NAVITAS LIFE SCIENCES

IDMP Imperative

To implement compliant and efficient processes, governance, and technology in line with IDMP Regulations

Why Navitas Life Sciences

- Domain knowledge and track record of delivery
- Unique insight on issues and approaches from **pvnet**, **pvconnect**, **labelnet**, and **rimnet**
- Understanding of linkages with adjacent squares
- Engagement model strategy, process, governance, technology

IDMP Impact

After 2016 medicinal product information will become available and traceable within the external regulatory domain

AEs and Product Complaints will become connected to medicinal product information via unique ID data fields

Companies need to form consolidated views on quality and safety risks that emerge in any part of their supply chain, including shared CROs, suppliers, distributors etc

Structured medicinal product information will have to become an integrated part of the PV system

One single source of validated medicinal product information maintained within the IDMP solution readily available for SC Execution and Regulatory Information Management

Managing medicinal product information requires a technical solution that supports both local as well as global (master) data

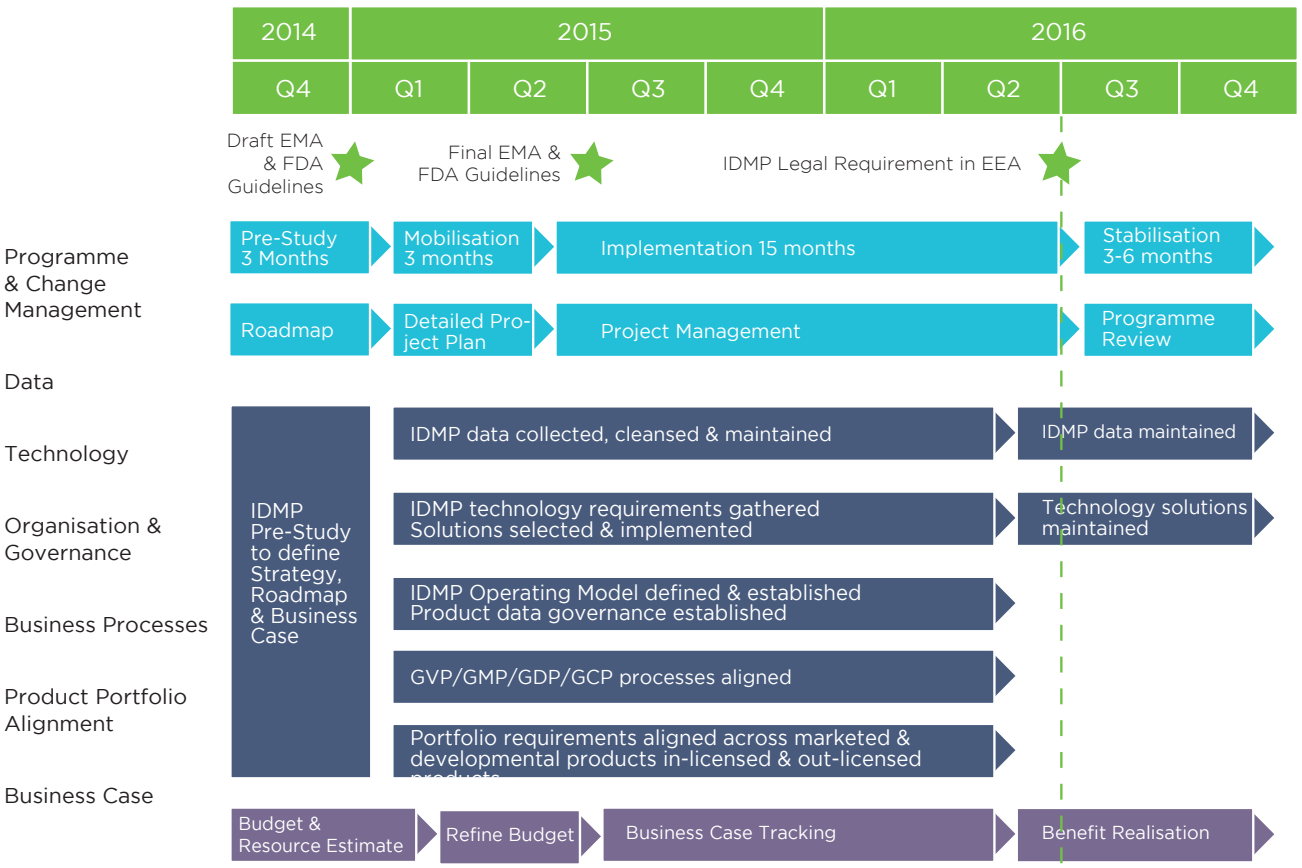
MDM technology is required to ensure consistency and unambiguity both internally as well as externally facing towards regulators (IDMP)

The most fundamental change will be ensuring a cross functional ownership of medicinal product information

Ensuring data consistency across the organisation will require a fundamental rethinking of data and system governance

Navitas Life Sciences Approach

A structured and rigorous plan ensures successful delivery



Business Benefits

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

Full transparency and traceability of product info improves consolidated view of any product safety risks emerging anywhere in the supply chain

Reduced lead times within labelling, artwork as well regulatory submissions and supply chain execution processes:

- Faster label and artwork update cycles in terms of regulatory approvals and change implementations
- Improved recall of (obsolete) SKUs and introduction of new (or updated) SKUs in the manufacturing and distribution channels
- Regulatory data readily available, reducing lead times to bring(new) product to market
- Improved change control and associated variation management

Reduction of effort and waste due to removing duplication of product information out of the product life cycle

Single source of high quality product information throughout the entire product cycle

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 2016 onwards

For further information, please contact **neil.richards@navitaslifesciences.com**

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A TAKE Solutions Enterprise

About Navitas Life Sciences

Navitas Life Sciences brings together the proven strengths of its legacy brands Navitas, Ecron Acunova and Intelent to serve as a strategic partner to global Life Sciences companies. Navitas life Sciences leverages its industry insights and domain expertise to develop and implement consulting, technology and functional services across the spectrum of Clinical, Regulatory and Safety, to innovative and create value to address the needs of the industry uniquely.

For more information

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