

IDMP Readiness & FAIR Data Adoption: Where Are Life Science Organisations Now?

Pharma companies remain at differing levels of readiness for implementing ISO IDMP product data standards, and in their maturity around adopting FAIR data principles, geared to making data more Findable, Accessible, Interoperable, and Reusable. Here, MAIN5's Michiel Stam unpacks the findings of new research which benchmarks the industry's progress, as well as plans to adopt Pistoia Alliance's IDMP-Ontology to optimise standardised data use.

Although ISO IDMP standards, designed to harmonise the way the life sciences industry records and manages data about its products, have been more than a decade in the making, companies' state of readiness to implement and harness IDMP still varies considerably.

The same is true of their relative maturity in supporting FAIR data principles, geared to making data more Findable, Accessible, Interoperable, and Reusable. These are goals that are actively promoted by Pistoia Alliance, a nonprofit industry coalition working to lower barriers to innovation in life science and healthcare R&D through pre-competitive collaboration. Its IDMP-Ontology (IDMP-O) project, launched in early 2024, aims to create a shared ontology (a representation of data properties and the relations between them), to encourage uniform adoption of the IDMP standards and, by extension, consistent information exchange.

With renewed momentum around EMA's IDMP implementation in Europe, FDA's own related plans in the US, as well as the cross-industry initiatives outlined above, MAIN5 recently partnered with Pistoia Alliance and data registry specialist Accurids to conduct new benchmark research to determine companies' latest progress and planning around IDMP implementation.

Silos and a Lack of Standardisation Have Compromised Companies' Digitalisation Ambitions

Large pharma companies now generally have good awareness of the value of IDMP-based

product data standardisation as part of wider process digitalisation ambitions, the survey confirmed. More than 70% of those surveyed identified IDMP's value as an enabler of cross-functional data integration; only 11% saw compliance as the primary goal of IDMP projects.

Companies generally plan to integrate IDMP data from Regulatory, Manufacturing, Pharmacovigilance, Supply Chain, and Quality functions within the next three years. Research, (pre-) Clinical, and Commercial data integration will follow in the mid-term (within five years). This phased approach indicates that companies are initially prioritising data that supports regulatory submissions and compliance, followed by broader data integration to support product development and commercial strategies to maximise the benefits of IDMP.

As things stand, however, product data management continues to pose a challenge for companies across the board. The benchmark study identified particular issues with manual data collection, data silos, and a lack of data integration across systems. An unclear source of truth and insufficient use of trusted external sources were also flagged as barriers to harnessing product data more strategically.

Those actively striving toward more seamless data integration across and between functions felt that a lack of resources and issues with 'ownership' were the main barriers to achieving this (indicated by 44% and 41% of respondents), beyond a current lack of data standardisation (the main obstacle, cited by 56%). Surprisingly, the quality of data (and therefore its usefulness) was ranked below these factors (cited by 33%).

Master Data Alignment & IDMP-O

When asked if companies currently use IDMP as the master data model for their product information, many respondents were unsure how well aligned their existing model is. Just 40% felt confident that they possess an IDMP-compatible model, although 75% use IDMP to guide product information. This is one of the gaps addressed by Pistoia Alliance's IDMP-O project, in that it allows the exact measurement of how compatible existing

data models and ambitions are with IDMP.

Promisingly, 43% of the large pharma companies taking part in the benchmark research expressed a willingness to take IDMP-O into production within their organisations within the first year of its release. (IDMP-O production release 1.0 was published in January 2024; version 1.3 is now live.) Although an encouraging observation, many of the organisations that participated in the survey are inherently closer to IDMP-O than others in the industry, so the finding may not be representative.

Respondents were then invited to express, in their own words, where they anticipated deriving the most value from IDMP-O. Their open-ended responses confirmed good awareness of the ontology's strategic benefits, including the associated scope to enhance the integration and exchange of product data – with regulators and industry partners, among other stakeholders.

Operationally, respondents recognised that the Pistoia Alliance ontology supports cross-functional alignment on data ownership, standardisation of data definitions, and adoption of a shared data model to enable system interoperability, and improve overall data quality. These factors pave the way for improved 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.) There is still work to be done before companies can harness those benefits, however.

IDMP Project Momentum Now Needs to be Reignited

Where early enthusiasm around IDMP programmes had waned in response to slow progress from EMA in Europe toward clarifying specific requirements, reigniting momentum behind IDMP-based projects should be a priority now – both among life sciences companies, and the supporting vendor community.

A raft of recent developments will help companies define concrete next steps and



avoid potential rework. These include the EMA's go-live of the Product Lifecycle Management portal (with Product Management Services and electronic application forms), as well as improved clarity on implementing SPOR services and integrating with EMA systems and processes. Certainly, for companies with larger product portfolios, advanced technological capabilities will be needed to efficiently prepare data in bulk for what could be thousands of registrations. Manual updates per product by re-entering data in the PMS system is not feasible.

Defining the right strategy, implementing supportive system capabilities, recruiting and training a workforce to collect, transform, and submit data according to specific requirements is a significant undertaking that requires careful planning and execution.

The survey does suggest that many companies are now actively working toward enterprise-wide integration of data and

IDMP-related processes. Harnessing Pistoia Alliance's IDMP-Ontology offers them their best chance of cross-functional alignment on data ownership, standardisation, and adoption of a common data model to enable interoperability and improvement of data quality in line with FAIR data principles.

Ultimately, robust IDMP compliance lays the foundation for a more interconnected and streamlined regulatory landscape, benefiting pharmaceutical companies, regulatory authorities, and patients worldwide. It is an opportunity to revolutionise how pharmaceutical data is managed and used – toward a more sustainable future for healthcare.

RESOURCES

1. The IDMP benchmark survey of 18 pharma companies was conducted in Q3 2024 by Pistoia Alliance, MAIN5, and Accurids, and supported by the IDMP-Ontology project with participants from Abbvie, Amgen, AstraZeneca, Boehringer Ingelheim, Bayer, and Novartis.

2. <https://fairtoolkit.pistoiaalliance.org/why-fair-data-is-important/>
3. <https://www.pistoiaalliance.org/>
4. <https://www.pistoiaalliance.org/projects/current-projects/idmp-ontology/>



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