NAVITAS LIFE SCIENCES

A TAKE Solutions Enterprise

Why Navitas Life Sciences?

- Domain knowledge and track record of delivery
- Unique insight on issues and approaches from **pvnet**, **pvconnect**, **labelnet**, and **rimnet**
- IDMP readiness assessment engagement experience
- IDMP Strategy Roadmap
- IDMP Implementation
- **idmpREADY**
- IDMP Services

IDMP compliance - driven by the power of TrackWise

Understand the Background

Identification of Medicinal Products (IDMP) is a global set of ISO standards addressing the need for unique, global identification of medicinal products throughout the lifecycle of a product. Cross-organizational data consistency and cross-functional ownership of medicinal product information will require fundamental changes to data and system governance.

Although EMA are the only authority that has so far made a solid commitment to implementing IDMP other regulators are considering implementing the standards. Japan has expressed a definite interest in adoption and US FDA have already partially implemented some of the standards through the SPL.

Companies who have already implemented XEVMPD (Extended Eudravigilance Medical Dictionary) have made a start towards IDMP compliance. However, XEVMPD was only a stopgap measure and covers only a small fraction (10-25%) of the IDMP content.

The information to be submitted is managed via 4 master data management systems SMS, PMS, OMS and RMS. OMS and RMS are already live and the data is now being used for eAF prior to an IDMP launch:

- Substance data – describing the ingredients (both API and excipients) of a medicine;
- Product data – describing the marketing and medicinal information relating to a product;
- Organization data - providing the contact details of organizations and individuals responsible for various aspects of a medicine
- Referential data – providing controlled vocabularies (e.g., dosage, pharmaceutical forms, country codes, package codes) for a medicine explicitly defined for Europe

Assess Current Situation

The guidelines are postponed to first half 2018. Regardless of the detail that will be provided when those documents are issued, the data model should remain constant. The delay gives companies several additional months to prepare for compliance.

Organizations continue to be faced with the daunting task of identifying the location of the required data for each of their marketed medicinal products – and in some cases, adjudicating which value is correct. The scope of this data identification activity alone can be overwhelming.

Navitas provides a low cost, limited engagement consulting offering where we will work with your organization to

- Evaluate your state of readiness to comply with IDMP regulations
- Identify key components of IDMP strategy such as enacting master data management (MDM) discipline, data governance, and aligning business processes

Realize the Benefits

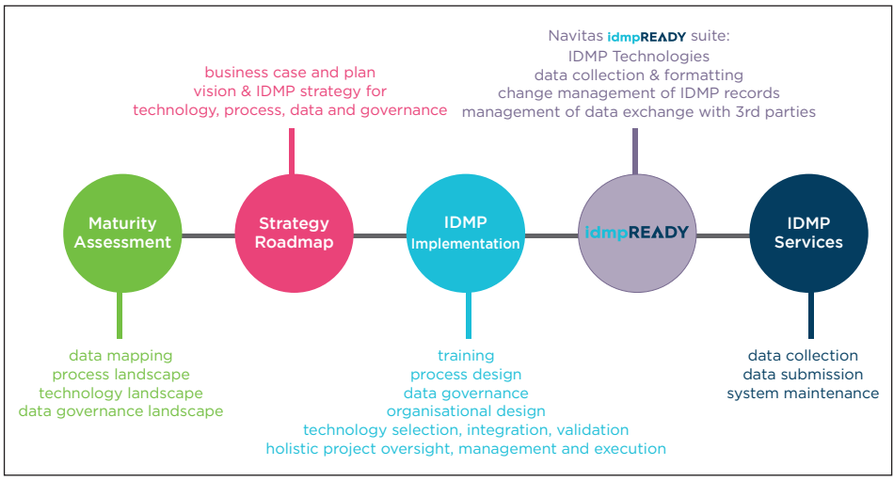
Adoption of the IDMP standard will ensure that a single product definition can be adopted across different departments and throughout the product lifecycle.

Improved substance (API; excipients), product, SKU and package component traceability upstream throughout the entire supply chain and downstream throughout the distribution network up to the patient

Full transparency and traceability of product information can provide a consolidated view of any product safety risks emerging anywhere in the supply chain including improved recall of (obsolete SKUs and introduction of new (or updated) SKUs in manufacturing and distribution channels

Key regulatory documents, like the eCTD, CCDS or SmPC are converted from e-paper documents into automated (re-usable) database structures

Ensure compliance with upcoming IDMP regulations (EU Regulation (EC) No 726/2004 Article 57) from 2017 onwards



Provide a Solution

idmpREADY provides the smart database features your organization will need to ensure data consistency across the enterprise. Integration with TrackWise provides the controls required in a compliance-driven system, permitting visibility into new, cross-functional creation, ownership, and submission of medicinal product information via workflows, messaging, and dashboards

idmpREADY provides document scraping technologies enabling organizations to identify the Substance, Product, Organization & Referential data needed to populate the required IDMP data elements. While some of this data may be migrated from existing manufacturing and regulatory systems which are more structured in nature, the vast majority will be embedded in unstructured documents in various enterprise systems.

idmpREADY comes with set of configuration options such as prioritizing data sources, metadata management, xEVMPD mappings etc… to assist the data collection process, It provides optional adapters for Excel and databases if it needs to be managed within the solution. It harvests the data from product registration processes which covers 95% of data points required for xEVMPD, which also forms the crucial data points for PMS 1st iteration requirement.

idmpREADY integrated with TrackWise allows companies to leverage their investment in their EQMS to manage quality and regulatory issues with a broader and deeper view across the organization. The integration also facilitates the early identification of potential problems and supports a systematic approach to solving them. Updates to key data are managed via change control in TrackWise and versioned data in **idmpREADY**

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About Navitas Life Sciences

As a partner for the industry, Navitas Life Sciences leverages industry insights, consulting and technology capabilities to deliver full service clinical, regulatory and safety solutions and desired outcomes to clients. As the dedicated life sciences brand of TAKE Solutions, Navitas harnesses the combined knowledge and experience of three legacy brands—Ecron Acunova, Navitas, and Intelent—to provide end-to-end services and solutions. Navitas helps clients address their most critical problems by bringing together the capabilities of a full-service CRO, a technology-led life sciences services provider across clinical, regulatory and safety, and a life sciences big data services and analytics provider. Operating from 7 countries across the globe, Navitas works with over 150 customers in Life Sciences.

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