

Data management – A critical constituent for IDMP compliance

Infosys recognizes that identifying, sourcing, qualifying, and curating the data required for IDMP is the most critical part of the implementation journey.

In their constant endeavors for safer medications and to improve patient safety, regulatory organizations are gradually moving towards the implementation of the Identification of Medical Products (IDMP). While the IDMP guidelines are maturing, life sciences organizations are making efforts to be ready to achieve compliance.

Through the readiness phase, companies are increasingly realizing the importance and magnitude of the data management challenge that IDMP specifications pose to them. Life sciences companies need robust data management strategies to meet IDMP compliance requirements. Data required for IDMP needs to be sourced from multiple structured and unstructured

sources, spanning centralized and localized systems and departmental controls across the medicinal product value chain. This diverse data needs to be further complemented by standardized referential data provided by external, third-party agencies, thereby, further complicating data management challenges.

Key data management challenges

Increased scale of compliance needs

The data elements required for assembling product information as per IDMP specifications is far more complex than what is being captured for current requirements like xEVMPD. For an organization with a larger product portfolio, data management complexities only increase.

Data collaboration across business units

The medicinal product data required for IDMP specification is present across a wide set of functions and systems within life sciences organizations, possibly including partner systems. This poses a challenge for defining robust data assembly and management processes.

Ensuring data consistency

Ensuring consistency of data collected from multiple sources on an ongoing basis is challenging, and robust data curation processes must be put in place to address this issue.

Infosys solutions and services for IDMP data management

Strategic services to address IDMP data management



Data assessment and management

- Application landscape analysis and readiness assessment
- Source data identification and mapping
- Data quality assessment

Infosys IDMP Assessment and Data Management solution



Data extraction / mining and enrichment

- Data from unstructured sources like documents and images
- Classification of sources and text extraction rules

Infosys Data Extraction and Enrichment platform

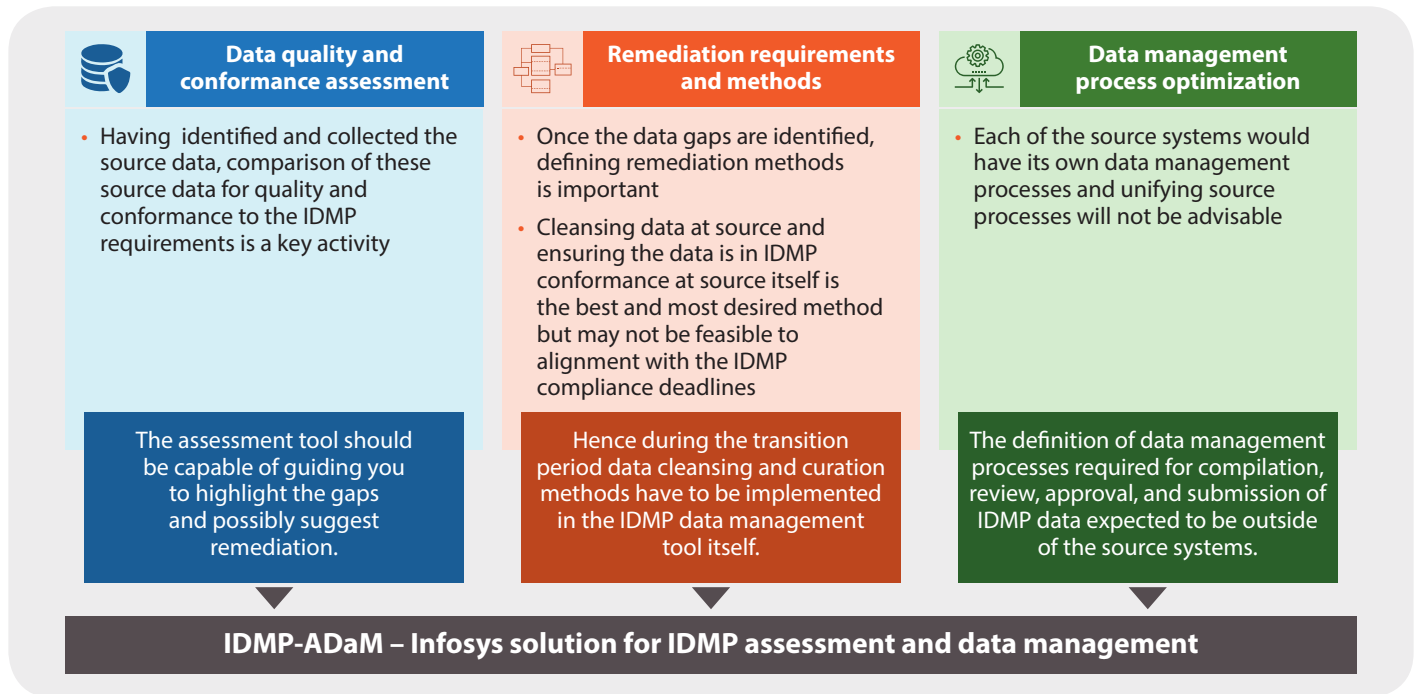


Data quality management

- Data quality management framework
- Data validation and curation
- Master data management requirements and governance

Infosys Data Quality Management services

Focus areas in data assessment and management as well as how the Infosys Assessment and Data Management solution can address challenges



Key features

A web-based solution to achieve an efficient mechanism for data collection, assessment, and management, in accordance with IDMP-ISO standards that provides an easy and multilevel drill-down view of data at different levels.

- IDMP objects, source application, and summary view
- Creation of medicinal product data (manual or automated load)
- Management of the collected data through workflow-based processes and life-cycle mechanisms
- Data quality assessment through comparison and reporting features
- Data quality management and curation capabilities
- Integrated with controlled vocabularies providing auto-coding features
- Integration to extract structured data from the source
- Integration with a text mining component to bring unstructured data into the system
- Flexible and configurable models designed to address the evolving IDMP model specifications

Business benefits

- Tactical data governance model aligning with your strategic approach, which often goes well beyond IT, with a focus on Master Data Management (MDM)
- A flexible solution based on the IDMP object model that adapts to changes to IDMP objects and also supports IDMP future iterations
- Reduce manual efforts of entering data through bulk upload interfaces and integration features. Leverage and integrate Infosys DEEP platform to process data from unstructured data sources
- Integrated solution to gather and curate the quality assessment and governance of IDMP data – an approach that readies data with the end-state in mind
- Data and process harmonization across your functional and regional boundaries



For more information, contact askus@infosys.com

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