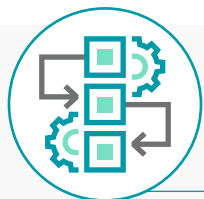




The Power of Collaboration

The Pistoia Alliance is a global, not-for-profit members' organization collaborating to lower barriers to innovation in life science and healthcare R&D. Now more than ever, the world needs our industry to work together to solve common challenges and achieve scientific advances and breakthroughs. The fruits of our collaborative innovation can be seen across our portfolio of member-driven global projects, made possible through our legal framework for pre-competitive collaboration that enables companies to share resources, data, expertise and best practices.



PROJECT OPPORTUNITY TO DELIVER VALUE THROUGH PRE-COMPETITIVE COLLABORATION

IDMP Common Core Ontology Project

Bridging different regional or functional perspectives on common substance-related data objects requires a well-defined common core ontology that connects the perspectives to global and scientifically objective representations.

The goal of our project is to build an IDMP Common Core Ontology that enables deep, semantic interoperability based on FAIR principles to augment the existing ISO IDMP standards of the European Medical Agency.



UPCOMING EVENTS

Don't miss these opportunities to connect with other advocates for life sciences innovation.

Explore more of our educational webinar series at www.pistoiaalliance.org/events



PROJECT RESOURCES

[Pistoia Alliance's
Ontology Mapping Project](#)

[Webinar on Demand:
Expert Panel Discussion
on Ontologies and FAIR](#)

[Webinar on Demand:
Semantics of Data Matrices
& The Stato Ontology](#)





Why is this project important to the life science R&D industry?

The European Medicines Agency (EMA) will be the first health agency to mandate compliance with ISO IDMP (Q1, 2023), 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 with interpretation across implementing organizations.

Given that there is no semantic alignment between regulatory bodies, there exists regulatory risk that will lead to large compliance, integration and interoperability costs and the benefits from IDMP in drug safety, innovation and other areas will not be fully realized. Rather than concentrating on 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 this project achieve?

Due to our robust framework for pre-competitive collaboration, the Pistoia Alliance was selected to manage this initiative with the goal of creating a minimal viable product (MVP) 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 success factors for the project include:

- > Phase 1 implementation of a quality MVP that can be used by pharmaceutical companies and others.
- > Demonstration of the usability and added value of the ontology, which will be the foundation to obtain investment for the next phase of the project to build out the ontology more fully.
- > Demonstration of governance capabilities.
- > Open communication with all relevant stakeholders with results being shared openly.



Be a part of that future by joining one of these developing projects!

Reach out to us at ProjectInquiries@PistoiaAlliance.org to learn more or join the next member meeting.

