Getting Started

IDMP Ontology

A well-defined ontology that bridges between regional and functional perspectives on common substance-related data objects and global and scientifically objective representations is required. The IDMP Ontology is a semantic data model based on and augmenting the existing ISO IDMP standards to enable deep, semantic interoperability based on FAIR principles.

For more information on the project please visit the IDMP Ontology page at Pistoia Alliance.

Why is this important?

The European Medicines Agency (EMA) will be the first health agency to mandate compliance with ISO IDMP (Q4, 2024), with the FDA not far behind. Governance of essential IDMP standards and implementations is not assigned to a specific, overarching governing body. Diverging implementations of IDMP across geographical regions and jurisdictional domains are already causing inconsistencies in the interpretation across implementing organizations. Given that there is no semantic alignment between regulatory bodies, there exists a risk that regulatory compliance needs will lead to large integration and interoperability costs and that the benefits from IDMP in drug safety, innovation, and other areas will not be fully realized. Rather than concentrating on the discovery of new medicines, organizations will be struggling with data issues, e.g., the need to map product data across the organization, throughout the product lifecycle.

What will the project achieve?

Due to the robust framework for pre-competitive collaboration, the Pistoia Alliance was selected to manage this pharma initiative with the goal of creating an ontology that demonstrates added value to the ISO IDMP standards for data usability across organizational boundaries and regulatory jurisdictions. We have pulled together a core team consisting of Pharmaceutical stakeholders, regulatory bodies, standards organizations, non-profit groups, and solutions providers for this project.

The key objectives for the project include:

- Provide a digital, machine-processable standard. The PDF implementation guide provided by EMA is not enough as different groups implement it differently
- Solve ambiguities of the ISO IDMP standards enabling feed improvements back to ISO through systematic reviews
- Bridge different views with ONE product data model between internal pharma departments and between industry groups
- Provide a vendor-agnostic, and open-source model. The ontology is fully standards-based without any proprietary aspects
- Reduce implementation effort through a common core

The IDMP Ontology Releases are available here, with the MIT open source license.

Find out more at the following links:

- Github repository with ontology files
- OnoViewer to browse the ontology
- Demo instance with IDMP Ontology aligned public data

How to get involved?

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