

Achieving IDMP Compliance Through Precise Data Alignment

The **Identification of Medicinal Products (IDMP)** standards are crucial for the structured and harmonized exchange of medicinal product information on a global scale. These standards, developed by ISO, aim to improve **pharmacovigilance**, ensure **patient safety**, and facilitate **data exchange among stakeholders** such as regulatory authorities, pharmaceutical companies, and healthcare providers.

At Asphalion, we understand the importance of achieving and maintaining compliance with IDMP standards. Our team of experts is equipped to guide you through this complex process and ensure your data aligns with the necessary requirements.

Pre-standardization Steps

Regulatory Strategy Development

Our team **collaborates** with your organization to develop a robust **regulatory strategy** that aligns with IDMP requirements. We provide tailored solutions that address your specific needs, minimizing risks and maximizing efficiency.

Training support

We acknowledge that the implementation of IDMP can be a complex and resource-intensive process, requiring **direct collaboration** across numerous departments within the organization, extending beyond Regulatory Affairs to include areas such as Pharmacovigilance, Supply Chain, and Quality. Consequently, our experts are equipped to **provide comprehensive training** sessions tailored to the needs of your team. These sessions can be structured as general overviews involving **multiple departments** within the organization or focused on specific subjects where we work with the client to define and clarify the activity requirements.

Successful Implementation Roadmap

1- GAP Analysis and mapping: We conduct a comprehensive analysis of your existing data, mapping it to the IDMP standards to identify any gaps or inconsistencies.

This ensures that your data is accurate, complete, and ready for submission.

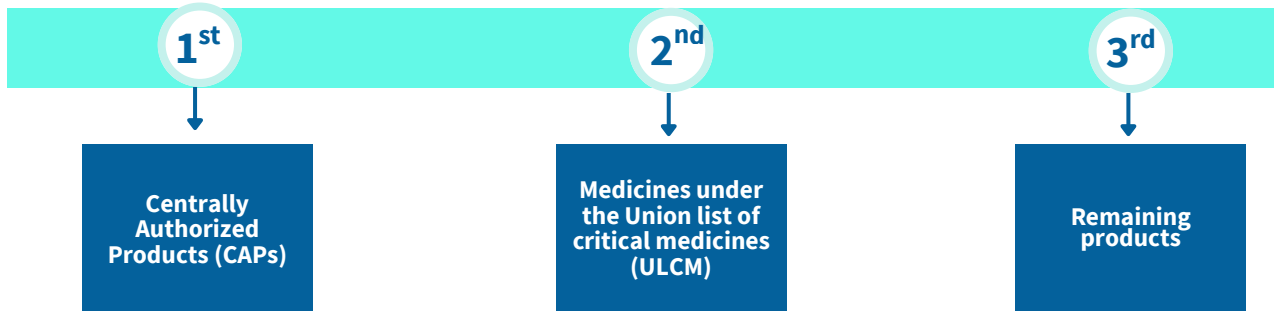
2- Data Enrichment: Once the gaps are identified, we proceed with the enrichment of data based on our enrichment template, which is aligned with the latest version of the **EMA Implementation Guide**.

3- Pack size split: Currently, it is **necessary to submit authorized packages via** Extended EudraVigilance Medicinal Product Dictionary (**xEVMPD**) within 15 days of approval for these medicinal products under Union List of Critical Medicines (ULCM), and the rest of the products according to the established deadlines. Asphalion is fully equipped to provide expert support for these activities.

4• PMS Data Review: Data from existing databases (xEVMPD and SIAMED) are matched and merged and mapped against SOR as part of the migration process to PMS implemented by the EMA. Validation of the final migrated data is crucial.

Asphalion expertise has established a prioritization strategy to efficiently conduct the review of product portfolio.

Prioritization strategy



5• Data Remediation: Perform **identification, analysis, and remediation of any errors** detected within the PMS. This process includes submitting tickets to address errors and executing updates in the Extended EudraVigilance Medicinal Product Dictionary (**xEVMPD**) to rectify them. It also involves assessing whether the issue aligns with the **EMA's catalog** of known issues.

6• RIM System Data Review: Many clients have a Regulatory Information Management System (RIMS) where they store their data. It is essential to align this data according to the current version of **EU IDMP IG**. At Asphalion, we provide support for these activities by:



7• PMS Data Submission: Submit data to **PMS** in compliance with EMA's established deadlines for authorized data fields to be edited (manufacturers, MBOs, structured pack sizes, etc.).

Unlock the full potential of your data with our **IDMP compliance services**. Partner with us to streamline your data alignment processes and adopt cutting-edge development strategies.

Leverage our expertise not just for regulatory compliance, but to propel your success across diverse markets and enhance the prospects of potential acquisitions.