

# BUSINESS CASE

## Case Study: support for the implementation of Data Regulatory solutions



### CHALLENGE



The Client is a leading French pharmaceutical company with an extensive network of **global partnerships**.



The company manages around 200 Marketing Authorizations (MAs) across the EU.



The Client sought support for the implementation of Data Regulatory solutions, including:

- Registrations
- Submissions Archive
- Submissions
- Publishing



In parallel, the Client sought to achieve IDMP compliance as part of the RIMS implementation.



### SOLUTION

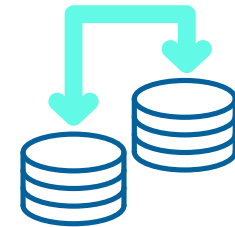
Asphalion successfully completed the parallel Implementation of the Data Regulatory Solutions and the **transition to ISO IDMP** through the following activities:

- **Data mapping** between the client's databases and affiliates' databases to align with RIM data model.
- **Gap Analysis and data enrichment**, including support during the data collection phase.
- **Data cleansing and transformation** in accordance with client requirements, as well as vendor and IDMP standards.
- **Data migration** into the new RIM system, including IDMP-related data.
- **Data entry, verification, and remediation** as well as SOP and WIs development for ongoing data maintenance within the new system.
- **Trainings and workshops** conducted according to the client's needs throughout the different phases of the project.



### OUTCOME

Due to the concurrent implementation of the RIM system, **ISO IDMP data was included and uploaded during the initial data migration.**



### Ongoing

Following the **Go-Live of the Registrations module**, a **second phase of data enrichment** is currently in progress to further enhance data quality and compliance.