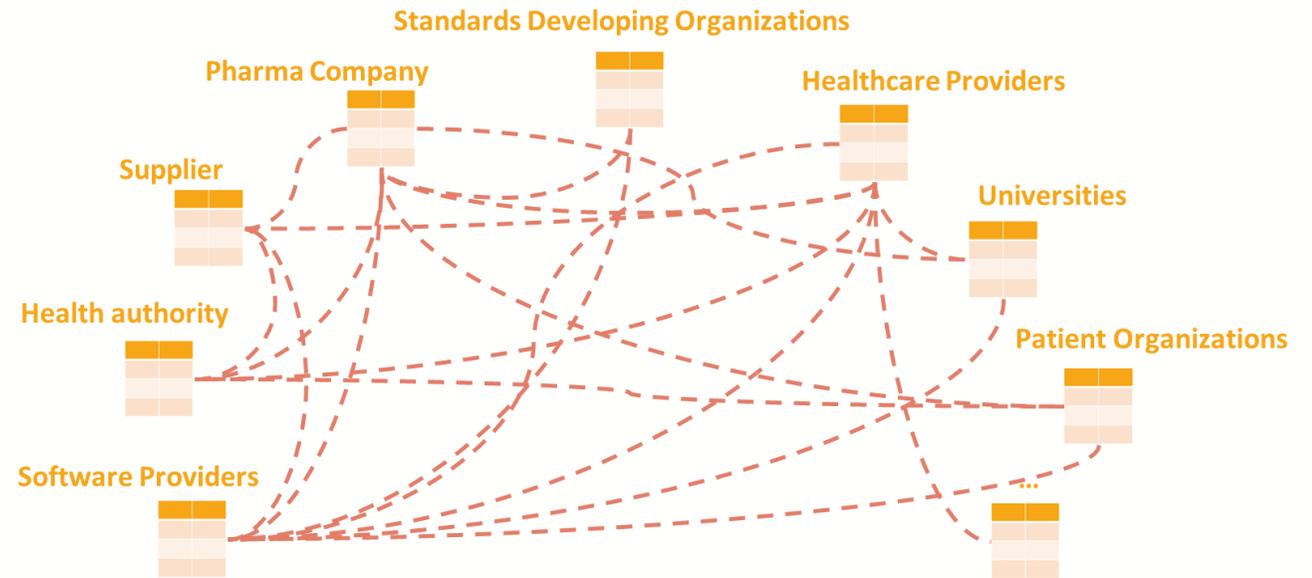
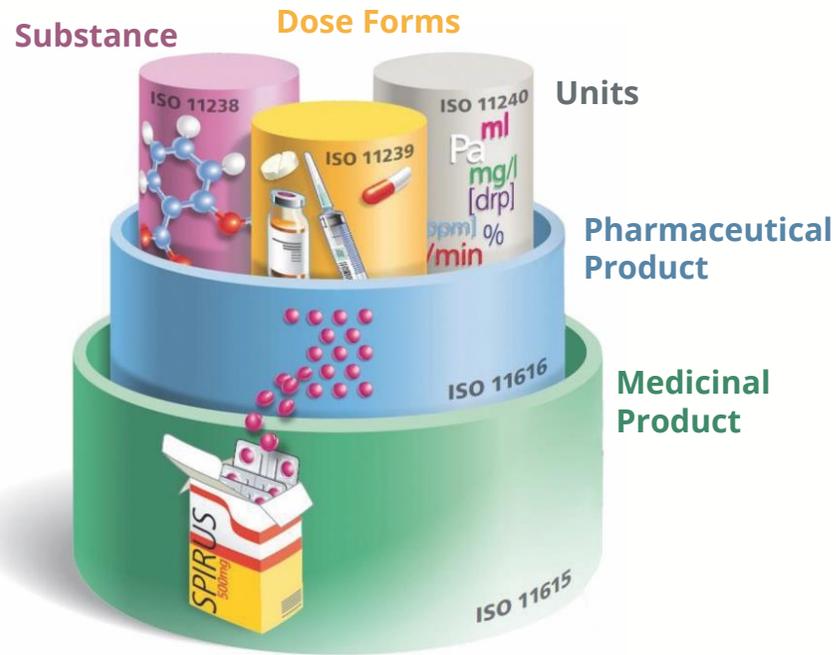


# The IDMP Ontology

Collaborative Implementation of  
the IDMP Standards in Pharma

# The Problem:

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

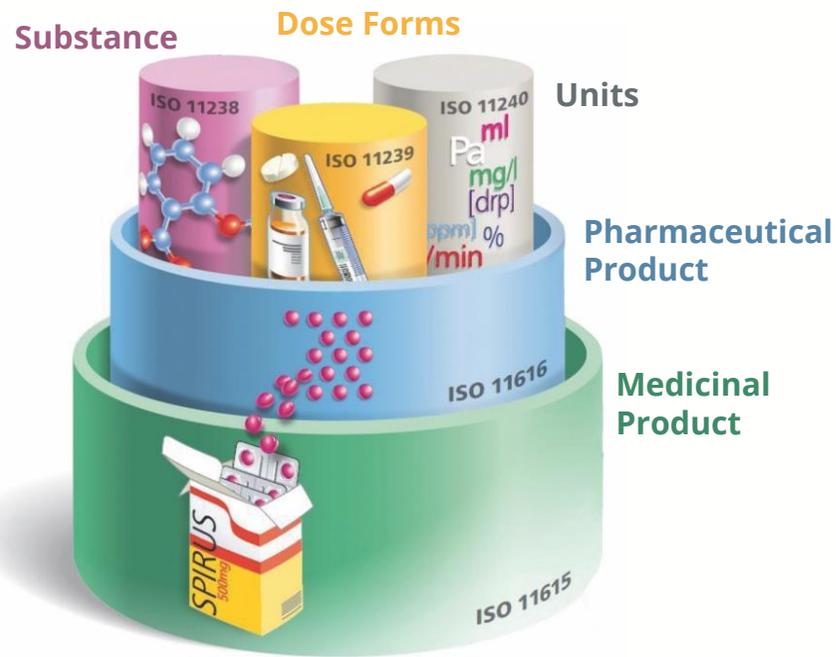


ISO IDMP Standards

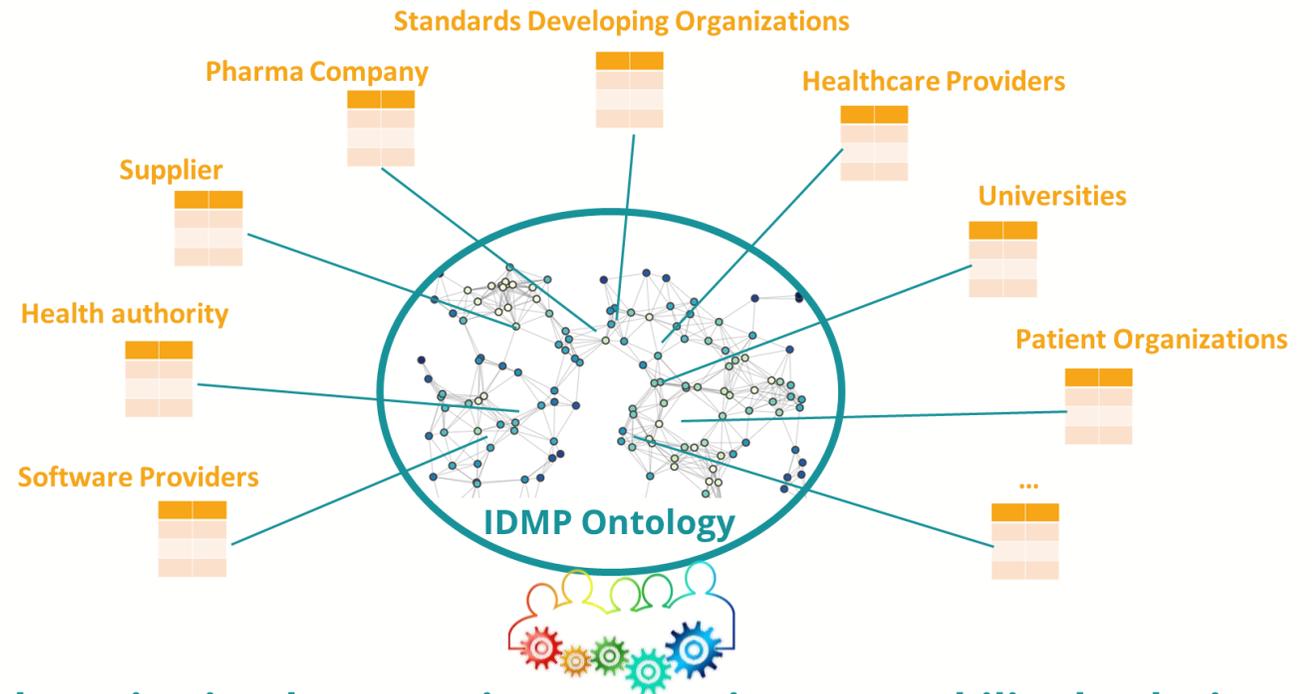


Silos and many costly point-to-point integrations

# 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.



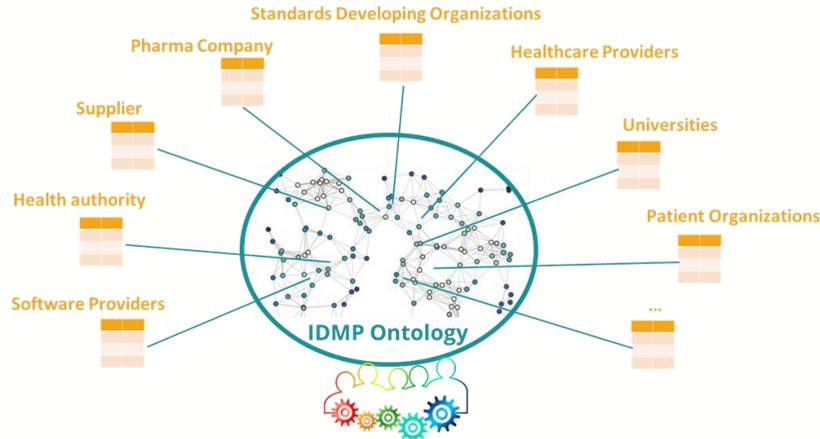
ISO IDMP Standards



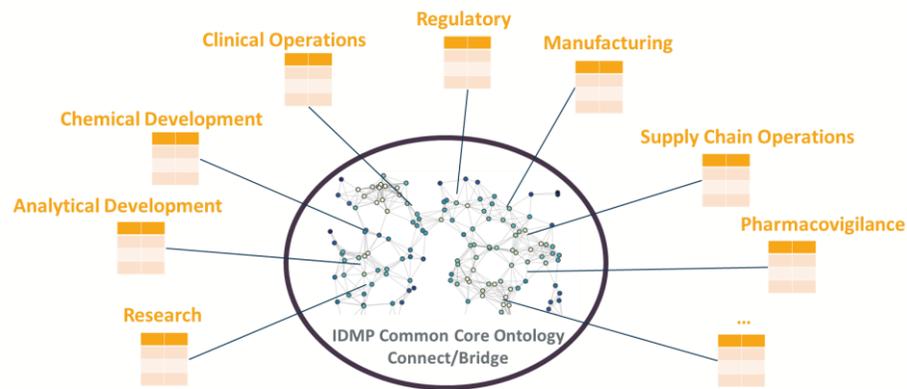
Collaborative implementation creates interoperability by design

# Why an Ontology for IDMP?

- 1 Provide a digital, machine-processable standard  
PDF is not enough as different groups implement it differently
- 2 Solve ambiguities of the ISO IDMP standards  
and feed improvements back to ISO through systematics reviews
- 3 Bridge different views with ONE product data model  
between pharma internal departments and between industry groups
- 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 model for internal specifics

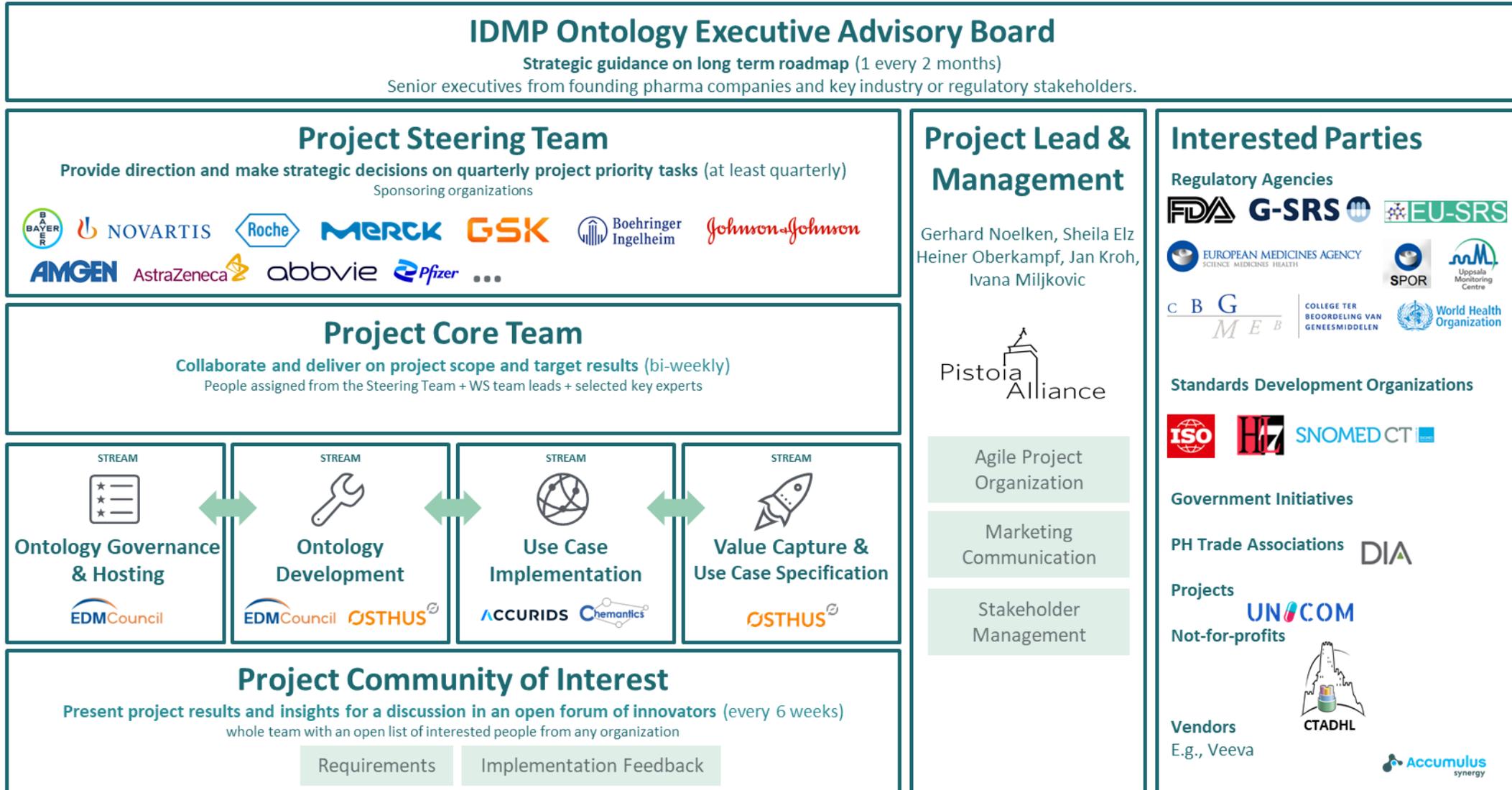


Collaborative implementation creates interoperability by design



Alignment across the pharma value chain

# Our agile governance framework ensures effective industry alignment.



# How do the pharma companies plan to use the IDMP Ontology?

Company	Representative	Planned Use of the IDMP Ontology
 BAYER	Sheila Elz	Product Data Model Backbone and cross-functional integration (Regulatory, Product Supply)
 NOVARTIS	Raphael Sergent	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.
 GSK	Jean-Gonzague Fontaine	Creation of an IDMP Ontology aligned Knowledge Graph to bridge PLM with Manufacturing
 Roche	Quentin Darasse	<i>Planning still ongoing</i>
 MERCK	Petra Kristic	Enhancement of the Merck Substance Ontology and integration into a broader R&D ontology.
 Boehringer Ingelheim	Boris Klockow	Broaden an MDM approach established with SAP for materials to further IDMP data domains
 Johnson & Johnson	Gang Xue	Establish a common Product Data Model backbone to connect Discovery, CMC, and Commercial Scientific data to enable digital twins and automation of dossier authoring.
 AstraZeneca	Sridevi Nagarajan	Part of our Product Data Model backbone, supporting cross-functional integration and as a FAIR Data Product that supports AI/Analytics.
 AMGEN	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)
 abbvie	Rainer Winnenburg	<i>Planning still ongoing</i>
 Pfizer	April Marshall	Plan to Use the project as an opportunity to get our data to work more smartly across our internal functions

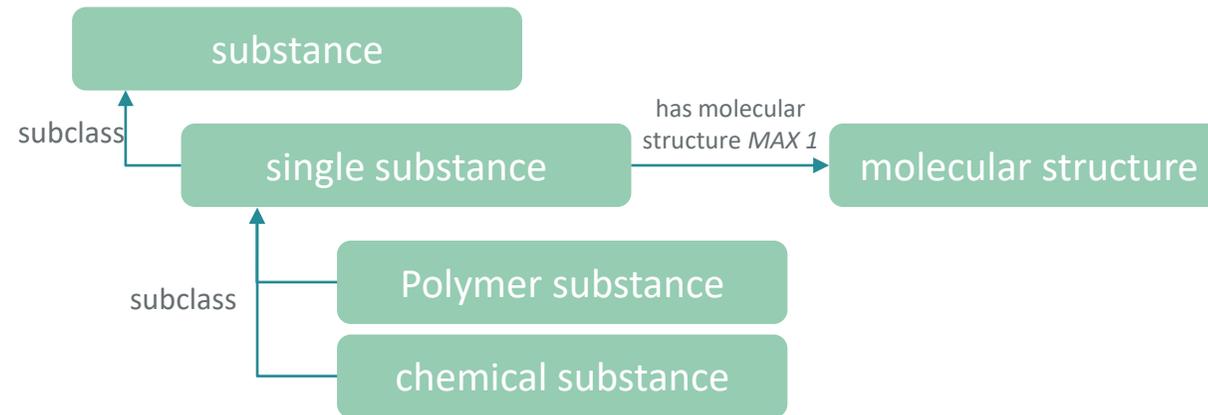
# IDMP Knowledge Graph: IDMP Ontology + IDMP Data Graph

Testing the ontology along concrete use cases and data

## IDMP Ontology

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

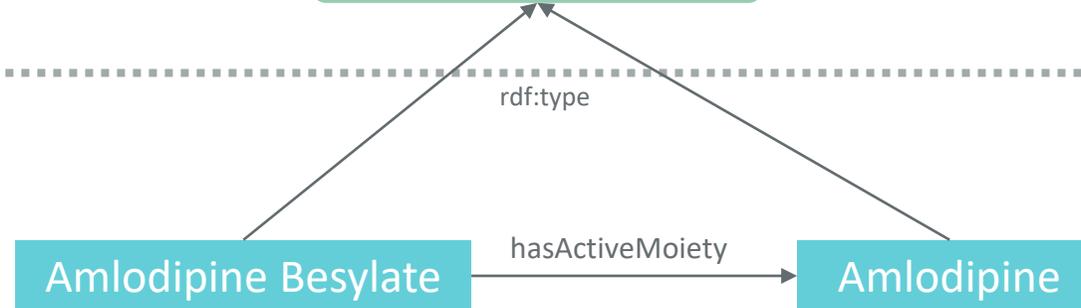
- A few hundred concepts
- Need accurate and agreed patterns



## IDMP Data Graph

Any data object 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



# Benefits for Pharma Sponsors

- 1. Reduce risk and effort of your IDMP implementation through collaboration with other pharma companies** maximizes learning, distributes development efforts and speeds 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



# Marketing & Communication

The IDMP Ontology is positioned and recognized within important communities and initiatives.

- ✓ Bi-monthly public Community of Interest webinars
- ✓ Quarterly CTADHL Transatlantic workshops
- ✓ Regular exchange with authorities from FDA, EMA, WHO
- ✓ Regular updates at e.g., IRISS, IDMP industry round table
- ✓ Presentation at various conferences including DIA Global RSIDM Forum, OMG etc.

CTADHL = Call To Action-Delivering Health Literacy; OMG = Object Management Group; DIA = Drug Information Association

# Our Financial Strategy

## Short-term (Phase 2: Nov 2022 – Dec 2023)

1. Increase the number of companies involved, from 7 to 12 in Q1, to 14 during 2023.  
Approx. \$120k expected by each pharma company for Phase 2 in 2023
2. Take a milestone-based scoping approach to allow flexibility in scope and investment per quarter

## Long-term development and maintenance strategy

- Seek additional funding sources like IHI — Gravitare Health, WP5, UNICOM
- Elevate IDMP-O methodology into an ISO Technical Specification (ISO TS)

# Our Executive Advisory Board



**Christian Baber / J&J**  
Head of Scientific & Pharmaceutical  
Data, Informatics & Systems



**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



**Benjamin Slade / Novartis**  
Enterprise Data Management



**Thomas Seck / Boehringer**  
Head of Global Regulatory Affairs



**Vada Perkins / Bayer**  
Executive Director, Regulatory Policy &  
Innovation, Head of Research & Policy-Regions



**Saskia Schmidt-Riddle / Bayer**  
Head R&D Data Assets



**Vanni Carapetian / Roche**  
Regulatory Capability Lead



**Janet Cheetham / Amgen**  
Executive Director, Analytical Research  
and Development



**Frits Stulp / CTADHL**  
Chairman of CTADHL Board



**Victoria Gamerman / Boehringer**  
Global Head of Data Governance & Insights

# & Project Leadership



**Gerhard Noelken / Pistoia Alliance**  
IDMP Ontology 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



**Ivana Miljkovic / OSTHUS**  
IDMP Ontology Project Co-Lead  
Senior Consultant, Project & Team Lead

*Join us and  
get involved*



**Learn More**

[www.pistoiaalliance.org](http://www.pistoiaalliance.org)



**Contact Us**

[ProjectInquiries@PistoiaAlliance.org](mailto:ProjectInquiries@PistoiaAlliance.org)



**Join the Initiative**

The IDMP Ontology

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