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

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

## Background

*The new global regulation known as 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 the 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 provides a single source of truth for the product entity.

## IDMP Solution: Fresh Gravity 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 IDMP solution brings a data model that spans across multiple processes and functions from R&D clinical to commercialization and safety.

The approach is broken down into three phases:

Planning ››› Implementation ››› Business As Usual (BAU)

During the **Planning Phase**, a gap analysis must be conducted to assess IDMP requirements vis-à-vis the data available within the organization. Another focus 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, Fresh Gravity works in collaboration with our clients to create a strategy for IDMP compliance along with high level timelines, pricing, resources, and a complete execution plan.

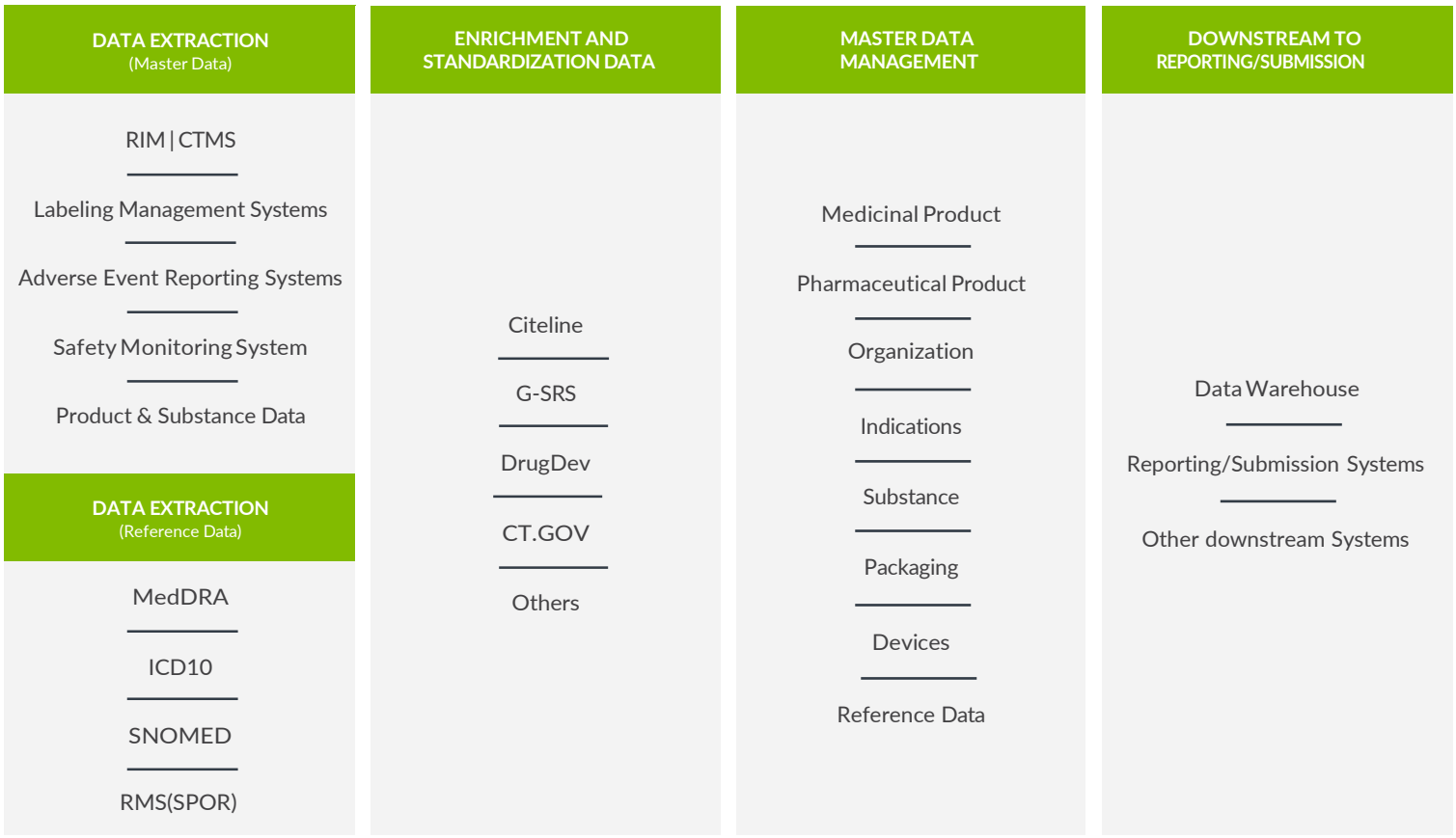
The second step is the **Implementation Phase**. Fresh Gravity's IDMP Solution accelerates implementation in many key core activities and components:

- Data Discovery and Extraction
- Enrichment and 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 RMS data
- Data Stewardship and Governance workflows
- Downstream to reporting/submission

The third step, **Business as Usual (BAU)** is a combination of adopting new business processes and integrating the MDM system output into day-to-day work.

## IDMP Data Flow

The IDMP Solution covers extraction of Master Data and Reference Data, enrichment and standardization of data using multiple external data sources, the MDM hub itself (with key IDMP entities), and it even helps facilitate downstream reporting.




## Fresh Gravity Solution Value Add

- A comprehensive data model that ensures IDMP compliance for pharma companies
- Integration with EMA's (European Medicines Agency) SPOR (Substance, Product, Organisation and Referential) RMS (Referentials Management System) service
- Submission-ready messages to downstream applications
- Master Data Management implementation expertise
- Robust tracking of important IDs such as PMS, MPID, PCID, PhPID throughout the drug lifecycle

## About Fresh Gravity

*Founded in 2015, Fresh Gravity is an innovation-driven Data and Analytics consulting firm that helps businesses make data-driven decisions. We are driven by data and its potential as an asset to drive business growth and efficiency. We are passionate innovators who solve clients' business problems by applying best-in-class data and analytics solutions. For more information, contact us at info@freshgravity.com.*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