

## MDM Driven Identification of Medicinal Products (IDMP) Compliance

Fresh Gravity's comprehensive Master Data Management solution helps Pharma companies achieve compliance for Identification of Medicinal Products (IDMP) global regulation in an uncomplicated and time-efficient manner.

### Background

*New global regulation-IDMP has made it mandatory for pharmaceutical organizations to maintain product information in a systematized manner and submit it to the regulatory authorities using standard messaging protocols.*

*The IDMP definition allows for standardization and unique identification of medicinal products across the globe and facilitates exchange of product information between pharma companies and global regulators, ultimately leading to improved patient safety. This internationally accepted framework can be achieved by following ISO mandated standards and guidance.*

### Overview

IDMP necessitates that input from multiple functions (R&D, Clinical, Commercial, Regulatory, Pharmacovigilance) and systems from across the organization (Regulatory Information Management System (RIM), Clinical Trial Management Systems (CTMS), systems of record for Reference Data, Supply Chain Systems, Labelling Management System, Manufacturing ERP Systems, Adverse Event Reporting and Safety Monitoring Systems along with Unstructured data sources) are brought together in order to track attributes required to stay consistently compliant. This definition ensures that all the medicinal products and substances are uniquely identifiable across the enterprise, and do not stay limited in view to the Regulatory function alone.

Fresh Gravity has extended its Medicinal product master to build a complete solution that includes ISO mandated attributes for IDMP compliance. It encompasses integration for standard Reference data sets, workflows for data governance and stewardship, processes to de-duplicate data across multiple systems and provide a single source of truth for the product entity.

### Fresh Gravity's Implementation Approach:

Fresh Gravity views the IDMP compliance requirement as a unique opportunity to:

- Build a repository of enterprise-wide Data Assets
- Identify opportunities to bring efficiencies including Data Quality and Data Governance practices
- Create an Enterprise Architecture view for data across the Drug Development Value Chain
- Improve Operational Efficiencies

Fresh Gravity's *Molecule to Market* solution is an end-to-end data model that focuses on mastering data with "Medicinal Product" as an anchor entity. This data model spans across multiple processes and functions from R&D to clinical to commercialization and safety. The solution inherits an additional Data Governance and stewardship layer that helps better manage data quality on an ongoing basis.

The approach is broken down into three phases:

### Planning >>> Implementation >>> Business As Usual (BAU)

As a first step in the Planning phase, a gap analysis needs to be conducted to assess IDMP requirements vis-à-vis the data available within the organization. Another outcome of this stage is to unearth organizational readiness with respect to the availability of people with specific roles, specific data sets and process for data management. The gap analysis also reveals opportunities for data standardization and data enrichment using external sources.

After a complete assessment, FG works in collaboration with the clients to create a strategy for IDMP compliance along with high level timelines, pricing, resources, and a complete execution plan.

The second Implementation phase consists of the following core components:

- Data Discovery and Extraction
- Enrichment & Standardization
- Comprehensive data model designed to support all entities, attributes and relationships mandated by ISO for IDMP compliance
- Master Data Management for Medicinal Products
- Reference Data Management to manage and map SPOR PMS data
- Data Stewardship and Governance Workflows
- Downstream to reporting/Submission

## Key Benefits:

- A holistic FG solution with many products coupled together for a seamless user experience, starting with Structured Data Extraction, Unstructured Data Extraction using NLP, GraMME: Data Discovery for Data Extraction, Mapping reference data to SPOR, Reltio Connectors to external data, Clinical trials.gov Reltio Data Tenant for Enrichment and Standardization Data, “Molecule to Market”: an IDMP compliant Data Model, Data Governance and Stewardship, MDM Program Management and Implementation expertise for master data management and all the way to construction of submission ready messages to downstream applications along with other transactional data for Submission/downstream
- With most of the in-built products, the whole process gets about a 30-40% of jumpstart and an ease in the change management process
- Robust record management system simplifying the tracking and iterations for additional ids such as MPID, PCID, PhPID

DATA EXTRACTION (Master and Reference)	ENRICHMENT AND STANDARDIZATION DATA	MASTER DATA MANAGEMENT	DOWNSTREAM TO REPORTING/ SUBMISSION
RIM   CTMS Labelling Management Systems Adverse Event Reporting Systems Safety Monitoring System Product and Substance Data	Citeline G-SRS	Medicinal Product Pharmaceutical Product Organization	Data Warehouse
MedDRA ICD10 Dosage Form Route of Admin SNOMED RMS(SPOR) Units of Measurement	DrugDev CT.GOV Others	Indications Substance Packaging Devices Reference Data	Reporting/ Submission Systems  Other downstream Systems

## About Fresh Gravity

Founded in 2015, Fresh Gravity helps Life Sciences companies adopt digital transformation through innovation driven by modern technologies. This Molecule to Market solution is a result of our steadfast commitment to finding solutions to the most pressing problems in the industry. To know more about us and our offerings, contact us at [info@freshgravity.com](mailto:info@freshgravity.com)

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