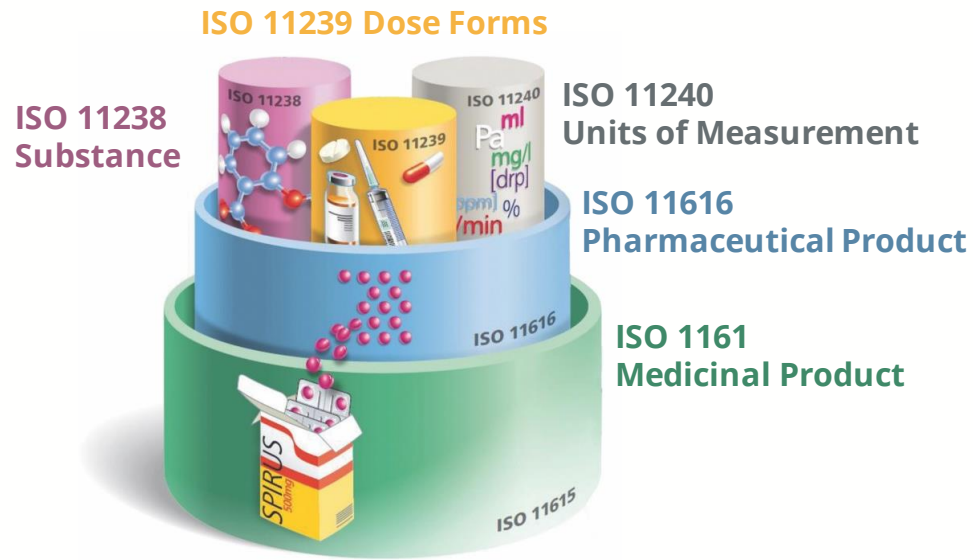


The IDMP Ontology

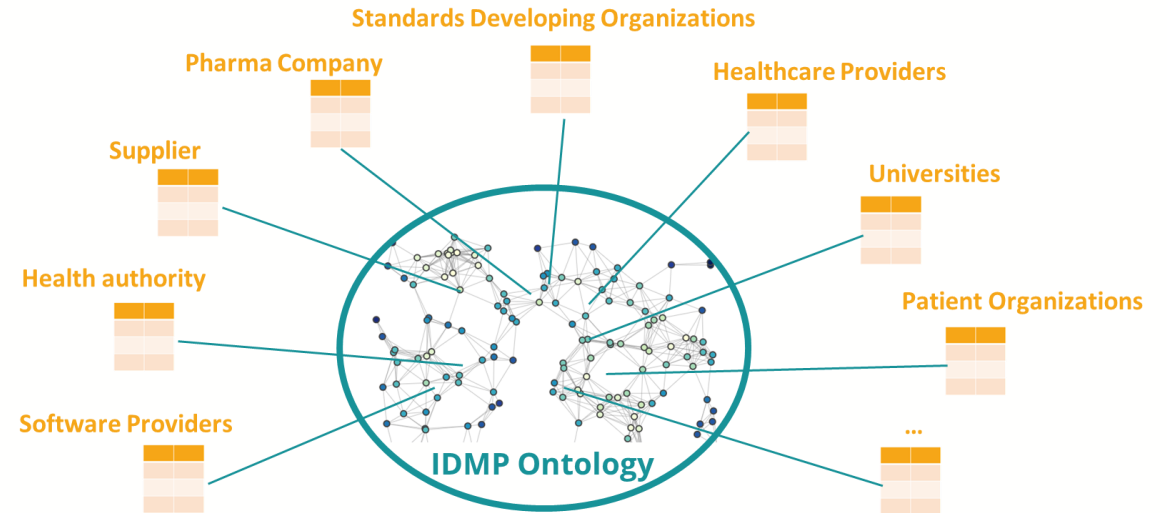
Collaborative Implementation of
the IDMP Standards in Pharma

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:

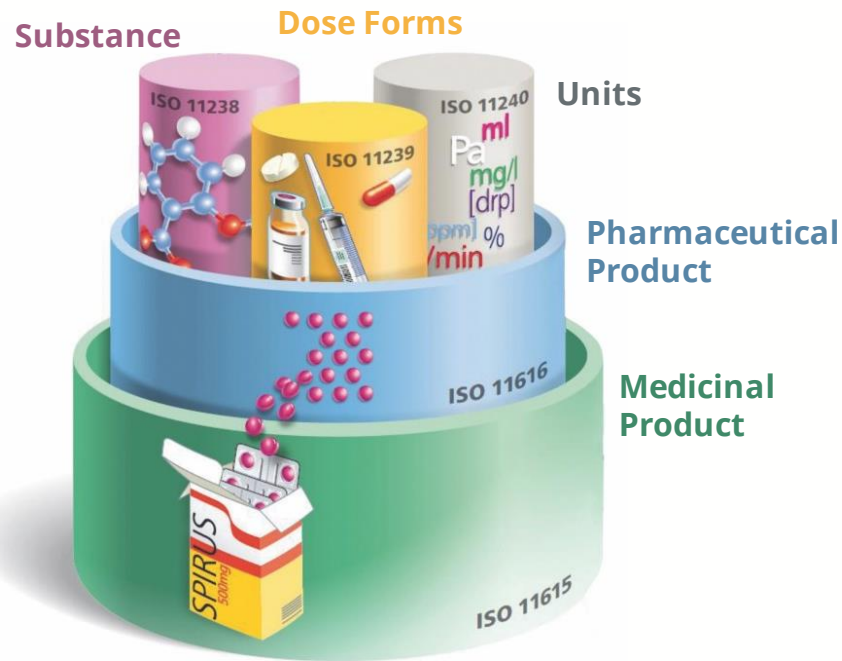
Improved regulatory compliance, patient safety, product development and data management; efficient global product registration and supply chain optimization

IDMP Ontology:

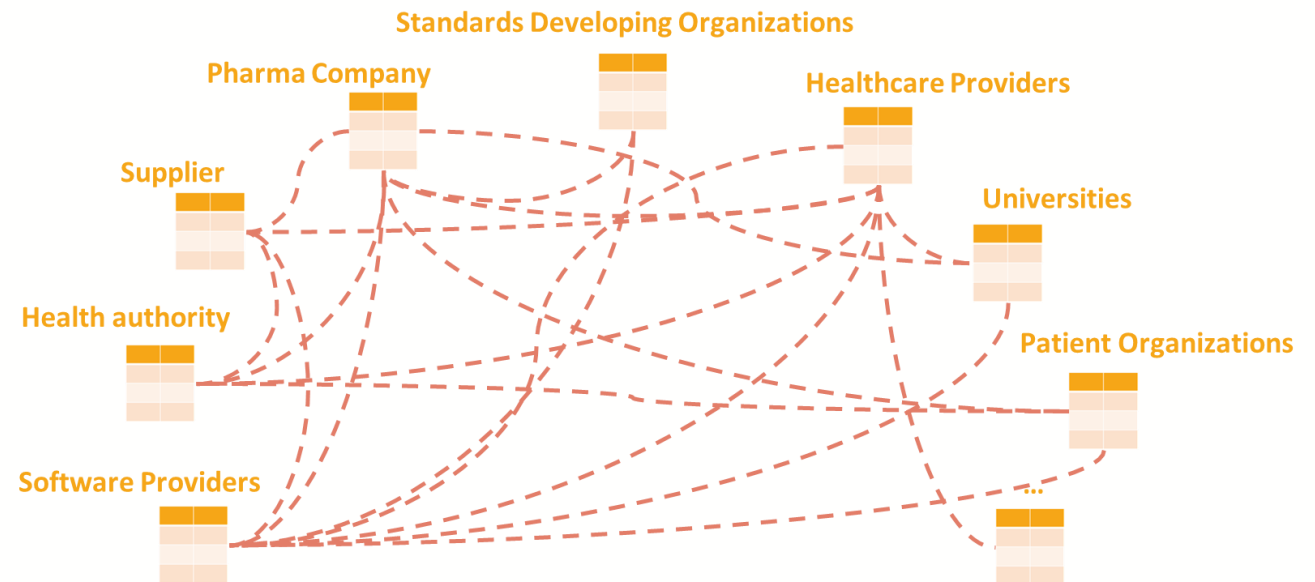
Collaborative development by 11 Pharma companies of the IDMP product data model in an ontology sponsored by the not-for-profit member-driven Pistoia Alliance

The Problem:

Diverging IDMP implementations create silos and are a risk for envisioned standardization benefits of IDMP for drug safety, innovation and operational efficiency.

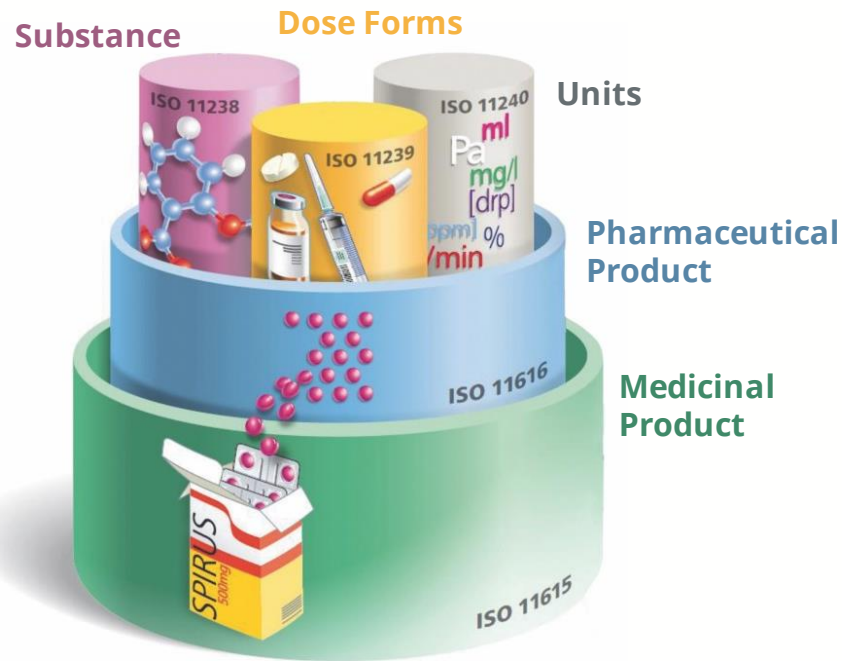


ISO IDMP Standards

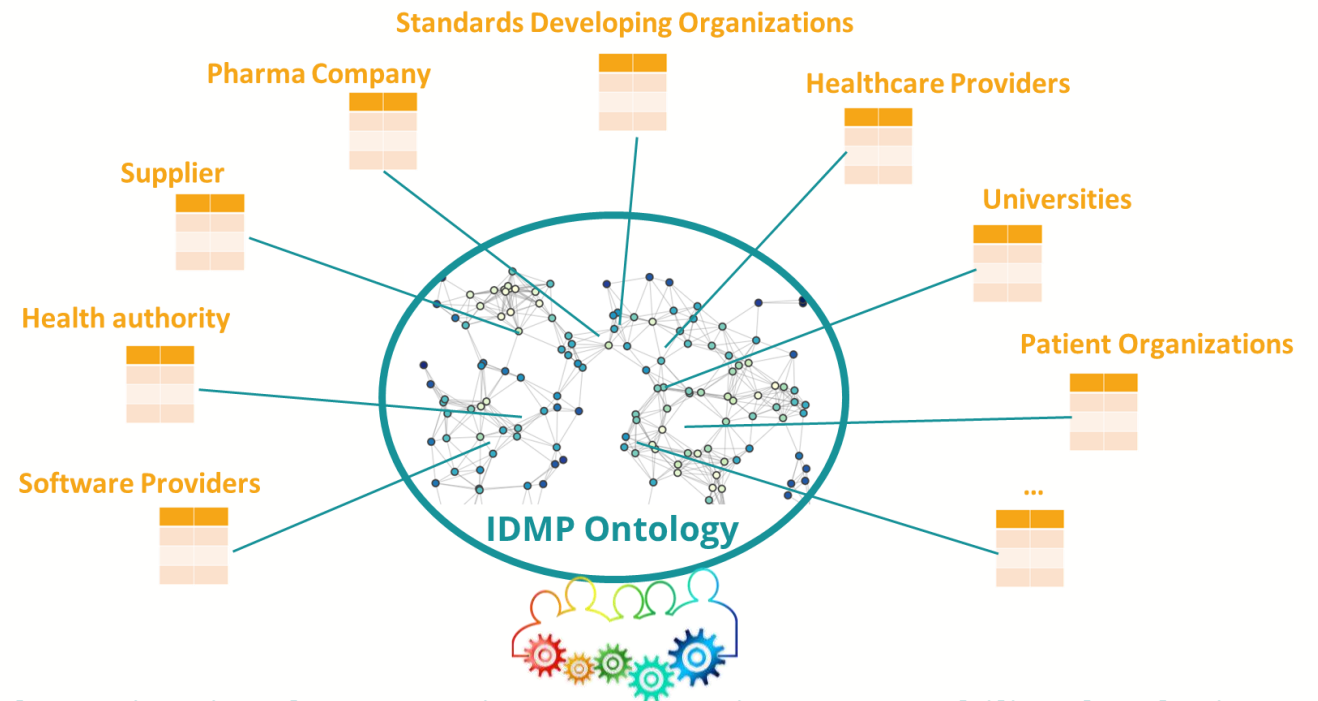


Silos and many costly point-to-point integrations

The IDMP Ontology provides a universal implementation of the IDMP product data model as a common language to effectively bridge the gap between people, processes, and systems.



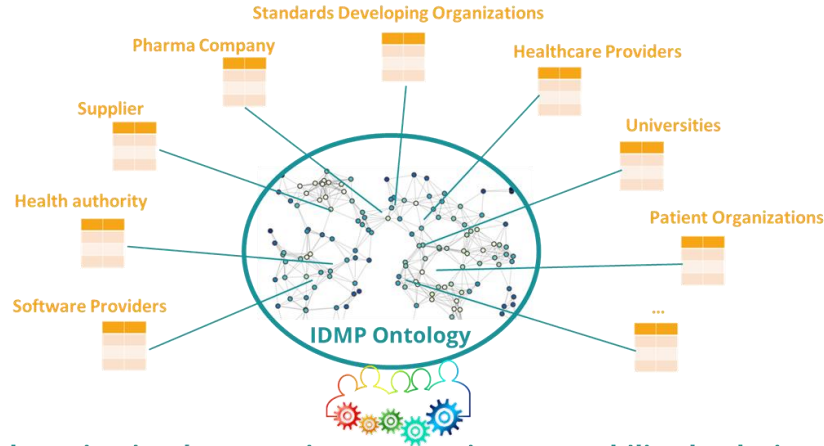
ISO IDMP Standards



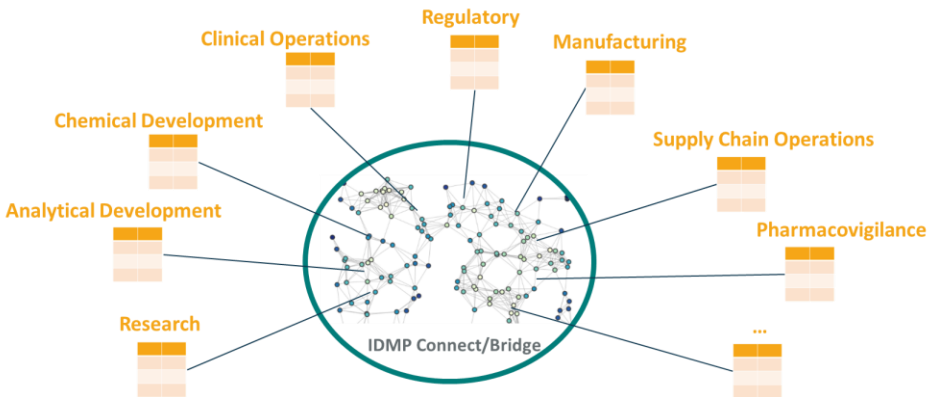
Collaborative implementation creates interoperability by design

Benefits of ISO IDMP as an ontology

- 1 Perform fewer transformations**
A single transformation to IDMP-O instead of many point-to-point integrations
- 2 Solve ambiguities of the ISO IDMP standards**
and feed improvements back to ISO through systematic reviews
- 3 Simplified and Agile Data Governance**
Formal semantics ensure consistency throughout iterative augmentations.
- 4 Provide a vendor-agnostic, and open-source model**
The ontology is fully standards-based without any proprietary aspects
- 5 Reduce implementation effort through a common core**
A pharma company only needs to augment the ontology for its internal specifics



Collaborative implementation creates interoperability by design

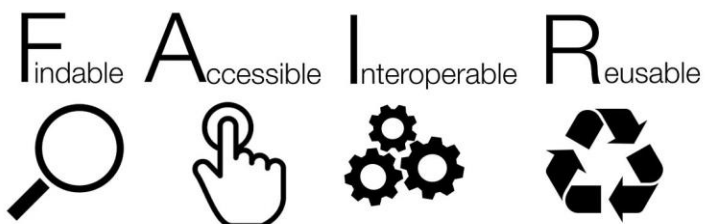


Alignment across the pharma value chain

Ontology for semantic interoperability

What is an Ontology?

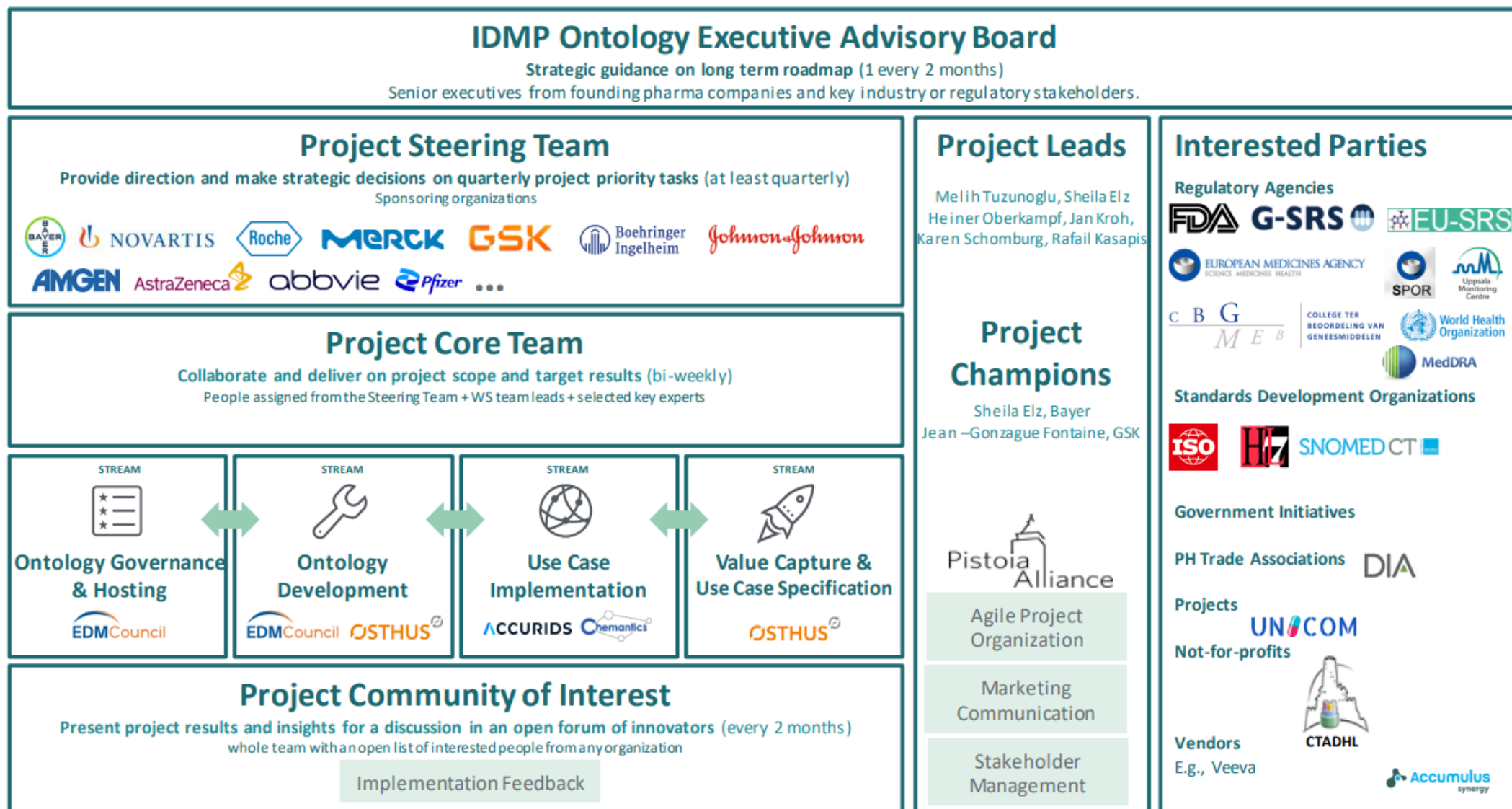
A formal representation of knowledge that defines the **concepts and relationships** within a particular domain, which enables the organization, management, and use of knowledge, leading to more effective and efficient decision-making and problem-solving.














Benefits of an Ontology

- Enhanced knowledge sharing and reusability facilitate reuse across systems and applications
- Enhanced accuracy and consistency with formal representation of concepts and relationships
- Enhanced interoperability with shared vocabulary and conceptual framework
- Improved search and discovery in data source queries with structured representation of knowledge
- Facilitate automated reasoning to draw logical inferences based on relationships defined within the ontology

Our agile governance framework ensures effective industry alignment.



How pharma companies plan to use the IDMP Ontology

Company	Representative	Planned Use
	Sheila Elz	Product Data Model Backbone and cross-functional integration (Regulatory, Product Supply)
	Martin Petracchi	Explore how data-centric Regulatory Information Management based on IDMP-O and a cross-functional digital product structure can reduce time-to-market for original submissions.
	Jean-Gonzague Fontaine	Creation of an IDMP Ontology aligned Knowledge Graph to bridge PLM with Manufacturing
	Quentin Darrasse	Progressive implementation IDMP-O by benefiting from its machine-readable capabilities and canonical data model.
	Petra Kristic	Enhancement of the Merck Substance Graph by using IDMP-O (G-SRS) Graph as a source for the Merck substance ontology. Integration into a broader R&D ontology.
	Boris Klockow	Broaden an MDM approach established with SAP for materials to further IDMP data domains with an Enterprise Knowledge Graph.
	Gang Xue	Establish a common Product Data Model backbone to connect Discovery, CMC, Regulatory Affairs, and Commercial Manufacturing data to enable digital twins and automation of dossier authoring.
	Sridevi Nagarajan	Part of our Product Data Model backbone, supporting cross-functional integration and as a FAIR Data Product that supports AI/Analytics.
	Gerd Kleemann	The IDMP ontology is used as the first instant of a data-centric approach to a product data lifecycle that produces a federated Product Record comprised of a connected data fabric that will eliminate the manual quality control burden, give us interoperability of data enabling increased process automation and unlock the potential for new product insights and innovation (IP)
	Rainer Winnenburg	<i>Planning still ongoing</i>
	Jennifer O'Leary	Plan to Use the project as an opportunity to get our data to work more smartly across our internal functions

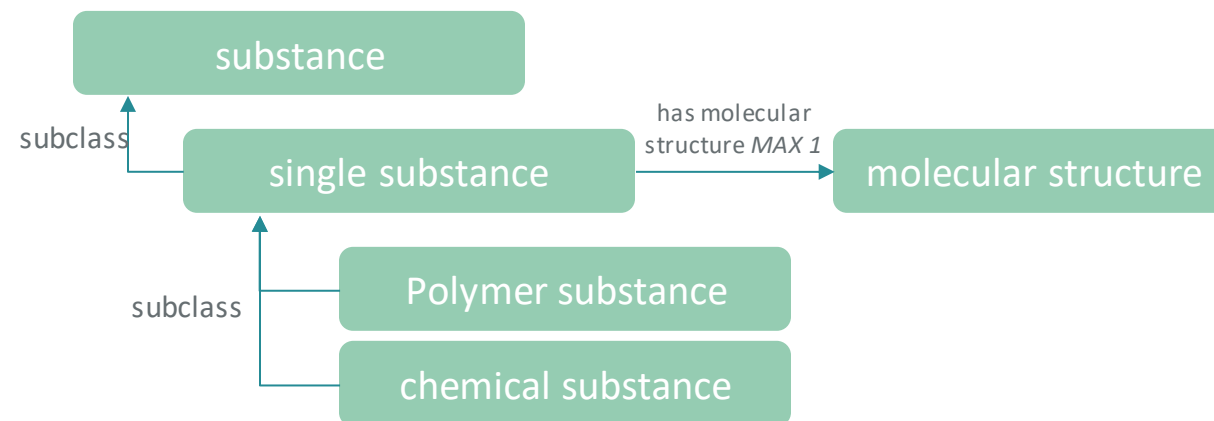
IDMP Knowledge Graph: IDMP Ontology + IDMP Data Graph

Testing the ontology along concrete use cases and data

IDMP Ontology

Formal semantic definition of concepts, relationships and attributes from the ISO IDMP standards.

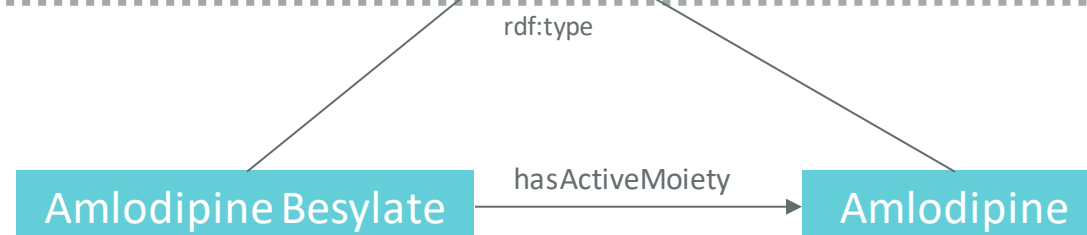
- A few hundred concepts
- Need accurate and agreed patterns



IDMP Data Graph

Any public or pharma internal data objects that are described by the concepts of the IDMP Ontology

- Many millions of objects
- Our test data



Enable business users to answer questions

What substances have a common active moiety?

Which products contain titanium dioxide?

YOUR USE CASE

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

specification



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



Pharmacovigilance

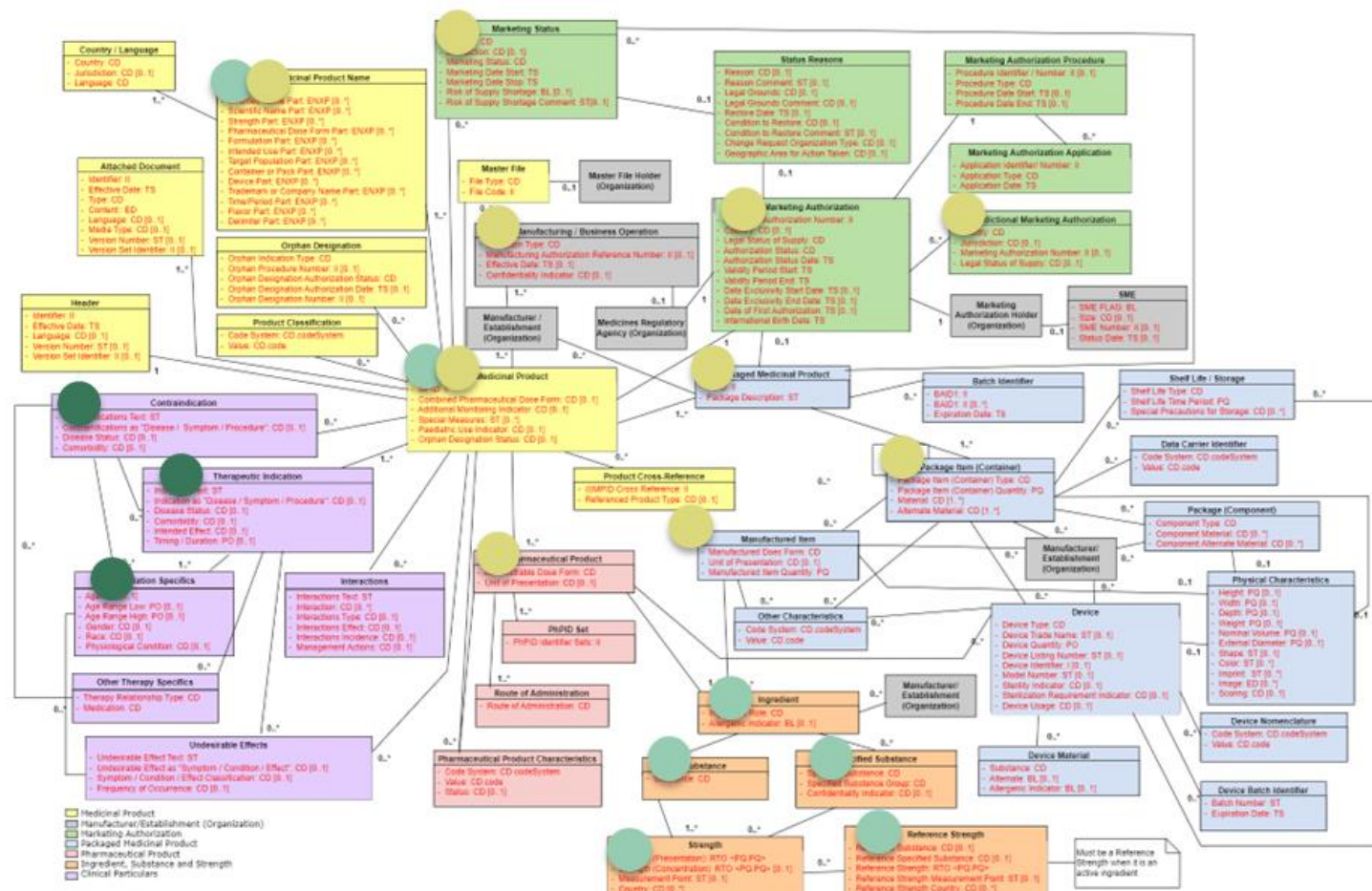
Global Impact Assessment of Safety Risks Across the Product Life-Cycle

backlog



Clinical and Regulatory

Enabling interoperability between ClinOps and Regulatory incl. reference to CDISC





Benefits for Pharma Sponsors

1. **Reduce risk and effort of your IDMP implementation through collaboration with other pharma companies** maximizes learning, distribute development efforts and speed up IDMP adoption internally
2. **Participate in close alignment with regulatory authorities and standards development organizations**
3. **Ensure that your use cases, data challenges and technical/functional implementation requirements are addressed**
4. **Includes support for your internal adoption by project consultants** and fast onboarding for Phase 2 joiners

Executive Advisory Board



Walid Mehanna / Merck KGaA
Group Data Officer, Senior Vice President



Michel Rider / GSK
VP & Head, Digital, Data and Analytics Transformation



David Yee / Novartis
Global Head, NIBR Portfolio Systems at Novartis Institutes for BioMedical Research



Sridevi Nagarajan / AZ
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Lars Greiffenberg / AbbVie
Senior Director R&D Informatics

Project Leadership



Melih Tuzunoglu / Pistoia Alliance
IDMP-O Project Lead



Sheila Elz / Bayer
IDMP Ontology Project Champion
Master Data Manager



Jean-Gonzague Fontaine / GSK
IDMP Ontology Project Champion
Product and Substance Master Data Lead



Heiner Oberkampff / Accurids
IDMP Ontology Project Co-Lead
CEO and Co-Founder



Jan Kroh / EDM Council
IDMP Ontology Project Co-Lead
Director Open Knowledge Graph Lab



Karen Schomburg / OSTHUS
IDMP Ontology Project Co-Lead
Senior Consultant



Rafail Kasapis / OSTHUS
IDMP Ontology Project Co-Lead
Senior Consultant

This is what our community thinks about IDMP-O

IDMP-O is one of the Pistoia Alliance's flagship projects with nearly a dozen of our large member companies contributing to this important initiative. Thanks to our legal framework for pre-competitive collaboration and the extensive expertise of our global network of life sciences and technology thought-leaders, together we can more effectively address the data challenges required to ensure regulatory compliance and drive innovation.

Dr. Becky Upton, President of the Pistoia Alliance

Like many of our peers, Janssen is working to improve the ways in which we can generate value and insights from our regulatory-related data. Pistoia's IDMP-Ontology project provides a vision of the potential value to be extracted from legacy product data sets whilst also bringing structure, consistency, and interoperability. We have been able to take the early work done by the IDMP-O project and use it to shape our own approach and short-cut some of the essential architectural work when developing our own product data strategy.

Christian Baber, J&J

Join us and get involved



Learn More

www.pistoiaalliance.org



Contact Us

ProjectInquiries@PistoiaAlliance.org



Join the Initiative

The IDMP Ontology



Pistoia
Alliance