PISTOIA ALLIANCE

Accelerating Digital Transformation in Pharma with IDMP

An industry benchmark report on the status of IDMP standards implementation in Pharma and the role of the IDMP Ontology for accelerating digital transformation

ACCURIDS

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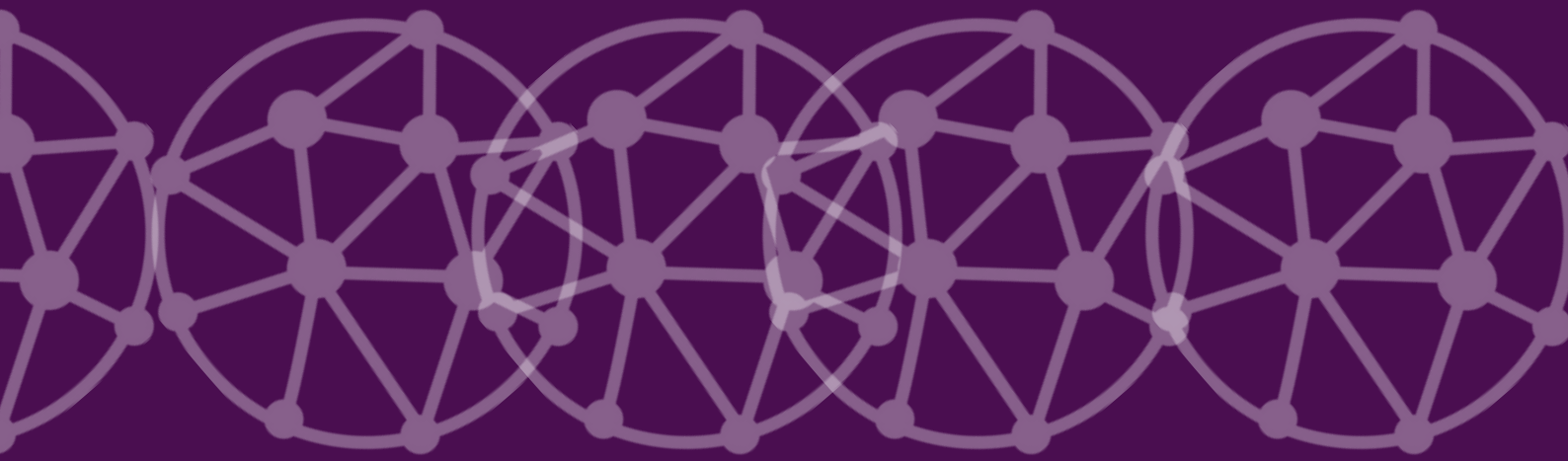


Executive Summary

The European Medicines Agency (EMA) continues to advance the implementation of the Identification of Medicinal Products (IDMP) standards, a regulatory framework that will become mandatory across the EU, with the FDA likely to follow close behind. Failure to implement IDMP could lead to a number of risks including regulatory penalties, inefficiencies in operations and threats to patient safety.

The Pistoia Alliance and its IDMP-Ontology project team have undertaken an industry benchmark survey in collaboration with members and key supporters to determine the state of IDMP standards implementation across the pharmaceutical value chain.

18 organizations have shared their insights into the challenges, opportunities and value IDMP implementation delivers and what stage they are at in adopting the Pistoia Alliance's IDMP-Ontology.

Key highlights:

•43% of companies said they plan to implement IDMP-Ontology in 2024 – an extremely encouraging take up in the first year of its release.

•Pharmacovigilance is no longer seen as key to the success of IDMP even though it was its original purpose.

•89% of companies recognize the long-term value of IDMP beyond compliance and as part of their digitalization strategy, although compliance is the key driver in the short-term.

•The standardization of data is the biggest hurdle preventing effective data integration for 56% of companies. A standardized implementation of IDMP via IDMP-Ontology is a key way to address this for product data.

The Pistoia Alliance welcomes all companies to get involved in driving forwards and sharing the benefits of its award-winning IDMP-Ontology project. For further information contact: projects@pistoiaalliance.org

Contributors

This survey was conducted by Pistoia Alliance, ACCURIDS and MAIN5 and supported by the IDMP Ontology project with participants from Abbvie, Amgen, AstraZeneca, Boehringer Ingelheim, Bayer and Novartis. Our thanks go to everyone who shared valuable insights and to Steve Gens from Gens & Associates for supporting the study design and analysis.

About The Pistoia Alliance: A global, not-for-profit members' organization made up of life science companies, technology and service providers, publishers, and academic groups working to lower barriers to innovation in life science and healthcare R&D. It was conceived in 2007 and incorporated in 2009 by representatives of AstraZeneca, GSK, Novartis, and Pfizer.

Its projects transform R&D through pre-competitive collaboration. It overcomes common R&D obstacles by developing standards and best practices, sharing pre-competitive data and knowledge, and implementing technology pilots. There are currently over 200 member companies collaborating on projects that deliver significant value for the worldwide life sciences R&D community, using the Pistoia Alliance's proven framework for open innovation.

Introduction

The ISO standards for Identification of Medicinal Products (IDMP) provide an internationally accepted framework to uniquely identify and describe medicinal products. Driven by regulatory requirements, the role of IDMP is to globally align the pharmaceutical industry on data standards around product and substance and packaging information.

Failure to implement IDMP standards will have widespread consequences. Non-compliance with mandatory regulations could lead to fines and delays in product approvals with a knock on affect on marketing authorizations and the ability to bring products to market. Data fragmentation could result in inefficiencies in data management and errors in regulatory submissions and labelling. In addition, IDMP facilitates better product traceability and without proper implementation of IDMP standards, it may be more difficult to trace products through the supply chain, complicating recalls, audits, or investigations. Given that IDMP aims to harmonize the way medicinal products are identified globally, a company's ability to operate efficiently in multiple jurisdictions could be impacted too. Failure to adopt these standards could also impact digital transformation, the use of AI, innovation, and ultimately patient safety due to inaccurate product information and delayed safety reporting.

Realization of the full potential of IDMP depends on self-describing data to counteract diverse, non-standard IDMP implementations. For this purpose, the existing IDMP standardization have been augmented by the IDMP Ontology that enables deep, semantic interoperability based on FAIR data principles. This will ultimately enable entirely new ways of collaboration and enable early adopters to gain a competitive advantage in innovation, drug safety and overall operational efficiency.

Survey Purpose

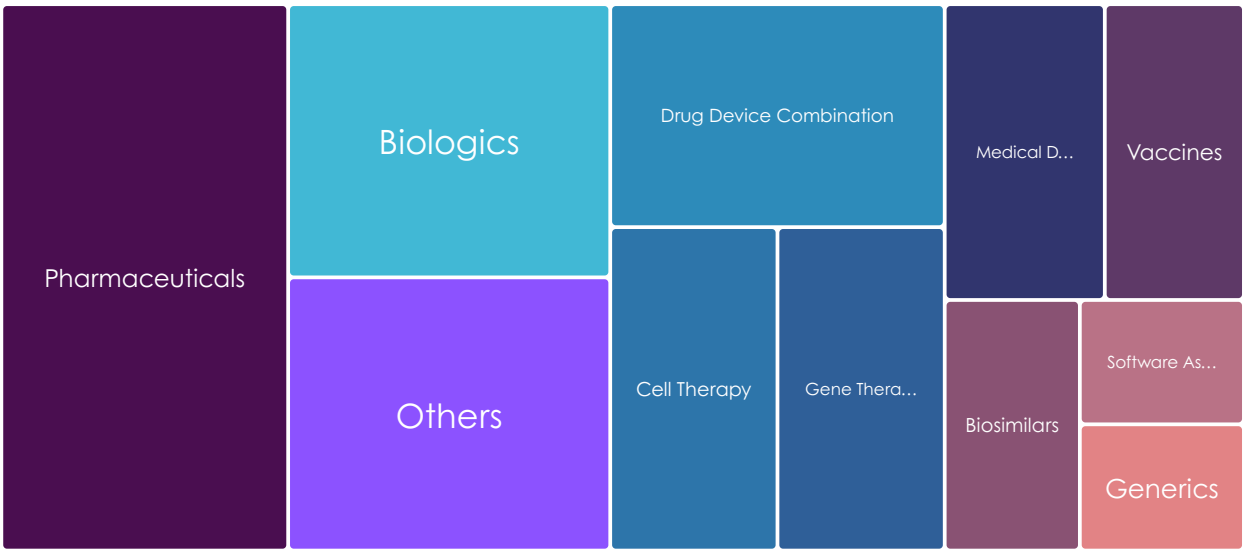
While the ISO IDMP standards were originally driven by regulatory and pharmacovigilance use cases, we see the biggest potential of IDMP and the IDMP Ontology to serve as the product data harmonization backbone to connect data along the entire pharma value chain including R&D, clinical, manufacturing and commercial operations. To realize this immense potential, we need to significantly accelerate the adoption of IDMP.

Our survey aims to help the pharma industry better understand the current status of IDMP implementations and the role IDMP Ontology plays in accelerating adoption in pharma. It examines the viewpoints of different stakeholders and provides a benchmark to measure success against.

Survey Methodology

Interviews were conducted among 81 individuals from 18 organizations (results have been consolidated into an overall score per company).

The survey participants represent a broad spectrum of the pharmaceutical industry and cover a wide range of products:



For which division or domain are you most involved with the management of data?

Despite a small over-representation (30%) of respondents working on authorization and lifecycle management, there is a good representation of all product life-cycle stages.

30%

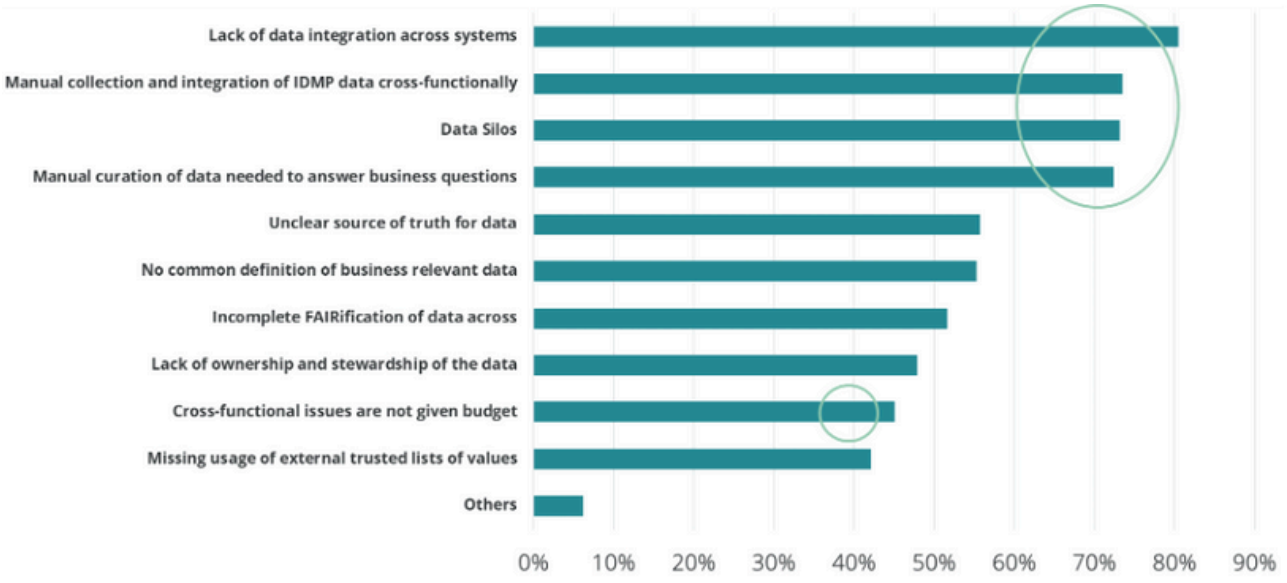
28%

28% of respondents work on research and development products with a good representation of investigational versus authorized perspectives.

Survey Results

In the following section, we present the key findings of the survey.

What are your biggest challenges with respect to product data management?



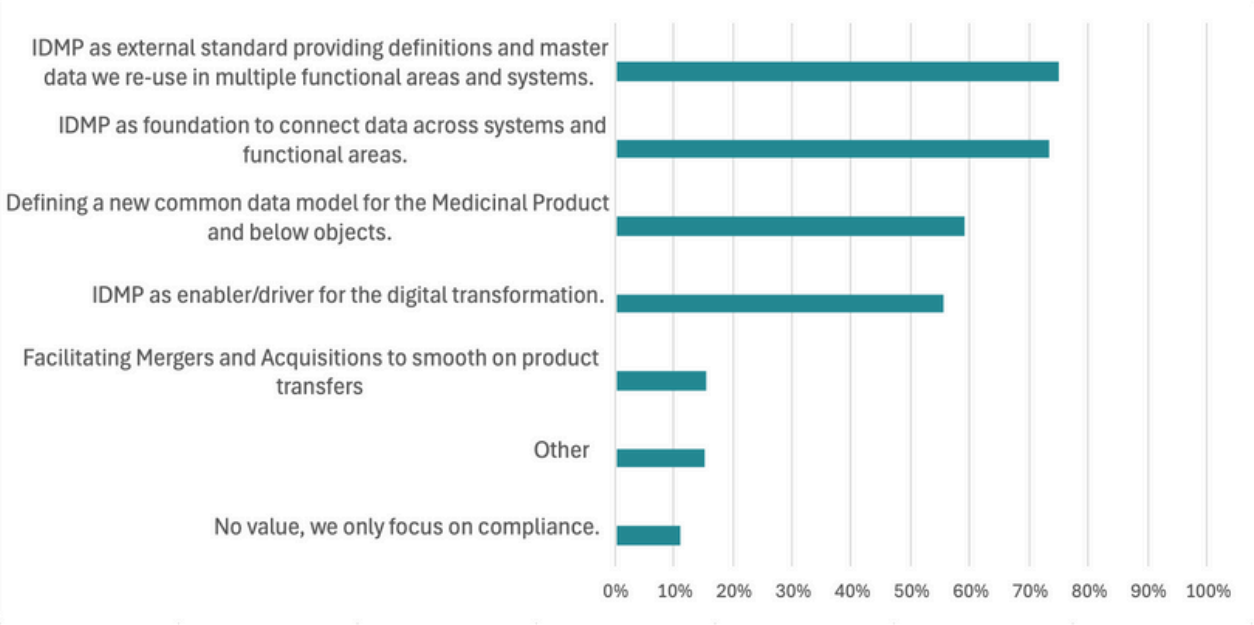
- The biggest challenges identified are manual data collection, data silos, and the resulting lack of integration across systems. Budget constraints affect fewer than half of the companies when it comes to product data management.

- Technical challenges include a lack of data integration, manual data collection and curation, and insufficient use of trusted external sources.

- Governance challenges involve data silos, an unclear source of truth, lack of standardized definitions, and gaps in ownership, stewardship, budget, and resources.

- The industry prioritizes technical implementation over governance or resource issues. One possible reason for this could be that technical challenges are not being prioritized by department heads.

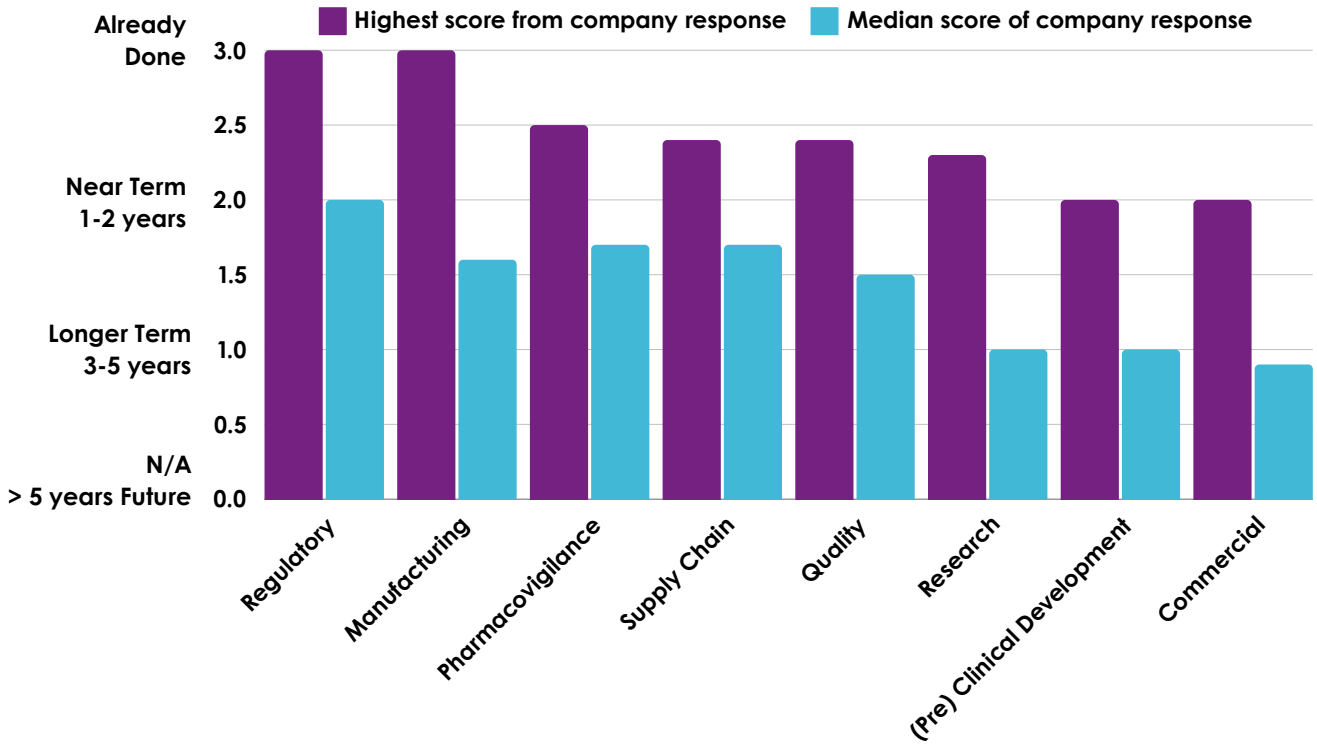
What value does IDMP provide you with for your digitalization strategy?



- More than 70% re-use IDMP an external standard for cross-functional data integration. More exchange and emphasis on the benefits of IDMP standards for cross-functional data integration would be beneficial for the entire industry.

- 89% of companies recognize value in IDMP beyond compliance, indicating their efforts extend beyond regulatory compliance. Only 11% of the responding companies only focus on IDMP compliance with no value on their digitalization strategy.

Indicate the timing of integrating or linking data from the following functional areas for IDMP

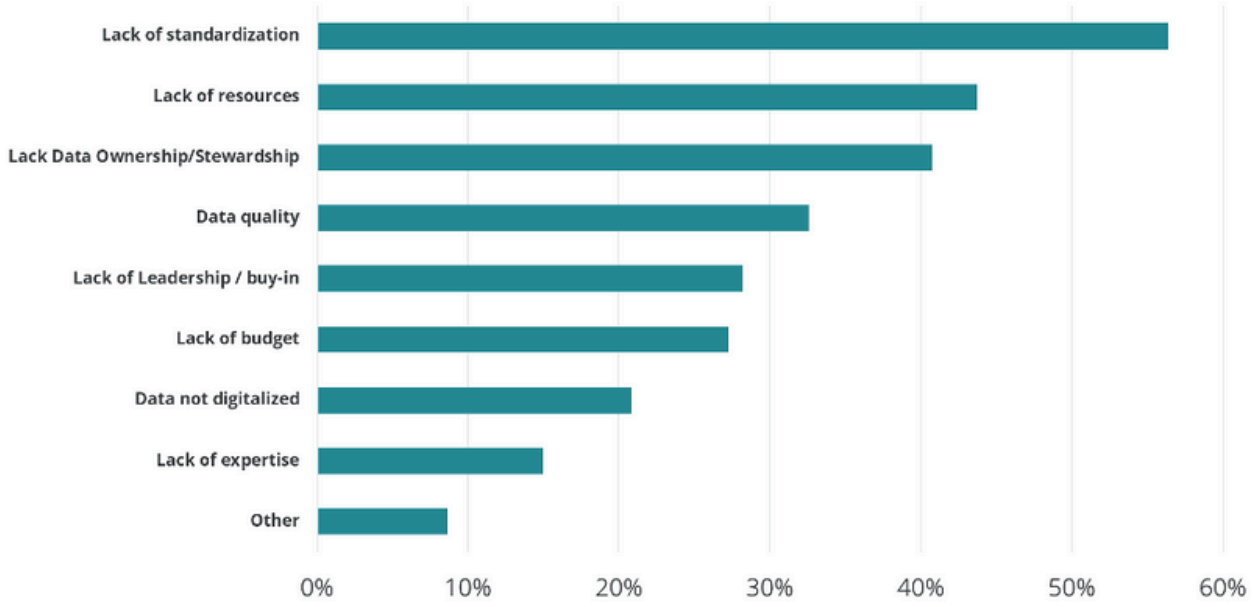


- Most participating companies focus on integration of the main EMA IDMP iteration 1 data sources and consumers of IDMP data: Regulatory, Manufacturing and Supply, Quality, Pharmacovigilance. IDMP data on investigational products, (early) research and commercial are less of a priority for now, but seem to be relevant.

- Compliance seems to be an important driver for integration. The prioritization of regulatory requirements suggests that compliance is the main driver.

- Long term value is more than just compliance but short- term integration is driven by compliance

What are the biggest hurdles (max. 3) in your organizations that prevent effective data integration?

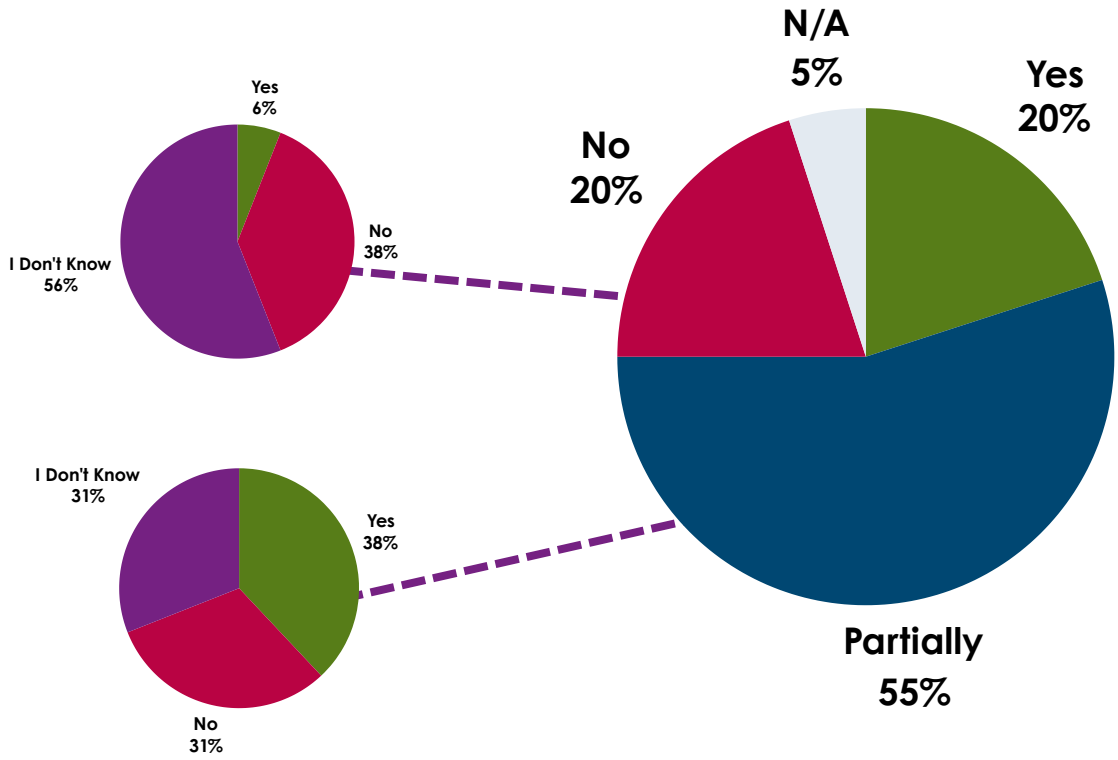


- The biggest challenges identified are the lack of standardization (56%), resources (44%), and ownership (41%), while the anticipated top issue, 'Data Quality', only ranked fourth with 33%.

- On the lack of resources, participants were asked to differentiate between resources (people), budget (money) and expertise (knowledge). Hence the struggle comes here from the limited people available to perform the tasks in the IDMP area.

- Standardization of data appears to be biggest hurdle to data integration. A standardized implementation of IDMP via IDMP-O is a key way to address this for product data.

Do you use IDMP as the master data model for your product information?



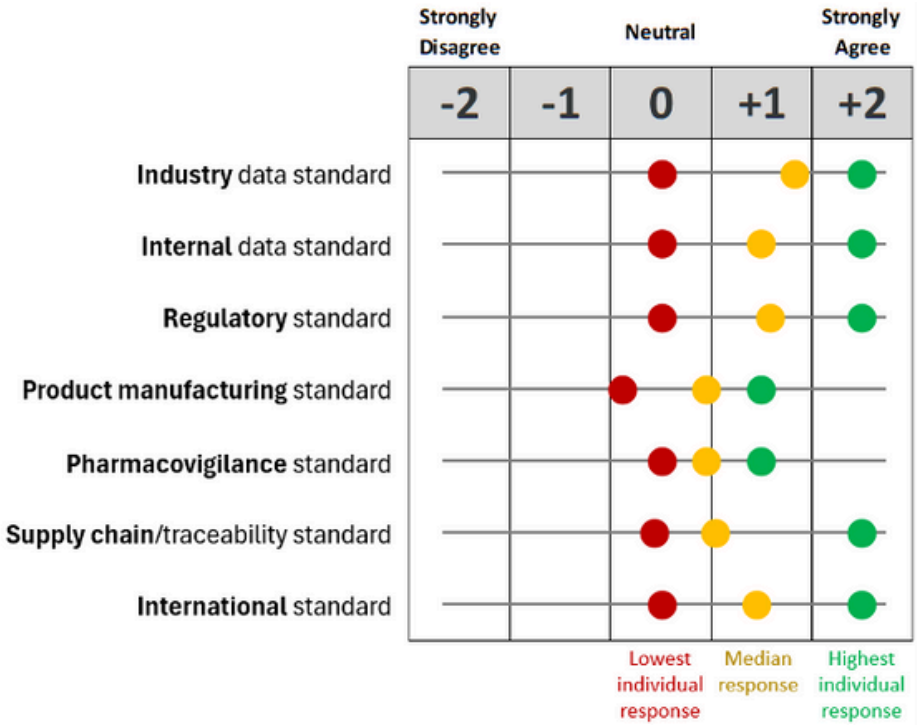
If not or only partially: Is your internal product data model compatible with IDMP?

- From the participants, a total of 42% have an IDMP-compatible data model, 20% are using the standards directly, 21% have a partial IDMP model which is compatible, and a little over 1% have a different data model which would still be IDMP compatible.

- 75% use IDMP as the guiding model for product information. 20% are fully aligned to the standard. 55% only take 'inspiration' or loosely align or only for some parts of their model or some parts from IDMP. Interestingly many don't know how well aligned their model is - which might be because it is hidden deep in software applications where they don't have insights or there is a lack of measurement for how much it is used aligned with IDMP. With the IDMP-O we can measure exactly how compatible the data is to the standard.

- Only 40% have an IDMP compatible model but 75% of the companies use IDMP to guide product information. Data model isn't aligned with how they are thinking and IDMP-O fixes that.

To understand the biggest value potential for IDMP we asked in which areas success is likely. Respondents believe in the success of IDMP as a...

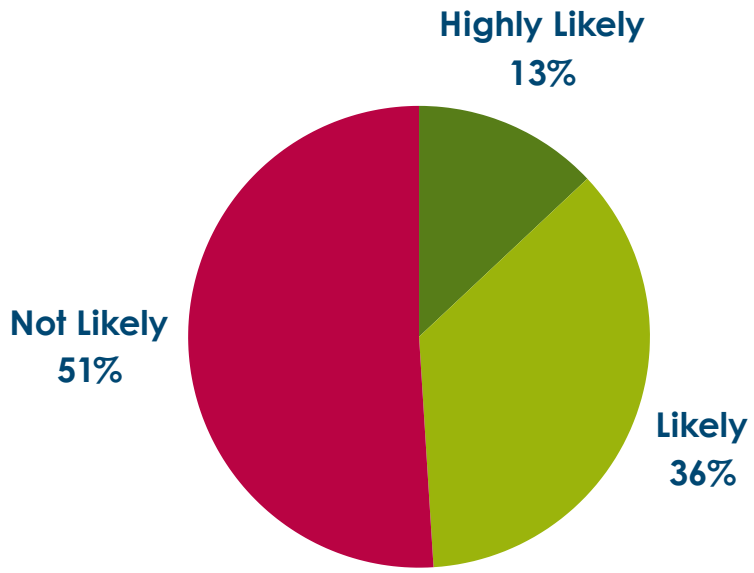


- All participating companies agree in the success of IDMP, although only 11% focus on IDMP compliance.

- There is a consensus amongst the participating companies believing in the success of IDMP as both an internal and industry/regulatory standard, but less as a product manufacturing standard which is likely due to the extra properties needed that are covered by ANSI/ISA 88/95. Overall, companies are optimistic that IDMP can serve as a cross-functional standard meeting diverse needs.

- Interestingly, pharmacovigilance is no longer viewed as an IDMP success even though that was the original purpose and use case.

How likely is your organization to use IDMP Ontology internally in production in 2024?



- Encouragingly, nearly half of the large pharma companies are willing to take IDMP-O into production in the first year of its release.

- IDMP-O production release 1.0 was published Jan-2024, and version 1.3 is now live, and already 43% of the respondent companies are likely to implement it in the first year of release. Although this is a very promising result, this should not be taken directly as an overall industry figure as many of the organizations that participated in the survey are 'closer to the IDMP Ontology' than other industry organizations.

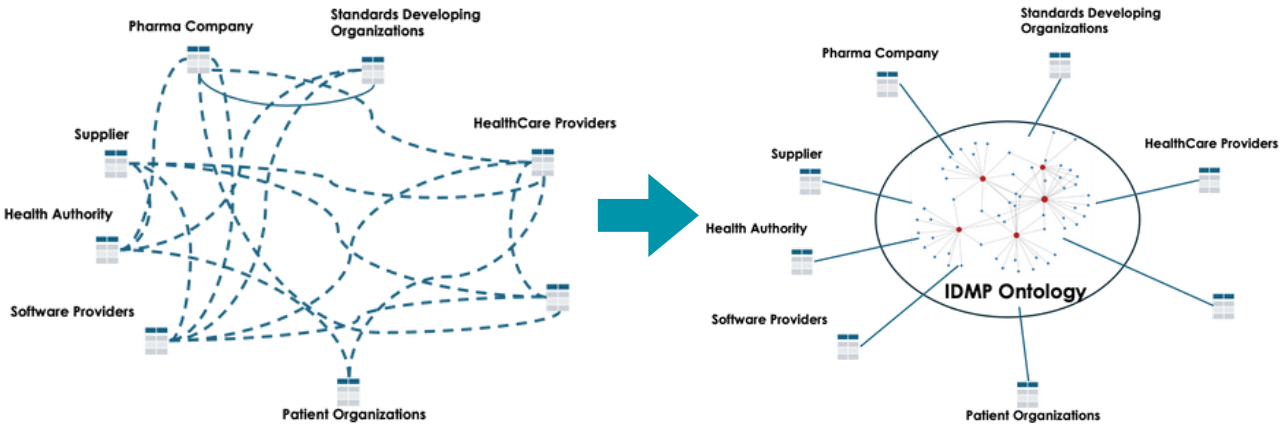
Where do you see the biggest value of an IDMP Ontology for your organization? Free text responses were summarized as follows:

IDMP-O can facilitate the use of common industry-wide standards which enhances the integration and exchange of product data among all stakeholders, including regulators and industry partners. The ontology supports cross-functional alignment on data ownership, standardization of data definitions, and adoption of a shared data model to enable system interoperability and improve overall data quality. This leads to efficiencies in data management, decision-making, submissions, and compliance. The IDMP-O can drive and facilitate master data management, automation, and AI, positively impacting analytics and ultimately reducing costs.

Key topics and categories mentioned by participants

- **Alignment and Standardization:** Alignment of data from different systems/functions facilitated by the standardization of data, definitions & relations combined with a common enterprise model and terminology/master data will provide foundational data models for product records.
- **Business efficiency and Collaboration**: Standardized data integrated across systems lead to enhanced collaboration across business lines faster decision making and improved efficiency. Combined with industry wide alignment with regulators and partners, this should lead to a reduction of costs.
- **Regulatory Compliance:** IDMP has been embraced by the regulators and an internal IDMP-aligned data model will improve compliance and speed up time-to-submission.
- **Technological Advancement:** Modern data management methods & technology combined with structured data will facilitate the use of both data analytics and more advanced techniques such as AI/ML.
- **Data Quality:** Standardization will allow for improved data quality and consistency across domains with a reduction in complexity and FAIR data leading to less data re-entry and improved data integrity.
- **Industry, Regulator, and Enterprise Management:** Alignment with industry-wide standards and practices; it will increase cross-functional use of data by Regulators and improve the international exchange of Medicinal Product information.

Get Involved In The Pistoia Alliance IDMP-O Project



The Pistoia Alliance's award-winning IDMP-Ontology (IDMP-O) project aims to create a shared ontology to align with ISO standards for the Identification of Medicinal Products (IDMP), ensuring consistent medicinal product information exchange. The IDMP-O project provides a collaborative platform to address these challenges and ensure uniform adoption of the standards.

Pistoia Alliance has brought together industry stakeholders to standardize the IDMP framework, developing the IDMP-O to streamline medicinal product identification. IDMP-O serves as the backbone of product information, acting like a "Rosetta Stone" to facilitate communication and interoperability between organizations using different terminologies. By centralizing this data management process, IDMP-O improves regulatory compliance, patient safety, product development, and global supply chain efficiency.

Get Involved In The Pistoia Alliance IDMP-O Project

The primary goal of the project is to broaden industry participation by developing use cases and achieving wider implementation. Collaboration with regulatory bodies like the EMA, USFDA, and WHO is a key focus, as regulatory agencies require structured data for decision-making. Interoperability with other domains, such as clinical operations and CMC (Chemistry, Manufacturing, and Controls), is also being actively pursued. These interactions help form a broader ecosystem of ontologies across the pharmaceutical sector. By centralizing medicinal product identification through IDMP-O, the project is expected to eliminate silos, reduce dependencies, and create a more streamlined process for data exchange. This is expected to lead to greater operational efficiency, regulatory alignment, and overall industry innovation, benefiting not only pharma companies but also regulatory bodies and healthcare organizations globally.

The IDMP-O project emphasizes the importance of cross-functional collaboration and building trust with key stakeholders like ISO and health agencies. Pistoia Alliance also seeks to involve vendors and consultancy firms to enhance the ontology's adoption and impact. By making part of the ontology's core open-source, the project encourages broader participation and development, allowing companies to incorporate IDMP-O into their own solutions and innovations.

Another significant aspect of the project is transitioning to a sustainable governance model, ensuring long-term maintenance of the IDMP ontology. Pistoia Alliance is focused on developing a comprehensive plan that includes securing long-term governance structure to maintain and evolve the ontology. The project seeks to engage its community members in this effort to ensure the ongoing success and relevance of IDMP-O.

Contributors

About ACCURIDS

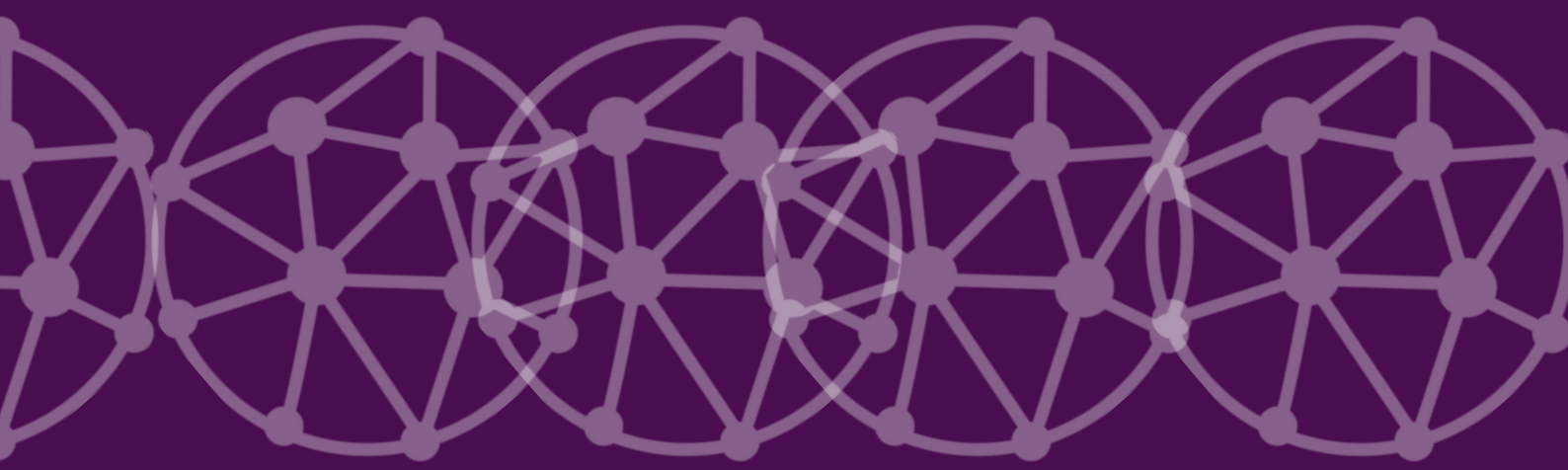
ACCURIDS is a German software company specializing in Data Registry MDM solutions that enable large organizations to manage distributed data collaboratively, adhering to FAIR data principles. Focused on the pharmaceutical sector, ACCURIDS accelerates the adoption of data standards like IDMP, tackling regulatory, drug safety, supply chain, and R&D challenges. Co-initiator of the IDMP Ontology initiative with over 10 pharma companies under the Pistoia Alliance, ACCURIDS advances a standardized platform for medicinal product information. Through collaborations, including with the Uppsala Monitoring Center (WHODrug IDMP-O Knowledge Graph PoV), and membership in ISO's Working Group 6, ACCURIDS champions IDMP standards. AI-driven technology supports inquiries based on IDMP knowledge graphs, facilitating access to harmonized data across systems and significantly reducing data integration efforts and costs.

About MAIN5

MAIN5 is a European consulting firm specializing in digitally-enabled change for Life Sciences R&D organisations. Its customized, high-value services and solutions span the product lifecycle - from regulatory affairs and data governance, to quality management and systems validation.

Its experienced consultants and practitioners are committed to helping clients navigate industry changes and achieve their goals through strategic guidance, robust project management, and advanced technological solutions underpinned by tailored, end-to-end support and measurable outcomes. In addition to strategic advice on process and data optimisation, compliance, and organizational change management, MAIN5 provides roadmap design, implementation support and optimized data migration.

MAIN5 is an agile service provider that takes pride in its long-standing partnerships with global pharma/biotech companies, which empower clients rather than encourage dependency on its consultants.



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