDMP ?
- Challenges in implementing for the USA
- Lessons learnt from initial attempts
- Conclusions

This project has received funding from the European Union's
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What is IDMP ?

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The UNICOM Project

UNICOM

► What if

We would be able to recognise any medicinal product
from anywhere in the world
anywhere in the world.

That is the ambition of the 5 ISO/CEN Standards

The ISO IDMP standards establish definitions and concepts and describe data elements and their structural relationships that are required for the unique identification of:

- ***Medicinal* products** (MPID) and **packages** (PCID) - ISO 11615
- ***Pharmaceutical* products** (PhPID) - ISO 11616
- **Substances** (Substance ID) - ISO 11238
- **Pharmaceutical** dose forms, units of presentation,
  routes of administration and packaging - ISO 11239
- **Units of measurement** (UCUM) - ISO 11240

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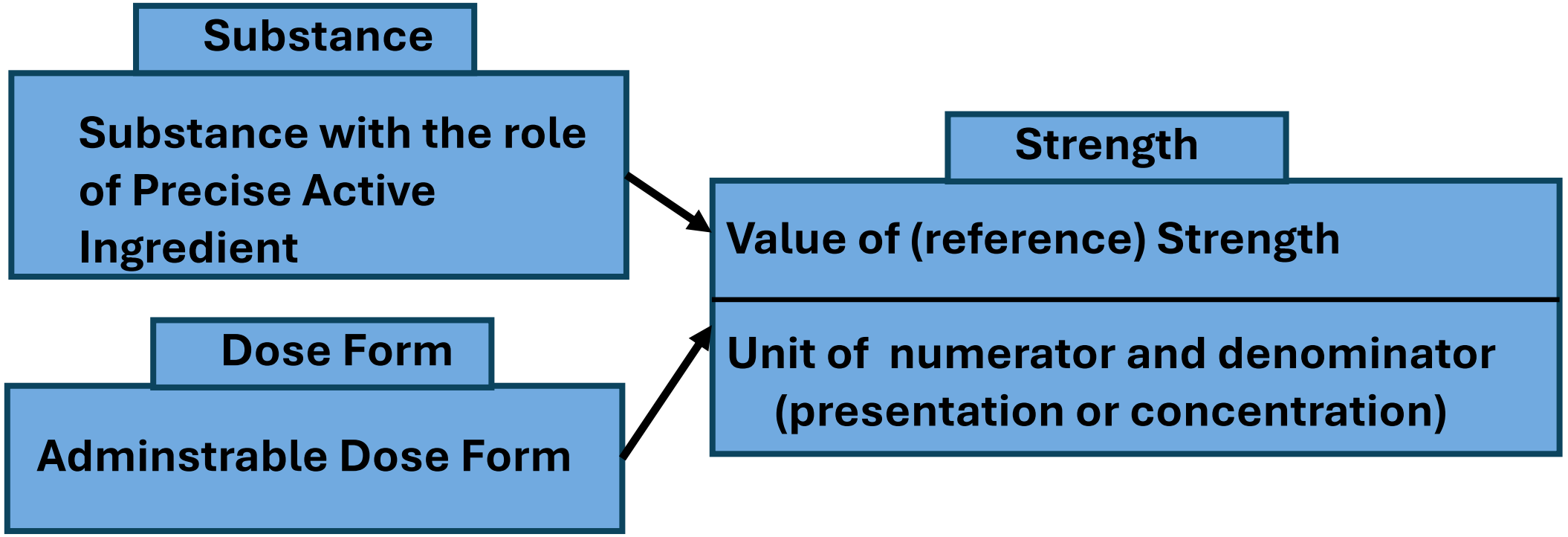
The key elements in IDMP identification of Products

- Substance, Dose Form, and strength are key elements that determine the pharmaceutical product.



Note: Substance with dose form and strength determine the effect of the medication

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Levels of implementation of IDMP

Crude implementation
for creating or linking to the global Pharmaceutical Product ID (PhPID)

Substance with the role of Precise Active Ingredient
Granular Administrable Dose Form,
Normalised Strength

Intermediate implementation of IDMP
for cross-border and trans-atlantic exchange of ePrescriptions

A minimum attribute list of ± 25 IDMP variables to be added to the national dictionary

Full implementation of IDMP in the national Drug Model

All IDMP variables (± 150 variables)
Incorporating the structural IDMP Drug model

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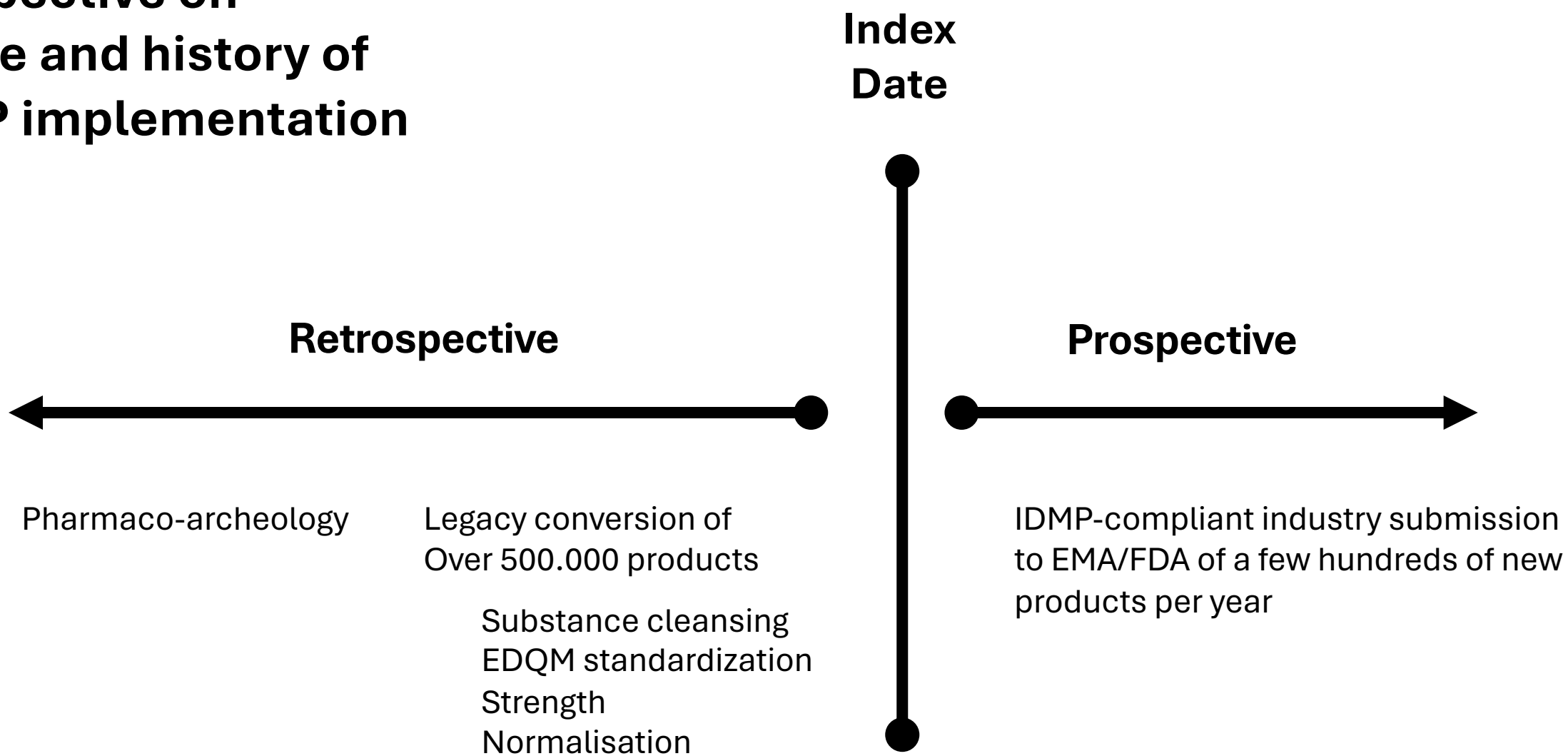
Perspective on future and history of IDMP implementation



What if

a Greek patient shows up on in a foreign pharmacy and requests a prescription for

αμλοδιπίνη ταμπλέτα 10 mg (Norvasc Upjohn)

By identifying the IDMP data on the box, the pharmacist realizes that this about

amlodipine,

and more specifically

amlodipine oral 10 mg,

and even more specifically :

amlodipine besilate capsule, hard 10mg

In Belgium available as : Amlor 10 mg (Upjohn), and 7 generic companies, with choice between 20 packs.
In the US available as : Norvasc 10 mg (Pfizer), and 54 generic companies with choice between 275 packs
(generics mostly as tablets or coated tablets)

International support for the adoption of IDMP

- 2012 : Approval of the 5 ISO/CEN IDMP standards
- 2012 – 2024 : EU funding for 3 consecutive action programs of 4 years
  EpSoS, openMedicine, UNICOM
- Adoption by the International Council of Harmonisation (ICH)

  https://ich.org/page/e2br3-individual-case-safety-report-icsr-specification-and-related-files
  - of ISO Individual Case Safety Reports (ICSRs)
  - of EDQM Standard Terms (European Directorate for Quality of Medicines) as reference terminology for electronic transmission of reports in ICH E2B(R3) format in the jurisdictions for Pharmacovigilance
  - of the use IDMP identifiers in the future (PhPID, MPID, PCID)
- 2019 - : International Cooperation in GIDWG (Global IDMP Working Group)
  - between WHO Uppsala Monitoring Centre for Phamacovigilance, FDA, EMA, and other stakeholders
- 2020 Publication of the EU IDMP Implementation Guide V1
- 2024 : Revision of all 5 IDMP Standards by ISO / TC 215 / WG6 : Pharmacy

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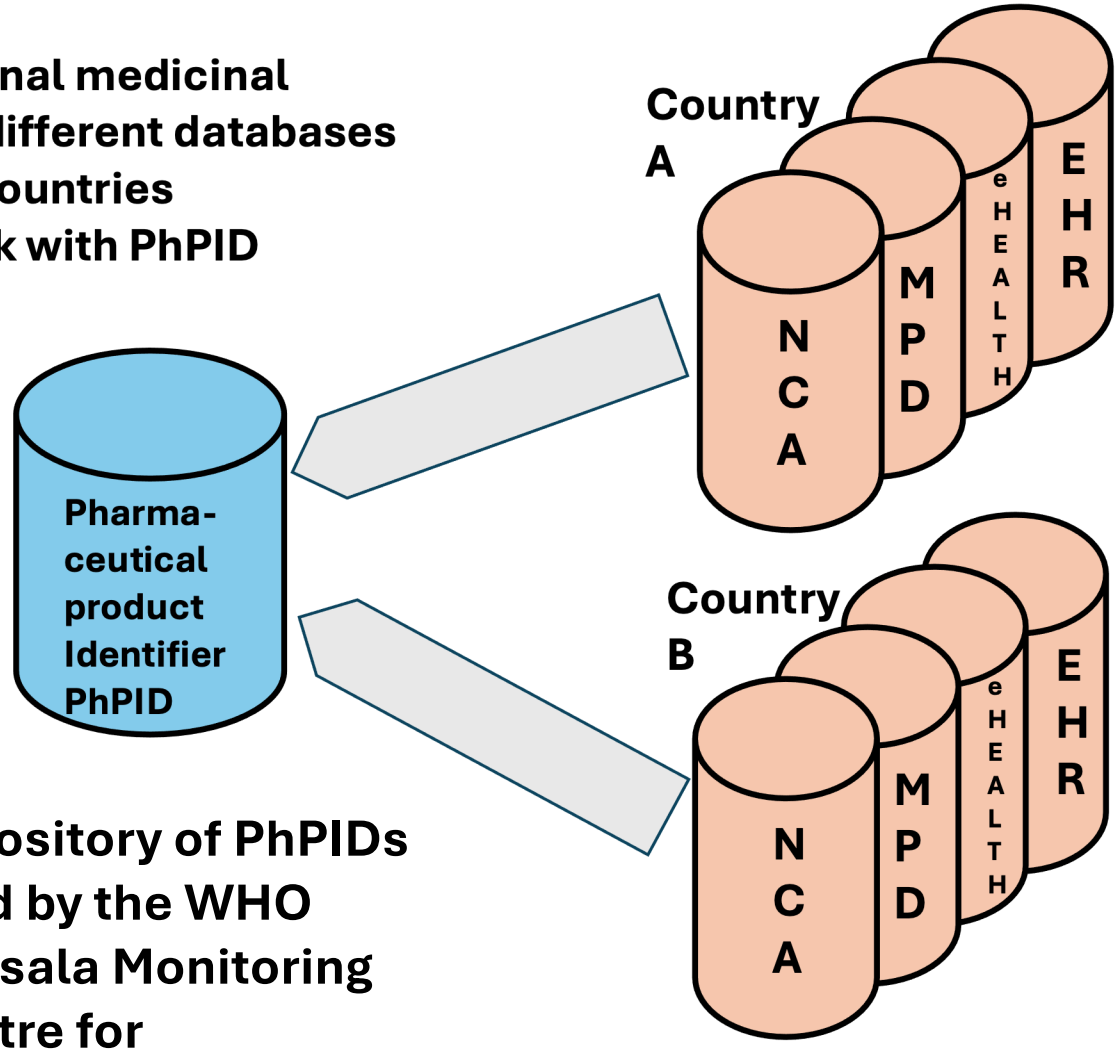
Pharmaceutical Product Identifier (PhPID)
as a global virtual concept for linking similar national medicinal products

Linking national medicinal products in different databases in different countries through a link with PhPID



Repository of PhPIDs Held by the WHO Uppsala Monitoring Centre for Pharmacovigilance

The ambition of IDMP is to be an identifying system through all of the 5 domains of the life cycle of medicinal prducts

Challenges in implementation in the USA

This project has received funding from the European Union's
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Challenges for the USA to implement IDMP

- The sheer size of the therapeutic arsenal in the US

  RxNorm : 1 x 500.000 National Drug Codes

  EU : 27 x average of 15.000 Medicinal Product Packs per country

- The virtual drug model of RxNorm starts at an aggregated level
  - Clinical Drug :
    - Substance without modifier
    - RxNorm Dose form

- Limited granularity of RxNorm Dose form
  - Value set of only 180 terms, no distinction between manufactured and administrable dose form, simple definitions of terms, no attributes of concepts

- Normalisation of strength

  . Especially for concentrations

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Lessons learned from initial attempts

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Lessons from a joint analysis between

Beth Israel Deaconess Medical Centre
National Library of Medicine
Unicom / I-HD

An analysis of all medicinal products available on the market for 4 substances

(amlodipine, carbamazepine, diclofenac, simvastatine)

In 5 countries : Belgium, Greece, Italy, Norway, USA

Results :

	Medicinal Products	National Drug Codes for Packs
Belgium	81	141
Greece	197	238
Italy	165	221
Norway	43	81
USA	1004	5167

Lessons learned on tools to facilitate the task

- Although the information for substances is not used in construction of virtual concepts, it is available within the RxNorm system.

- Close cooperation between EMA (EU-SRS) and USA (UNII) for cleaning of the substance database has been very productive. There is now the possiblity of a global Substance ID (GSID).

- Clever use of mappings is possible
  - Mappings between virtual concepts of Snomed-CT, RxNorm, IDMP, and Dm+d resp. Clinical Drug Precise / Clinical Drug / PhPID / VMP
  - Mappings between Snomed-CT, EDQM, RxNorm Dose forms
  - Mapping between ATC, RxNORM, PhPID, National NDCs

- International cooperation and use of the Repository of Pharmaceutical Product IDs in WHO UMC will help

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Conclusions

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Conclusions : IDMP is here to stay

- The EU has a preference for a granular implementation of the Pharmaceutical Product ID (PhPID) as regional, in line with the European IDMP implementation and EMA SPOR codification system for EDQM Standard Terms
- GIDWG and FDA are still exploring less granular solutions (closer to the current RxNorm representation of medicinal products)
  - Less precise specification of the substance
  - Use of unique combinations of characteristics of dose form instead of the full granularity of the value set of EDQM administrable dose forms
- That is understandable because legacy conversion of older products is a huge endavour, especially in the USA.
- However, modern technology and international cooperation (also with industry) should make it possible to elaborate the most granular and most precise approach.
- The benifit will be fair substitution rules in crossborder ePrescriptions, more precice decision support, more precise Pharmaco-Epi with Real World databases.

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DCI Network and UNICOM presents

Unlocking the Potential of IDMP: Global Strategies for Enhanced Pharmacovigilance and Data Management

Wednesday, 05/22/2024 - 12:00 EDT

Robert Stegwee, PhD
Work package leader EU UNICOM project on behalf of Nictiz - CEN/TC 251
Strategic Consultant for Health IT, focusing on meHealth for citizens and professionals in health and care

Robert Vander Stichele, PhD
Work Package Task Leader EU UNICOM project at I-HD
Professor, Ghent University, Ghent, Belgium

Ron Fitzmartin, PhD, MBA
Senior Advisor, Office of Regulatory Operations, Data Standards Branch, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration

Yuri Quintana, PhD
Chief of Division of Clinical Informatics, Beth Israel Deaconess Medical Center
Assistant Professor of Medicine, Harvard Medical School

Beth Israel Deaconess Medical Center | HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

50+ YEARS Division of Clinical Informatics

DCI Division of Clinical Informatics
An academic division at BIDMC and Harvard Medical Faculty Physicians | Beth Israel Lahey Health Beth Israel Deaconess Medical Center | HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

Making IDMP Implementation a Global Reality

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

22 May 2024

FDA Disclaimer

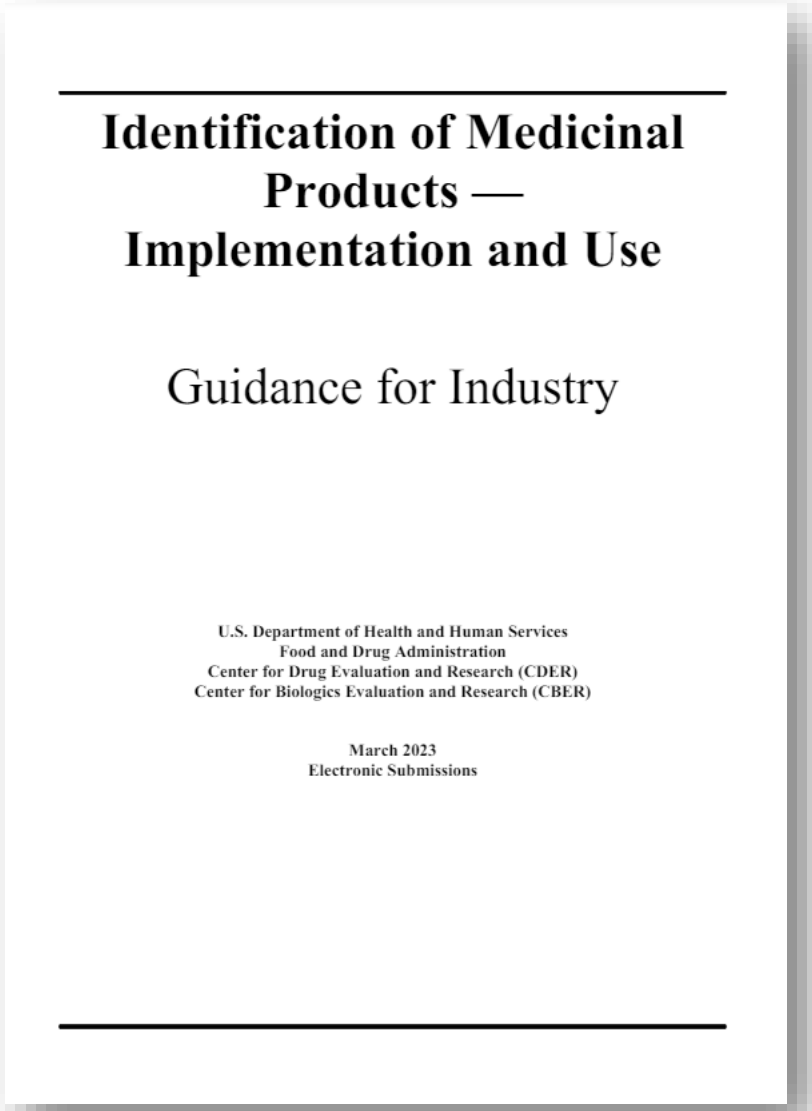
The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.

Topics

- FDA Guidance to Industry on IDMP
- Where are we Now with the IDMP standards
- Global IDMP Working Group
- Connecting the IDMP Dots
- International Stakeholder Meeting

FDA Guidance for Industry (1/4)

- Currently, FDA does not have a statute or regulation requiring the implementation of IDMP.
- In March 2023, FDA published its Guidance for Industry to make clear its policy on IDMP.
- FDA published the guidance for industry as final and for immediate effect.



Identification of Medicinal Products — Implementation and Use

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

March 2023
Electronic Submissions

FDA Guidance for Industry (2/4)

- Provides FDA's position and progress on aligning the Agency's standards to IDMP standards.

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

FDA Guidance for Industry (3/4)

Objectives are to inform that…

1. 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)*

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

FDA Guidance for Industry (4/4)

Objectives are to inform that…

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

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

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

Global IDMP Working Group (GIDWG)

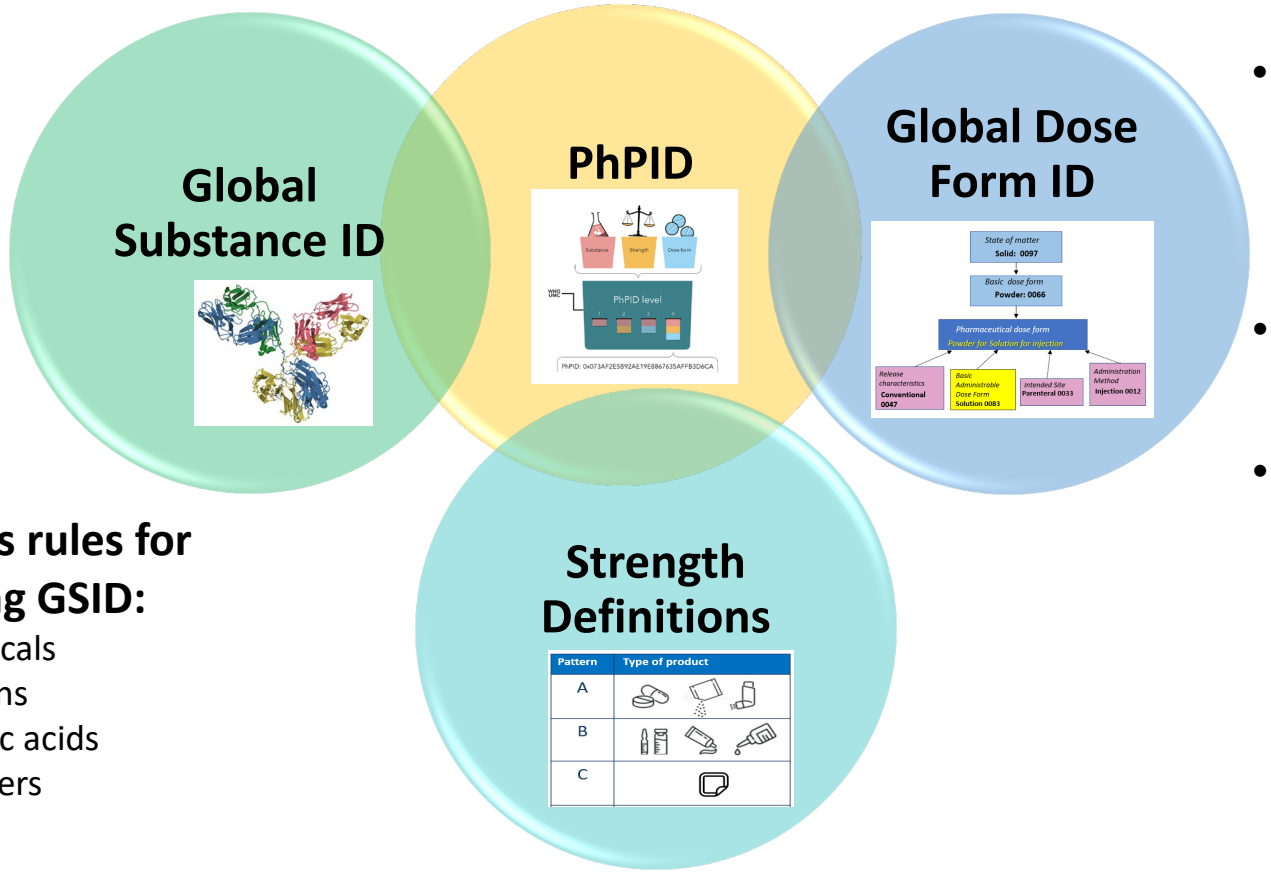
- Chartered in 2021 based on a recommendation from a 2019 WHO IDMP Workshop in Geneva
  - **Why was GIDWG established?**
    - *There was no organization focused on demonstrating that the standards could implemented globally.*
  - **The GIDWG focus?**
    - Develop and execute projects to demonstrate 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.

Global IDMP Working Group (GIDWG)

- **Membership**
  - **Founding members**
    - EU EMA, U.S. FDA, and WHO-UMC.
  - **Regulatory Agencies**
    - Health Canada, Swissmedic, Brazil ANVISA, Saudi FDA, and Norway (NoMA)
  - **Industry**
    - International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- **Co-Chairs**
  - Malin Fladvad, WHO-UMC; Ron Fitzmartin, U.S. FDA; Panagiotis Telonis, EMA

GIDWG Projects – Making the Standards “fit for global use”

Global IDMP Working Group



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**

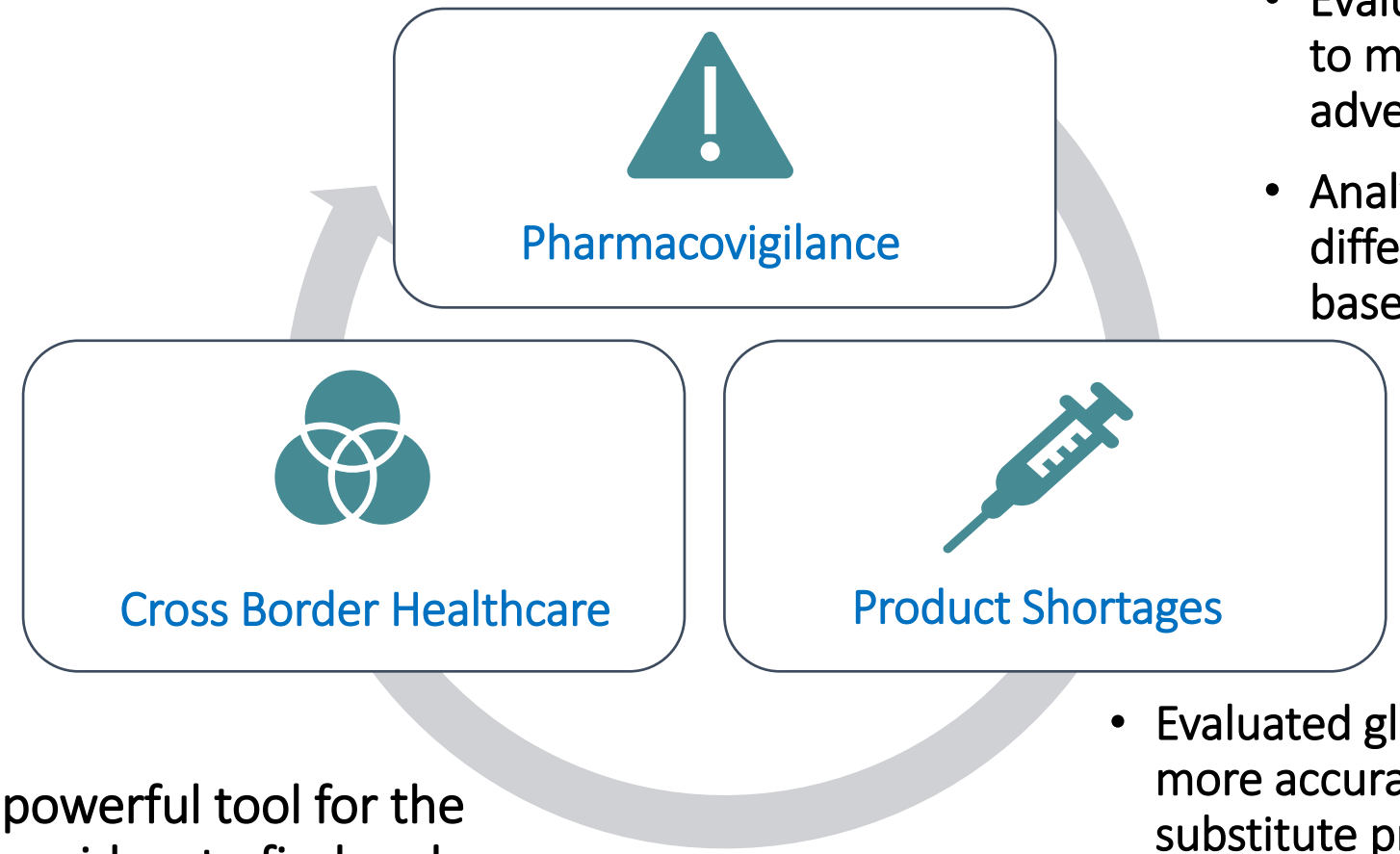
Utilizing a pattern framework determines how the strength should be expressed.

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 / EVA
IFPMA

Value of a PhPID in Global Healthcare – Use Cases



- Evaluated global PhPIDs (gPhPID) to more quickly & reliably signal adverse events.
- Analysis can be performed at different levels of granularity – based on what data you have

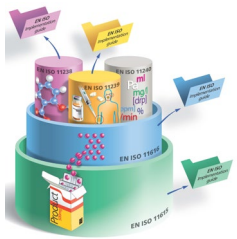
- gPhPIDs – a powerful tool for the healthcare providers to find and dispense substitute medicinal products from all regions and to ensure public health safety globally.

- Evaluated global PhPIDs for faster & more accurate identification of a substitute product – at early stages of a shortage.
- Of course, the gPhPID must be connected to Medicinal Product information.

GIDWG's Journey so far…

Global IDMP Working Group

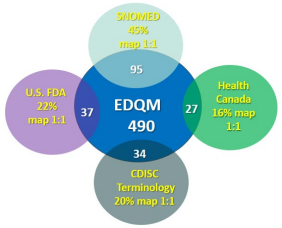
ISO IDMP



2012

2018

ISO 11239 – Dose Form for Global implementation



2019

WHO Workshop

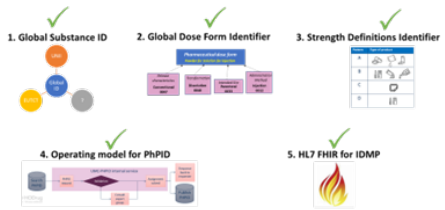
2021

GIDWG

Global IDMP Working Group

2022

GIDWG Projects



Q4 2023

Use Cases

2024

End to End Testing

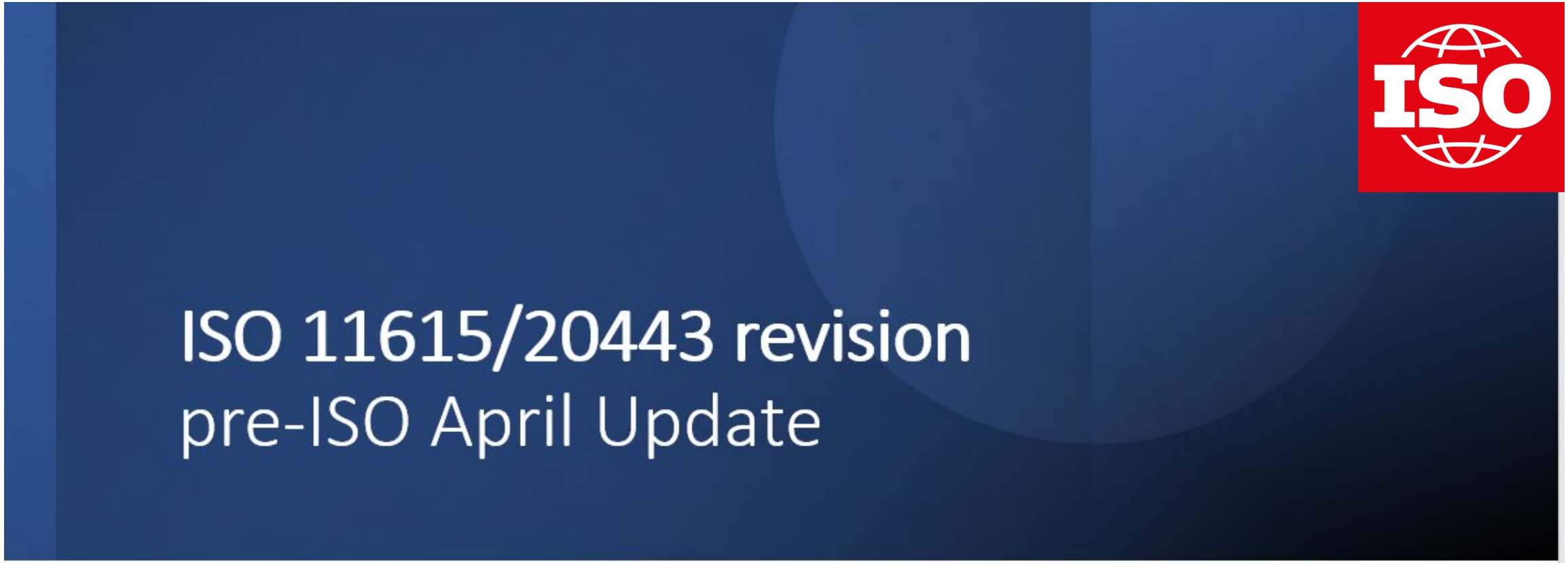
Where are We Now?

- In 2012, ISO released the initial versions of ISO IDMP standards.
  - *Over the past ~5 years U.S. FDA and other stakeholders recognized that the standards could not be implemented for global use without additional testing, revision, and much more.*

- In 2023, ISO 11239 (dose form) was revised by ISO based on findings from the Global IDMP Working Group (GIDWG) and others.

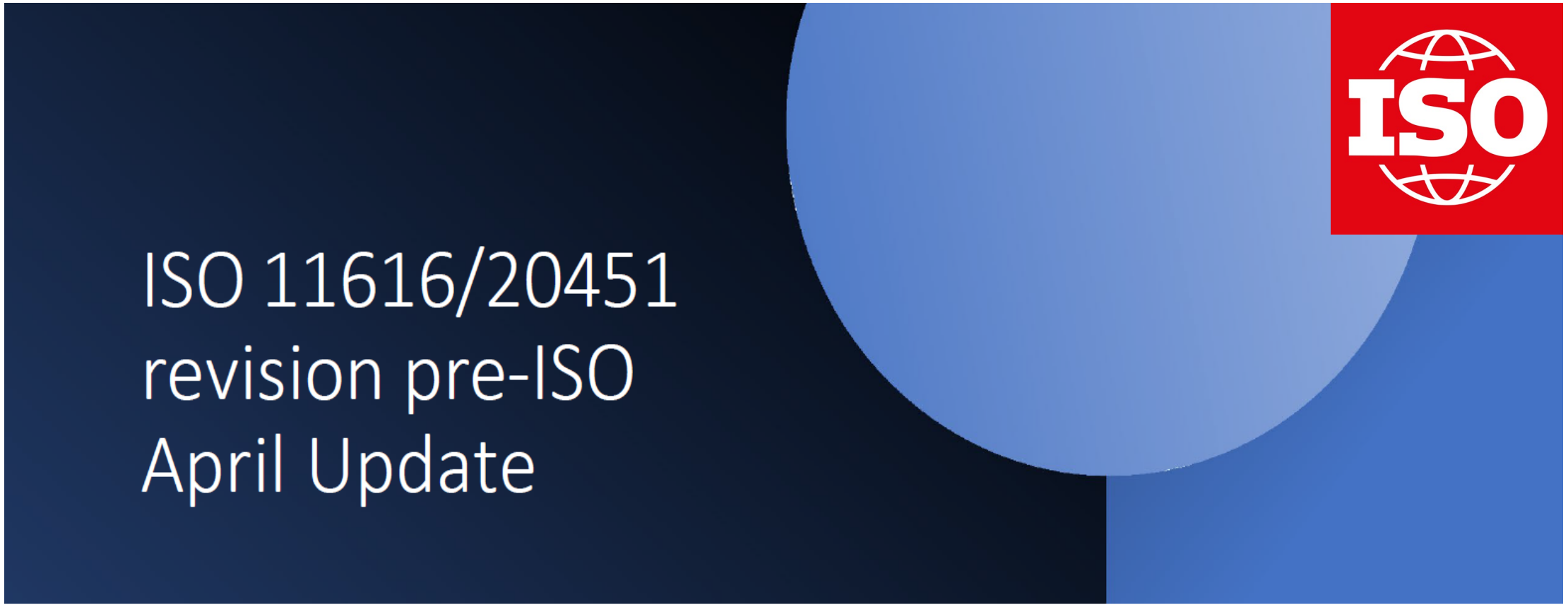
- Regulatory agencies, industry and the key SDA, ISO TC 215 WG 6, have come together to collaborate and work to make them fit for global and regional use (e.g., UNICOM).

Where are We Now?



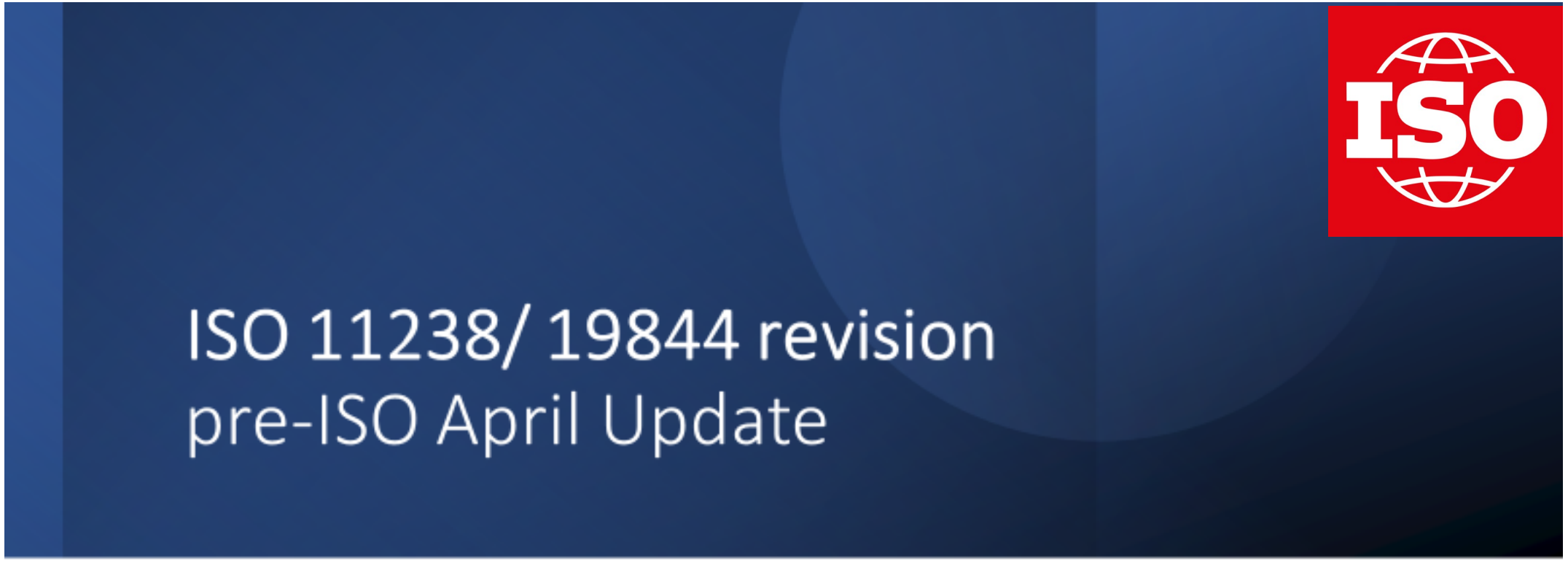
Vada Perkins, Paolo Alcini, Norman Schmuff, TJ Chen, Panagiotis Telonis

Where are We Now?



Paolo Alcini, Ron Fitzmartin, Malin Fladvad, Julia Nyman, Vada Perkins

Where are We Now?



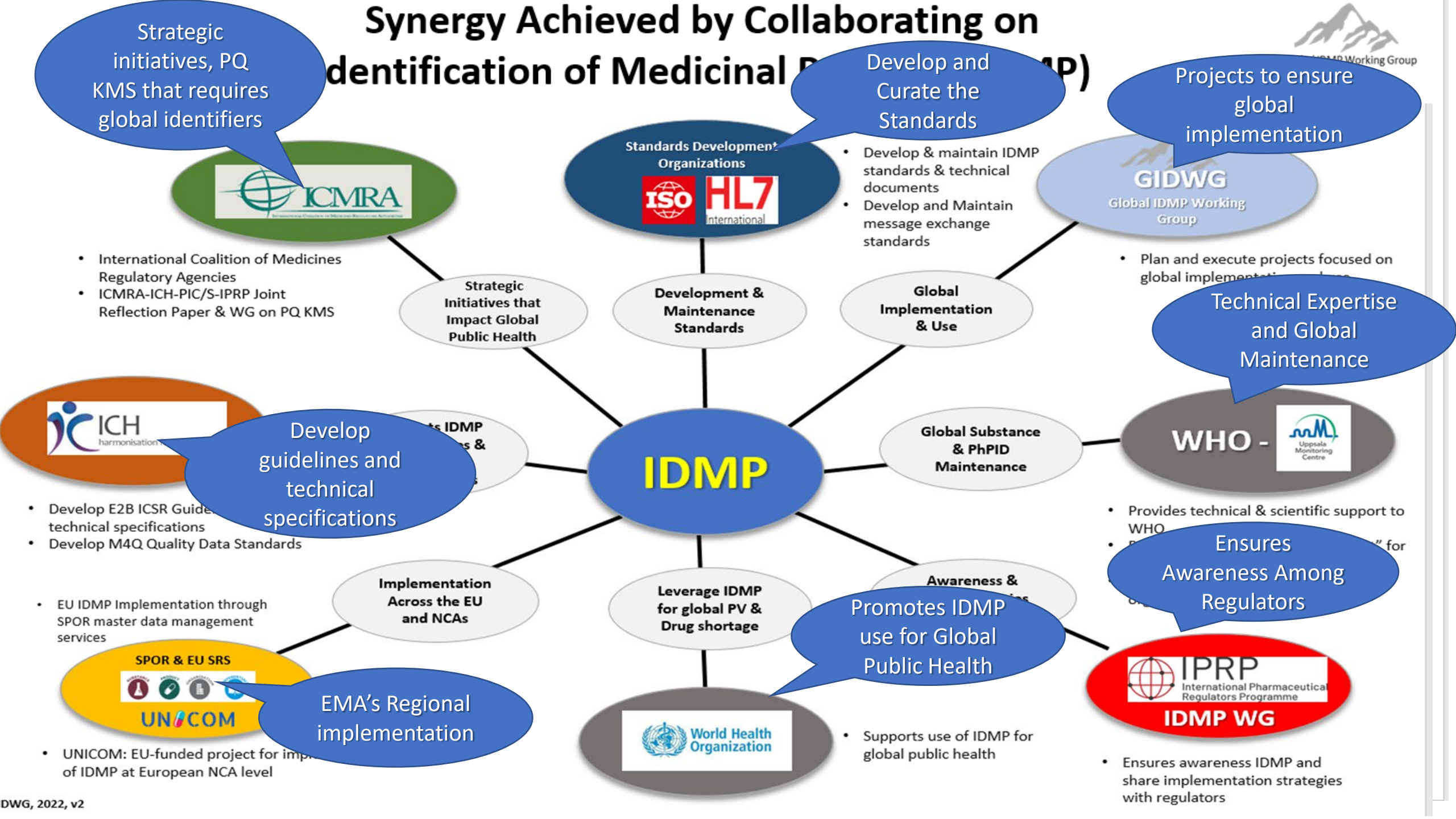
Larry Callahan, Jean-Gonzague Fontaine, Norman Schmuff, Panagiotis Telonis

2

IDMP is not about any one regulator, sponsor, organization, or region.

For global implementation it requires collaboration of all stakeholders.

Synergy Achieved by Collaborating on dentification of Medicinal P)



DWG, 2022, v2

GIDWG

Technical & Stakeholders Meetings

hosted by

National
Health Surveillance Agency (ANVISA)
&
WHO / UMC

São Paulo, Brazil

9 -12 September 2024

GIDWIG Schedule

09 September 2024
09:00 – 17:00
Technical Meeting

10 September 2024
09:00 – 17:00
Technical Meeting

11 September 2024
09:30 – 12:30
Regulatory Forum

13:30 – 15:30
Industry Forum

12 September 2024
07:00 – 12:30
Stakeholder Public Meeting

Meeting Registration

TBD

- **9-10 September**
  - GIDWG Technical Meetings
- **11 September**
  - Regulator and Industry Forums
- **12 September**
  - Public Meeting (Remote & In-person)

Thank You