Toward Global Identification of Medicinal Products (IDMP) Implementation: A Focus on Biologics

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CDER Small Business & Industry Assistance (SBIA)
January 27, 2022

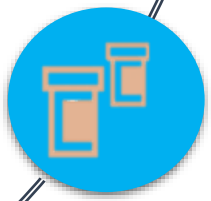
Topics

ISO IDMP Standards

Challenges to Global IDMP Implementation

Cross-Region Collaboration on Global IDMP Implementation

Solutions for Global IDMP Implementation



IDMP Use Cases for Drugs and Biologics

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IDMP Use Cases for Drugs and Biologics

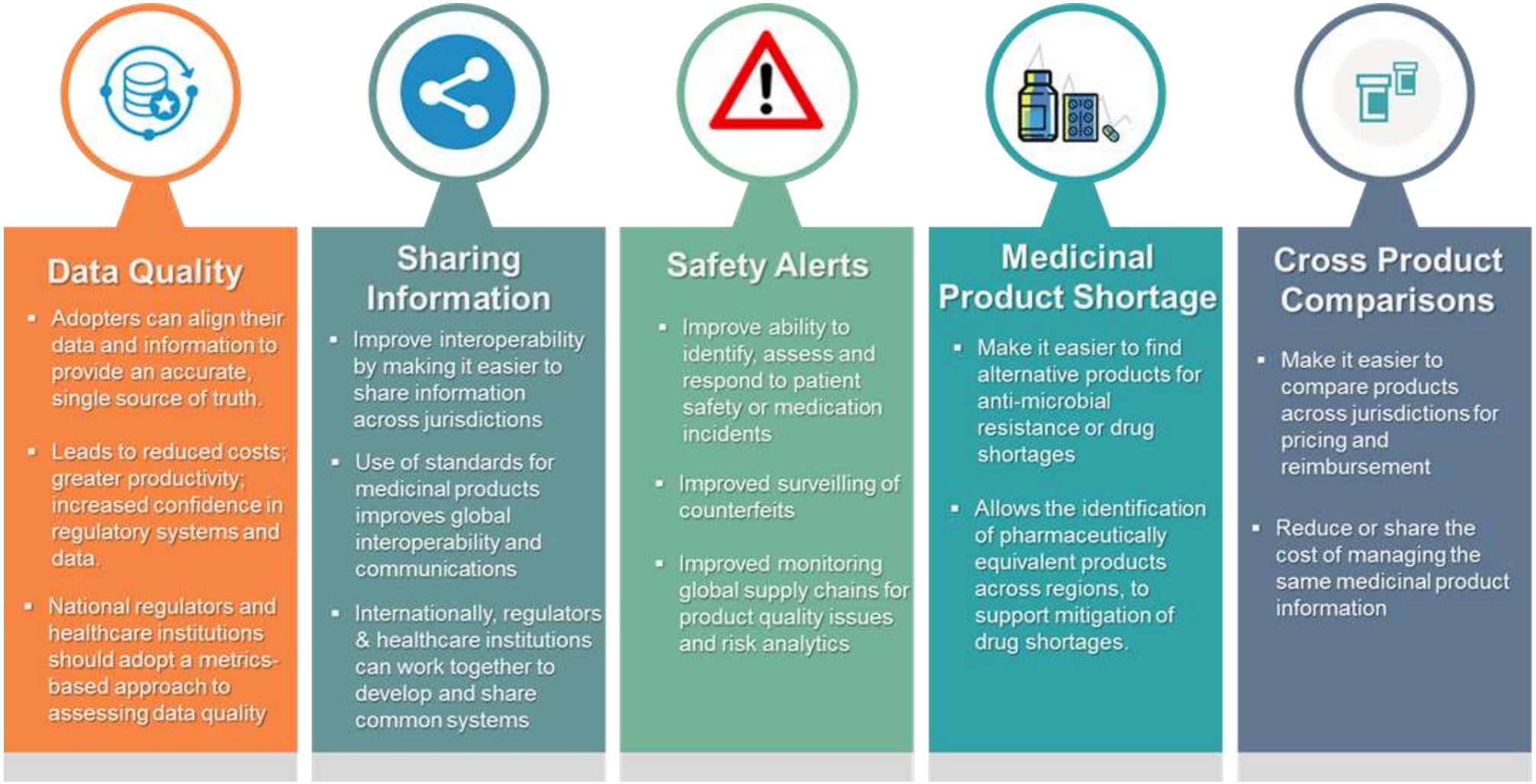
What is IDMP

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
- **common message standards** for improved IT system 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

Key Benefits of IDMP



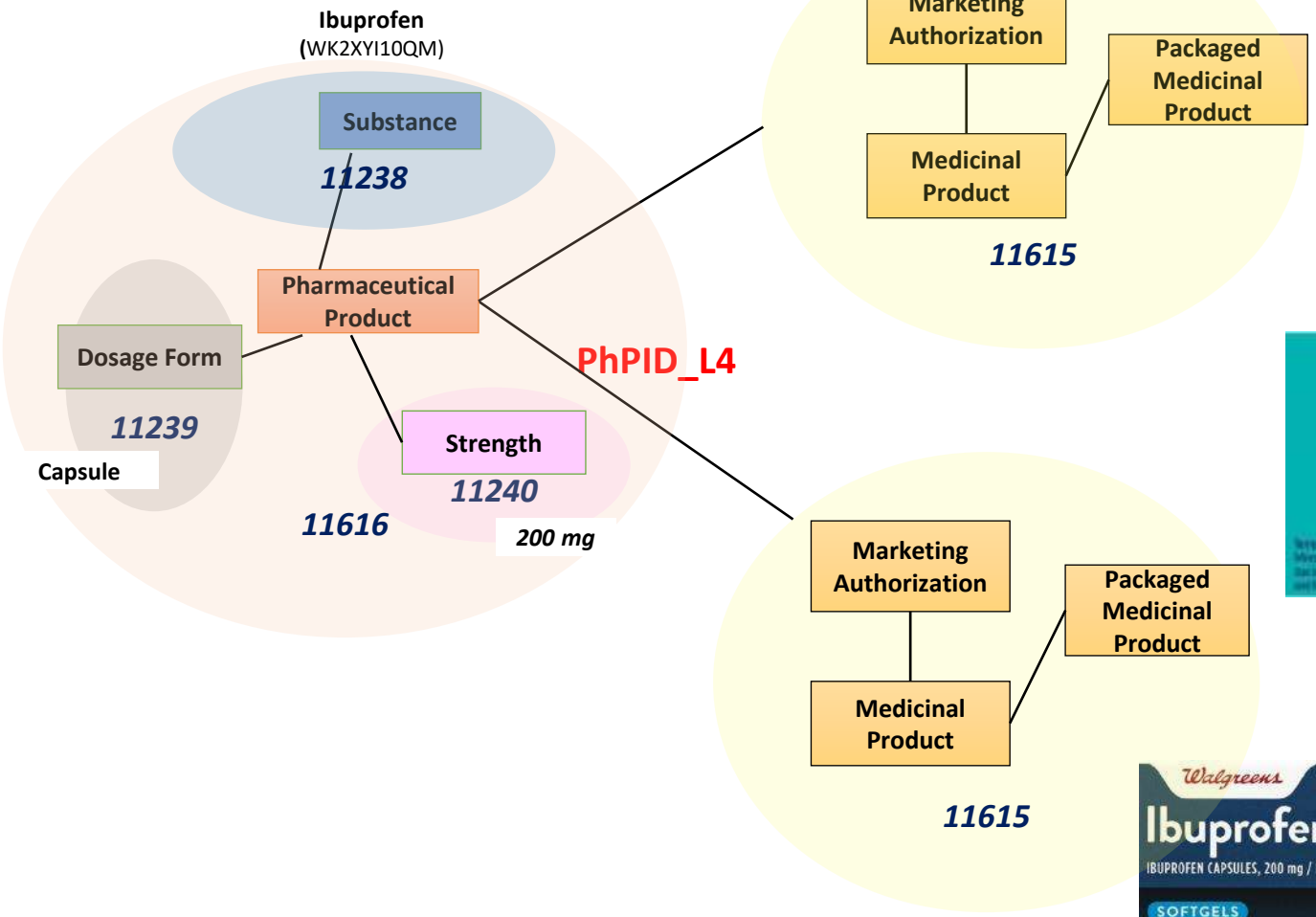
Cross-regions or global agreement on common substance ID and dose form is needed to maximize the benefits

Closer Look at PhPID

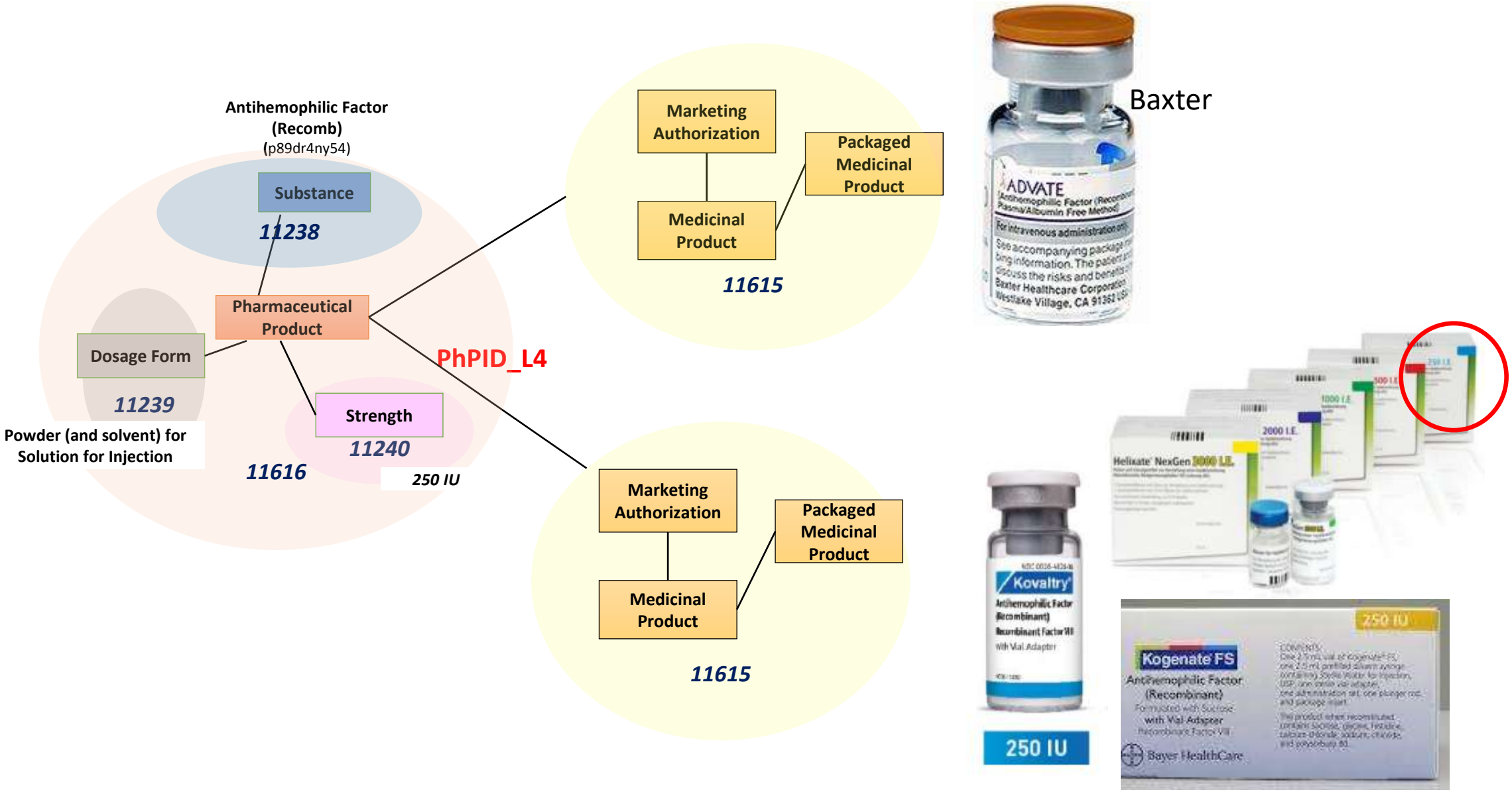
PhPID Set

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

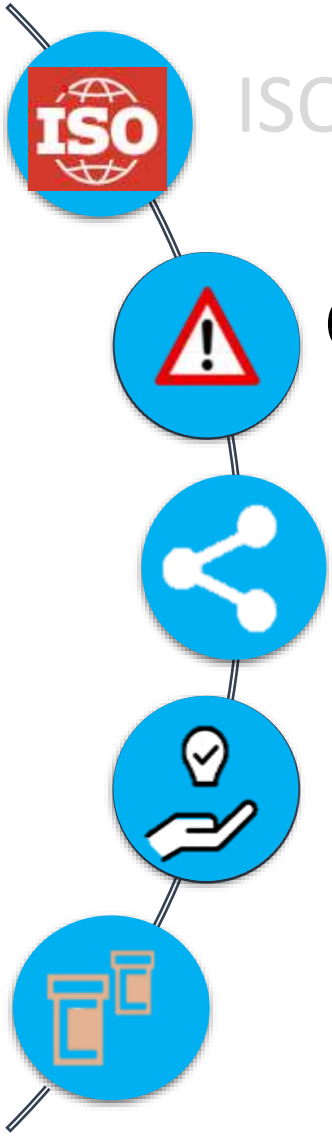
Connecting Medicinal Products - Drugs



Connecting Medicinal Products - Biologics



Topics



ISO IDMP Standards

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Challenges with ISO Standard for Global PhPID

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

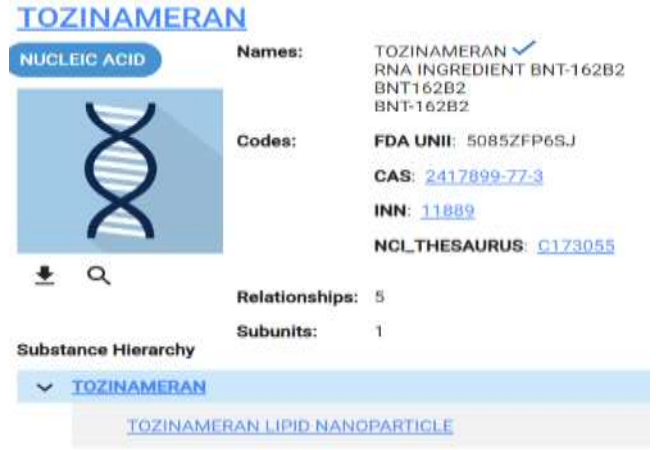
- No global agreement on common substance IDs for Global PhPIDs at all levels
- No global consensus on Dose Form Representations for level 3 and level 4 Global PhPIDs
- Dose Form expression variations among regions
- Strength (and units) expression variations among regions

Challenges discovered and relation to ISO Standards for **substances** (ISO 11238 / TS 19844)

- **Issues:**
  1. Global Substance ID has not been identified by regulatory agencies
  2. Consistent identification of substance will require global maintenance
  3. Can a core set of data fields with non-confidential unambiguously identify a substance?
  4. Harmonized capture of standardized information not always well defined for global Substance and PhPID

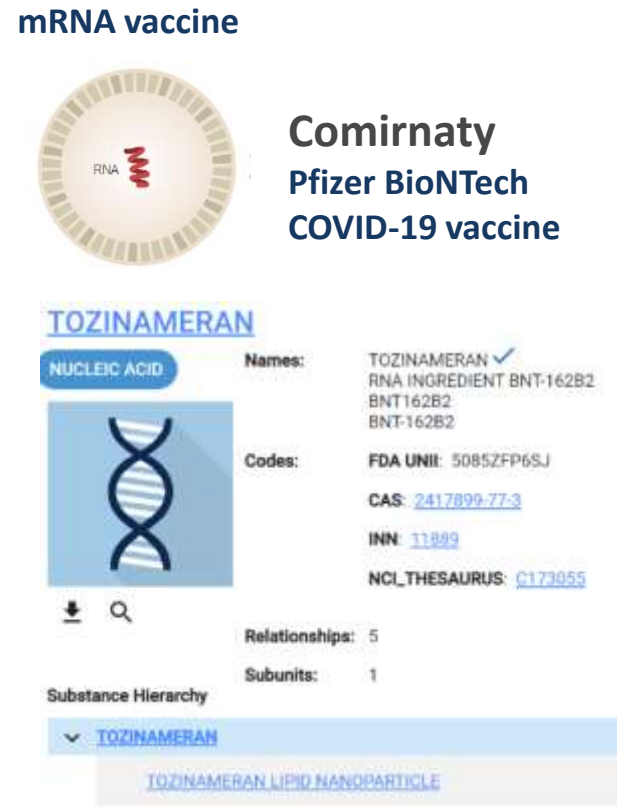
mRNA vaccine

Comirnaty
Pfizer BioNTech COVID-19 vaccine



Issues discovered and relation to ISO Standards for substances (ISO 11238 / TS 19844)

- **Actions**
  1. Recommend that UMC be established and recognized as the IDMP maintenance organization (IMO) for substance identifiers
  2. Identify the process to establish UMC as the IMO
  3. Conduct a pilot for global substance ID
  4. ISO TC 215 WG6 to ensure framework for capturing of standardized information including signature field

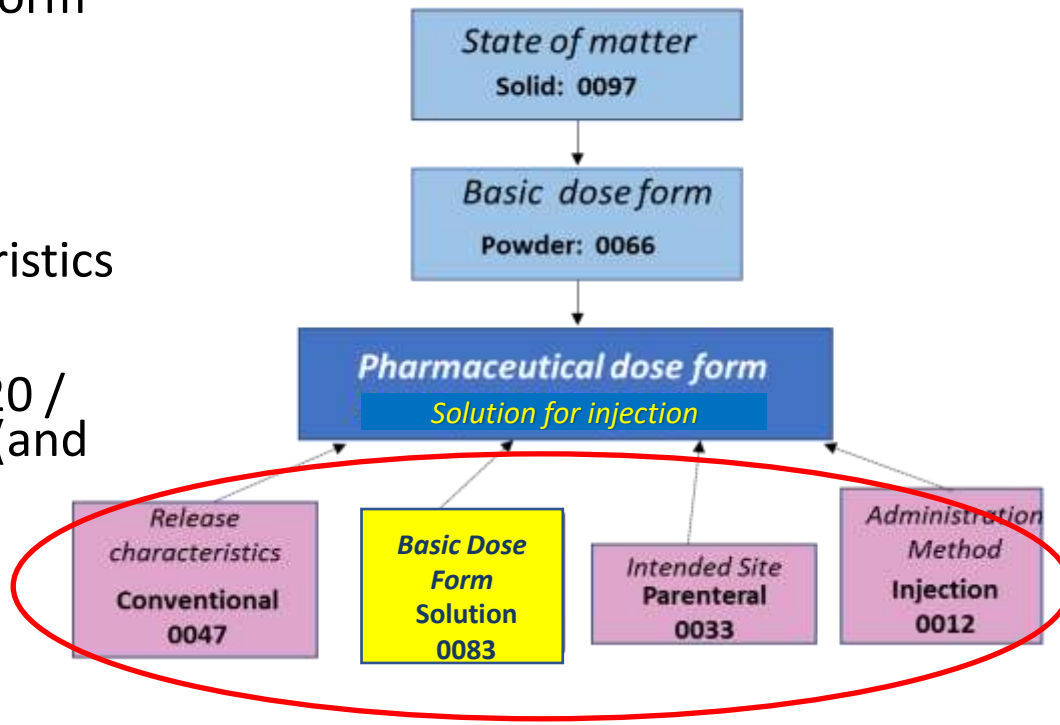


Challenges discovered and relation to ISO Standards for **dose form** (ISO 11239 / TS 20440)

- **Issues**
  1. No cross-region/global agreement on common dosage form
  2. Mapping regional dosage form terms is not viable

- **Solution:**
  1. To use a centrally maintained set of dose form characteristics for use in global IDMP and generation of PhPID.
  2. A pilot project with FDA and UMC was conducted in 2020 / 2021 that demonstrated that dose form characteristics (and codes) is viable solution for global IDMP.

- **Actions**
  1. Based on the Pilot project findings, as well as UNICOM findings, ISO TC 215 WG6 has revised the standard documents (in draft).
  2. Conduct an additional pilot for dose form characteristic mappings



Challenges Discovered with Dose Form and Strength

❖ Dose Form expression variations

❖ Pfizer Covid-19 vaccine

- EMA – ***Dispersion*** for Injection
- FDA – ***Suspension*** for Injection
- UK – ***Solution*** for Injection*

❖ **Strength expression variations** – different units

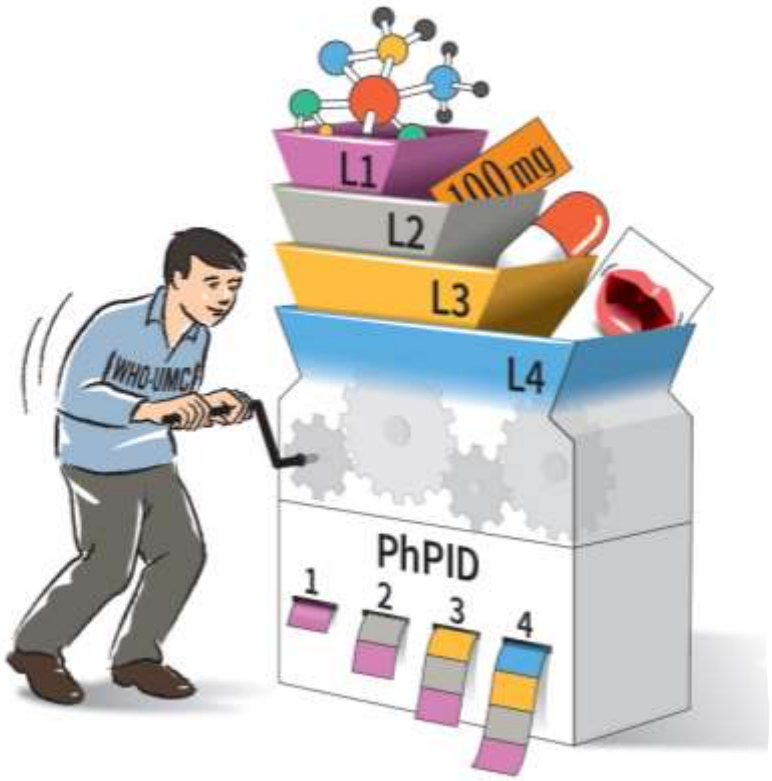
- %, IU, mg/g or mg/mL

❖ AstraZeneca Covid-19 vaccine

- EMA – 2.5×10^8 ***infectious units***
- UK – 5×10^{10} ***viral particles***
- Australia – 5×10^{10} ***viral particles***

** As of 2021*

Challenges discovered and relation to ISO Standards for **Pharmaceutical product ID** (ISO 11616/ TS 20451)



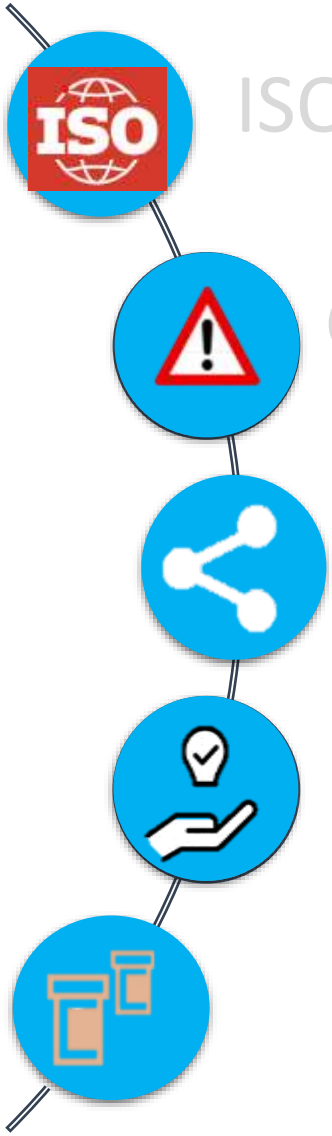
- **Solution:**
  - Global dose form ID and Substance ID need to be identified and agreed to by regulatory bodies.
  - Propose to include PhPID business rules in a new ISO Technical Report
- **Actions**
  - Recommend that WHO-UMC be established and recognized as the IDMP maintenance organization (IMO) for global PhPIDs
  - ISO TC215 WG6 to update standard to issues such as use of different units in different regions

Challenges for Global Implementation and Use

- FDA supports and promotes the implementation of the ISO IDMP standards.

- When outstanding challenges with the ISO IDMP standards are resolved and processes for use established, IDMP will be enabled for global use.

Topics



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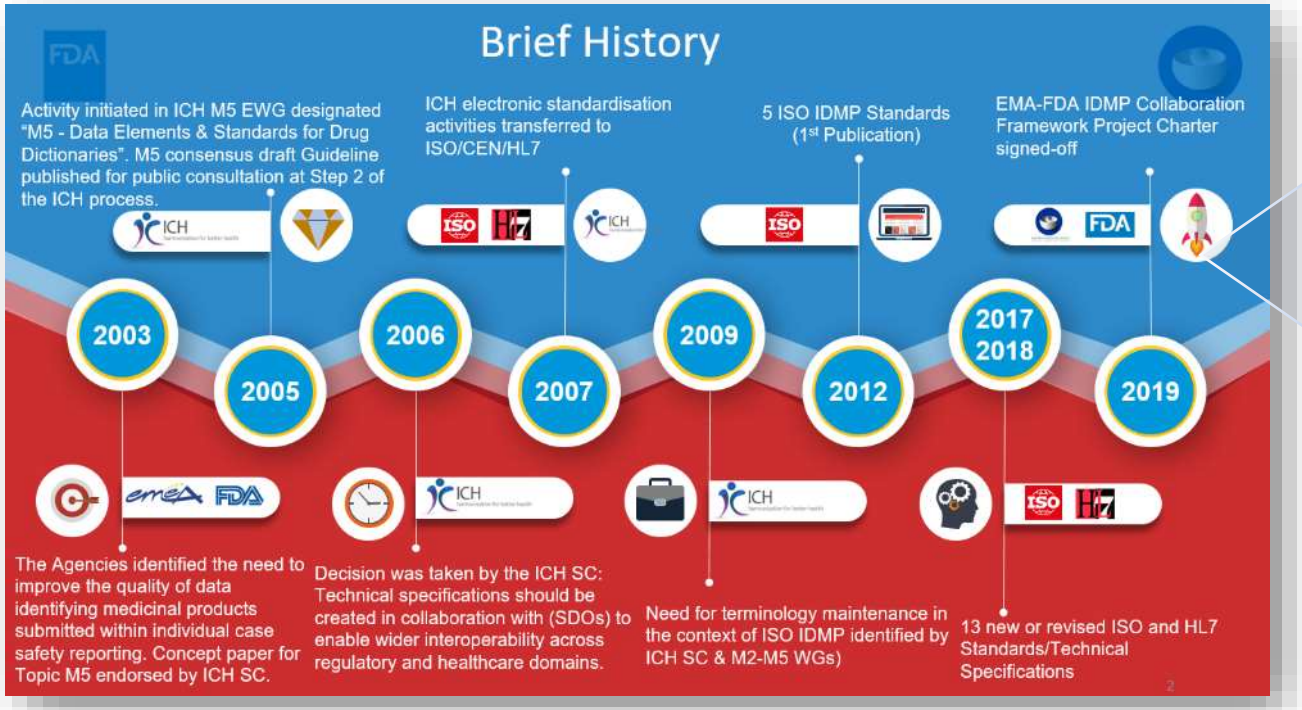
EMA-FDA Collaboration Framework Charter



EUROPEAN MEDICINES AGENCY

U.S. FOOD & DRUG ADMINISTRATION

EMA-FDA Identification of Medicinal Products Collaboration Framework

Charter

Purpose

This charter establishes the EMA – FDA Identification of Medicinal Products (IDMP) Collaboration Framework (Framework) and sets its background, scope and membership, as well as procedures.

The mission of the European Medicines Agency (EMA) is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of human and animal health in the European Union (EU). In the context of International Standards Organisation (ISO) IDMP implementation through SPOR data management services and EU Telematics projects, EMA is responsible for implementing the EU Telematics strategy, leading internationally, or coordinating and supporting interactions between over fifty national competent authorities for both human and veterinary medicines.

The mission of the US Food and Drug Administration (FDA) is to protect the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices, as well, the safety of the nation's food supply, cosmetics, and products that emit radiation. As FDA focuses on the challenges of the global supply chain and foreign sourcing of medicinal products, FDA continues to participate in the development of and to promote the adoption of international harmonized IDMP to ensure the safety of medications throughout the world.

It is recognised that the EMA and FDA (Agencies) have collaborated on IDMP standards development and systems for a number of years. This Framework further supports and enhances that collaboration through the establishment of governance that focuses on authority, decision-making and accountability with respect to joint IDMP activities.

Background

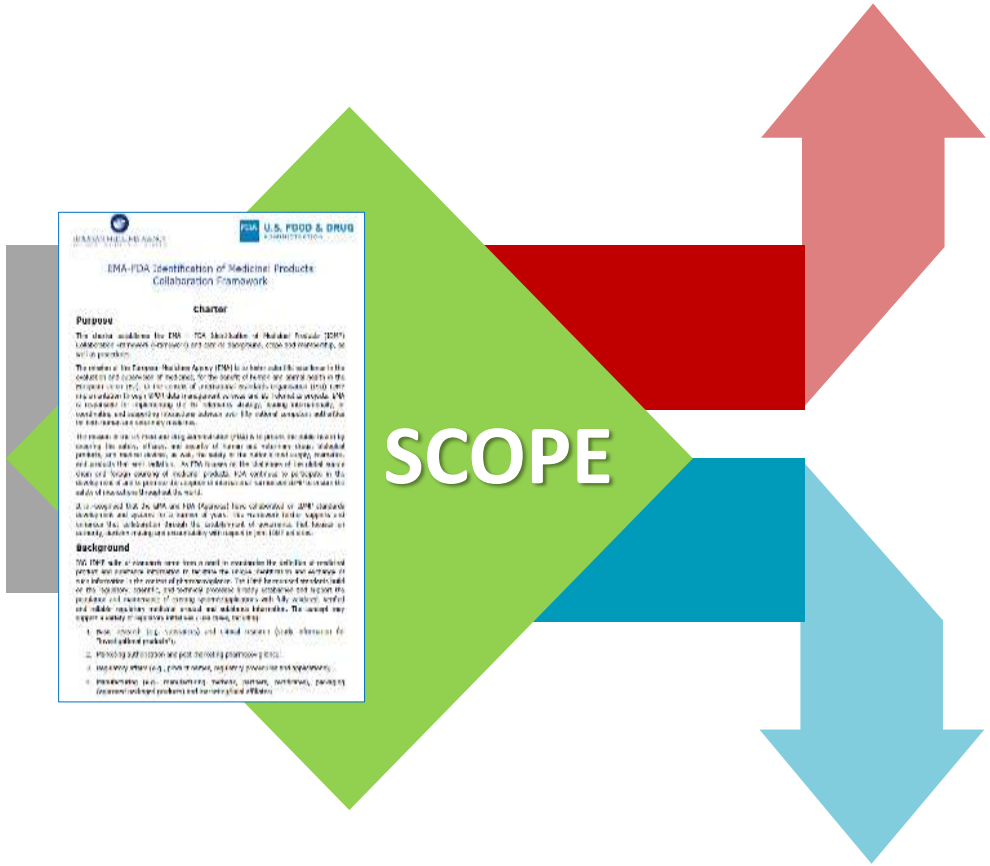
ISO IDMP suite of standards came from a need to standardise the definition of medicinal product and substance information to facilitate the unique identification and exchange of such information in the context of pharmacovigilance. The IDMP harmonised standards build on the regulatory, scientific, and technical processes already established and support the population and maintenance of existing systems/applications with fully validated, verified and reliable regulatory medicinal product and substance information. The concept may support a variety of regulatory initiatives / use cases, including:

1. Basic research (e.g. substances) and clinical research (study information for "investigational products");
2. Marketing authorisation and post-marketing pharmacovigilance;
3. Regulatory affairs (e.g., product names, regulatory procedures and applications);
4. Manufacturing (e.g., manufacturing methods, partners, certificates), packaging (approved packaged products) and marketing/local affiliates;

EMA-FDA Collaboration Framework Charter

Further supports and enhances the collaboration via a governance focused on decision-making, authority & accountability

EMA-FDA Collaboration Framework Charter



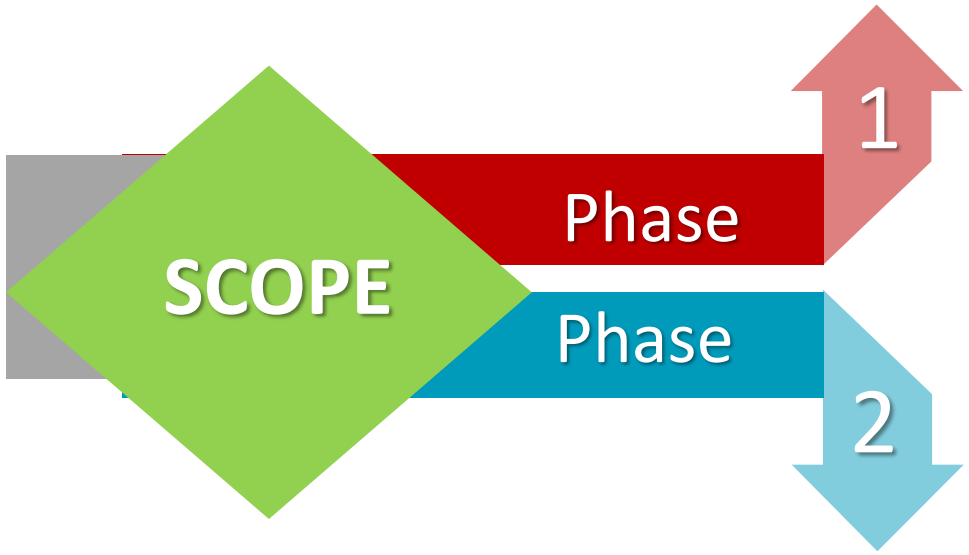
Development & Maintenance

Enhance, review and maintain of the ISO IDMP standards, technical specifications and technical reports via ISO/TC 215, CEN/TC 251 to ensure current and new EU and US business and legal requirements, as necessary, are met.

Implementation

Support the implementation of ISO IDMP standards and related terminologies to ensure current and new EU and US business requirements, as necessary, are met.

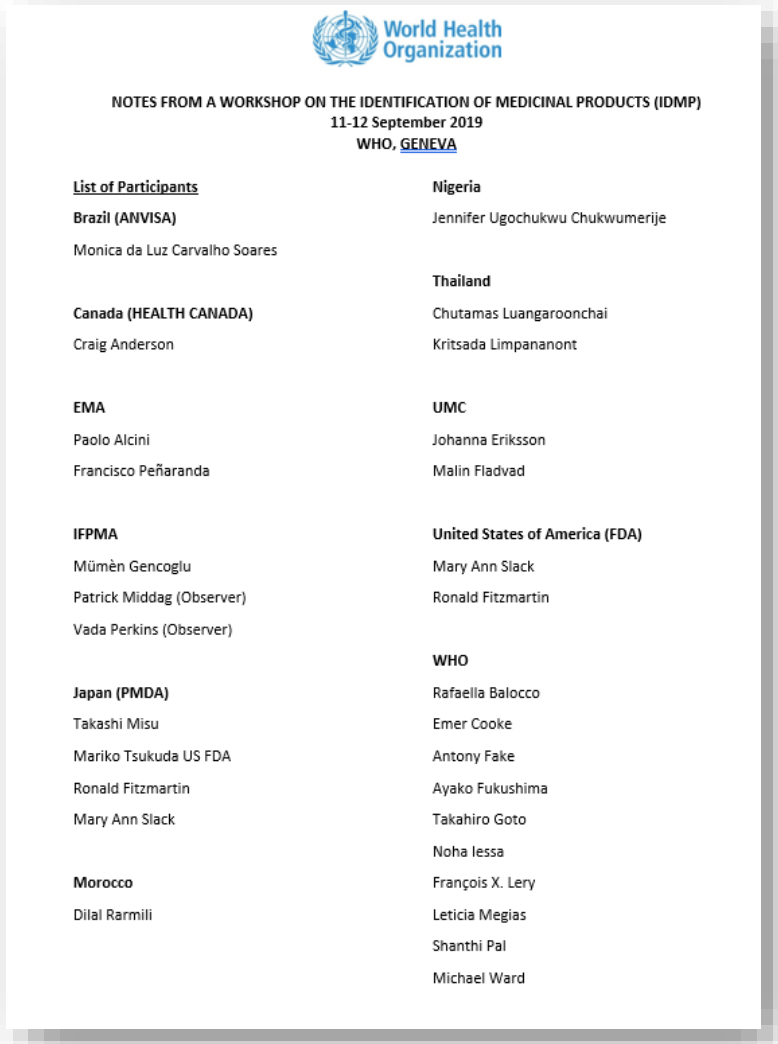
EMA-FDA Collaboration Framework Charter



- **Joint cooperation with SDOs**
- **Development and maintenance of the ISO standards**
- **GSRS / EU SRS: Scope and Maintenance**

- **Initiate pilots for various to ensure info exchange**
- **Coordinate with other international standardization activities**
- **Focus GSRS / EU SRS on global content & support**

Global IDMP Working Group



World Health Organization

NOTES FROM A WORKSHOP ON THE IDENTIFICATION OF MEDICINAL PRODUCTS (IDMP)
11-12 September 2019
WHO, GENEVA

List of Participants

Brazil (ANVISA)
Monica da Luz Carvalho Soares

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EMA
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Takahiro Goto
Noha Iessa
François X. Lery
Leticia Megias
Shanthi Pal
Michael Ward

- Global Identification of Medicinal Products Working Group (GIDWG) is chartered based on the recommendations from the IDMP Workshop in Geneva hosted by the World Health Organization on 11-12 September 2019.
- Phase 1 of GIDWG will have European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA) and WHO -Uppsala Monitoring Center (UMC) as its chartered members.

Goal of the Global IDMP Working Group

Conduct and report on projects leading to the establishment of a framework for the global implementation of the ISO IDMP standards and maintenance of global identifiers.

GLOBAL IDMP WORKING GROUP

Charter

1. INTRODUCTION

This charter establishes the Global Identification of Medicinal Products Working Group (GIDWG). The initial Phase 1 members are European Medicines Agency (EMA), United States Food and Drug Administration (US FDA) and the World Health Organization Collaboration Center for International Drug Monitoring / Uppsala Monitoring Center (WHO-UMC). The Charter sets the GIDWG's mission, scope, membership, roles and responsibilities, and governance.

This working group was established as a result of the IDMP Workshop hosted by the World Health Organization on 11-12 September 2019 in Geneva, The summary notes of the workshop proposed a set of actions and recommendations that included the formation of a working group to explore and conduct pilot projects focused on the creation and maintenance of global substance and pharmaceutical product IDs (PhPIDs) that would lead to the global implementation of the IDMP standards and further outreach and collaboration with stakeholders.

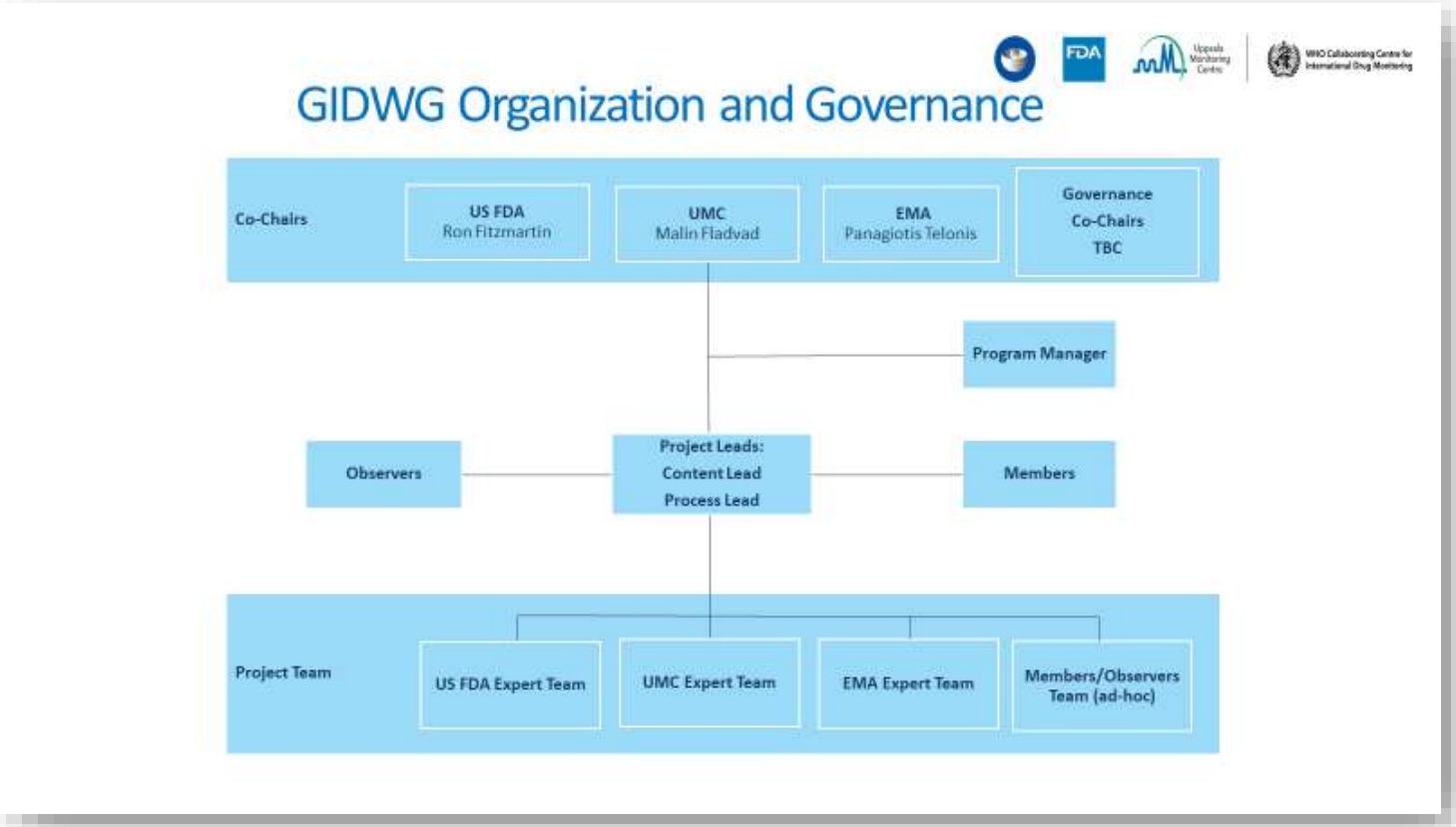
2. MISSION

The GIDWG will conduct and report on projects leading to the establishment of a framework for the global implementation of the ISO IDMP standards and maintenance of global identifiers.

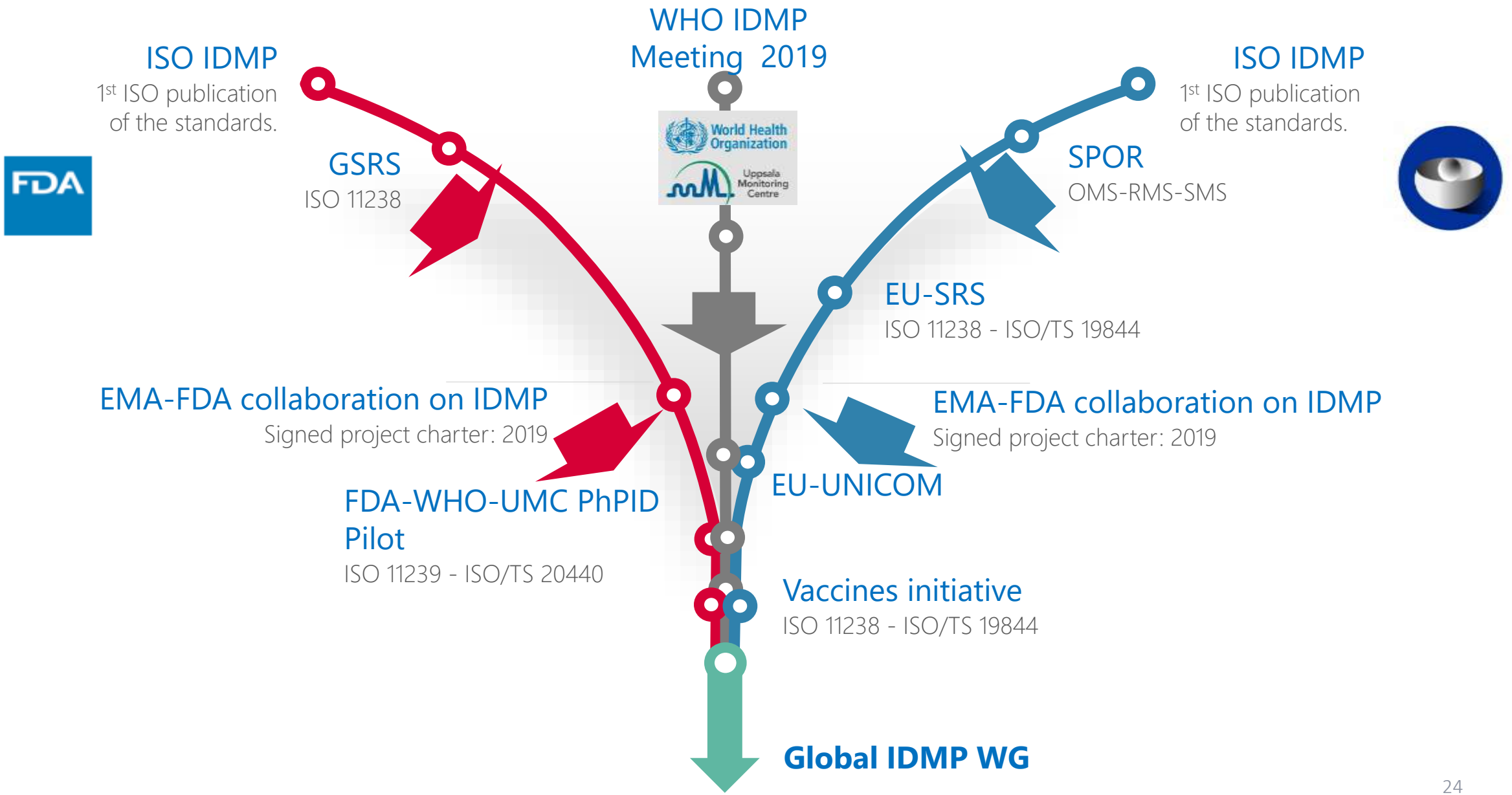
3. SCOPE

The scope includes:

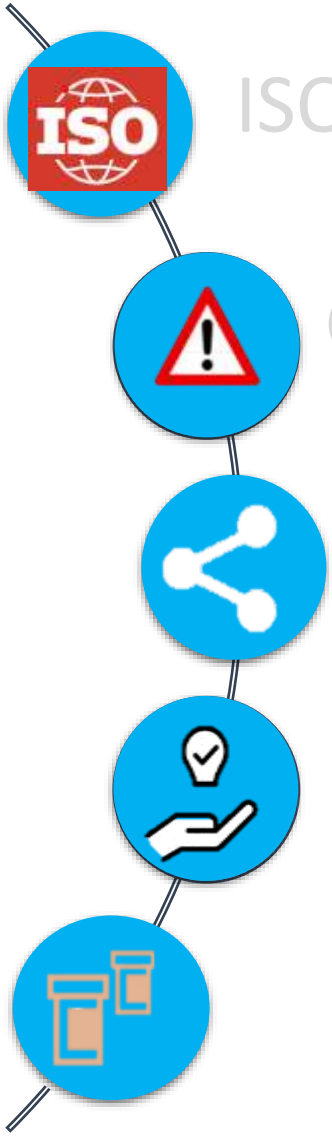
1. Understand and develop consensus on the issues and mitigation strategies with the ISO IDMP standards, their Technical Specifications and message infrastructure.
2. Develop and prioritize a list of global IDMP implementation use cases.
3. Understand the IDMP implementation status and challenges in each region.
4. Understand and develop a consensus on what is the best pathway to a global substance ID.
5. Articulate and develop consensus on use of UMC as the organization for maintenance of global identifiers, i.e., Substance ID and PhPID.
6. Develop a consensus on best practices, processes, operating model for maintenance of global identifiers for marketed medicinal products.
7. Identify, recommend, and participate in pilot projects.
8. Identify and recommend best approaches for communicating outcomes / summary of findings to other stakeholders.



Convergence in Cross Region Collaboration



Topics



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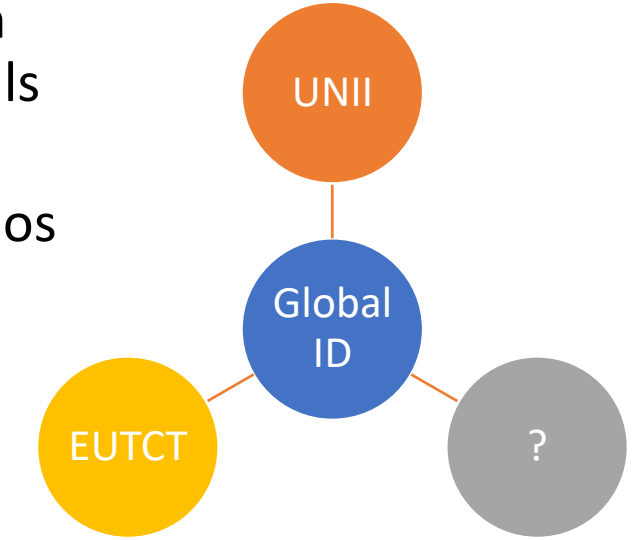
Planned Pilots to Conduct in 2022

1. Global Substance ID

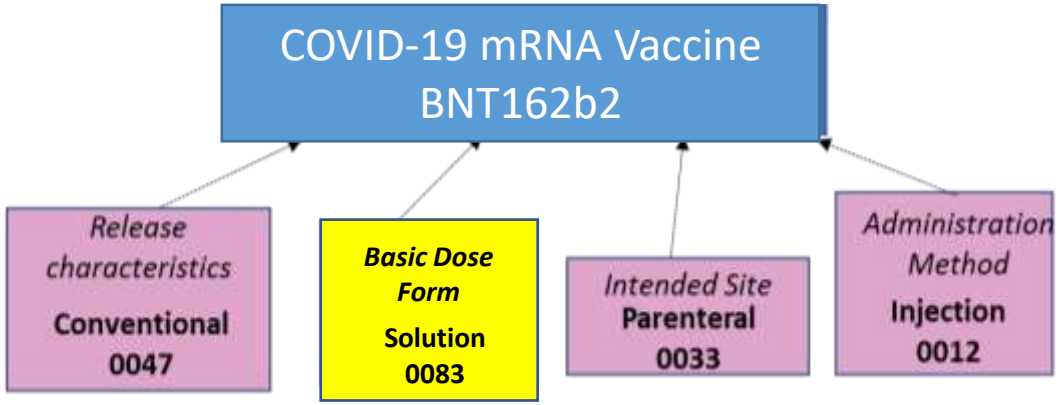
- Scope
  - Mapping EU-SRS EUTCT, FDA UNII, and one additional region (if possible) to Global identifier for a set of selected Chemicals in WHO Model List of Essential Medicines
  - Review all substance classes including more complex scenarios like certain biologics
- Success Criteria
  - Meet requirements for unique substance identification
  - Identify and address issues and challenges
  - Identify and address regional legacy substance definition/identification
  - Propose a feasible, scalable, and most efficient operation model to maintain global substance identifiers (and definition and identification)



Planned Pilots to Conduct in 2023

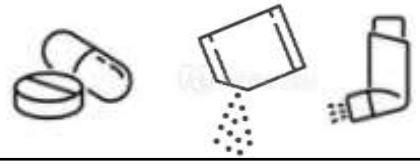
2. Global Dose Form Identifier

- **Rationale**
  - To ensure consistent mapping to EDQM characteristics for products with less granular dose form expressions
- **Scope**
  - Map DF to another region using the DF characteristic approach
  - Further investigate DF characteristic combination and EDQM DF characteristic with multiple values
- **Success Criteria**
  - Identify and address issues and challenges
  - Documented rules to apply proper DF characteristics, for the generation of global PhPID, regardless regional DF variations



Planned Pilots to Conduct in 2022

- **3. Strength Definitions Identifier**
  - **Rationale**
    - To build on the FDA/ WHO-UMC pilot developed concepts the use of strength presentation versus strength concentration for different products
  - **Scope**
    - Identify and address different representation of strength for products in different regions
    - Work with ISO, clarify the use of presentation strength and concentration strength

Pattern	Type of product
A	
B	
C	
D	

Planned Pilots to Conduct in 2022

- **4. HL7 FHIR for IDMP**

Scope

- Participate in the development, verification, and ballot of HL7 FHIR resources related to IDMP

Success Criteria

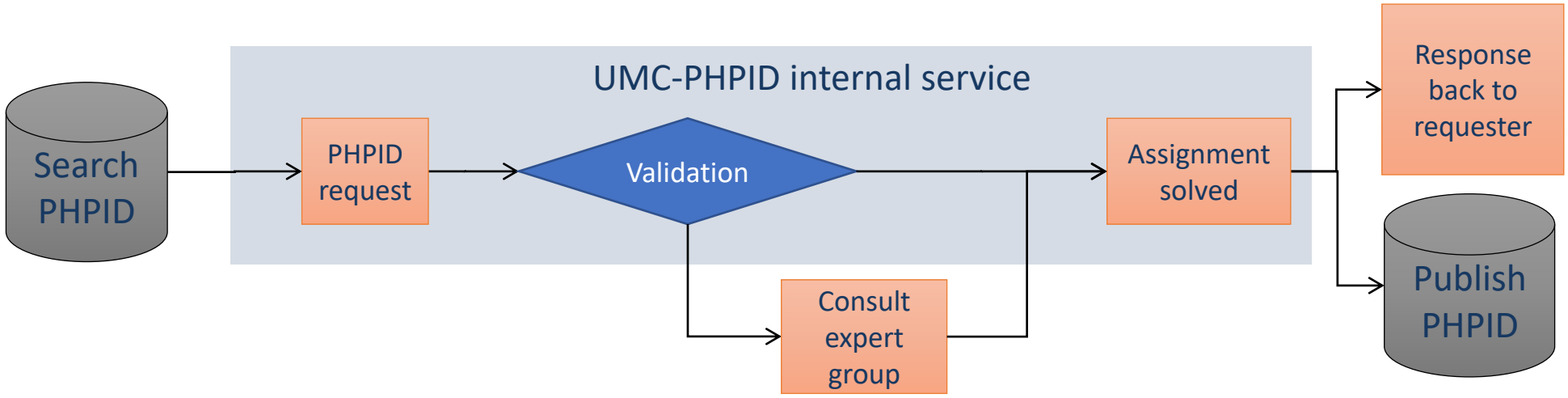
- Successful exchange of medicinal product and substance information including EU-SRS/SMS,FDA-SRS and UMC-SRS using HL7 FHIR as the underling messaging technology for ISO IDMP standards
- Demonstrate in HL7 FHIR connectathons and other stakeholder events

Dependencies

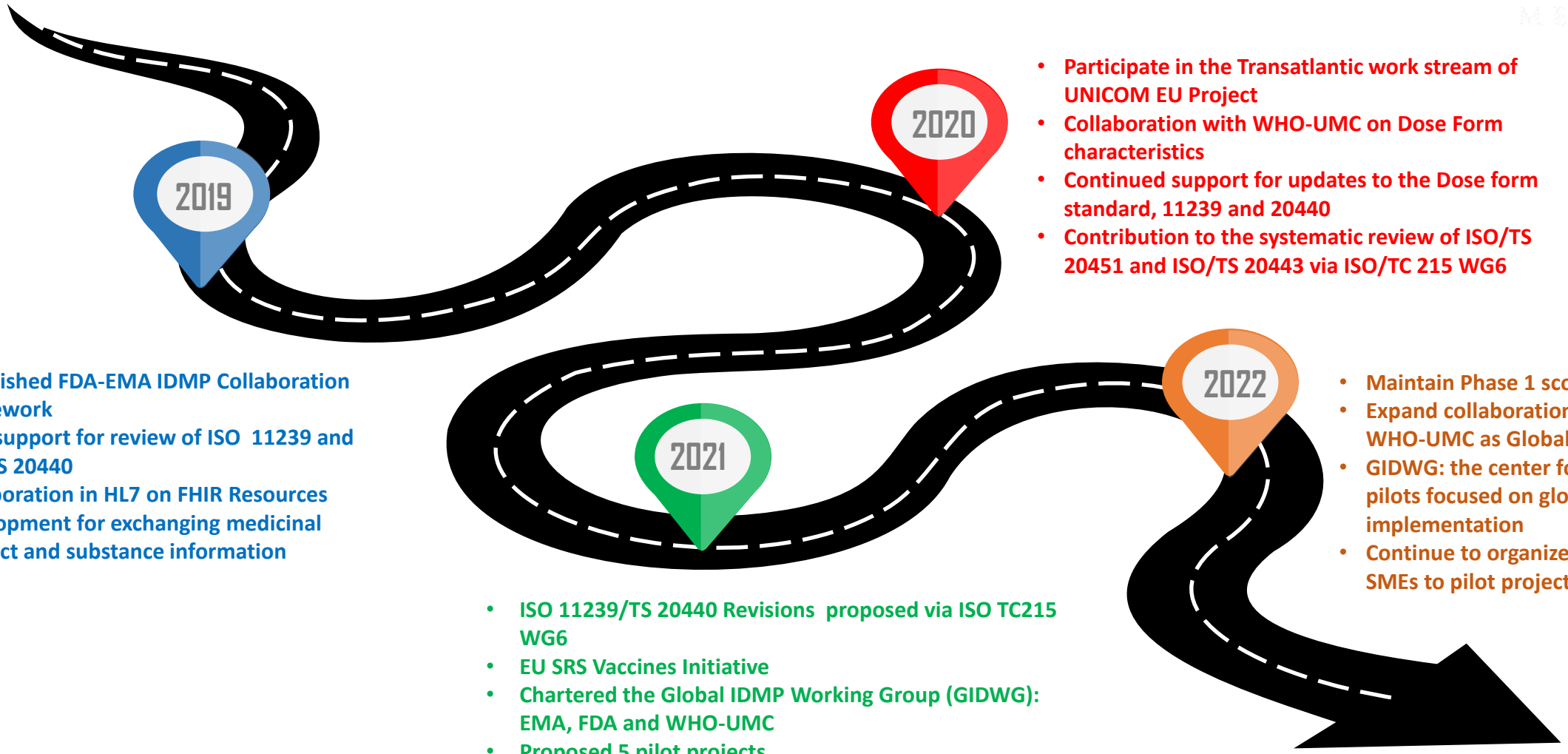
- ISO 11615 and ISO/TS 20443
- ISO 11238 and ISO/TS 19844

Planned Pilots to Conduct in 2022

- **5. Operating model**
  - **Scope**
    - Demonstration of the consensus-based operating model for WHO-UMC as the international maintenance organization as an end-to-end pilot
  - **Success Criteria**
    - Successful process from request to publication of global PhPID for a set of selected cases



IDMP Collaboration Roadmap 2019-2022



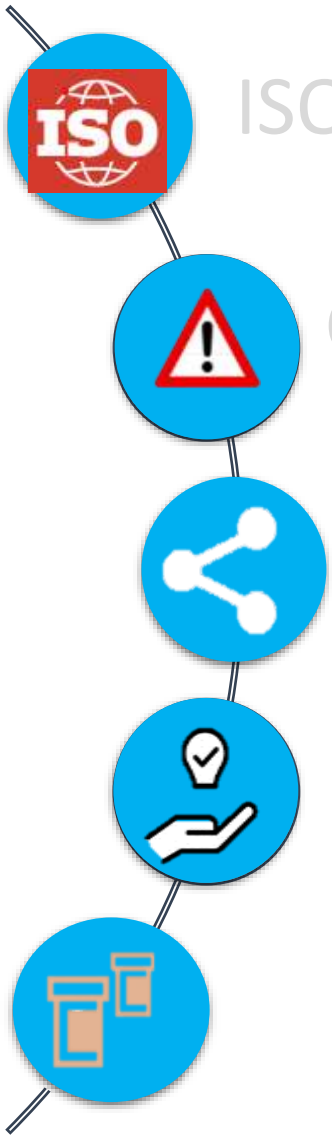
- Established FDA-EMA IDMP Collaboration Framework
- Joint support for review of ISO 11239 and ISO/TS 20440
- Collaboration in HL7 on FHIR Resources development for exchanging medicinal product and substance information

- ISO 11239/TS 20440 Revisions proposed via ISO TC215 WG6
- EU SRS Vaccines Initiative
- Chartered the Global IDMP Working Group (GIDWG): EMA, FDA and WHO-UMC
- Proposed 5 pilot projects
- Development of EMA-FDA Implementation Action Plan
- Participated in HL7 FHIR Connectathons
- ISO/TS 19844 Revision via ISO/TC 215 WG6

- Participate in the Transatlantic work stream of UNICOM EU Project
- Collaboration with WHO-UMC on Dose Form characteristics
- Continued support for updates to the Dose form standard, 11239 and 20440
- Contribution to the systematic review of ISO/TS 20451 and ISO/TS 20443 via ISO/TC 215 WG6

- Maintain Phase 1 scope activities
- Expand collaboration with the WHO-UMC as Global MO
- GIDWG: the center for IDMP pilots focused on global implementation
- Continue to organize and assign SMEs to pilot projects

Topics



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IDMP
Points to Consider for Biologics

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Bayer Pharmaceuticals

Toward Global Identification of Medicinal Products (IDMP) Implementation

January 27, 2022

Global Substance and Pharmaceutical Identifier Challenge

- In order to have a robust global substance identifier and global pharmaceutical product identifier, the unique and scientific **identification of a substance** must occur.
  - Objective, defining (mandatory) elements to associate and differentiate substances utilized in medicinal products to ensure global harmonization given that regional requirements will still need to be accommodated.

Challenges with ISO Standard for Global PhPID

- PhPID Set
  - PhPID_Substance Level_L1 → Substance(s) Term
  - PhPID_Substance Level_L2 → Substance Term(s) +Strength+ reference strength
  - PhPID_Substance Level_L3 → Substance Term(s) + *Administrable Dose Form*
  - PhPID_Substance Level_L4 → Substance(s) Term+ Strength + reference strength + *Administrable Dose Form*
- No global agreement on common substance IDs for Global PhPIDs at all levels
- No global consensus on Dose Form Representations for level 3 and level Global PhPIDs
- Dose Form expression variations among regions
- Strength (and units) expression variations among regions

Challenges discovered and relation to ISO Standards for substances (ISO 11238 / TS 19844)

- **Issues:**
  1. Global Substance ID has not been identified by regulatory agencies
  2. Consistent identification of substance will require global maintenance
  3. Can a core set of data fields with non-confidential unambiguously identify a substance?
  4. Harmonized capture of standardized information not always well defined for global Substance and PhPID

Characteristics: Small vs. Large Molecules

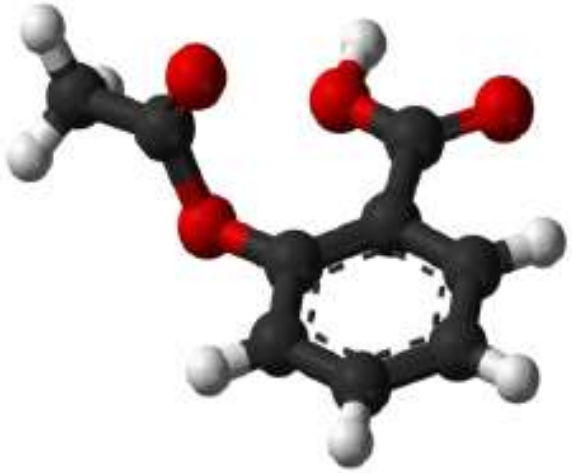
Small Molecule Drugs

- Simple, well defined, independent of manufacturing process
- Produced by chemical synthesis
- Predictable chemical process
- Identical copy can be made
- Easy to characterize completely
- Stable
- Mostly non-immunogenic

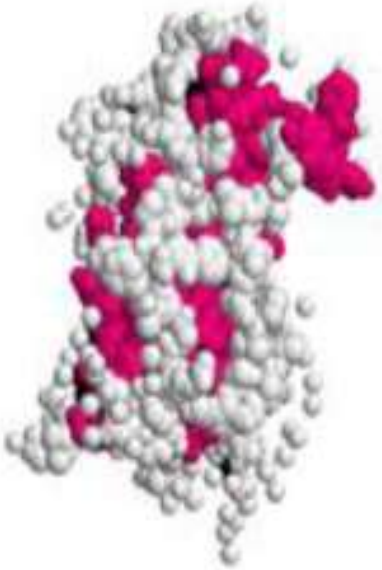
Biological Drugs

- Complex (heterogeneous), defined by the exact manufacturing process
- Produced in living cell culture
- Difficult to control from starting material to final API
- Impossible to ensure identical copy
- Cannot be characterized completely (e.g., molecular composition and heterogenicity)
- Unstable, sensitive to external conditions

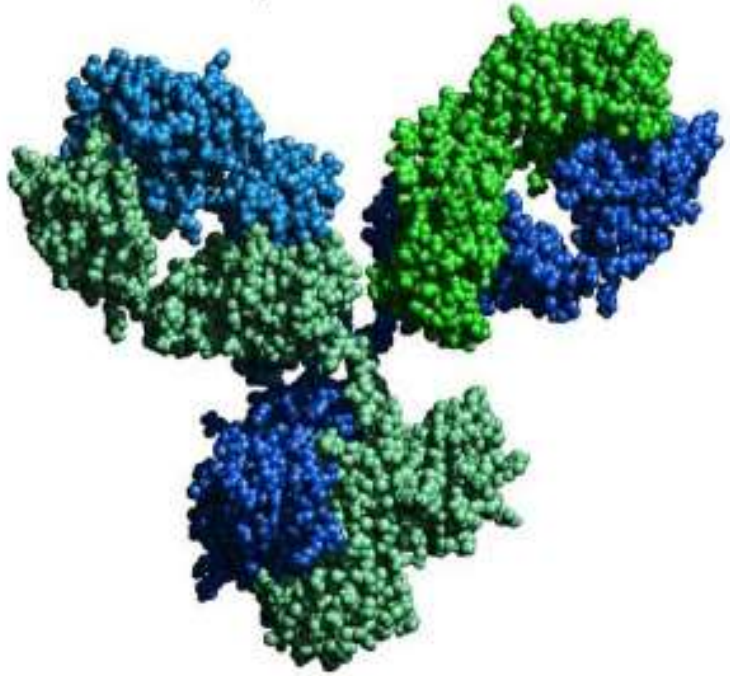
Small Molecule Drug / Pharmaceutical
Aspirin
21 atoms



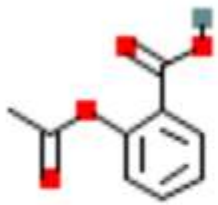
Large Molecule Drug
Human Growth Hormone
~3,000 atoms



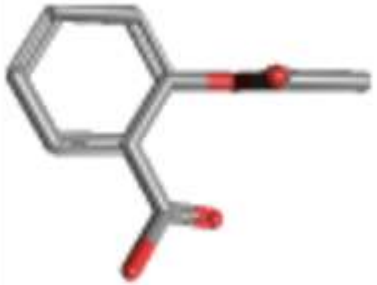
Large Biologic
Herceptin
~25,000 atoms



Aspirin



2D

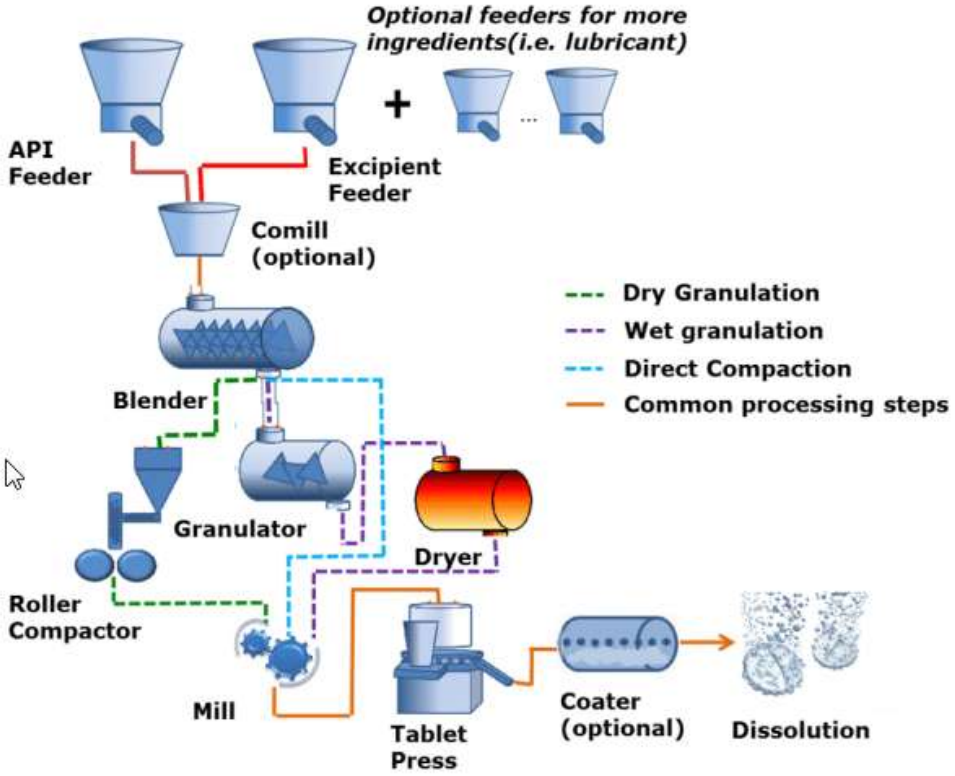


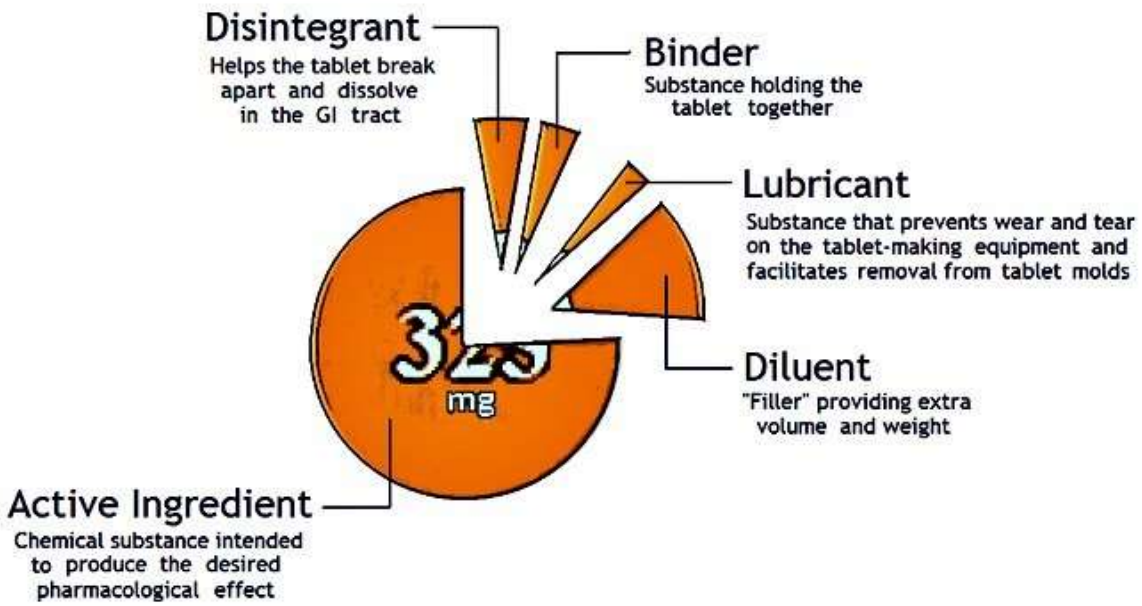
3D

Crystal

Source: PubChem & Mann Bioinvest

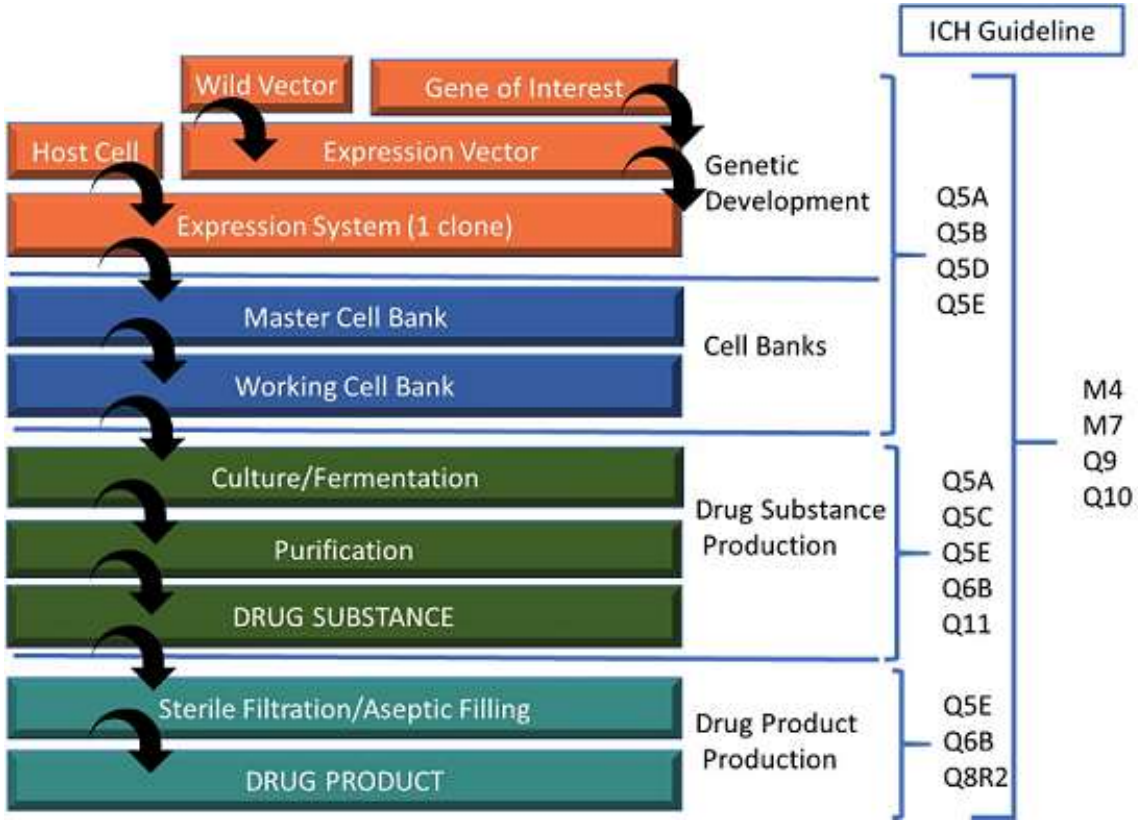
Tablet Manufacturing



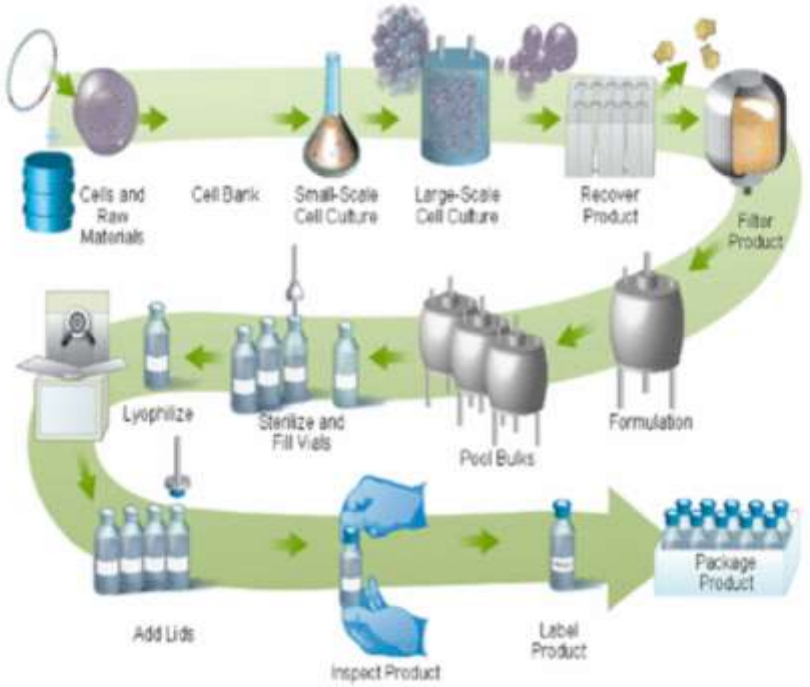


Source: saintytec

Biologics Manufacturing



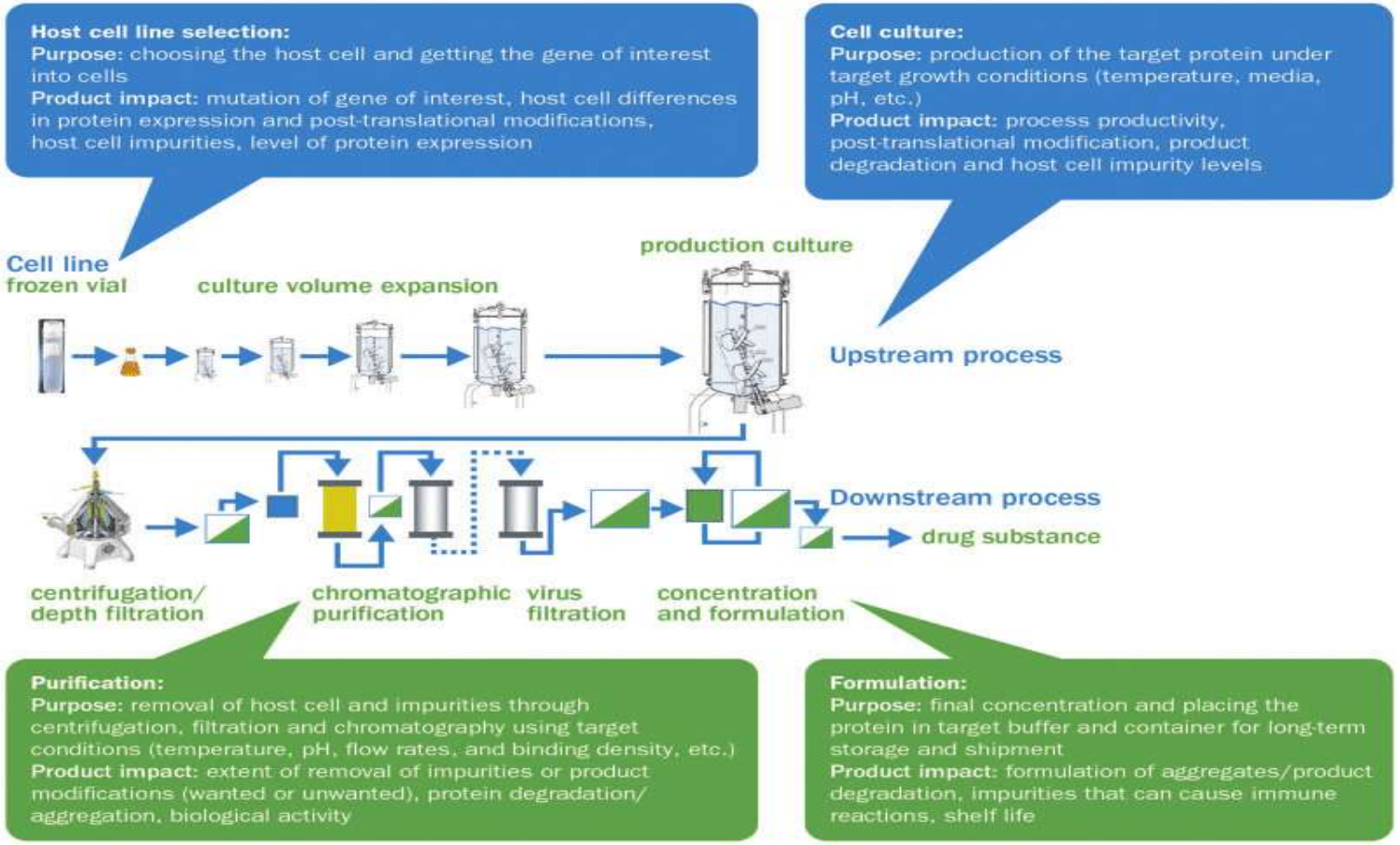
Source: [outsourcedpharma]



Source: sec.gov/genzyme

Biologics Manufacturing Process

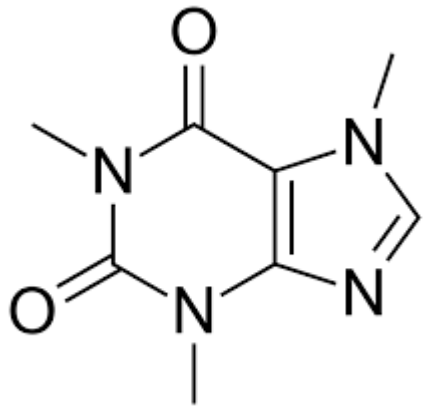
- Traditional drug products usually consist of pure chemical substances that are easily analyzed after manufacture
- Limited ability to identify the identity of the clinically active component(s) of a complex biological product
  - Biologics defined by their manufacturing processes
- Changes in the manufacturing process, equipment or facilities could result in changes in the biological product
  - May require additional clinical studies to demonstrate the product's safety, identity, purity and potency



Source: Rheumatology 2017;56:iv14iv29 doi:10.1093/rheumatology/kex278

IDMP: Substance Groups and Defining Elements

- **Chemicals**
  - **Defined primarily by molecular structure** (connectivity and stereochemistry)



- **Proteins**
  - **Amino Acid Sequence**, type of **glycosylation**, modifications

- **Nucleic Acids**
  - **Sequence**, type of sugar and linkage, modifications

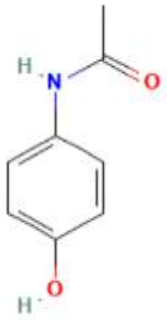
- **Polymers** (Synthetic or biopolymers)
  - Structural repeating units, type, geometry, type of copolymer (block or random), ratio of monomers, modifications, **molecular weight** or properties related to molecular weight, **biological source** for many biopolymers

- **Structurally Diverse Substances** (viruses, cells, tissues, complex materials)
  - **Taxonomic, anatomical, fractionation, physical properties, modifications**

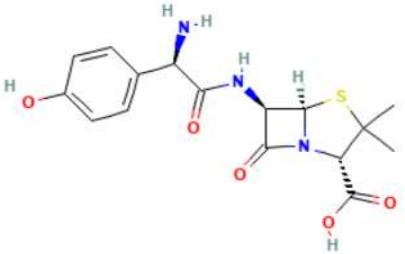
Considerations for Unique Substance Identification vs Product Identification

Naming Conventions : **USAN/INN**

- **Acetaminophen** (USAN)/**Paracetamol** (INN)



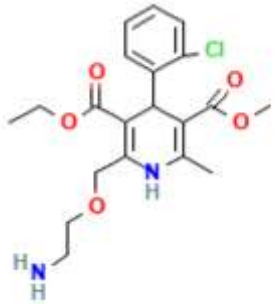
- **Amoxicillin**: INN-amoxicillin/USAN-amoxicillin
  - Trihydrate ($C_{16}H_{25}N_3O_8S$)
  - Anhydrous ($C_{16}H_{19}N_3O_5S$)



2.4.1 MeSH Entry Terms

Actimoxi
Amoxicillin
Amoxicillin Anhydrous
Amoxicillin monopotassium salt
Amoxicillin monosodium salt
Amoxicillin Sodium
Amoxicillin trihydrate
Amoxicillin, (R*)-isomer
Amoxicilline

- **Amlodipine** (compound, besylate, maleate, mesylate)
  - Amlodipine ($C_{20}H_{25}ClN_2O_5$)
  - Amlodipine besylate ($C_{26}H_{31}ClN_2O_8S$)



Considerations for Unique Substance Identification vs Product Identification

Naming Conventions and Substance/Product Identification for biologics is more complex…

ELSEVIER

Biologicals

Volume 60, July 2019, Pages 15-23

Review

The INN global nomenclature of biological medicines: A continuous challenge

James S. Robertson [a], Wai-Keung Chui [b], Armando A. Genazzani [c], Sarel F. Malan [d], Ana López de la Rica Manjavacas [e], Gilles Mignot [f], Robin Thorpe [a], Raffaella Balocco [g], Menico Rizzi [c]

Show more

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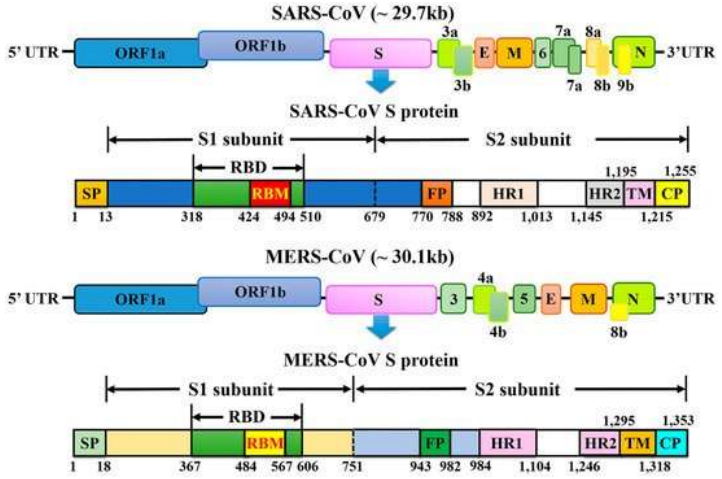
https://doi.org/10.1016/j.biologicals.2019.05.006

Examples: Unique Identification (Biologics)

Vaccines (SARS-CoV-2)

- **Viral vector**
- **Protein-based**
- **Genetic**
  - Genes administered directly as either DNA or RNA
  - **mRNA**
    - Pfizer (COVID-19 Vaccine, mRNA)
    - Moderna (COVID-19 Vaccine)

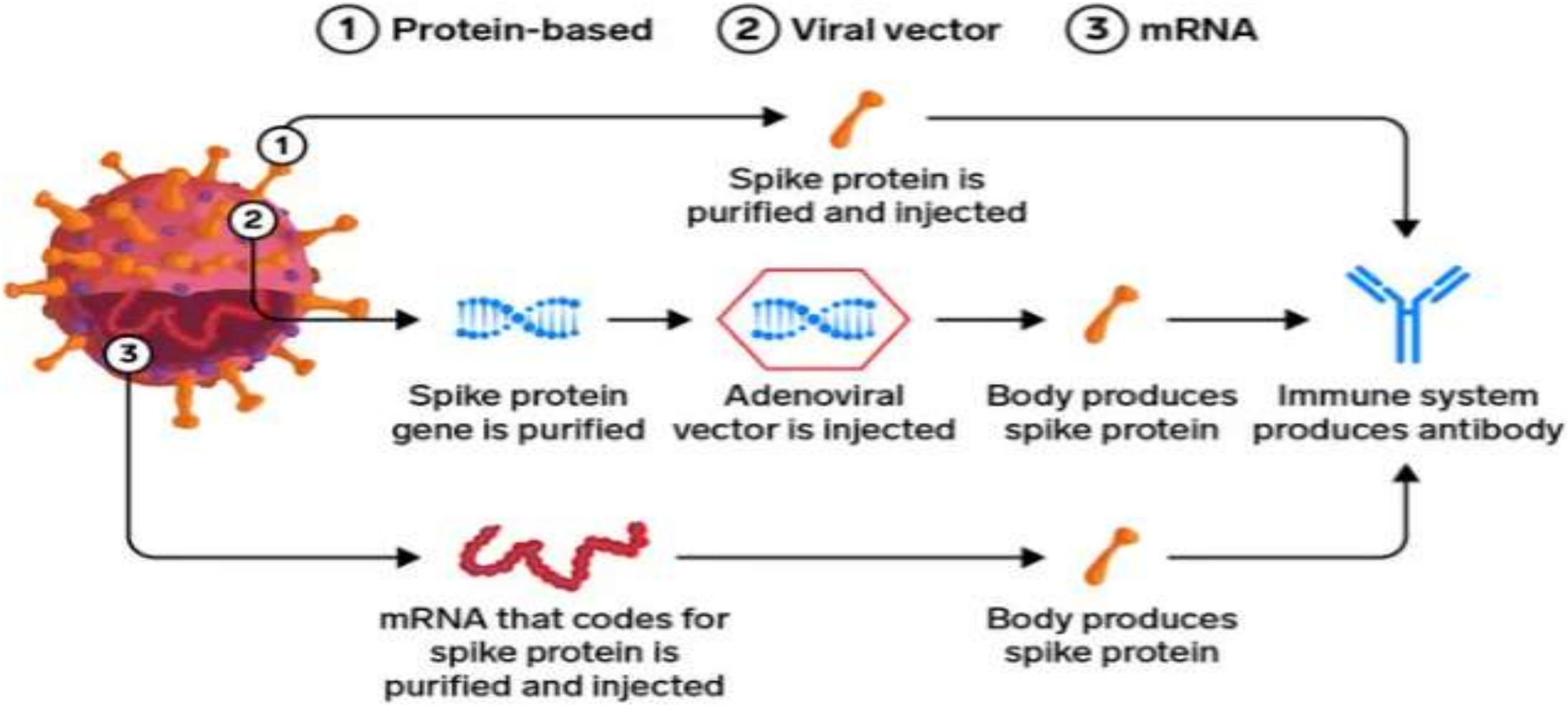


Insulin

- Insulin Aspart
  - Rapid-acting
- Insulin Glargine
  - Long-acting

- **Influenza**
  - Egg vs cell-based
  - Inactivation method

Example: Coronavirus Vaccines



Source: NIH

Unique Identification (Biologics): SARS-CoV-2 (mRNA)

ELASOMERAN

- **UNII:** EPK39PL4R4
- **Preferred Substance Name:** ELASOMERAN
- **2430046-03-8**
- **CX-024414**
- **ELASOMERAN [INN]**
- **ELASOMERAN [WHO-DD]**
- **M-1273**

MODERNA COVID-19 VACCINE RNA

- **MRNA-1273**
- **MRNA-BASED VACCINE**
- **TAK-919**

TOZINAMERAN

- **UNII:** 5085ZFP6SJ
- **Preferred Substance Name:** TOZINAMERAN
- **2417899-77-3**
- **BNT162B2**
- **BNT-162B2**
- **COMIRNATY**

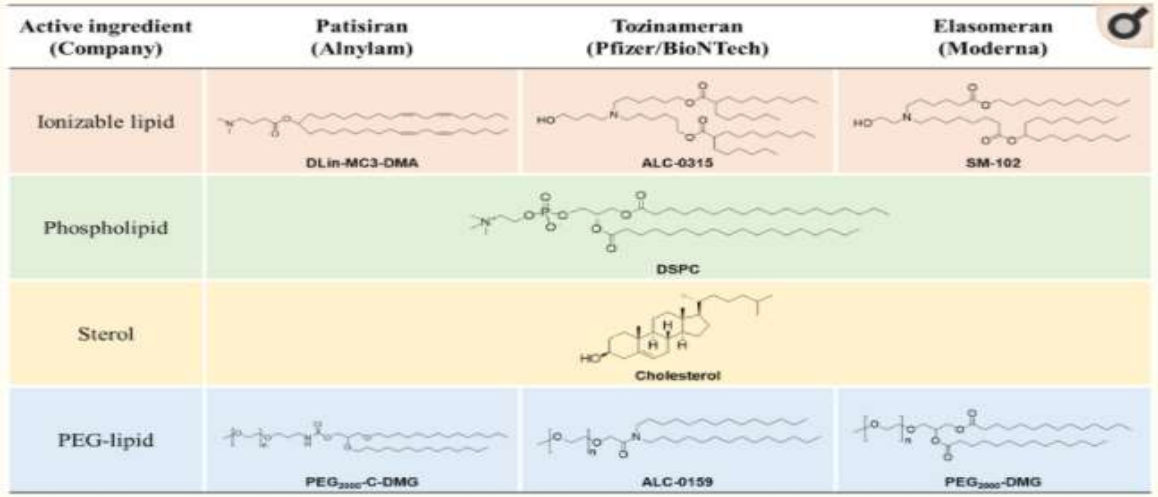
PFIZER COVID-19 VACCINE

- **RNA INGREDIENT BNT-162B2**
- **TOZINAMERAN [INN]**
- **TOZINAMERAN [WHO-DD]**

3. Difference in formulation

Go to:

The three LNP-based drugs share multiple similarities in their formulation, and hence, behave similarly as nanoparticles in vivo. Importantly, all LNPs are composed of four types of lipids; ionizable lipid, phospholipid, cholesterol, and PEG-lipid (Fig. 3). All 3 ionizable lipids have tertiary amine group with pKa 6.0–6.7. These lipids switch its charge from neutral to cationic based on the neutral pH in the blood and the acidic pH in endosomes. The 3 PEG-lipids have dialkyl chains 14-carbon long, which are important for the rapid dissociation from the surface of LNPs once inside the body [43]. The biodegradable design of ALC-0315 [44] and SM-102 [11] is described later.



Open in a separate window

Fig. 3

Chemical structure of lipids in lipid nanoparticles. ALC-0159 has PEG_{2000}. All 3 ionizable lipids have tertiary amine groups, namely Dlin-MC3-DMA (MC3), pKa 6.44 [12] or pKa 6.35 [11]; ALC-0315, pKa 6.09 [44]; and SM-102, pKa 6.68 [11]. The related patents are as follows: Dlin-MC3-DMA, WO/2010/144740; ALC-0315, WO/2017/075531 (Lipid No. 3); and SM-102, WO/2017/049245 (Compound 25).

Drug Metab Pharmacokinet. 2021 Dec; 41: 100424.
Published online 2021 Oct 10. doi: 10.1016/j.dmpk.2021.100424

What Now: OBSERVE & ENGAGE!

Health Authority Initiatives

- EMA-FDA Collaboration Framework Charter
- **Global IDMP Working Group (GIDWG)**
- EU SPOR Initiative
- US FDA Roadmap (2022-202x)

Trade Association Engagement

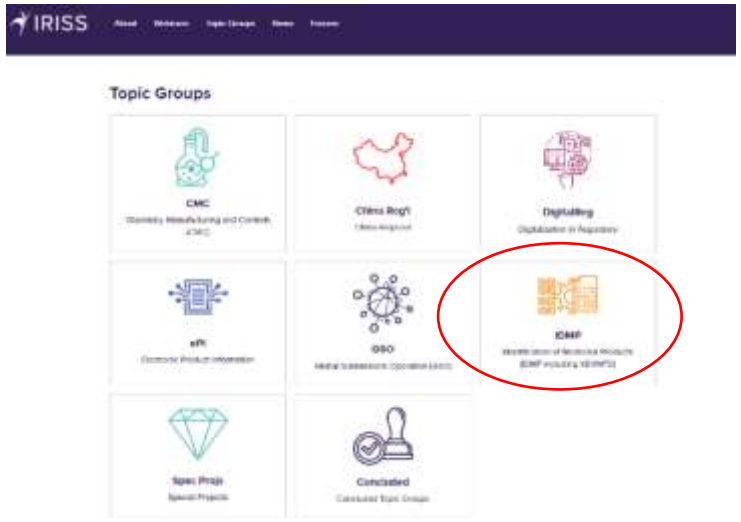
- PhRMA
- EFPIA
- Medicines for Europe, others…

IDMP-Specific Forums

- **IRISS Forum** (non-profit)
  - IDMP Topic Group

UNICOM (EU)

- EU Commission funded initiative for the implementation of ISO IDMP in Europe (and globally).
  - IDMP in a Capsule (infographic)



Global Substance Registration Public Resources (G-SRS)-FDA/NCATS Collaboration

- Software (open source), data and info on GSRS from NCATS
  - https://tripod.nih.gov/ginas

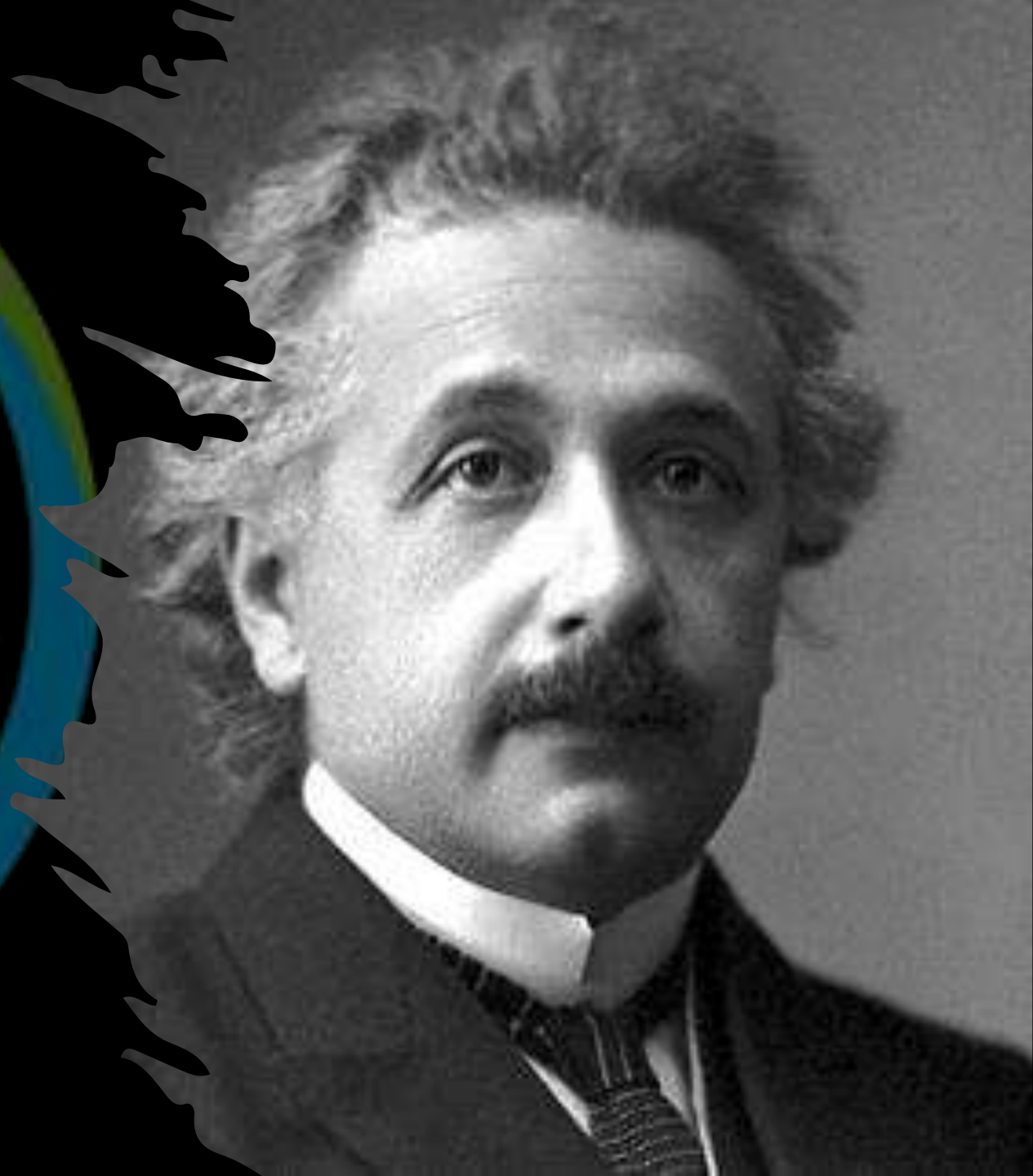
- Global Ingredient Archival System (GInAS)
  - GInAS Notification List
  - https://tripod.nih.gov/ginas

G-SRS (FDA) Expert and Point of Contact:
Dr. Lawrence Callahan/Dr. Frank Switzer

Summary

- Distinct points to consider for identifying biologics vs chemical substances
- Different considerations for different types of biologics
  - Global PhPID **will not work** if substances are not uniquely identified on an international scale
  - A global maintenance organization for substances and pharmaceutical product identification is key
- **Manufacturing process(es) is critical to global and unique identification**
- Nomenclature and robust scientific identification is **foundational**
  - Process by which small molecules (i.e., chemicals) are identified is not sufficient for large molecule identification
    - INN/USAN **(+)**

“The significant problems we have cannot be solved at the same level of thinking with which we created them.”



Thank You and Acknowledgments

Ron Fitzmartin, PhD, MBA
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Lawrence Callahan, PhD
Frank Switzer, PhD
Joan Blair
Mary Ann Slack

Toward Global Identification of Medicinal Products (IDMP) Implementation: A Focus on Biologics

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- PhRMA IT Working Group
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- ICH M2 EFPIA Topic Lead

Thank You for Attending

CDER Small Business & Industry Assistance (SBIA)
January 27, 2022