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A practical guide to IDMP preparations

Essential next steps for aligning technology, process, operating models, change activities, and data strategies to maximize the benefits of a data-driven future

Executive summary

IDMP is more than just a regulatory mandate. It is an unprecedented opportunity to transform regulatory product data management and unlock new efficiencies.

For each pharma organization, the IDMP challenge has multiple dimensions. It involves adopting new technology, adjusting process and operating models, making organizational changes linked to roles and responsibilities, and implementing new approaches to data management.

In this white paper Adnan Jamil, Manager at Iperion - a Deloitte business, with insights from Pratyusha Pallavi, Senior Director of Regulatory Market Strategy at RIM vendor Veeva Systems, shares some of the practicalities involved with preparations for IDMP, addressing each dimension in turn, to help companies make the most of their IDMP preparations.

Process	• Implementing new operating models and processes • Ensuring integrated data management
Organization	• Undertaking change management • Informing all stakeholders on updates
Technology	• Understanding current landscape • Maintaining customization and flexibility
Data	• Data collection, remediation and loading • Data quality and reporting • Data Governance

Introduction

The first step in making the most out of IDMP is to understand the scale and breadth of change required to operate efficiently and to optimal effect in the new world. Second, since IDMP regulations will continue to evolve and have the potential to support a wide range of use cases, it will be important to maintain agility in order to maximize that potential.

For each pharma organization, the IDMP challenge has multiple dimensions. It involves adopting new technology, adjusting process and operating models, making organizational changes linked to roles and responsibilities, and most importantly, implementing new approaches to data management given that a growing range of outcomes will depend on data quality.

Below are some specific actions related to each dimension that will help companies make the most of their IDMP preparations.

Technology considerations

Successful outcome across most if not all of the other dimensions of the IDMP transformation challenge are very heavily dependent on the choice of supporting technology.
Having a clear understanding of your current technology landscape, your vendor's capability roadmaps, and how these align to your business and regulatory requirements is key.

In reference to Veeva's approach, Pratyusha Pallavi notes that the company publishes clear advance detail of its planned sequence of product releases, while its Customer Success Management and Product Management teams work closely with customers to keep them in the loop.

Maintaining the level of customization to the current system is important, too. Vendors with an agile release management approach are typically better able support dynamic market trends, customer needs and an evolving regulatory landscape, such as that around IDMP. This means that releases can more readily take into account and make provision for system data model changes.

These changes may render bespoke capabilities redundant. For this reason, it can be well worth re-aligning current systems with the out-of-the-box system configuration ahead of time, and transforming and migrating the data managed in custom fields to corresponding standard fields (adapting any related processes as needed). This will reduce the effort required to keep a SaaS RIM platform up to date with the latest innovation in each product release, and improve the company's responsiveness to a modern regulatory environment based on the IDMP roadmap.

Given that any changes to existing data models may have an impact on upstream and downstream integrations (with systems used by adjacent functions, for instance), a detailed impact analysis is advisable to quantify these implications.

Process & operating model adjustments

Since IDMP paves the way for efficient new ways of handling, exchanging and re-using critical information, organizations will need new operating models and processes to ensure that the data involved is of high quality, fit for purpose, and sustainable over time.

This demands an appropriate 'operating model' for the new data-driven world. Companies should specify the data management process for IDMP; identify who will spearhead and manage this to ensure timely delivery of high-quality data; and determine how they will keep this data consistent with the content in submitted documents.

It makes sense to start by establishing how current processes are executed within the business today, and creating an inventory of related Quality and Business documents. This will allow informed choices ensuring that data management, in line with IDMP requirements, is integrated within business and system processes. It will mean that the right data can be made available on time, to a high standard, to all relevant user groups.

One of the goals of a data-driven environment based on IDMP is to transform business processes by reducing manual interventions, or completely overhauling the way that activities are approached and completed.

Organizational change management

Companies will also need to undertake appropriate change management efforts to promote the adoption of IDMP.

As Veeva's Pratyusha Pallavi explains, "The key to conveying the importance of data quality is going beyond email and other standard communications routes." This must involve a conscious effort to make business stakeholders aware of the changes taking place, and of the associated drivers and benefits – and to train them in the new processes. Celebrating performance improvements is an important part of encouraging employees to accept new processes and workflows, too.

Given that the specifics of IDMP are still evolving, companies should take a proactive approach to communicate each set of updated requirements to all stakeholders.

Data considerations

Data quality & reporting

To achieve its higher ambitions, the adoption of IDMP will increase the scope of structured (regulated) data that will need to be managed and submitted to the Health Authorities. To scope the additional requirements, companies will need clear visibility of their product portfolio; of how much of the IDMP data set is already being managed in their existing system; and to what extent this already fulfills the specifications in EMA's IDMP implementation guide (e.g. uses the correct RMS values).

Furnished with these insights, companies can devise an appropriate data collection, remediation and loading activity to fill any gaps as required.

Depending on the product portfolio and the resources available to deliver the project, an organization might decide to start with Centrally Authorized products only, or to apply the new requirements to all products within the scope of the European Economic Area, knowing that IDMP's scope will ultimately be as broad as possible.

Note that while cleansing, transforming and loading of data can be done in phases, it is critical to perform a source system assessment for the entire IDMP scope at the start. This will help in formulating the right approach for phased data collection, remediation and loading.

When 'loading' supplementary data, it may be wise to bring in a specialist data migration partner, depending on the volume of data to be added to the system, and the need to migrate data from custom fields into standard, out-of-the-box system fields.

Speaking from a RIM vendor's perspective, Veeva's Pratyusha Pallavi notes, "There are multiple technology approaches to transforming and loading your source IDMP data into your target IDMP system - from building live integrations to performing a one-time migration followed by maintenance of product info in target system. The right choice of technology concept - whether based on REST APIs or Scheduled Data Exports provided by the Vault platform, or specialized migration tools used by migration service providers – will depend on the size of the product portfolio, the quality of source data, and the amount of transformation and augmentation needed."

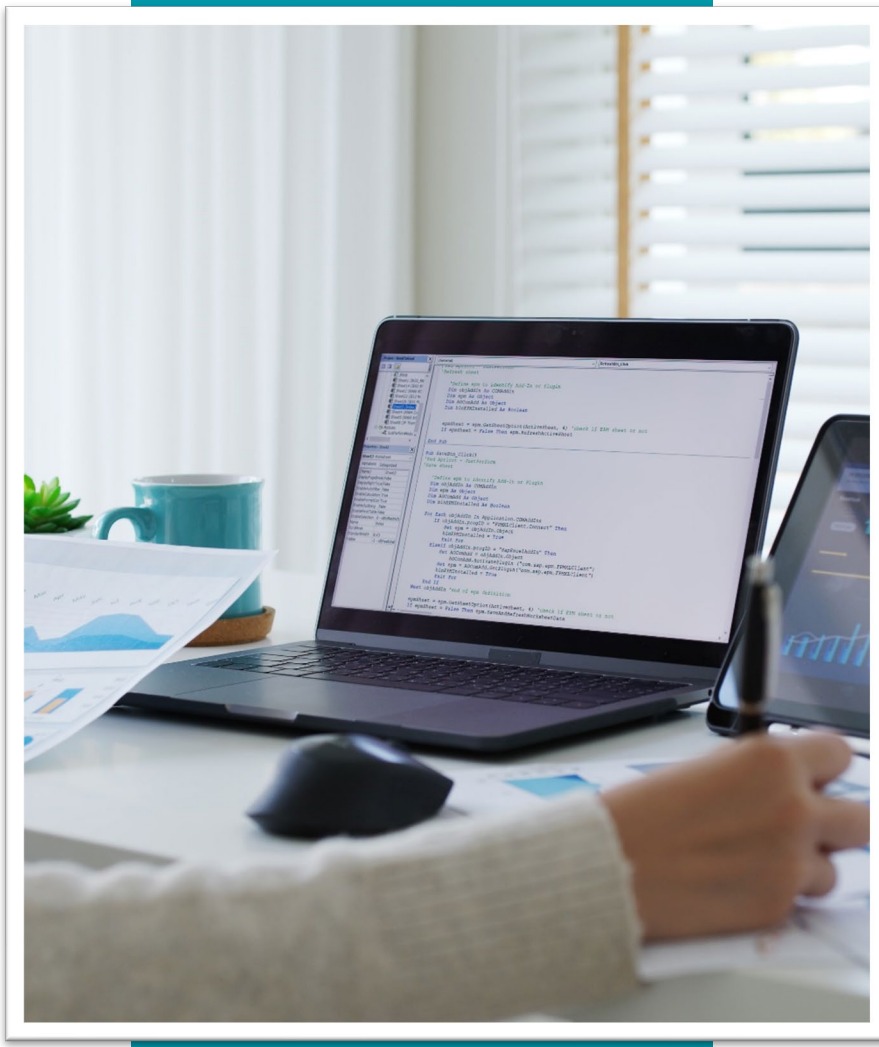
Data considerations

Data collection, remediation & loading

Creating a single source of truth is a recommended step to success. As Pratyusha Pallavi puts it, “Establishing a system as a high-quality source of truth of your product portfolio is critical because it will be used as the reference – currently by teams that are manually reviewing and providing edits in agency systems and eventually via FHIR messaging-based connections.”

Such systems should not only have simple controls around completeness (e.g. mandatory data should be available in the system) and consistency (e.g. the start date should be before end date) but also user-friendly wizards allowing data to be auto-populated using business rules, RPA or relevant AI technologies to reduce manual re-entry. Working closely with your software provider or implementation partner will be important here, to determine and balance the effort of deploying such system controls against the resulting benefits. This can be achieved by focusing on use cases or domain areas where automation results in maximum value.

From a reporting perspective, an impact assessment will help determine whether and which system and process changes will affect current reporting capabilities and what steps may be needed to update these capabilities.



Data governance

IDMP requires additional master data about products and their make-up beyond the scope of xEVMPD (organizational and referentials data, for instance). This must be captured and provided in a standard format to enable reliable data exchange with regulators, which in turn demands strong data governance and well-defined data responsibilities (such as data ownership and stewardship).

RIM vendors should provide optimum functionality related to IDMP’s controlled vocabularies, such as integration with EMAs RMS and OMS, as well as specific workflows to manage the changes and influx of new lists and values. Appropriate data governance will be important in ensuring these are properly reviewed - and that their use doesn’t impede other data operations (beyond the EU, for instance, where other values might be in use).

Beyond compliance: optimizing the scope for additional use cases

One of the greatest selling points of IDMP is its promise to support additional use cases beyond pure regulatory compliance, once companies are truly data driven and using agreed fields, formats and vocabularies.

To maximize the return on their compliance investments, companies will need to be clear about how they can harness these additional use cases to optimal effect. Scoping the possibilities sooner rather than later will pay dividends here. This is about identifying tangible business needs and how these might be facilitated by the new processes and the high-quality, granular data now being managed.

Possibilities to consider here include:

- End-to-end change control, enabled by live data;
- The ability to compare registrations across regions using common data standards;
- Batch release optimization and ERP-RIMS product alignment;
- Increased efficiency of recalls management - and recall avoidance - using data;
- Enhanced product acquisition capability, thanks to already standardized data sets;
- Reporting optimization across divisions and systems; and
- Reuse of core data across the investigational medicinal product (IMP) and substance from the investigator's brochure and IMP dossier, and using the IDMP dataset.

Taking action

Preparing to take advantage of the full potential of IDMP involves many substantial activities across spanning the dimensions of Process, Organization, Technology, and Information. Working closely with a preferred software vendor and advisory partner will be key to delivering a successful IDMP project with maximum outcomes.

As both an EU IDMP specialist in close dialogue with all major authorities and cross-industry stakeholders, and a valued Veeva implementation partner, Iperion can offer up-to-the-minute advice and guidance as companies expand their IDMP-related ambitions and progress their plans to be more data driven.

About the authors

Adnan Jamil is a Manager at Iperion, a Deloitte business. He has 10 years of experience within the Life Sciences industry, focusing mainly on Regulatory Information Management. Adnan's experience covers assessing, defining and implementing processes, technology, organizational and data changes in both small, medium and large pharmaceutical companies.

Pratyusha Pallavi is senior director of Vault RIM strategy at Veeva Systems. She has 18 years of experience in product strategy, product management and engineering in Life Sciences and Healthcare industries. Prior to Veeva, she served as product strategy and management head for the regulatory product suite of ArisGlobal. She started her career with GE Healthcare engineering in designing electronic health records for US and APAC hospitals.

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