WHITE PAPER

EFFECTIVE WAYS OF HANDLING EU IDMP SUBMISSIONS

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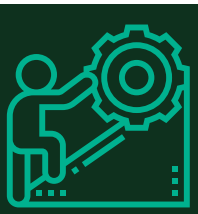
Identification of Medicinal Products (IDMP), an international pharmaceutical product data standard, is one of the biggest regulatory challenges for pharma companies that have marketing authorizations in the European Economic Area (EEA). IDMP compliance is not only about the submission of Medicinal product information across the domains of regulatory, pharmacovigilance, manufacturing, and supply chain, but also requires pharmaceutical companies to provide transparency across the entire lifecycle of the medicinal product.

Currently, European Medicines Agency (EMA) is focusing more on the PLM Portal eAF implementation project (i.e., DADI) [PLM=Product Lifecycle Management; eAF= electronic applications forms; DADI=Digital Application Dataset Integration], which is replacing current PDF-based electronic application forms (eAFs) with new web forms in a new eAF portal. These new Web-based forms are used in dossier submissions to get marketing authorisation approval, variations, renewals, etc. mandatorily. (Reference: EMA Newsletter on DADI)

With EMA shifting the IDMP implementation dates multiple times, pharmaceutical companies are facing numerous challenges in implementing IDMP in the EEA region.

Challenges in implementing IDMP in the EEA region



From a business perspective

Raising awareness of IDMP can be challenging for companies due to a lack of knowledge of ISO IDMP standards or SPOR (Substances, Products, Organisations, Referential) implementation guides, and SPOR practical use cases.
Lack of transparency of regulatory process/systems impacted (current as-is processes need adaptation to support IDMP).
IDMP is not an option. Pharma companies must adhere to EMA regulations.
Data will need to be captured structurally in every functional unit and compiled before the submission is sent to the authorities. So, cross-functional coordination between departments is necessary. EMA is recommending having data stewards in place to enable cross-functional coordination.
Given the dynamic nature of IDMP terminology definition, controlled vocabularies are continuously evolving and not finalized.
Lack of data governance and harmonization - Very often the data in pharma companies are not stored in a single location. Data for legacy products is not structured, and difficult to locate the required information in the systems. Even if the data is available, it may not be in IDMP-compliant format.
Requirements for IDMP submissions are dynamic - With every release of the EU (European Union) Implementation Guide (IG) version, new attributes get added. It is not a simple exercise to locate and collect the required information. It requires a lot of effort to involve the different functional teams and train/guide them for IDMP requirements.

From an information system perspective

One of the key challenges is the broad scope of data and how it is distributed over an organization. It is very much feasible that all the data is not available in the IT systems, a substantial chunk of it lies in an unstructured manner, and collecting that data is a daunting task.
Currently, EMA IDMP submission-compliant systems are not available due to guidelines evolving. So, the delay in implementing the IDMP system by the pharmaceutical company will attract more unstructured data.
In the case of mid-size and Big Pharma companies, upstream or downstream integrations are needed to support business processes.
SPOR Master Data Management (Mapping of SPOR data across different data sources) is needed.
Lack of dedicated resources with established roles within the organization
Company's internal project priorities (PLM, eCTD, DMS, ERP, change control, etc.)
Additional system setup may be needed to maintain the IDMP data. Hence, it will be a greater challenge for pharma companies.

Critical success factors for successful EMA IDMP compliance

IDMP supports FAIR principles (Findability, Accessibility, Interoperability, and Reusability) for data exchange in a standardized and controlled manner. It also enables data exchange with external partners (e.g., 3rd party suppliers) in a controlled way, facilitating data exchange through IT systems. Below are the best practices to be followed by pharma companies to implement the IDMP system and handle IDMP submissions in the best way.

- Assess current state business processes, identify gaps related to the upcoming IDMP compliance requirement, and close gaps in the processes. Significant process training will be required for the relevant stakeholders.
- Determine the IDMP data volume correctly – The volume of IDMP data that is in scope for the submission is based on the varying complexity of how many xEVMPD Authorised Medicinal Product (AMP) records we have in EEA, different Pack sizes including not-marketed licenses, if any, and multiple languages.
- Locate, identify, and declare authoritative source data fields and systems. Where data cannot be located beyond documents, apply NLP (Natural Language Processing) to extract the required IDMP data model structured data.
- Setup Data Governance for IDMP Master Data Management – Set up substances, organisations, and referential libraries, clean up, and map them to the SPOR libraries. Having a dedicated team comprising of requestors, SPOR users, and data stewards with established roles/responsibilities internally enables the SPOR data management process to be more efficient.
- Currently, the IDMP/RIM systems available in the market are compliant with EMA IDMP Implementation Guides (IG) Chapter 2 version 2.1. However, pharma companies must locate the required information related to the new attributes added in the EU IG V2.1.1, which requires a lot of manual effort. So, pharma companies must act early and identify the source systems for the new attributes and harmonize the data before PMS iteration 1 submission starts.
- A SPOR master data management process should be confirmed as foundational data before developing the submission documents. Pharma companies have already seen xEVMPD data issues difficulties during xEVMPD mandatory submissions in 2014. Not having robust Change Management resulted in data quality issues, taking several months to correct the data in EudraVigilance. So, as a lesson learned, establishing the IDMP data Change Management process, aligned with IDMP data collection and standardization, reduces the risk of IDMP data quality issues and brings assurance to the pharma companies to perform the IDMP submissions smoothly.
- The web-based DADI Human variation form (DADI form will replace the current electronic Application Form for EMA submissions) went Live for Centrally Authorized Products (CAPs) in November 2022 on the PLM Portal (Reference: DADI new timelines). So, ownership of the data and process for the DADI form must be defined if not done already. For that workshops/training are needed to identify and confirm process owners based on product and different procedure types.
- Define responsibilities to manage HA questions and commitments regarding IDMP submissions. A Business process will be needed to update IDMP data and/or documents if discrepancies between the two are identified during the Health Authority (HA) review.
- Collaborate and contribute to industry forums like UNICOM, IRISS, and other key webinars to solve issues and ensure stakeholders' readiness up-to-date with the changes in EMA regulation.

Conclusion

For pharma companies, the collection of IDMP data from various sources will become a big challenge. Adding to it, IDMP data requirements are several times more than xEVMPD requirements in terms of data fields and granularity of the information. So, pharma companies must focus on implementing the IDMP Program early. Thus, issues and challenges can be mitigated before actual submission starts. Ultimately, medicinal product data will be compliant with IDMP regulations.

List of Abbreviations

- IDMP - Identification of Medicinal Products
- EEA - European Economic Area
- EMA - European Medicines Agency
- DADI - Digital Application Dataset Integration
- eAFs - electronic Applications Forms
- SPOR - Management Services for Substances, Products, Organisations, and Referential Terms
- EU - European Union
- IG - Implementation Guide
- RIMS - Regulatory Information Management System
- PLM - Product Lifecycle Management
- eCTD - Electronic Common Technical Document
- DMS - Document Management System
- ERP - Enterprise Resource Planning
- NCAs - National Competent Authorities
- EudraGMDP - European database for manufacturing and wholesale distribution of human or veterinary medicinal products
- IRIS - Online platform for scientific advice questions
- CTIS - Clinical Trials Information System
- FMD - Falsified Medicines Directive
- NLP - Natural Language Processing
- xEVMPD - Extended EudraVigilance Medicinal Product Dictionary
- AMP - Authorised Medicinal Product
- IG – Implementation Guide
- CAPs - Centrally Authorized Products
- HA – Health Authority
- UNICOM – Up-scaling the global univocal identification of medicines
- IRISS - A non-profit dedicated to advancing for Implementation of Regulatory Information and Submission Standards for life sciences

About the Author

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Rajendra is a consultant with Infosys Consulting and has 10+ years of experience in Regulatory Operations, xEVMPD, IDMP & RIMS System Implementation and Data Management, Functional testing (OQ & PQ Testing) and Computer System Validation.

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