

# Mastering Data About Medicines

**Identification of Medicinal Products (IDMP)** is a set of five ISO norms developed in response to world-wide demand for internationally harmonized specifications for medicinal products. The EMA has also identified four master data domains involved in pharmaceutical regulatory processes: substance, product, organization, and reference data.

## Achieving Benefits Beyond IDMP Compliance With an MDM Framework

### Phased Compliance With Europe's IDMP

In lieu of a hard deadline for compliance with the Identification of Medicinal Products ISO standard required by the European Medicines Agency (EMA), a phased approach is being adopted to ensure the full value of the regulation can be achieved.

While the phased approach does not remove complexity, it removes the initial deadline and provides perspective, along with the capacity to adapt to what IDMP compliance fundamentally requires: to design, deploy, and demonstrate internal data processes for the control and accuracy of the data you hold about your medicines.

Phases have been structured so data that delivers the most business value and relative ease of collection and consolidation are part of the early compliance phases. Data that is more challenging to access (e.g., data held in unstructured documents) and that does not have a strong business case is included in later IDMP compliance phases.

Companies with few products to market in Europe may adopt a manual approach to compliance. For those companies who hold marketing authorizations for a medium to large number of medicinal products, establishing good data governance is essential to achieve and remain in compliance. A master data management (MDM) framework has proven successful in supporting IDMP compliance and is advocated by the EMA. Due to the benefits of MDM beyond compliance, many pharmaceutical companies have embarked on an MDM journey despite delays in the IDMP compliance deadline.

**In a recent study on regulatory information management (RIM), Gens & Associates has found that top performers are prioritizing RIM connection investments to master data management.<sup>1</sup>**

<sup>1</sup> Gens & Associates 2020 World Class RIM Study

“The underlying challenge of IDMP is fundamentally a master data challenge.”

– European Medicines Agency

## An MDM Framework for IDMP Compliance

IDMP regulation highlights not only the distributed and poorly managed state of product data with many pharmaceutical companies, but also the value of introducing better data governance, in which MDM plays a key role.

MDM identifies and optimizes the most critical information within an organization—and, on an ongoing basis, creates a single source of its truth to power business processes across lines of business, brands, geographies, or departmental functions. In this context, applying an MDM framework will fuel accuracy in IDMP submissions.

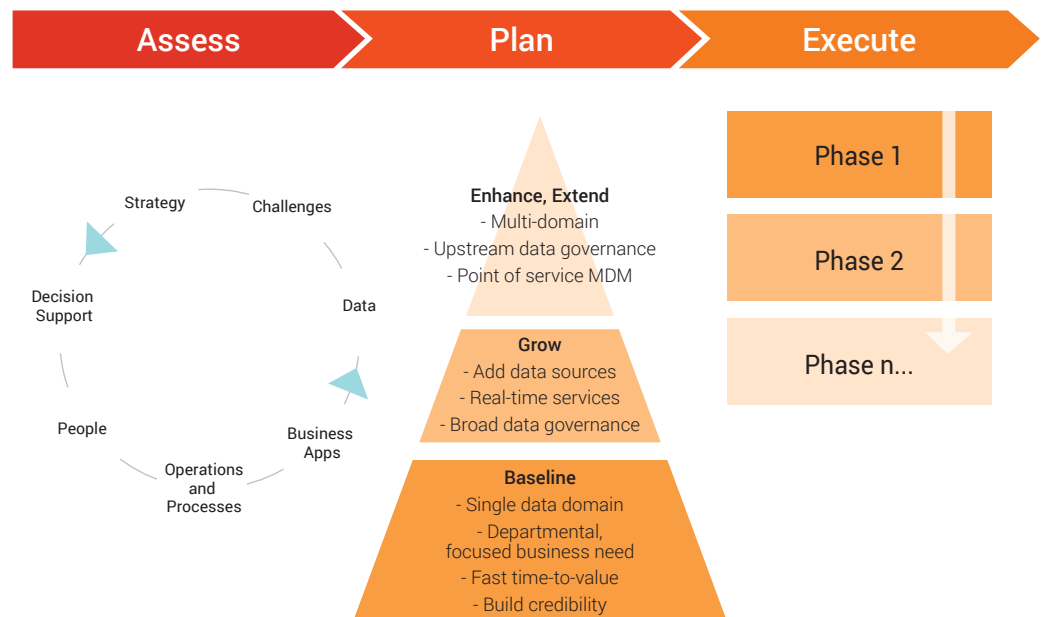


Figure 1: Infomatica's MDM Implementation Framework

A generic MDM framework mapped to IDMP compliance:

- **Assess:** Interpret and understand published guidance for each IDMP implementation phase
- **Plan:** Deliver the baseline MDM system with IDMP compliance in mind. Extend and enhance data services over time as needed
- **Execute:** Align IDMP phases to the MDM program phases

IDMP can achieve its full potential as envisaged by regulators only if it is accompanied by effective data management. An MDM framework ensures successful data management when employed properly by advancing organizational data governance maturity and providing visibility into the lineage and quality of the data itself.

The business benefits associated with MDM are largely consistent with the targeted IDMP benefits:

- More efficient (regulatory) processes and increased data integrity, leading to shorter product introduction timelines
- Improved internal and external communication, reducing the regulatory burden
- Better patient safety through improved accuracy in Individual Case Safety Reports (ICSRs) and faster implementation of requirements to address falsified medicines

In many pharmaceutical companies, IDMP has highlighted the poor availability of consistent product information throughout the organization. These companies have started their MDM journeys in advance of the IDMP mandatory compliance dates in order to harness the benefits of high-quality product data.

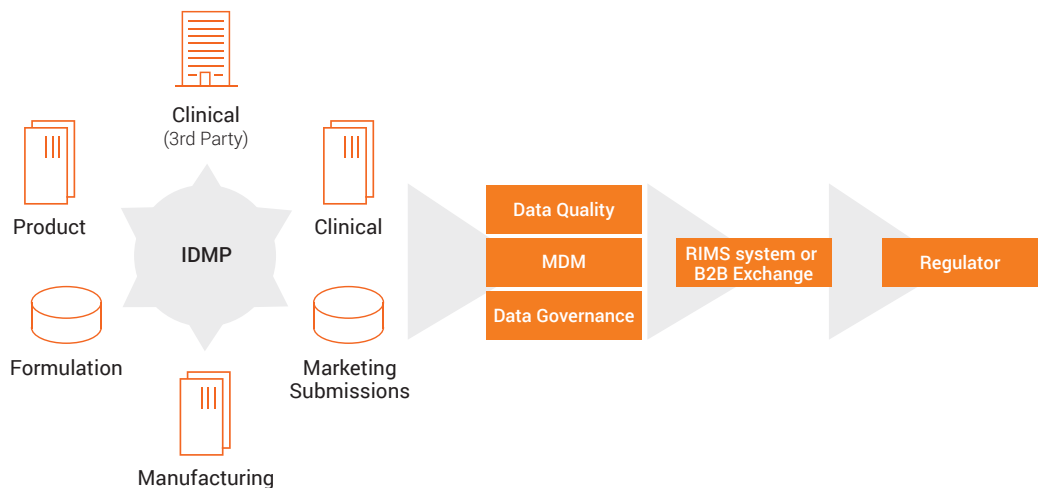


Figure 2: MDM consolidates IDMP data for submission purposes

## Addressing the Challenges Associated With IDMP Compliance

Several challenges around achieving IDMP compliance can be directly attributed to the broad scope of substance, product, organization, and reference data which is required to be collected, consolidated, cleansed, and submitted. The data challenges associated with IDMP compliance are summarized below.

### Organizational Challenge

Data is distributed across multiple departments and systems, all of which use their own unique vocabularies to identify and describe products. Senior-level sponsorship of an IDMP project is vital to encourage the broad organizational participation and alignment required for delivering a complete and accurate set of IDMP data.

### Technical Challenge

Discovery, collection, and consolidation of data from multiple systems. Typically, 10 to 15 data sources and systems create the 150 to 300 fields required per product for inclusion in the IDMP data model. Source systems may reside internally or externally, and a significant percentage of data is held in unstructured documents.

Regulators are entitled to question the source and accuracy of all data; consequently, a full history of submissions must be kept.

**Coordination Challenge**

Coordinating ongoing compliance requires the management of continuous change in data and alignment with each product as it passes through clinical trials and matures in the market. The broad scope of IDMP also implies that some data required for IDMP must also be submitted under other regulations. In these cases, coordinating the submitted data values across regulatory requirements should ensure that the submitted data be the same across all regulations, or time-consuming audits will be inevitable. Companies also need to maintain data integrity across internal processes and data submitted to the regulators.

MDM software is specifically designed for continuous reconciliation and consolidation of data, directly addressing these challenges and providing a single view of products and relating those data elements with other domains across your entire organization. When an MDM framework is applied to compliance efforts, it provides a proven facility to create and manage a single, trusted 360-view of your products for unlimited use both externally and internally.

Informatica MDM Capability	IDMP Challenge and Phased Approach Consideration
Configurable Workflow	<ul style="list-style-type: none"> <li>• Organizational: Involve representatives from multiple departments</li> <li>• Coordination: Synchronize data across systems and submissions</li> </ul>
Flexible Data Model	<ul style="list-style-type: none"> <li>• Phased Approach: Start with XEVMPD or other project (e.g., substance mastering) and expand to IDMP phases without a software upgrade</li> <li>• Technical: Configurable entities, attributes, hierarchies, and relationships to represent IDMP data model and map the base model to multiple regional vocabularies and submission guidance</li> </ul>
Automation of Data Quality Rules	<ul style="list-style-type: none"> <li>• Technical: Configurable rules for data cleansing, conforming to controlled vocabularies, matching, attribute survivorship</li> <li>• Technical &amp; Coordination: Cross-reference view for data lineage</li> </ul>
Visible Data History	<ul style="list-style-type: none"> <li>• Auditable: Auditable interactions, documenting data lineage and edits whether from source data or manually entered</li> <li>• Coordination: Data Stewardship Consoles, with the ability to enter and validate data held in unstructured documents</li> </ul>

Figure 3: Informatica MDM provides capabilities to address IDMP challenges and phased approach considerations

## About Informatica

Digital transformation changes expectations: better service, faster delivery, with less cost. Businesses must transform to stay relevant and data holds the answers.

As the world's leader in Enterprise Cloud Data Management, we're prepared to help you intelligently lead—in any sector, category, or niche. Informatica provides you with the foresight to become more agile, realize new growth opportunities, or create new inventions. With 100% focus on everything data, we offer the versatility needed to succeed.

We invite you to explore all that Informatica has to offer—and unleash the power of data to drive your next intelligent disruption.

## Advantages of Informatica MDM for IDMP Compliance

Informatica® MDM is the only end-to-end MDM solution that is both easy to deploy and flexible enough to evolve and scale to meet future needs with global adoption of IDMP requirements.

**Agility:** Our solution does not lock you in to specific use cases. It is designed to deliver trusted data across organizational boundaries—and anticipates changing requirements and use cases. Informatica MDM delivers value during all IDMP phases, and beyond.

**Business process enabled:** Integrated workflows and business-friendly user interfaces enable data owners and business experts across the organization to contribute to, and gain powerful insights from, a single trusted view of substance, product, referential, and organizational data.

**Breadth of offering:** Our end-to-end portfolio includes a full assortment of data integration, data quality, data security, and data governance capabilities required to successfully complete any IDMP program.

**Strong partner network:** Including leading system integrators and regulatory information management software vendors. Some of our partners have developed IDMP accelerators based on our MDM software for more efficient implementation projects.

**Focused on customer success:** A dedicated group within Informatica, our customer success team, was created with the sole purpose of ensuring customer satisfaction and ongoing relationships. As a result, Informatica has been named number one for customer loyalty twelve years in a row by independent research firm TNS.



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