IDMP – BUILD DATADRIVEN SUBMISSIONS

REGULATORY AFFAIRS

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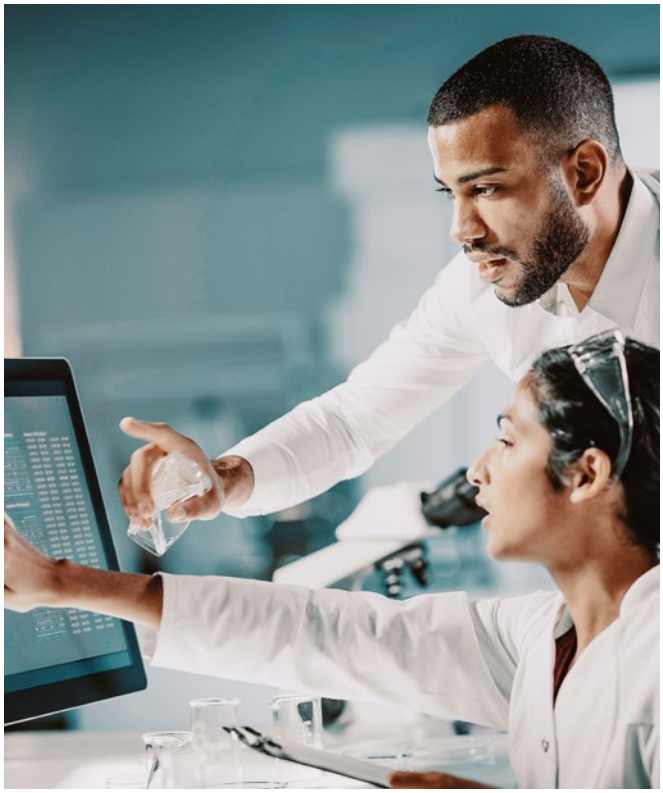
To ensure compliance with the IDMP requirements, NNIT has defined five phases to enable timely cross-organizational compliance. The NNIT five-phased framework ensures an efficient and timely process from initiation to execution – and each phase is customized to meet the specific demands of your business and organization. We can help with everything from initial assessment to execution – and each of the individual phases in between.

NNIT has executed IDMP projects for over 30 customers since 2013, and has a deep understanding of the requirements and processes necessary to move an entire pharmaceutical company from its current state to IDMP compliance. We can leverage our knowledge and expertise to ensure IDMP compliance in yourorganization by:

- Choosing the right solution for your organization
- Assessing system and data readiness
- Ensuring smooth and timely implementation
- Integrating existing IT systems to form IDMP compliant records
- Training your team members to understand and host the solution while ensuring smooth organizational change management throughout each phase.



Our tailored architectural solutions for IDMP

NNIT can provide advice on the implementation of IT solutions of all sizes, from minor submission setups to full-blown architecture with MDM components, data hubs, and separate submission layers.

Data Quality Services for IDMP

NNIT's Data Quality Services tool measures the data quality of relevant sources, mapped for IDMP submission or source field. The solution includes built-in IDMP rules and data standards, which ensure that every single data point adheres to the applicable IDMP data model requirements. The value we provide with our solution includes:

- Visibility of the data-quality concerns and baseline
- Actionable data insights with guidance for corrections
- Data confidence

Data management and IDMP

With the implementation of IDMP data standards, the life science industry will have to synchronize data in their local systems on an ongoing basis. To reflect the changes and updates to SPOR data in local systems, you may need to restructure your local data to align with the IDMP data formats in RMS, OMS, PMS, and SMS. This data management process involves two key activities:

- Data transformation – changing the data structure
- Data enrichment – to complete the data sets
- Data governance – to ensure ongoing data quality

IDMP – BUSINESS PROCESSES & SOPS

How does IDMP affect processes within Regulatory Affairs?

Detailed efficiencies expectedfrom process simplification and automation

NNIT's view is that automation may be built into a number of Regulatory Affairs processes, facilitated by the data, per the IDMP data model. Data quality, operation efforts, and KPIs for monitoring and decision-making are just a few of the possible advantageous outcomes of process transformation. Data quality may be automatically monitored through appropriate reporting features, to ensure the IDMP data quality level. Vocabulary harmonization through controlled vocabularies (CVs) is a direct implication of data quality automation.

NNIT's key elements of business process reengineering.

IDMP Advisory

Updates from the regulators

Insight into dependencies such as CTIS, FMD

Advice on industry practices

On-demand IDMP consultation

AS-IS to TO-BE

AS-IS process map, inluding dependen processes

IDMP impact assesment

Set of decisions and actions to be made

TO-BE process design subject to decisions and actions made

SOPs and WIs

Recommendations for approaches to updating SOPs and WIs

Final draft SOPs and WIs for review and approval

We make a mark

About NNIT

We are an international digital consultancy specializing in life sciences and the public sector. Our team of leading industry subject-matter experts and technology consultants help you empower those who change lives – and make a mark.

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