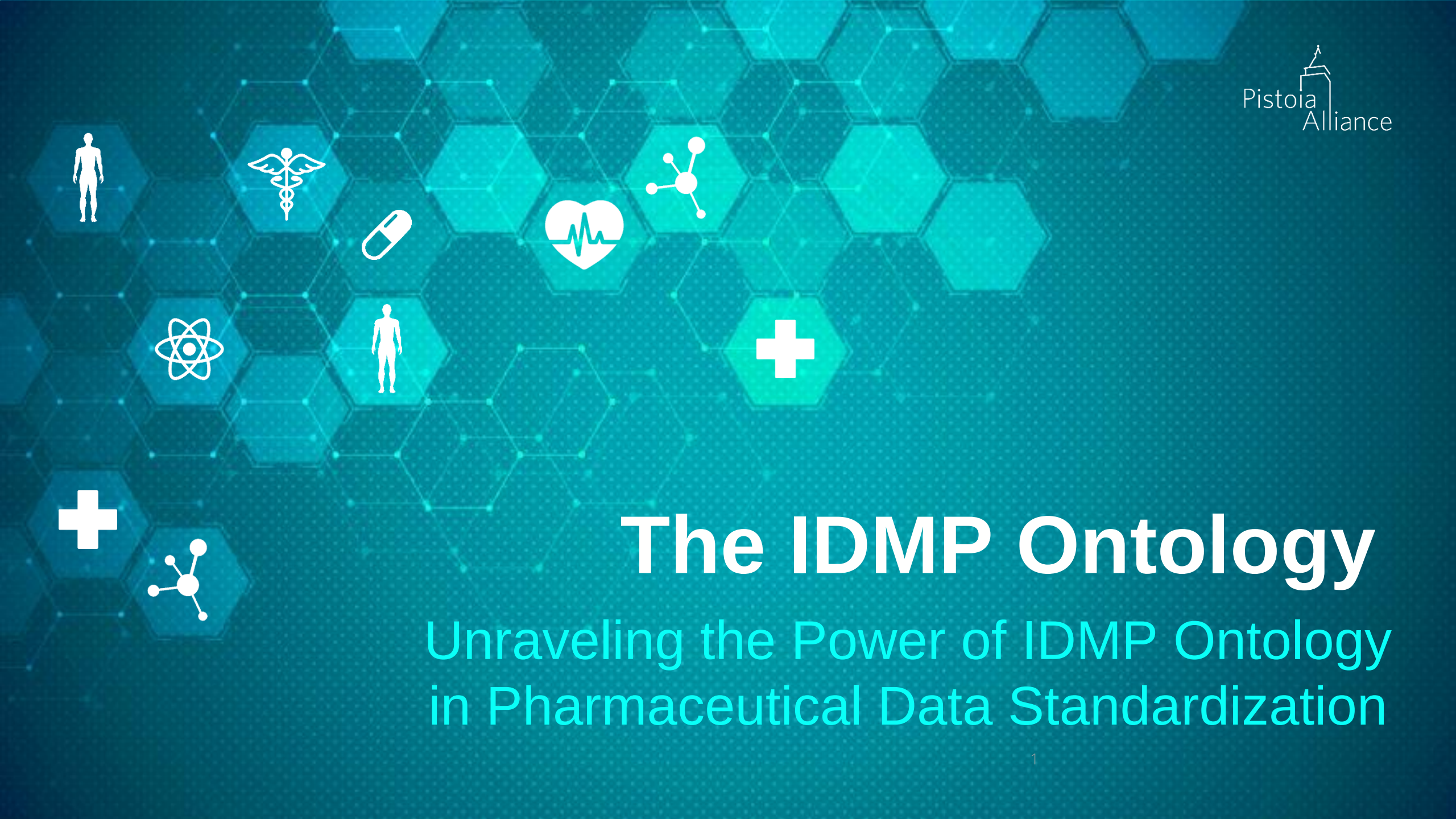
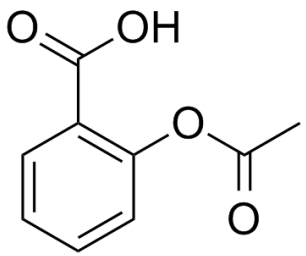


The IDMP Ontology

Unraveling the Power of IDMP Ontology in Pharmaceutical Data Standardization

Towards Data-Driven Submissions



ASA; Acetylsalicylic Acid

NSAID | COX-1 inhibitor

CAS No. : 50-78-2

R16CO5Y76E

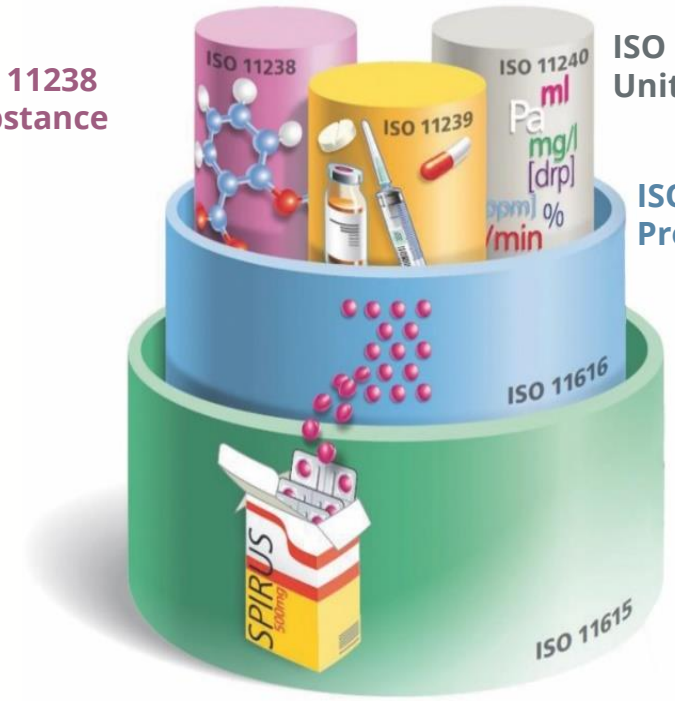
BAYE004465

SUB12730MIG

Benefits of Identification of Medicinal Products
IDMP Ontology

ISO 11239 Dose Forms

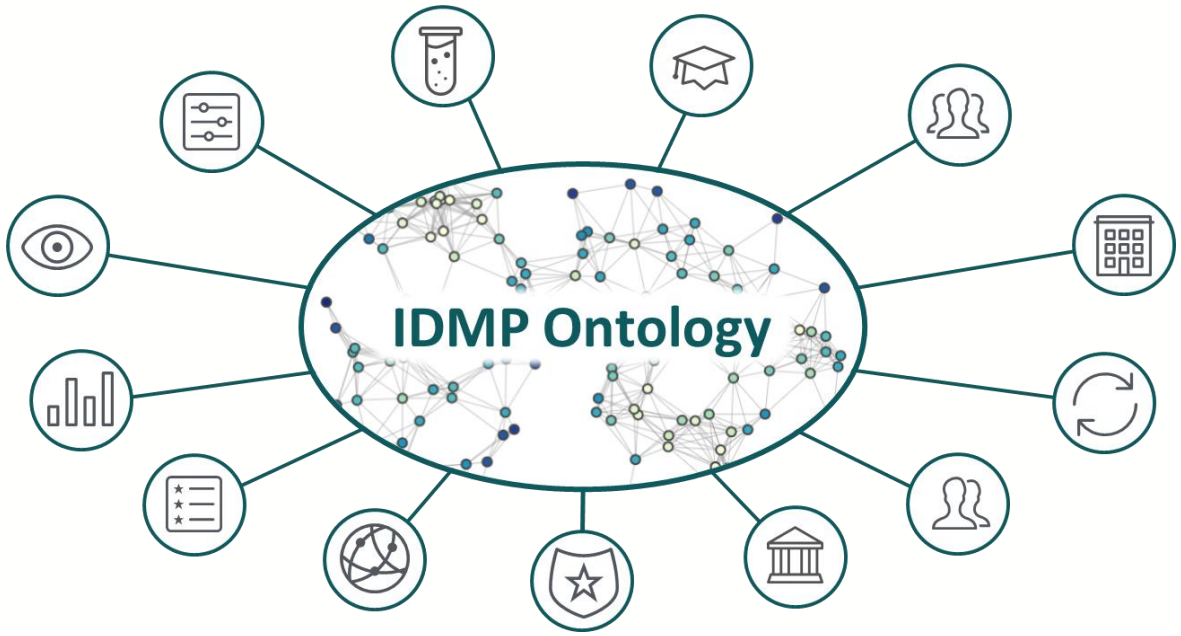
ISO 11238
Substance



ISO 11240
Units of Measurement

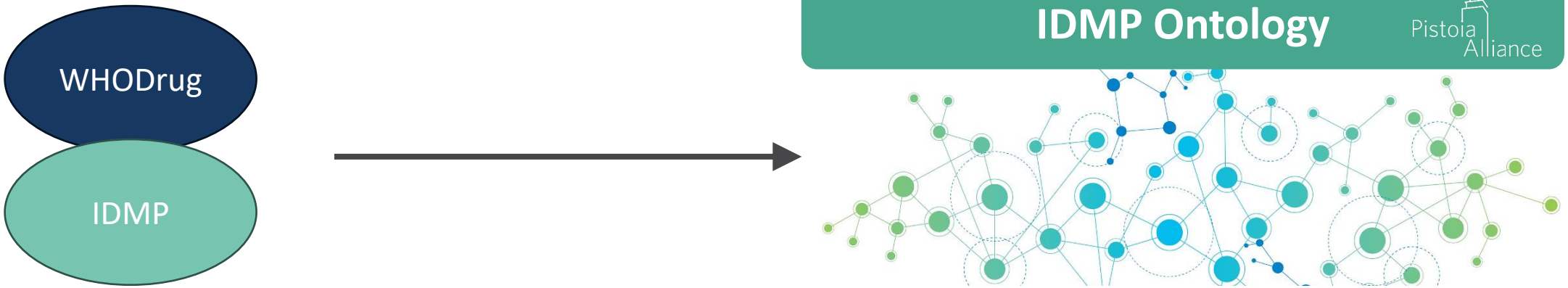
ISO 11616 Pharmaceutical
Product

ISO 11615
Medicinal Product



Upcoming: WHODrug as a Knowledge Graph within the IDMP Ontology

Idea: Support current and new use cases for WHODrug with IDMP within pharma by seamless integration with other IDMP-O aligned data sources (connecting to e.g., pharma, EMA SPOR, FDA GSRS)



https://www.pistoiaalliance.org/projects/current-projects/idmp-ontology/

in collaboration with ACCURIDS

PROJECT PRISM

A Regulatory Cloud Collaborative Initiative

precisionFDA Regulatory Information Service Module
FDA-Industry Research Collaboration Agreement
(Public-Private Partnership)

Vada A. Perkins
VP/Global Head of Regulatory Intelligence & Policy
Boehringer Ingelheim
PRISM Principal Investigator

April 2024

U.S. FOOD & DRUG ADMINISTRATION
DNAnexus
Boehringer Ingelheim
BAYER
EMD SERONO
Takeda
Bristol Myers Squibb™

Our Trajectory & Outlook

Initiation
2021

Phase 1:
IDMP-O
MVP
2022 Apr-Oct

Phase 2:
Build IDMP-O 1.0
for Production Use
Released in
January 2024
2023

Phase 3:
Pharma Implementation &
Industry Adoption
2024

- Focus on production implementations
- Collaboration with Health Authorities
- Interoperability with other domains
- Opening to vendors and consultancies
- Introduction of Open Core Model
- Release v1.1 in April

Phase 4 and Beyond:
Production & Sustainability
Planning for 2025

Pistoia Alliance and IDMP Ontology

Bio-IT World Conference Innovative Practices Award 2024 for Pre-Competitive Collaboration

Global Product Master Data …

Many thanks to the entire team:
Pistoia, Pharma, Accurids,
EDM Council and Stakeholders!

… can be achieved with pre-competitive collaboration and the **IDMP Ontology**

Expanding Global Implementation of IDMP Standards using IDMP-O

Frits Stulp, CTADHL

CTADHL

Call to Action- Delivering Health Literacy

Expanding Global Implementation of IDMP Standards considering IDMP-O

Pistoia Conference, April 24th 2024 – London, UK

What and who is CTADHL?

*CTADHL is a **501(c) 3 not-for-profit charitable organization** and was founded in 2017 by Vada Perkins with Frits Stulp and Christian Hay driving the global data and health literacy mission and vision. CTADHL is funded by the UNICOM project to promote trans-Atlantic communication and engagement to actionable results that are globally driven for patients worldwide.*

Vada A. Perkins
President (CTADHL)

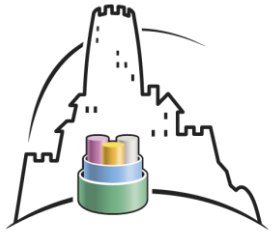
- VP, Global Head of Regulatory Intelligence & Policy, Boehringer Ingelheim
- ISO TC215, US Technical Advisory Group (TAG) Member
- Thought leader for regulatory policy & data
- ISO editor for 11615/11616

Frits Stulp
Chairman of the Board

- IDMP implementation SME in industry and regulator (Deloitte / Iperion)
- (former) Project Mgr EU-SRS implementation (UNICOM)
- Promotor of ISO IDMP (IRISS IDMP Topic Group Leader)

Christian Hay
Executive Board Member

- Senior Consultant Healthcare GS1
- Convenor ISO TC 215, WG6 since 2012
- PL CEN ISO TS 16791
- Engaged in openMedicine 2015-2017
- Engaged in UNICOM 2019-2024



CTADHL Mission

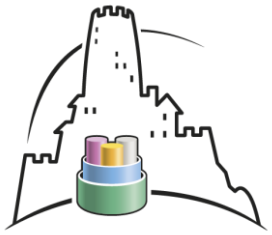
Call to Action- Delivering Health Literacy

*Our mission is to **support global data and health literacy initiatives** through **trans-Atlantic collaboration and partnerships** and become a strong advocate and expert of **applicable international data standards** to then facilitate the ISO-IDMP knowledge transfer and ways of working to EU and US stakeholders who are involved in IDMP implementation or its decision making.*

Amongst others, CTADHL works closely with the GIDWG to enable the Trans-Atlantic conversation on harmonised adoption of the standards, including the role of terminology

Enabling the conversation of adoption in the trans-Atlantic Workshops

IDMP landscape is a complex one..



GIDWG

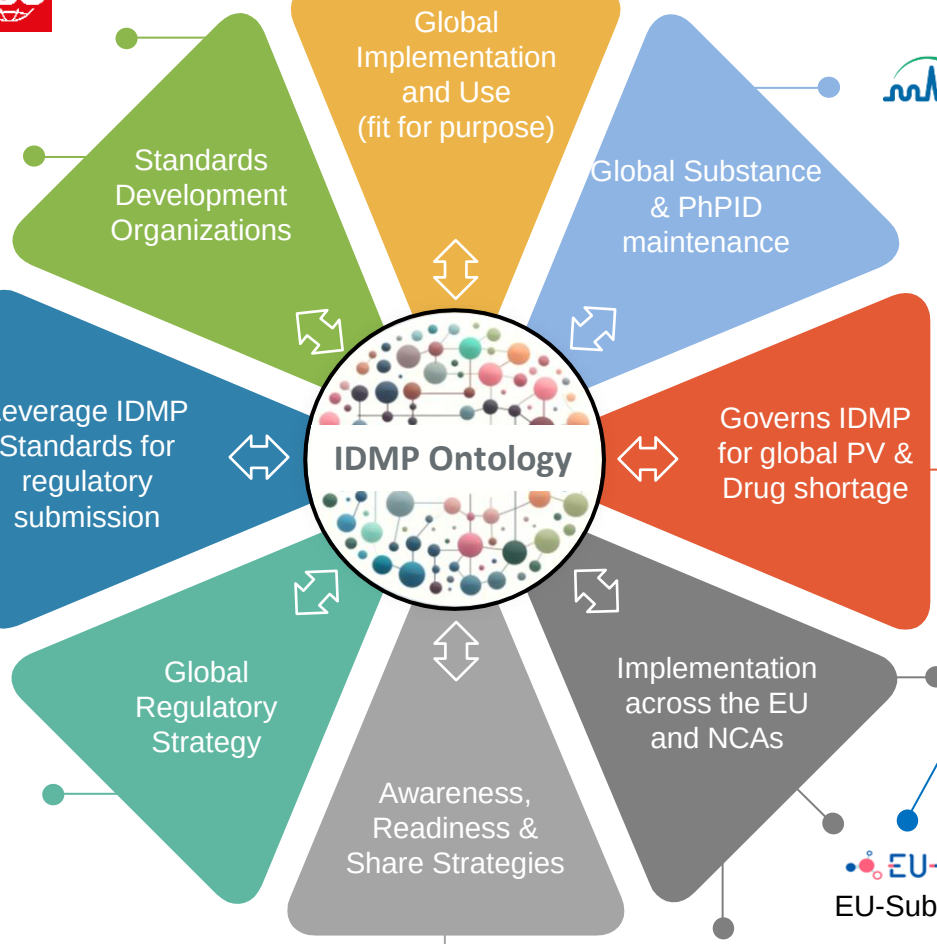
Technical WG: Plan and execute projects focused on global implementation and maintenance (EMA-FDA-WHO/UMC + Regulators + Observers +SMEs)

ISO

Develop and maintenance of the IDMP standards, technical specifications and reports

HL7

Develop and maintenance of the IDMP messaging standards



WHO-UMC

Proposed Global IDMP Maintenance Organization

WHO EWG

Use & support of global IDMP for LMICs.

- 12 experts appointed by WHO HQ (representing 6 WHO regions) + Observers + SMEs
- Regulators can be observers

- M4Q Quality Data Standards
- E2B ICSR

A Regulatory Pharmaceutical Quality Knowledge Management System (PQ KMS) to enhance the availability of quality medicines.

ICMRA-ICH-PIC/S-IPRP Joint Reflection Paper

EMA/EU

IDMP/ SPOR master data management services

EMA-FDA international CF on IDMP

EU-SRS

EU-Substance Registration System

- IDMP Frequently asked Questions
- IDMP Readiness Checklist

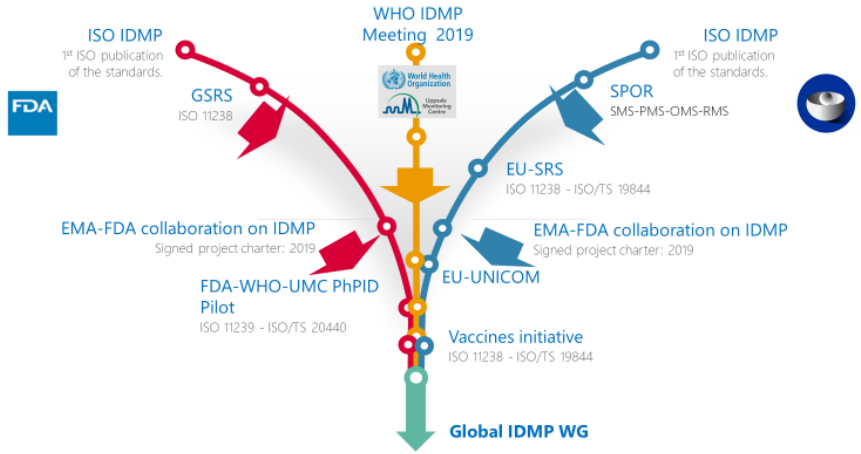
UNICOM

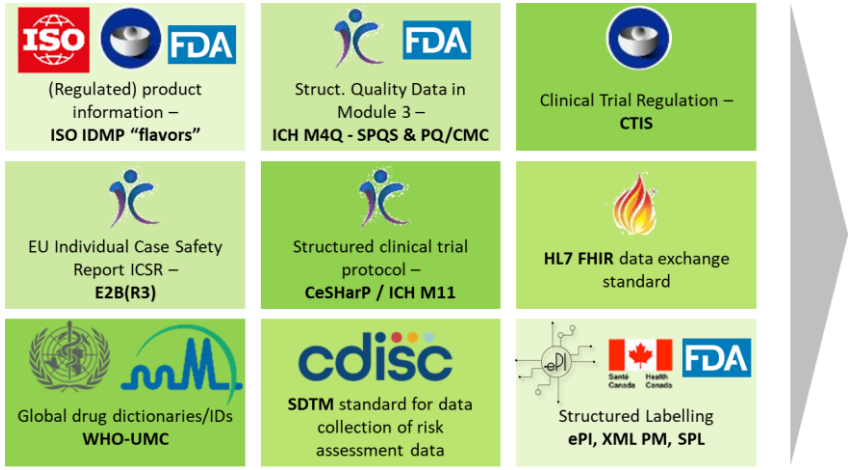
EU-funded project for IDMP implementation at NCA level

Source: EMA

Key observations

- ✓ Acceleration of IDMP adoption as data standard by regulators to support regulatory and other processes
  - ✓ FDA guidance, Industry soundboarding
  - ✓ UNICOM EU NCA progress
  - ✓ EMA: strong progress on PMS go-live as part of SPOR / IDMP landscape
  - ✓ WHO-UMC adopting data model and strength of interoperability and data analysis
  - ✓ Other regulators publishing plans: SwissMedic, ANVISA
- ✓ Use cases are including direct needs:
  - ✓ (European) Drug Shortage management
  - ✓ Regulatory process efficiencies
  - ✓ Cross-border prescription
  - ✓ Substance based use cases (New Substance Application, R&D)
- ✓ IDMP-O acceleration opportunities are various:
  - ✓ Basic interoperability and internal business glossary
  - ✓ System communication
  - ✓ Data analytics
  - ✓ AI capabilities supported by terminology as well as ontology

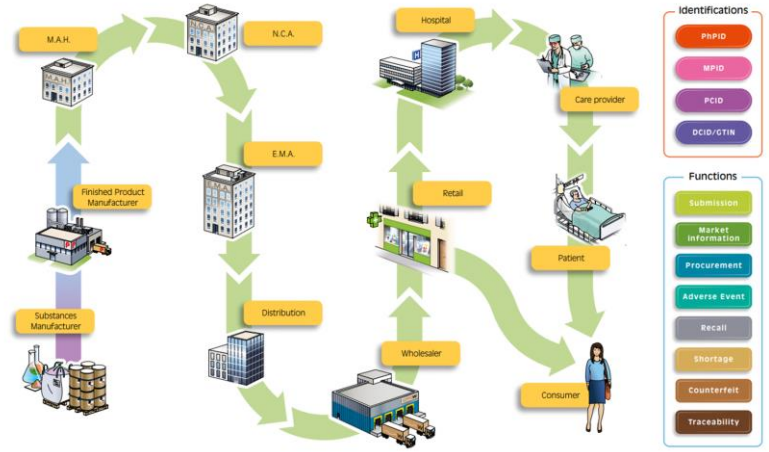




Closing

IDMP is a basis for data used across the Product Lifecyle so it is key to look across disciplines and IDMP-O unlocks the possibilities

- Along with the regional progress, the GIDWG is a key forum for harmonized progress
- CTADHL is supporting with “blue sky sessions” to determine solutions for common challenges, open up to new ways of working, and communicate across all
- Use cases are the optimal way to determine both benefits and obstacles, while achieving actual success
- More international regulators are joining the conversation, increasing the odds of global harmonization
- IDMP-O is an effective enabler for this progress!



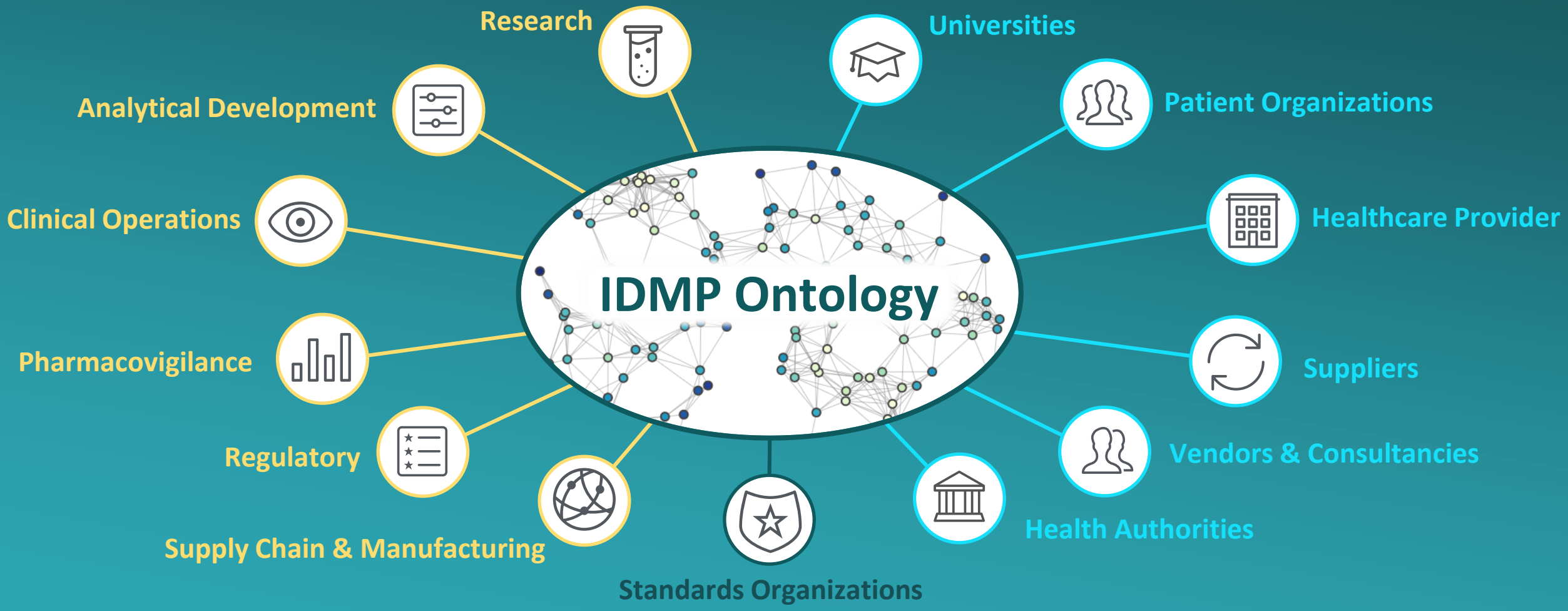
Thank you!

IDMP Ontology Survey Preliminary Results

Heiner Oberkampf, Accurids
Raphael Sergent, Accurids
Dominik Gigli, MAIN5

IDMP Ontology: shared data language for medicinal products

Pharma internally … and across the industry



How did we conduct the survey?

Survey Participants: Leadership roles in IDMP, MDM, Ontologies, Data Standards, Regulatory, Data Office, Data Governance, AI, CIO/CDO…

Effort required: 2 x 1h sessions*

Publication about industry analysis with **anonymized results**

2w: Dec 11th | 8w: Jan 8th – Mar 15th | 10w: Mar 15th - May 31st | 7w: Jun – July

1h* Survey Interview to fill online questionnaire

One Session with all Key stakeholders from your organization each filling the survey

Extra Questionnaires

Optional, non-guided

1h* Individual Results Review Sessions

- Summary presentation
- 1h session to explain/discuss your survey results and compare to peers

Participation – ISO IDMP Maturity Survey

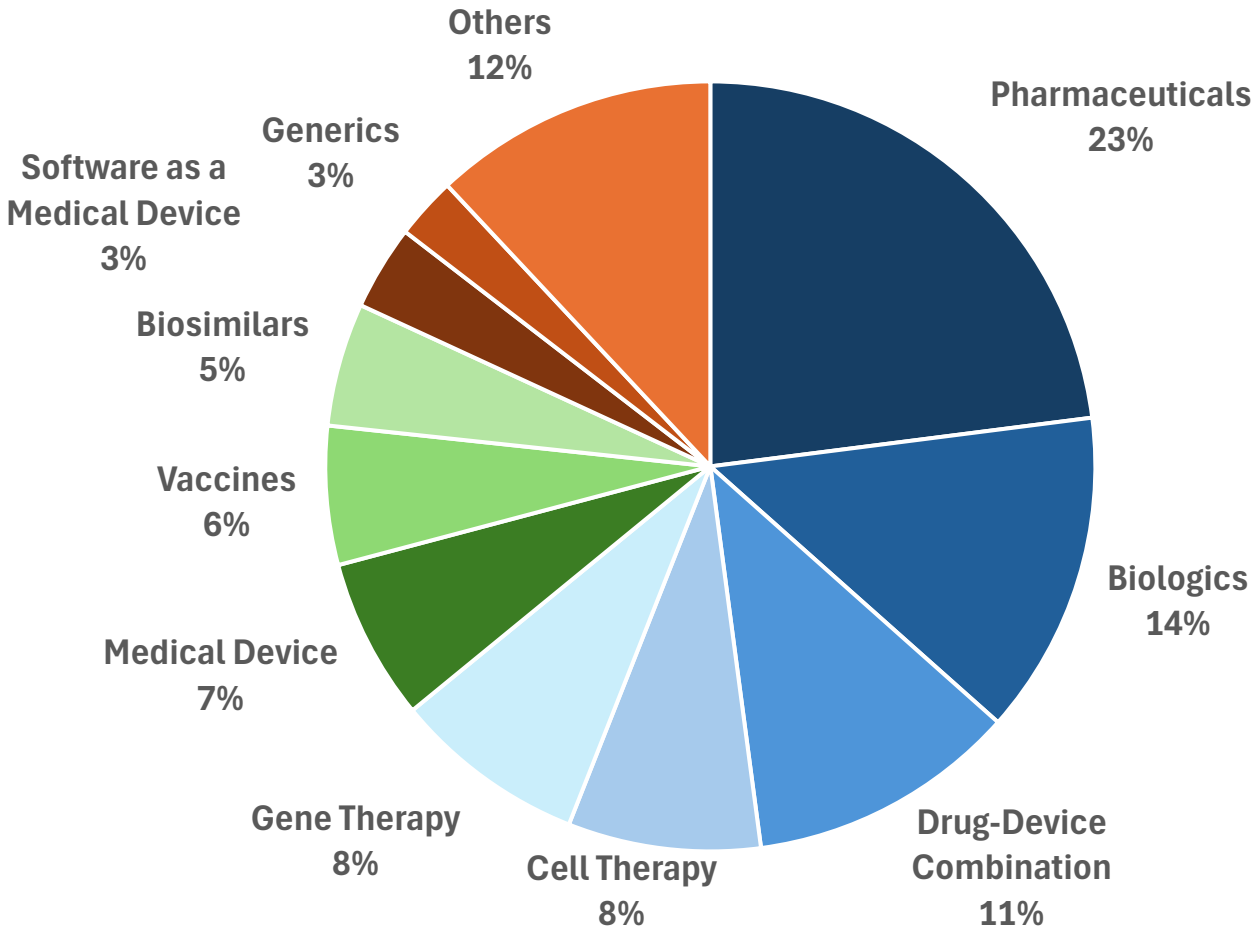
27 Questions

76 Participants

15 Organizations

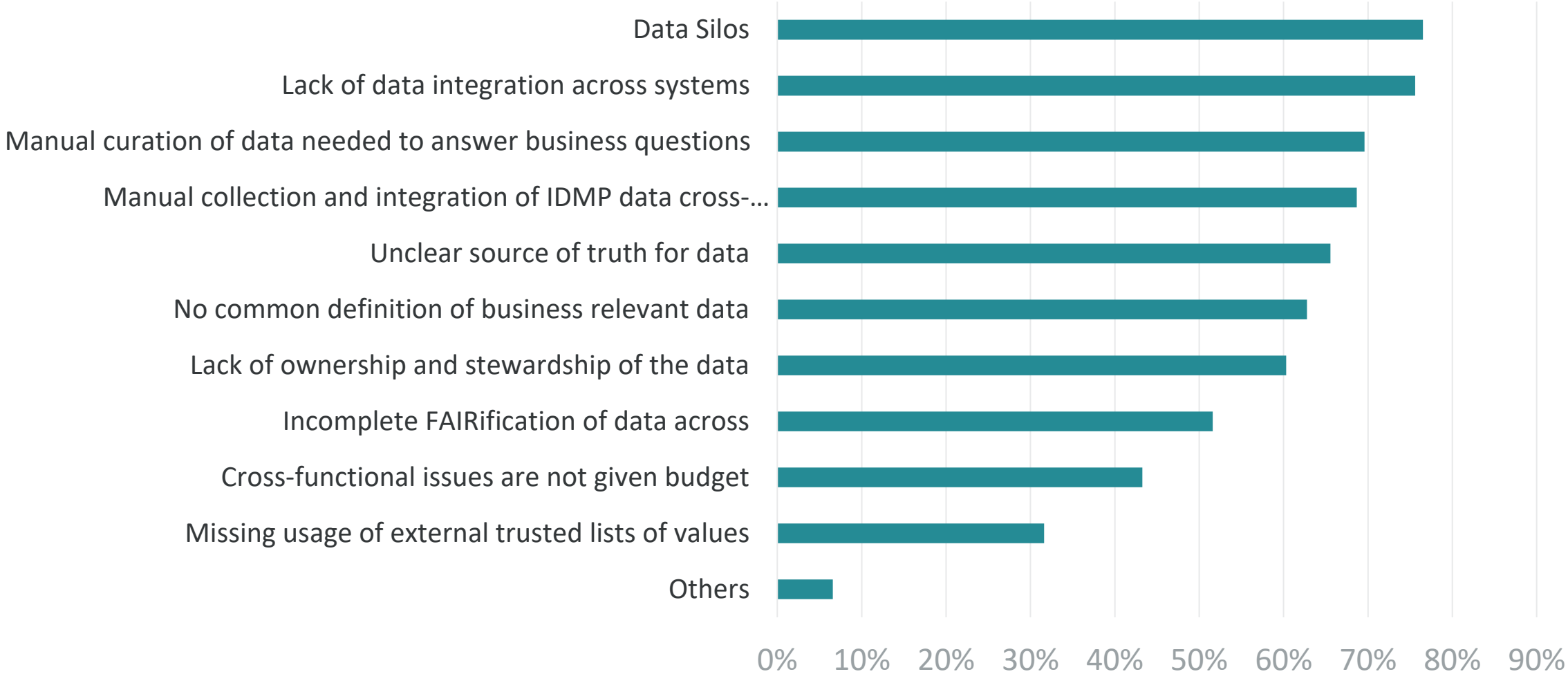
8000 Data Points

Participants' Types of Products



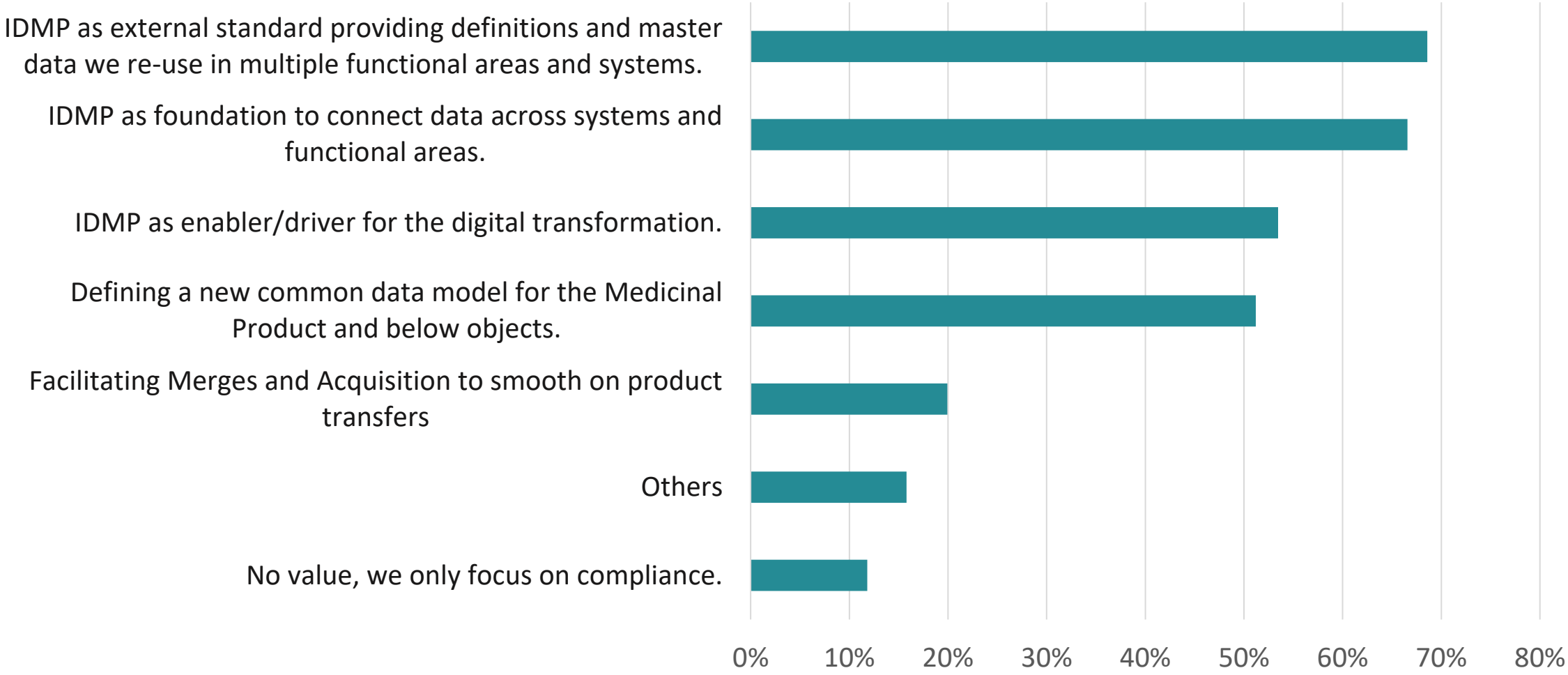
Biggest Challenges in Product Data Management

Preliminary Results



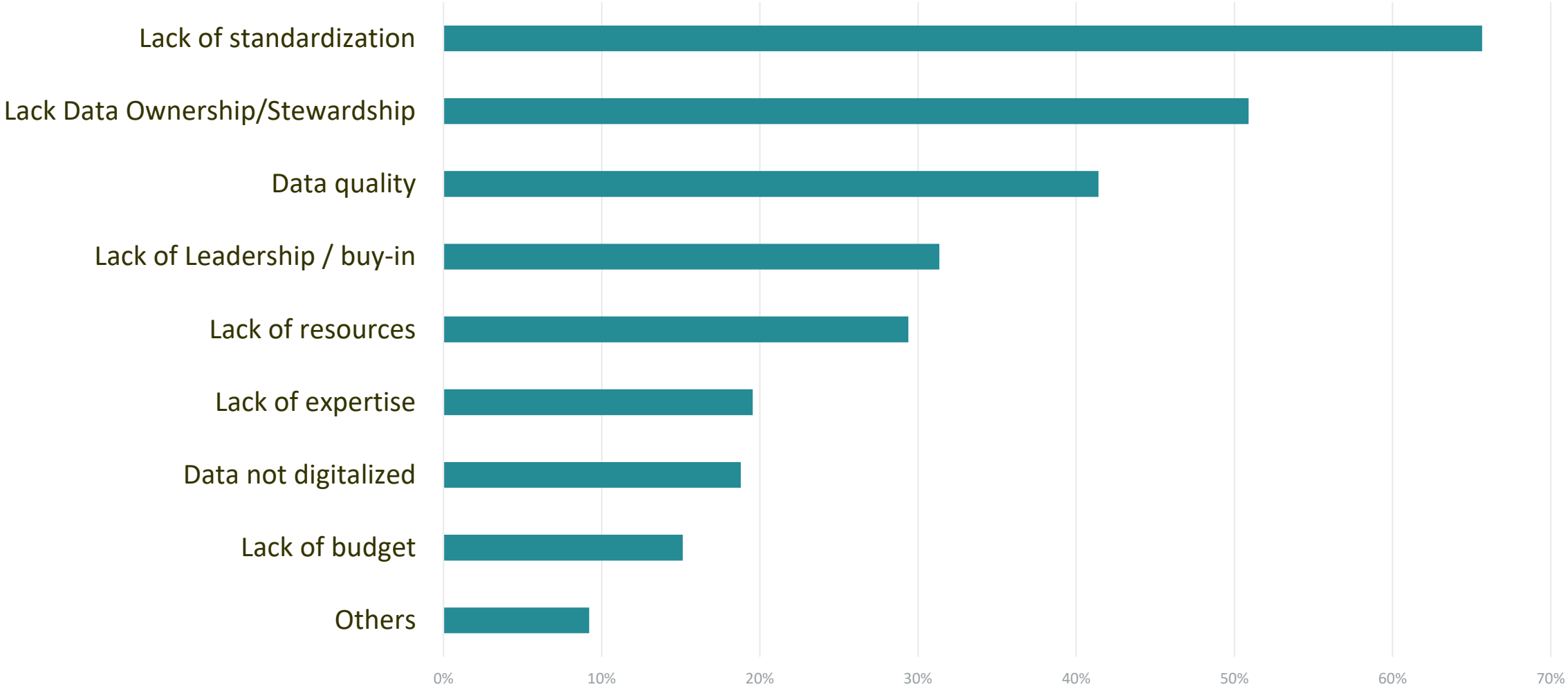
What value does IDMP provide for your digitalization strategy?

Preliminary Results



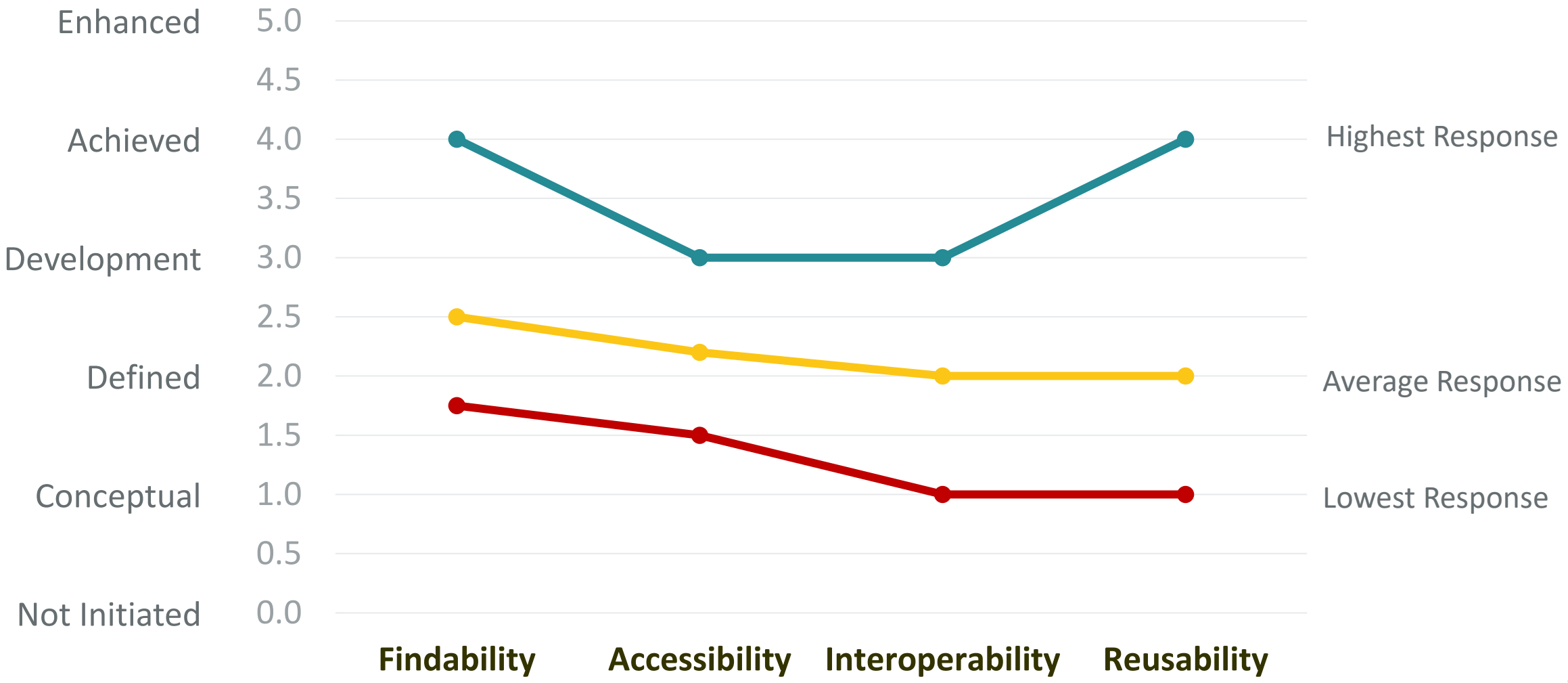
What are the biggest hurdles preventing effective data integration?

Preliminary Results



What is your FAIR maturity for each main area ?

Preliminary Results



Do you agree with following statements?

Preliminary Results

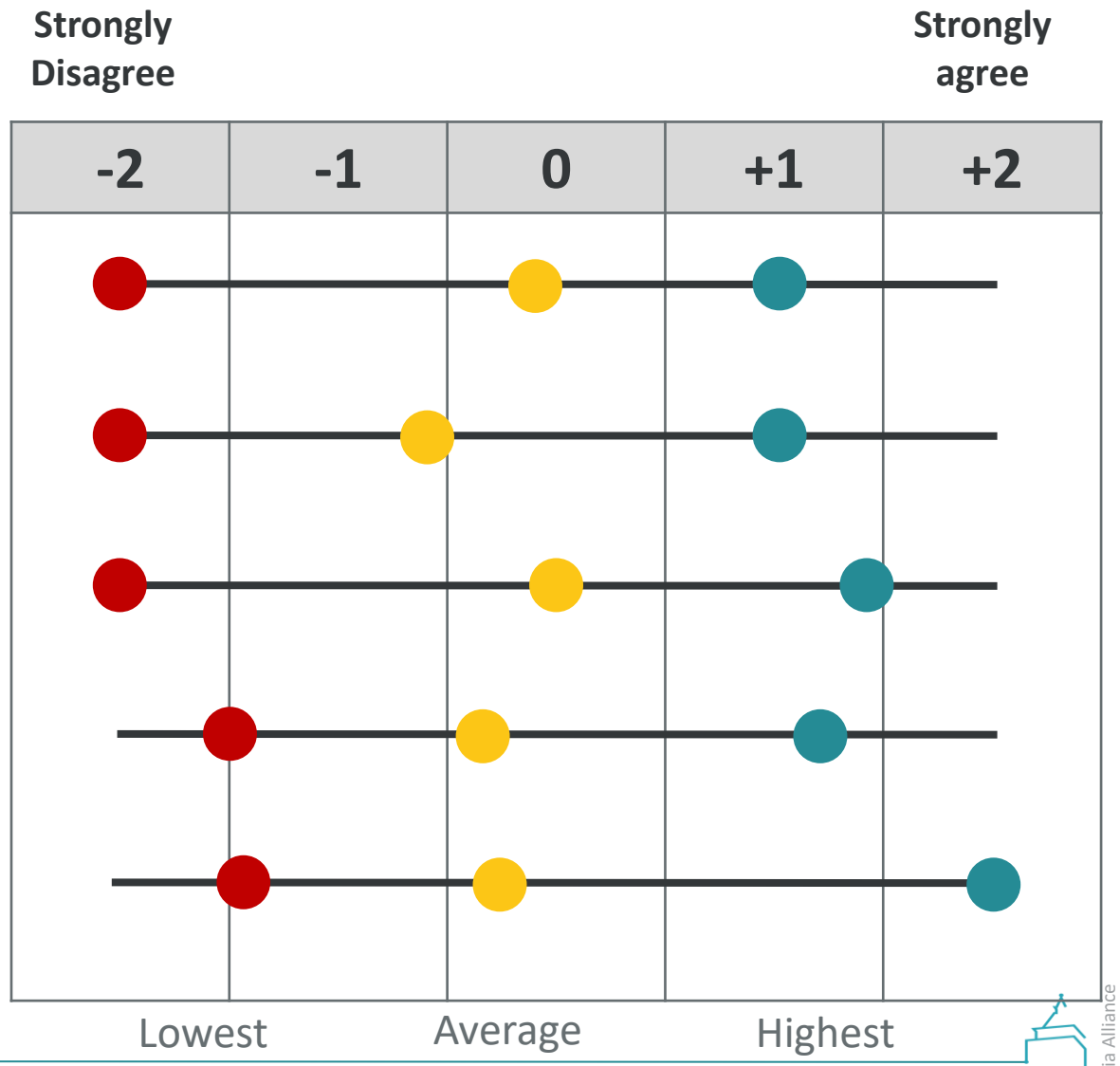
We implemented **robust, consistent, and effective Master and Reference Data Management**

We use **Unique Persistent Identifiers** to identify our data and concepts across the company.

We implemented a **RACI Matrix** to identify roles and responsibilities across the company

We have a **sustainable and financially secured Data Governance** team with enough resources to perform their duty.

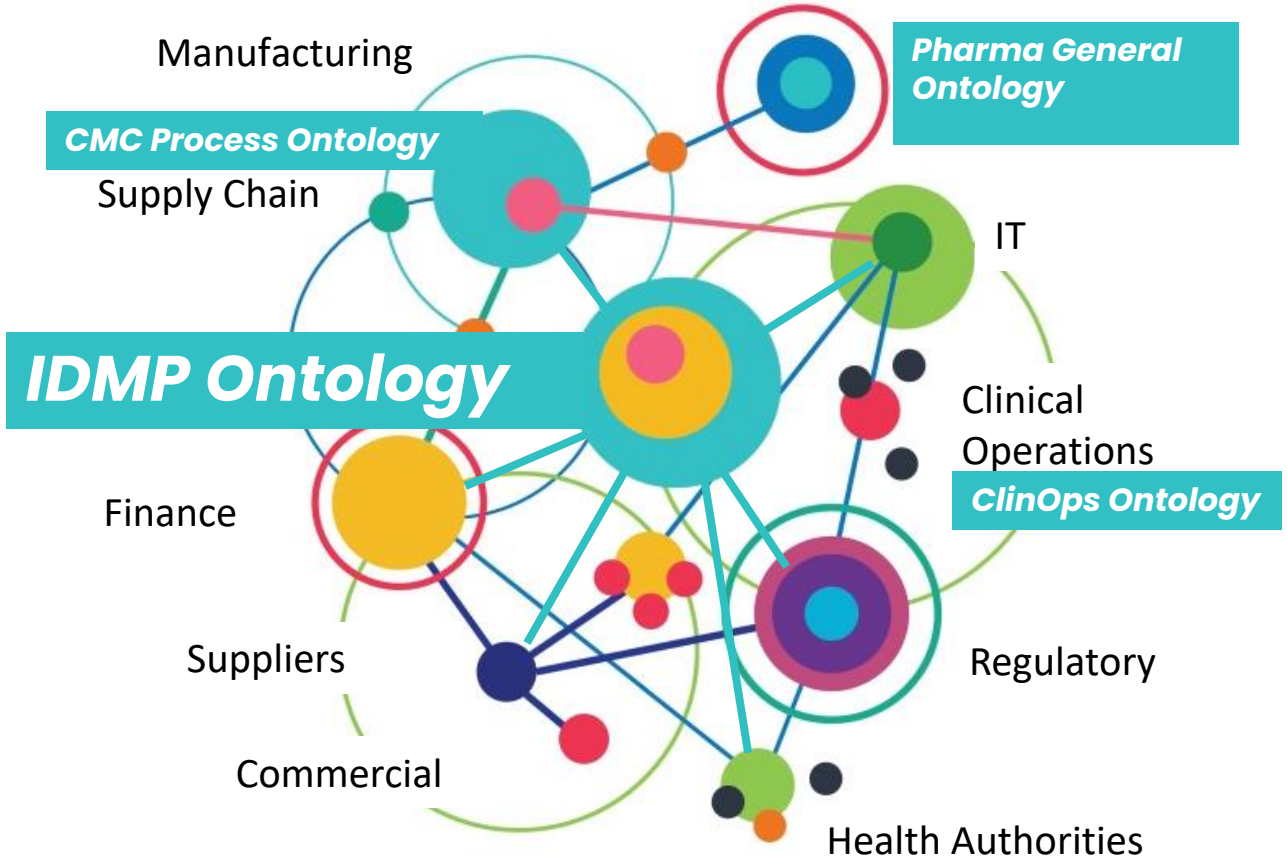
We know the **process- and data flows connecting our regulatory and IDMP data across functional areas**



How to Engage with the IDMP-O Project

Melih Tuzunoglu, Pistoia Alliance

Global Governance & Data Standards



Data Governance as a Service

Pistoia Alliance is building a sustainable, coordinated, ontology project portfolio for Pharma.

IDMP-O is leading the way and at it's core.

What's in for my company?

IDMP Ontology Phase 3 Sponsor

- ✓ Steer our goals and focus areas through membership in our Executive Advisory Board
- ✓ Reduce the risk and effort of your internal product data harmonization programs
- ✓ Get individual support for the adoption of IDMP-O as a cross-functional Product Data Model
- ✓ Learn about best-practices from pharma peers in a safe and trustful collaboration environment
- ✓ Shape a consolidated voice of the pharma industry to drive the standards implementation
- ✓ Get early access to restricted content, such as a pharma implementation guide

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Pistoia Alliance Member

- ✓ Participate in conferences and general projects
- ✓ Possibility to sponsor and steer any PA projects
- ✓ Get access to IDMP knowledge graph alignment scripts for SPOR and GSRS

Public Community of Interest

- ✓ Use the open-source version of IDMP Ontology
- ✓ Participate in bi-monthly Community of Interest meetings
- ✓ Schedule an individual intro call to learn more about how to get involved

Join us and get involved

Learn More
www.pistoiaalliance.org

Contact Us
idmpo@PistoiaAlliance.org

Join the Initiative
The IDMP Ontology