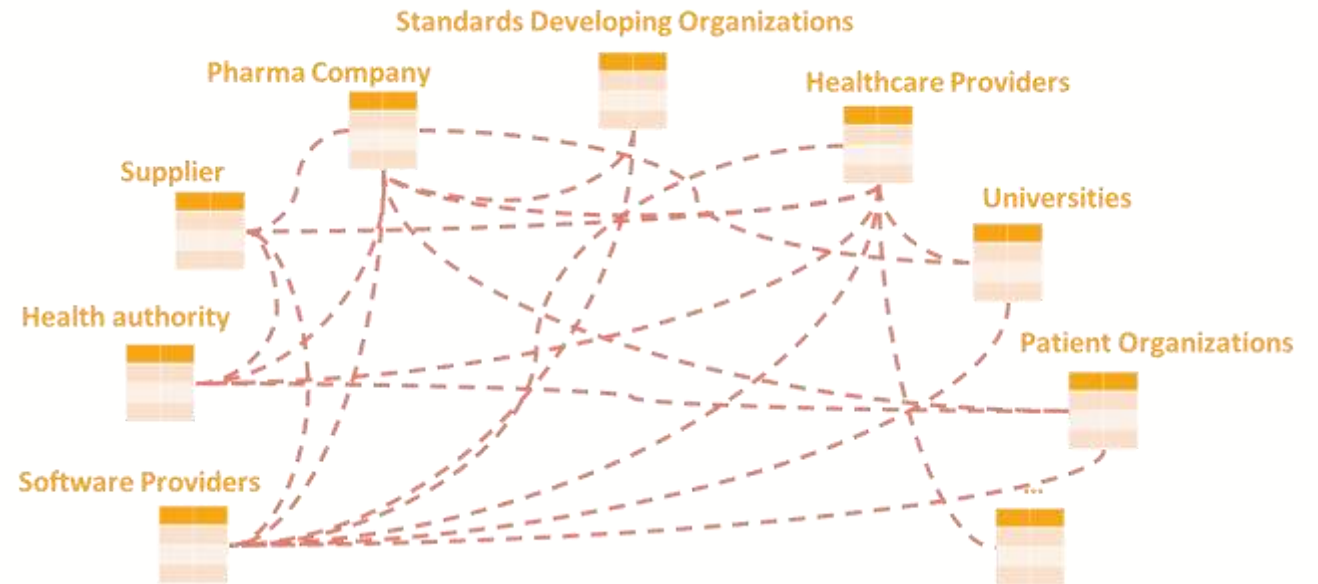
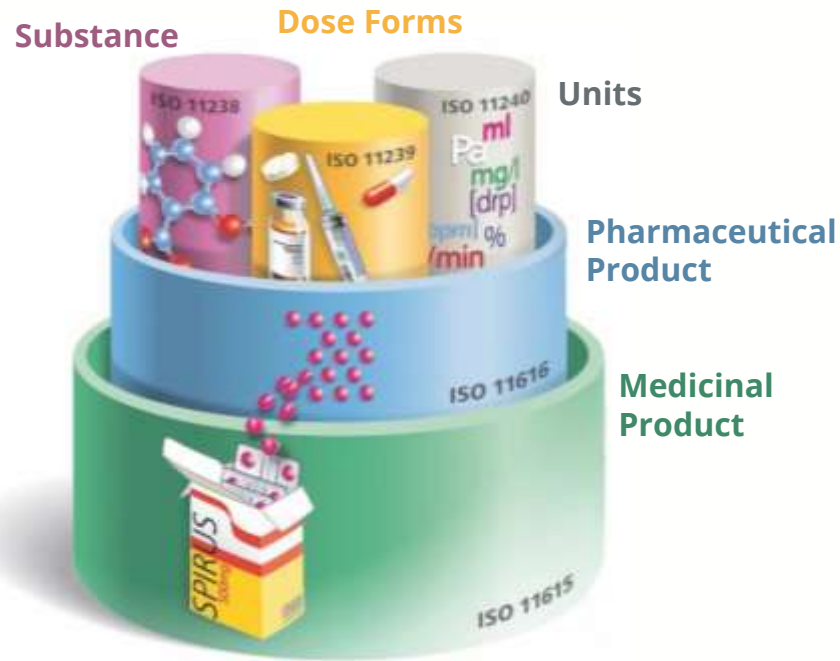


# The IDMP Ontology

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.

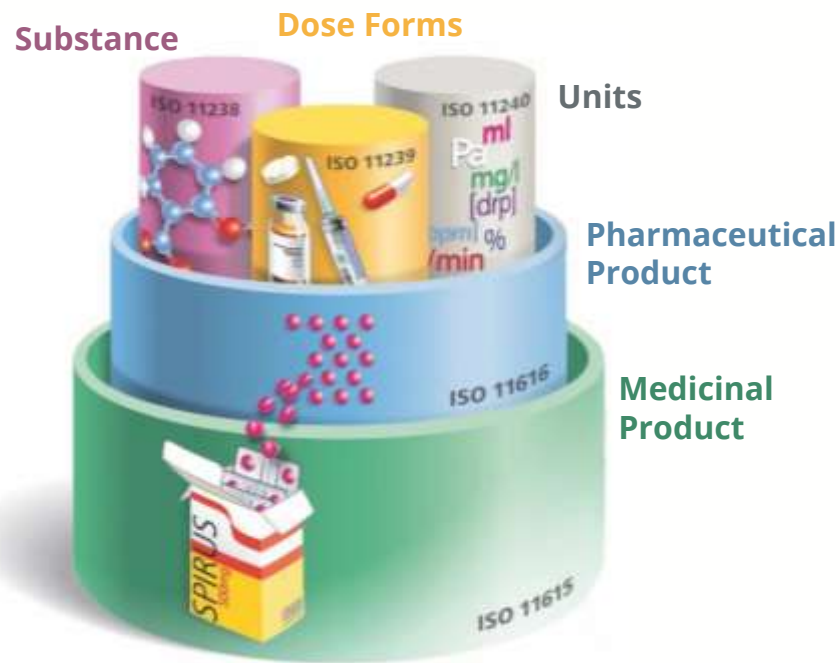


ISO IDMP Standards

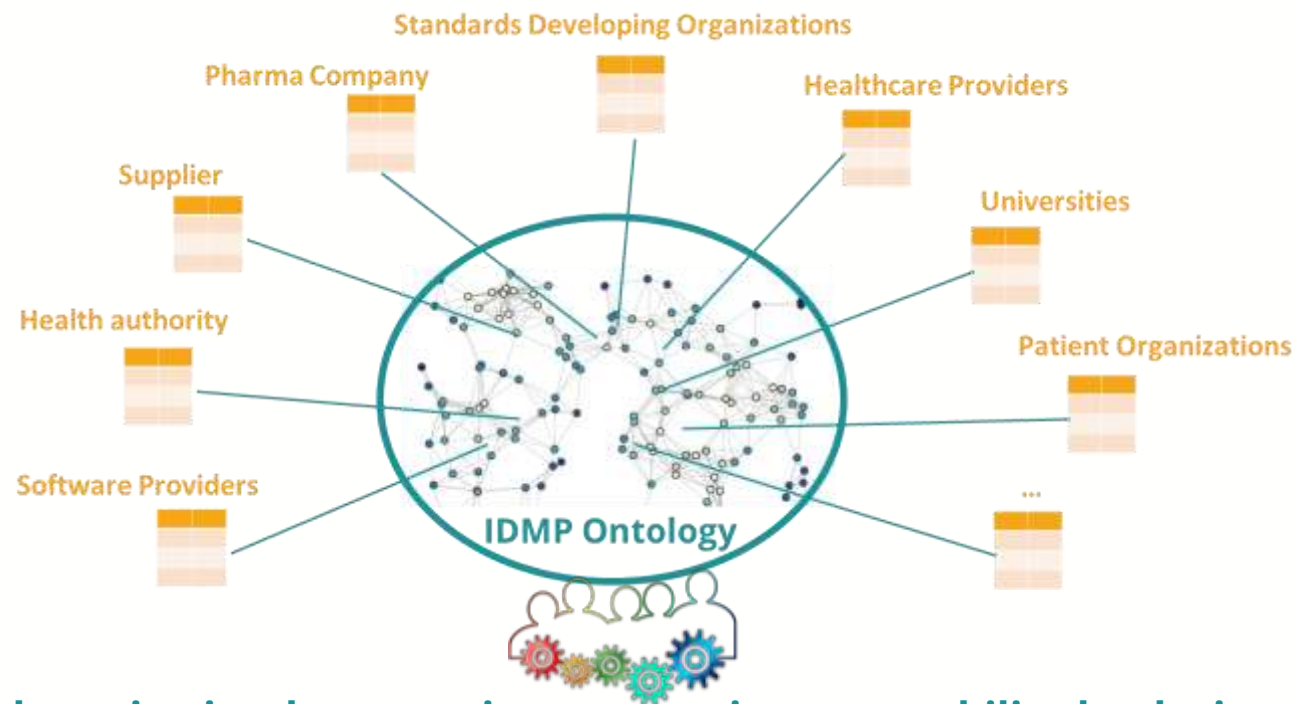


Silos and many costly point-to-point integrations

# 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.

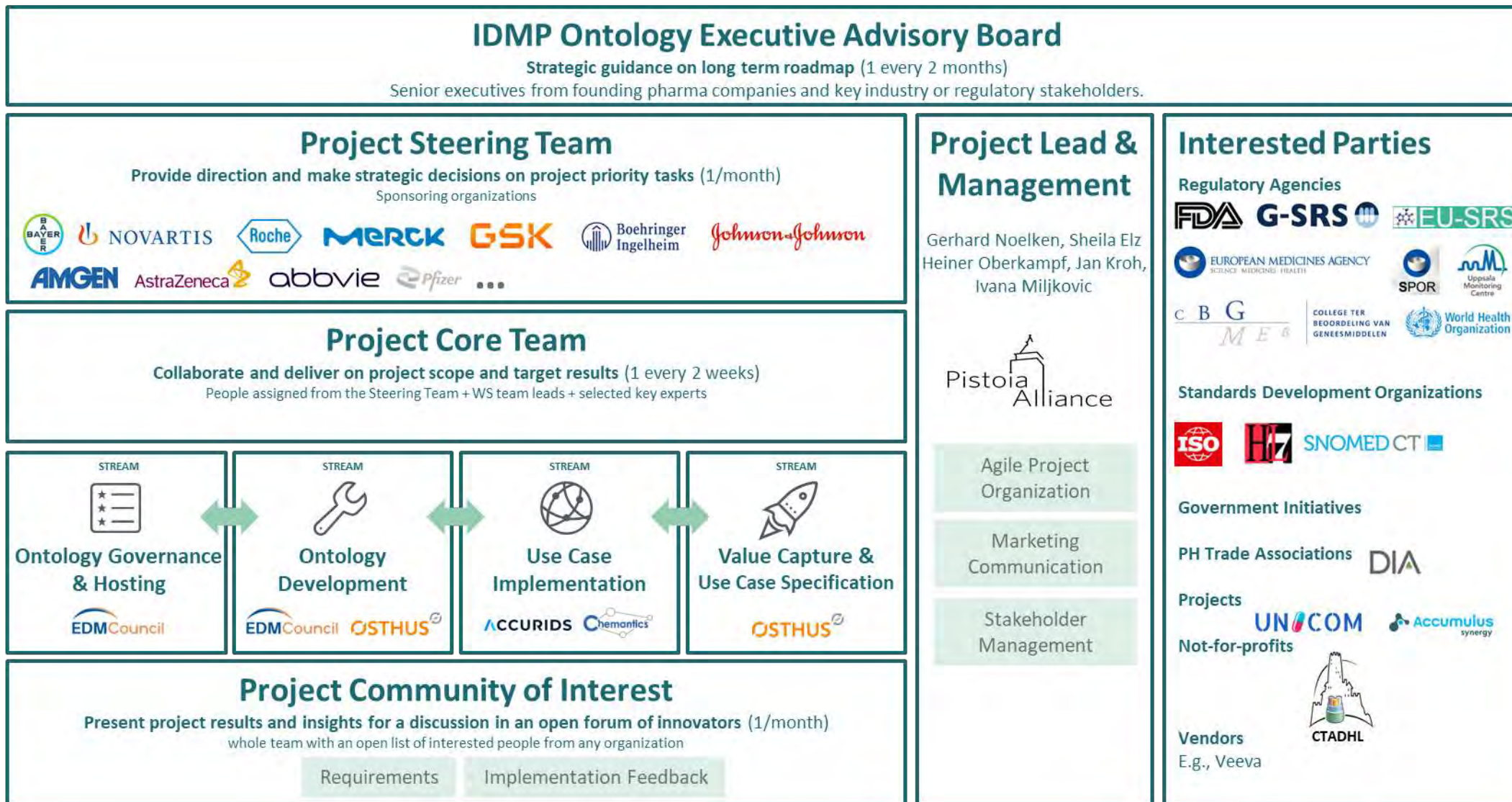


ISO IDMP Standards



Collaborative implementation creates interoperability by design

# Our agile governance framework ensures effective industry alignment.















# Benefits for Pharma Sponsors

- 1 Collaborative IDMP implementation with multiple companies in close alignment with regulatory authorities, standards development organizations, and vendors
- 2 Ensure that individual use cases and data challenges are addressed
- 3 Speed-up digital transformation and IDMP implementation across functions

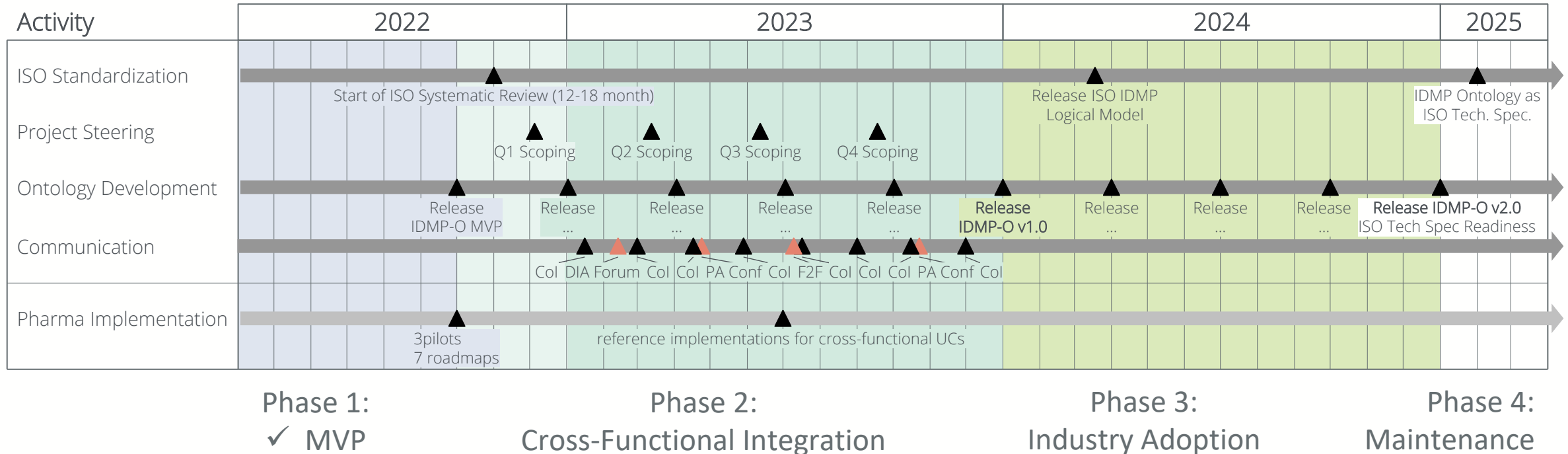
# How do the pharma companies plan to use the IDMP Ontology?

Company	Representative	Planned Use of the IDMP Ontology
	Sheila Elz	Product Data Model Backbone and cross-functional integration (Regulatory, Product Supply)
	Raphael Sergent	Pilot for data-centric Regulatory Information Management
	Jean-Gonzague Fontaine	Creation of an IDMP Ontology aligned Knowledge Graph to bridge PLM with Manufacturing
	Quentin Darasse	<i>Planning still ongoing</i>
	Petra Kristic	Enhancement of the Merck Substance Ontology and integration into a broader R&D ontology.
	Boris Klockow	Broaden an MDM approach established with SAP for materials to further IDMP data domains
	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.
	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 Winnenbourg	<i>Planning still ongoing</i>

# In 6 months, we created a useful MVP and gained project traction.

- ✓ **Created IDMP Ontology MVP** with an initial focus on the substance domain on time
  - Solved challenges that were discussed for several years in alignment with key experts and stakeholders
  - Established a set of collaboration principles and an effective governance framework
- ✓ **Demonstrated the use of the IDMP Ontology** with
  - Public data from GSRS and examples from EU CT and DailyMed
  - Pharma internal data from Merck, Bayer, Novartis
- ✓ **Increased project traction**
  - Increased pharma project members from an initial 5 to 9 companies
  - FDA, EMA, WHO and trade organisations to get involved and provide their requirements and feedback
- ✓ **Submitted proposal for IDMP Ontology to become an ISO Technical Specification [1]**

# Our Roadmap supports pharma implementations in alignment with ISO







## Marketing & Communication

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

- ✓ Monthly Community of Interest webinars with Pistoia Alliance
- ✓ Quarterly CTADHL Transatlantic workshops
- ✓ Regular exchange with authorities from FDA, EMA, WHO
- ✓ Regular updates at e.g., IRISS, IDMP industry round table
- ✓ Multiple conferences, e.g., OMG, EU OntoCommons, Pistoia Alliance Annual Conferences
- ✓ DIA Global RSIDM Forum

# Our Financial Strategy

## Short-term (Phase 2 started in November 2022)

1. Increase the number of companies involved, from 7 to 10 in Q1, to 12 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



**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

# & 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**

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