

## Identification of Medicinal Products (IDMP) compliance made simple

EU legislation requires pharmaceutical companies to submit their product information in conformance with a set of ISO standards called 'identification

of medicinal products'. This rollout is being enabled by multiple regulatory organizations such as EMA and FDA, among others, and makes it of utmost

importance to have an effective pharmacovigilance and improved patient safety.

### 5 ISO Standards

*Each of these standards define data element structures for unique identification of details pertaining to various aspects of a medicinal product*

**ISO 11615**  
Medicinal product

**ISO 11616**  
Pharmaceutical product

**ISO 11238**  
Substances

**ISO 11239**  
Unit of presentation

**ISO 11239**  
Unit of measurement

Substances, specified substances

Units of presentation, dose form, route of admin, packaging

Unit of measurement

Pharmaceutical product

Medicinal product

### Our proposition

At Infosys, we are helping various pharma clients chart their roadmap to compliance providing an end-to-end offering that is not just low on cost but also accurate

to ensure success. We recognize that identifying, sourcing, qualifying, and curating the data required for IDMP is the most critical part of the implementation

and therefore leveraging the master data management system, a key success factor. Here are some salient features of our offering:

Readiness assessment utilizing proprietary offerings like IDMP mapping toolkit, inventory of processes, etc.

Preconfigured data model and business rules relevant to IDMP can be deployed out of the box minimizing implementation time and cost.

Provide an early bird view into solution roadmap for choosing and deploying a long-term solution leveraging existing investments in SAP.

- Long-term solution in alignment with organization's overall architecture
- Deep relationship with SAP helping in solution implementation
- Unmatched expertise in SAP solutions as well as domain under consideration for forming of a formidable team

## Impact on your organization

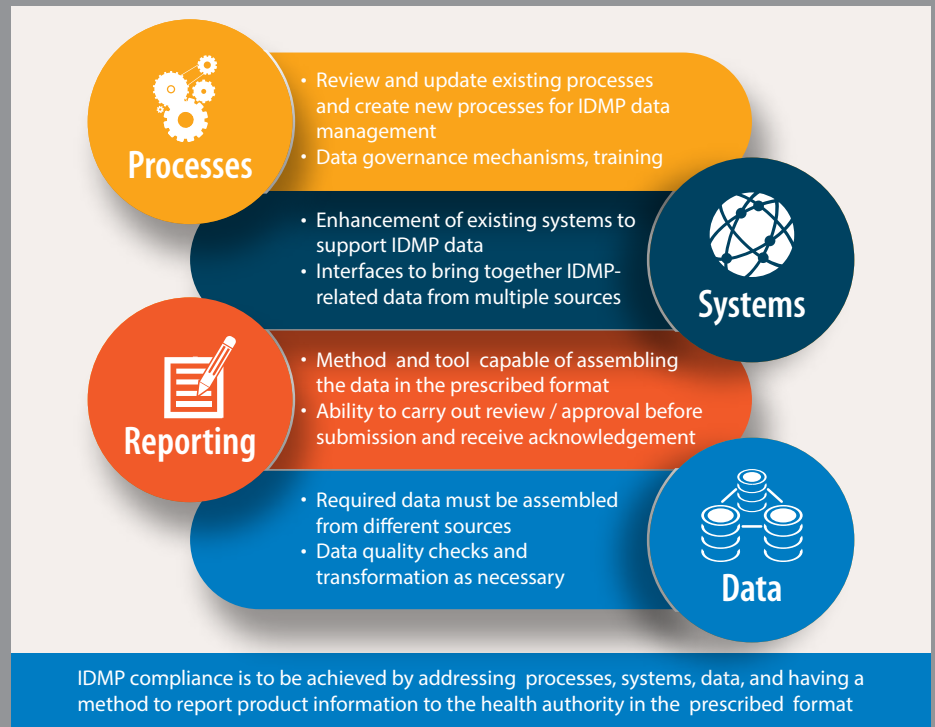
IDMP compliance requires a corporate-wide, cross-functional effort alignment on the standards, identification of source systems and data, master data management and data governance, and associated interfaces with electronic gate.

### Primary impact

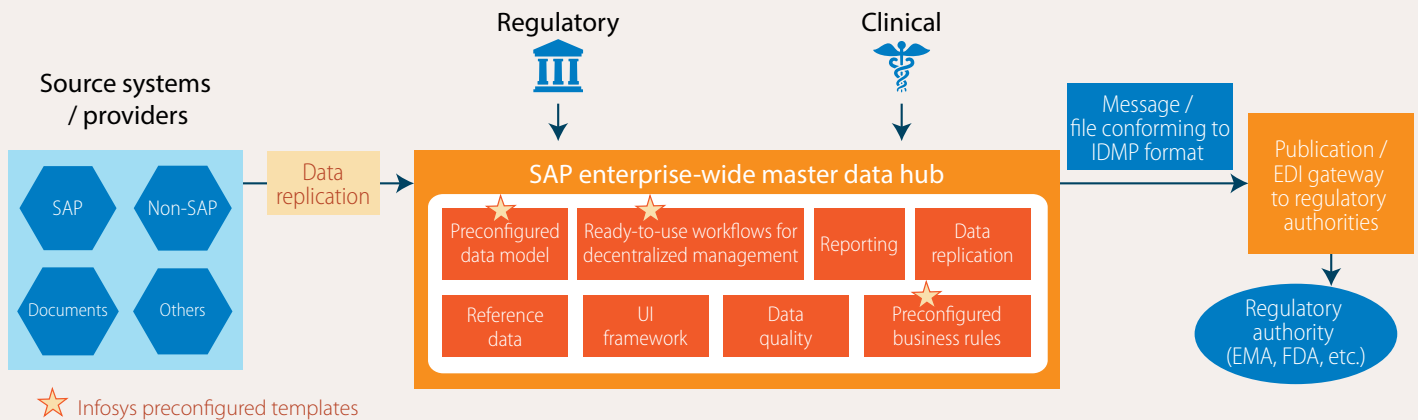
- Regulatory affairs
- Manufacturing
- Pharmacovigilance
- Clinical

### Downstream impact

- Indirect data sources
- Software vendors
- Supporting functions
- People



## Solution outline



## An IDMP solution addresses key requirements such as:

- Sourcing and extracting data from various organizational systems having both structured and unstructured content
- Transformation and loading alongwith aggregation of the data in a data hub capable of supporting data cleansing and curation
- Ability to publish the product data in IDMP-specified submission format and send it electronically to the regulatory authority

For more information, contact [askus@infosys.com](mailto:askus@infosys.com)

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