

IDMP Common Core Ontology

Pistoia Alliance Project

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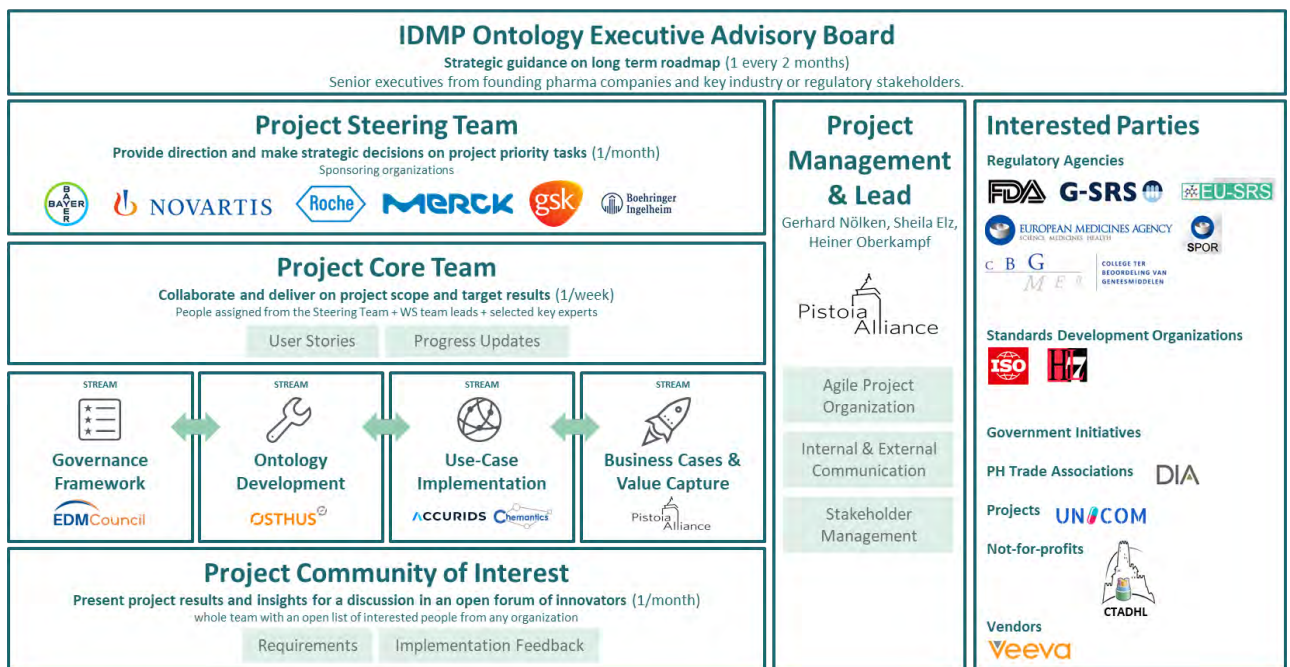
The ISO standards for Identification of Medicinal Products (IDMP) provide an internationally accepted framework to uniquely identify and describe medicinal products. Driven by regulatory requirements, the role of IDMP is to align the pharmaceutical industry on data standards around product and substance information. Realization of the full potential of IDMP depends on self-describing data to counteract diverse, non-standard IDMP implementations. For this purpose, we will augment the existing IDMP standardization efforts with an IDMP Common Core Ontology that enables deep, semantic interoperability based on FAIR principles. This will ultimately enable entirely new ways of collaboration and give early adopters the ability to gain a competitive advantage in innovation, drug safety and overall operational efficiency.

Why should I care?

- 1** Today's IDMP implementations are built in silos and have already created inconsistencies of interpretation.
- 2** Without an IDMP Ontology, the risk is that envisioned IDMP benefits and cost savings are not fully realized.

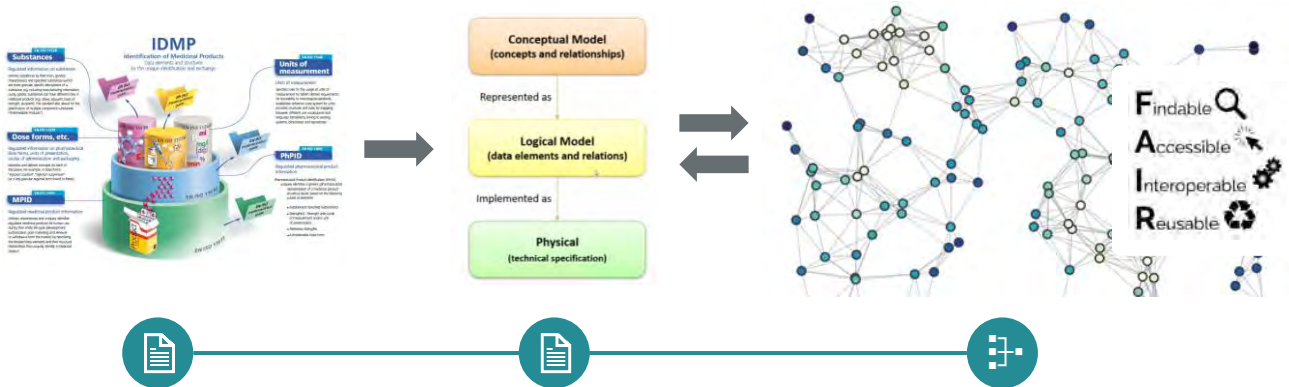
Participants

A group of pharma representatives have started an initiative to create the IDMP Common Core Ontology and selected Pistoia Alliance for the management and organization of the project.



Project Setup for the Phase 1 Implementation

- **Project Organization:** Pistoia Alliance
- **Driving organizations:** Bayer, GSK, Merck Healthcare KGaA, Novartis, Roche, Boehringer Ingelheim
- **Alignments:** all efforts are aligned with IDMP stakeholders such as ISO, EMA, FDA and the WHO
- **Executive Advisory Board:** set up for strategic guidance on the IDMP Ontology roadmap
- **Partners:** Enterprise Data Management Council (EDMC), Accurids, OSTHUS, Chemantics
- **Project Community of Interest:** anyone interested can get involved



ISO standards to ensure patient safety with unambiguous identification of medicinal products.

Facilitate implementation and automate connectivity with an agnostic data architecture.

Enable interoperability and connectivity across regulatory jurisdictions with a FAIR implementation.

Phase 1 Implementation: Ontology MVP

Phase 1 will demonstrate the added value of an ontology for the ISO IDMP standards for data usability and advanced collaboration across organizational boundaries and regulatory jurisdictions.



Ontology MVP: Development of a production-ready ontology based on existing pre-work.



Use Cases: Addressing concrete pharma data needs related to substance, ingredient roles and clinical trials.



Value Demonstration: Show-case the envisioned IDMP ontology benefits with demonstrations.



Governance Framework: Usage of EDMCs collaborative ontology development environment .

Why should I participate?

As soon as the IDMP standards become mandatory for drug submissions in 2023, today's manual workarounds will no longer be feasible. With this perspective, the IDMP ontology is a strategic opportunity for you to reduce wasteful and costly data complexity in your data and IT landscape so that steps along the value chain can be increasingly automated.

Active participation now brings strategic benefits

- 1 A seat on the IDMP Ontology Executive Advisory Board
- 2 Representation of your use cases
- 3 Ability to demonstrate how this works in your organization with your data
- 4 Influence on the design of the ontology
- 5 Head-start adopting the ontology



The Journey Forward

We already see strong interest from many different IDMP stakeholders for the MVP ontology. With the MVP success, we will scale the ontology implementation and standardization in subsequent phases to the entire scope of the IDMP standards and implement a range of use cases that we will collect in the current phase.