# IDMP Ontology

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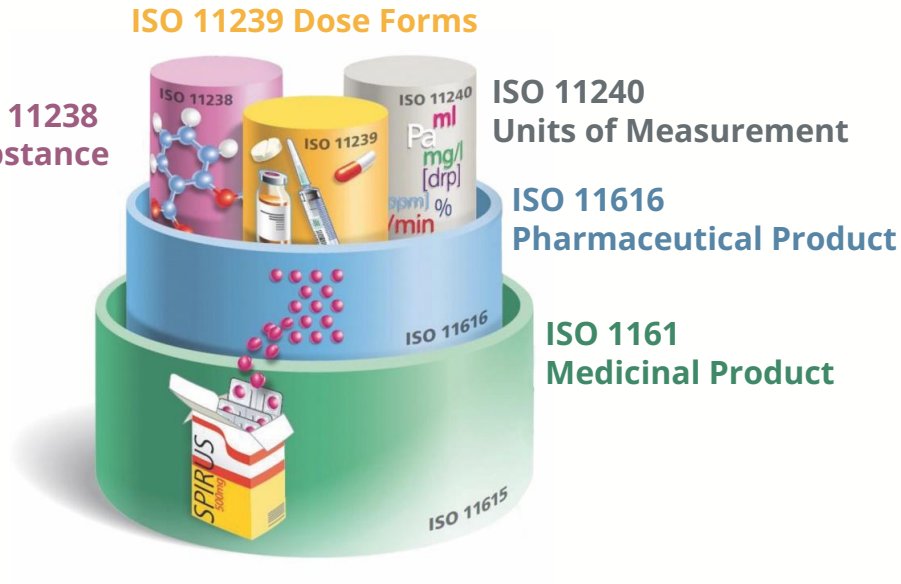
# IDMP Ontology

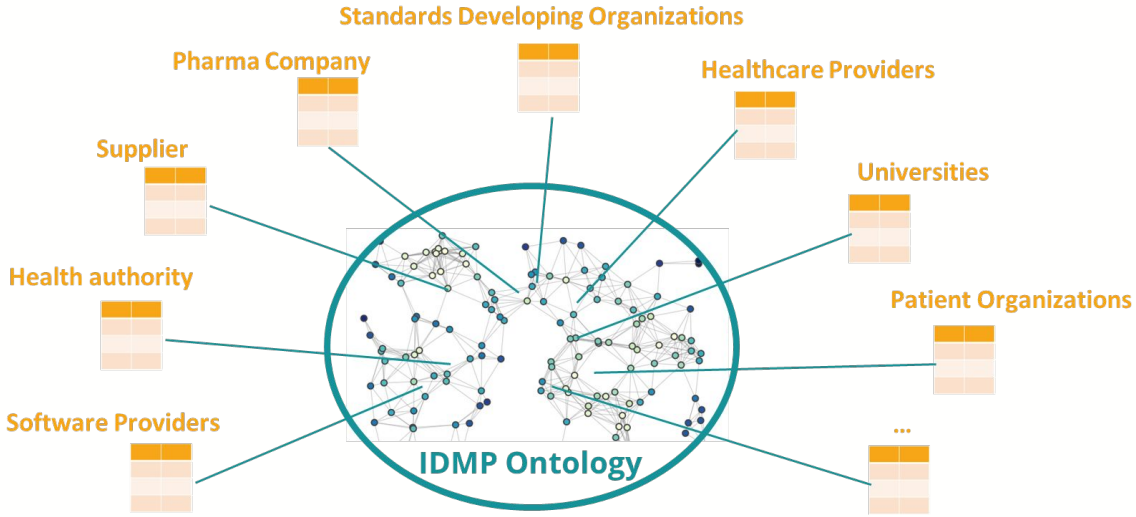
## Collaborative Implementation in Pharma

## *Pistoia Alliance Conference*

November 14, 2023

# IDMP Ontology Introduction




## Identification of Medicinal Products (IDMP)

is a set of global standards developed by the International Organization for Standardization (ISO) for the identification and exchange of information about medicinal products **to improve patient safety and facilitate the exchange of information** between regulatory authorities, healthcare professionals, and pharmaceutical companies.

## Benefits of IDMP implementation:

Improved regulatory compliance, patient safety, product development and data management; efficient global product registration and supply chain optimization

## IDMP Ontology:

Collaborative development by 11 Pharma companies of the IDMP product data model in an ontology sponsored by the not-for-profit member-driven Pistoia Alliance

# IDMP-Ontology use cases … drive the coverage of ISO IDMP

*implementation*

**Substance Identification and Roles**
Active moiety, ingredient strength & chemical groupings

**Regulatory and Manufacturing**
Enabling interoperability between manufacturing (bottom-up) and IDMP/labelling (top-down) perspective

**Therapeutic Indication**
Linking medication to clinical particulars

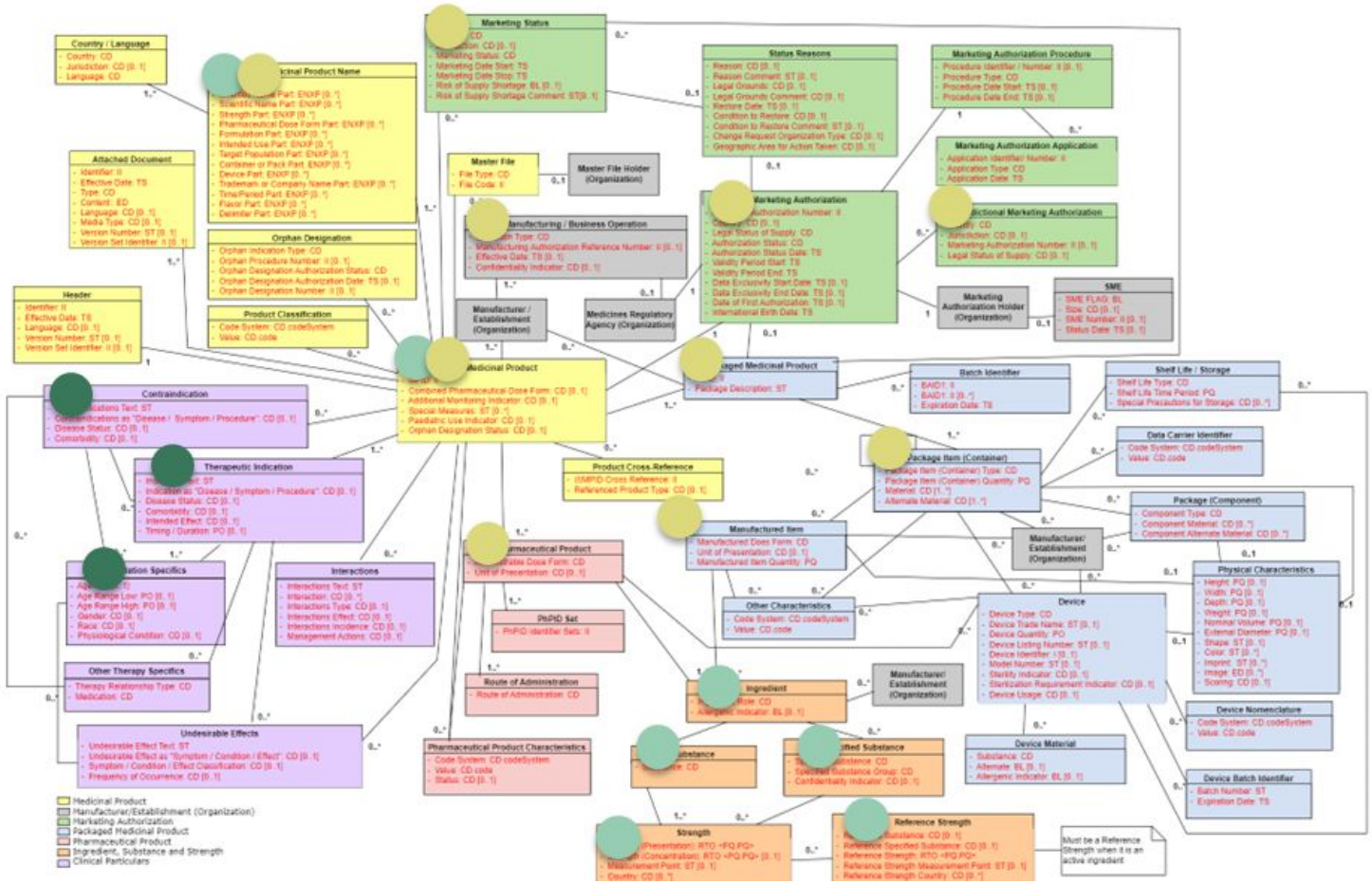
**Jurisdiction-agnostic Medicinal Products**
Global Medicinal product that industry can refer to without any regulatory-specific data

**Falsified Medicines Directive**
Integrated data for mandatory EMA reporting

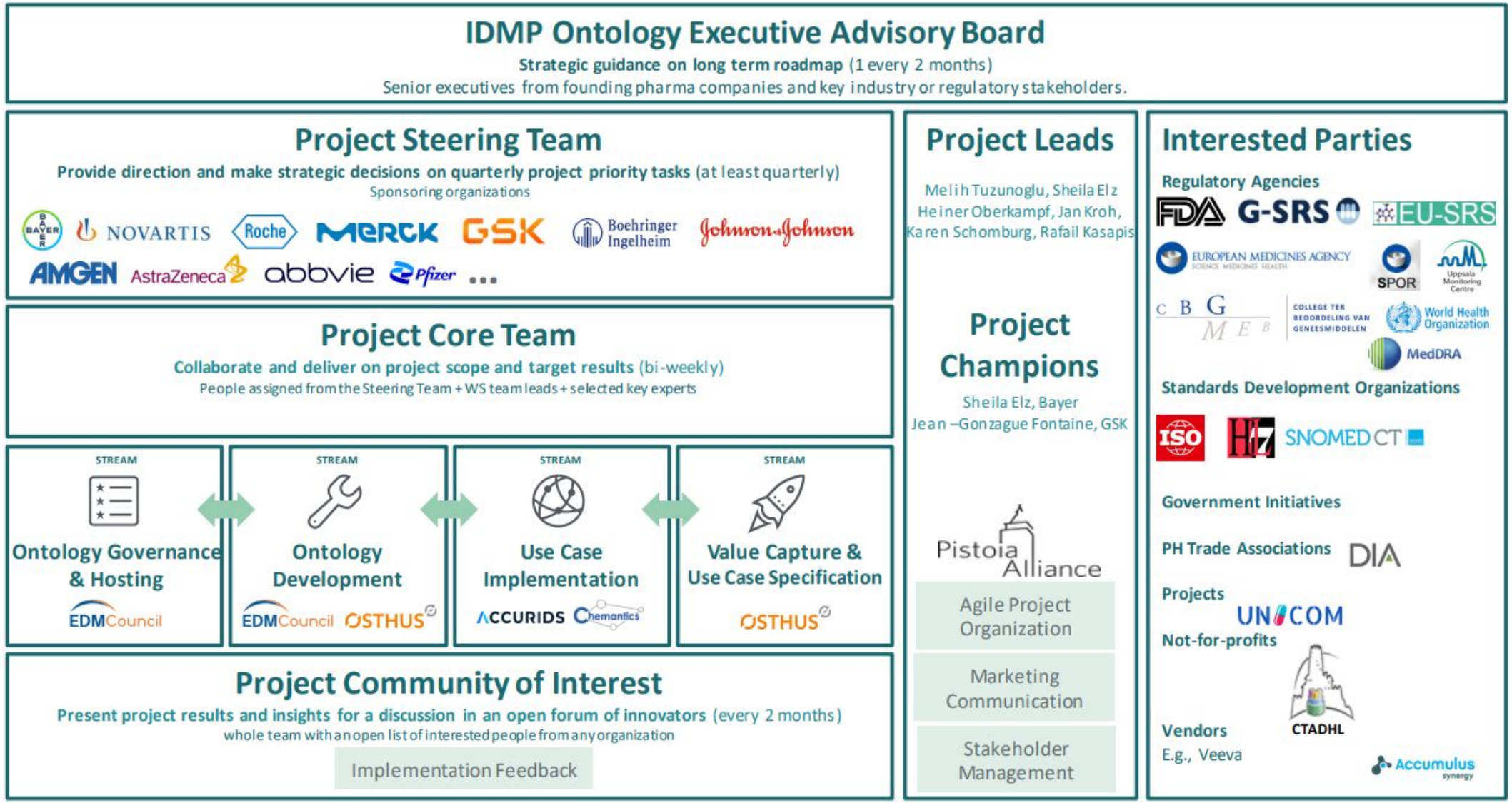
*backlog*

**Pharmacovigilance**
Global Impact Assessment of Safety Risks Across the Product Life-Cycle

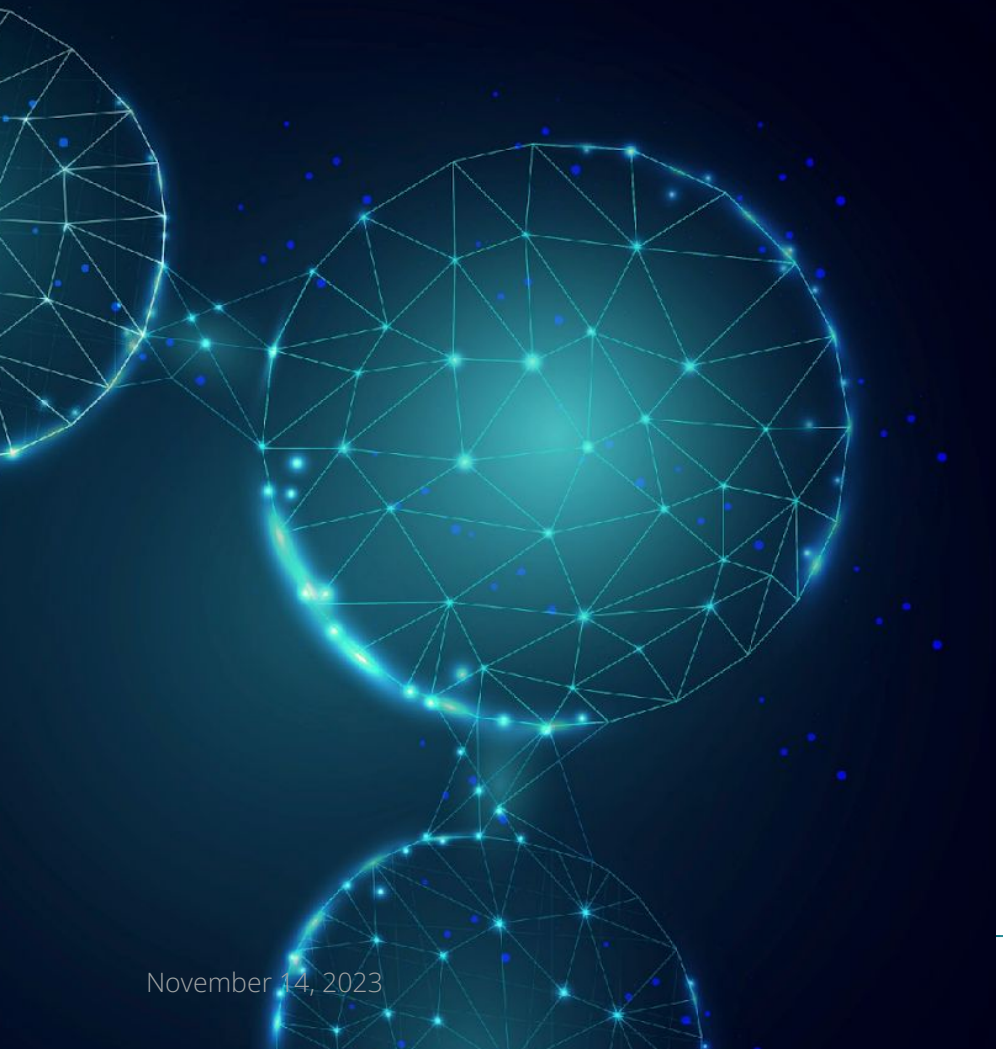
**Clinical and Regulatory**
Enabling interoperability between ClinOps and Regulatory incl. reference to CDISC



# Our agile governance framework ensures effective industry alignment



# Summary of Recent Highlights



## 1. IDMP-O v0.5 released and on-track for v1.0 production release end of this year

## 2. ISO/AWI TS 21405 Approved Work Item

"Health Informatics — Identification of Medicinal Products — Methodology and Framework for the Development and Representation of IDMP Ontology" – with project leads Sheila Elz, Vada Perkins

## 3. Several successful interoperability PoCs

- First IDMP-O/FHIR Interoperability PoC
- Initial alignment of the UNICOM product database
- Initial PoC with WHODrug including PhPIDs

## 4. We actively grow the IDMP-O community

- Bi-monthly webinars with recent demonstrations from BI and J&J
- F2F workshop with 8 pharma presentations + guests from BioNTech, Gruenenthal
- various talks: UNICOM Connectathon, IRISS, GPRAS, CTADHL, ISO…

# Our Trajectory and Outlook

Initiation
2021

**Phase 1:**
IDMP-O MVP
2022 Apr-Oct

**Phase 2:**
Build IDMP-O 1.0
for Production Use
2023

**Phase 3:**
Pharma Implementation
& Industry Adoption
2024

- Focus on production implementations
- Interoperability with other domains
- Opening to vendors and consultancies
- Introduction of Open Core Model