IDMP SERVICES

Getting ready for **IDMP compliance**

NNIT

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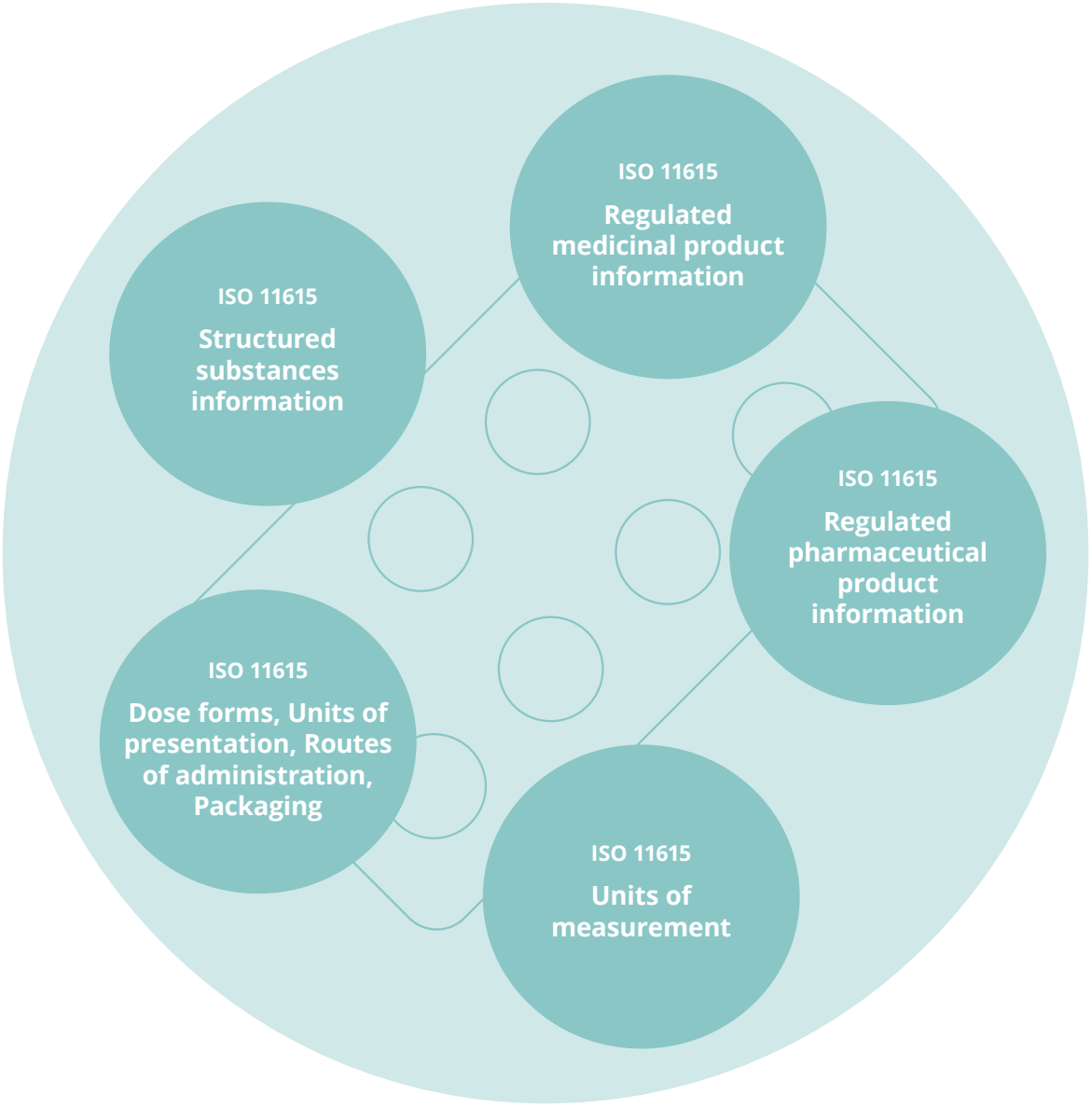
NNIT IDMP SERVICES

What is IDMP?

IDentification of Medicinal Products (IDMP) covers five ISO standards (11238, 11239, 11240, 11615, 11616) that describe how to structure data on medicinal products according to defined information models.

The collective goal for defined regulated information models is to globally standardize the identification of medicinal products. IDMP aims to improve and protect global safety. Marketing Authorization Holding (MAH) Organizations in the EU will soon need to demonstrate compliance with these mandatory standards, with the US following thereafter.



How does IDMP affect my organization?

EUROPE

From Q3 2022, if your company has medicinal products registered in the EU, you will have to submit product changes using a new type of web form called DADI. It will use structured data migrated from the Art. 57 database for applicants to select their products. For you it means increased scrutiny on your data, which you will be required to re-use for variation submissions.

USA

The US Food and Drug Administration (FDA) is expected to follow suit with:

- IDMP
- PQ/CMC
- G-SRS
- ICSR E2B (R3)

How can NNIT help my organization?

1. Deep insight and extensive experience

NNIT is represented in a number of industry organizations, scientific committees, and working groups, most notably the **ISO TC215 WG6**, the International Organization for Standardization's (ISO) Technical Committee on health informatics, the EMA SPOR Task Force and the Process Focus Group defining the IDMP Target Operating Model.

NNIT has completed IDMP projects for more than 30 customers since 2013 and has a deep understanding of the complex 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 execute IDMP compliance in your organization by:

- Choosing the right technology or business solution for your organisation
- Ensuring smooth and problem-free implementation
- Integrating the existing IT systems to form IDMP-compliant records
- Training your team members and senior management to understand what IDMP is and what its impact is on their daily work.

2. Five steps to ensure compliance

IDMP will have a widespread impact on the preparation and planning of the submissions and maintenance of data in life sciences companies – from manufacturing data and structured substance information to registration information throughout the lifecycle of a medicinal product.

To ensure compliance with the IDMP requirements, NNIT has defined five structured stages to enable timely cross-organizational compliance.

The NNIT five-step model 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.

PHASE I:
INITIATE

Impact Assessment

- Identification of source fields, systems and gap analysis
- Management Reports
- Project setup and scoping
- Business Case
- IDMP Vision

PHASE II:
ANALYZE

Business Preparation

- Definition of project charters (systems, documents and gaps)
- Architecture components
- Data quality assessment
- Implementation Strategy

PHASE III:
DESIGN

Opportunities & Solutions

- Requirements specification
- Implementation planning
- Vendor(s) & solution(s) selection

PHASE IV:
EXECUTE

Organizational Implementation

- Source systems integration & modification
- New supporting systems
- Data capture
- Implementation of IDMP solution
- Submission

PHASE V:
REALIZE

Hosting & Support

- Hosting
- Support
- Application development

Iterative

BUSINESS PROCESSES & SOPS

PROJECT SUPPORT & OCM

3. Data quality and compliance dashboards

NNIT has developed a proprietary data quality solution that measures the data quality of relevant sources mapped for IDMP submission or source field.

The solution has built-in IDMP rules and data standards measuring that every-single data point adheres to the applicable IDMP data model requirements.

The value that we provide with our solution is:

- Visibility of the data quality issues and baseline
- Actionable data insights with guidance for corrections
- Experience of data confidence.

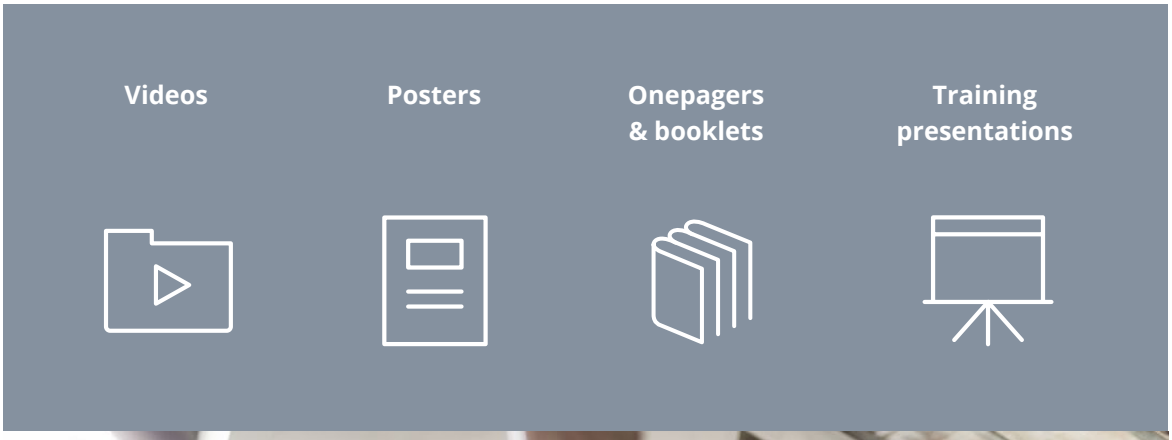
The solution can be easily implemented and requires minimal operational effort as well as easily embeds into all Microsoft 365 solutions.

4. Awareness, Training, and Organizational Change Management to get your organization on board

NNIT offers a solid Organizational Change Management (OCM) concept tailored to ISO IDMP. The key advantages of the package are speed and high quality at a low cost:

- **Speed:** Ability to execute awareness communication and training without affecting the program timeline. Ready to go due to our IDMP experience.
- **High quality:** Ability to obtain a high-quality OCM concept based on best practices from IDMP implementations.

The OCM awareness concept is created to fit all organizations in their analysis phase.



5. Our tailored architectural solutions for IDMP

NNIT can provide advice on the implementation of IT solutions of all sizes; ranging from minor submission setups to full grown architectures with MDM components, data hubs, and a separate submission layer.

Manual Entry

Pros

- Extension of current xEVMPD processes
- Small impact on the organization

Cons

- Time consuming
- Risk of errors
- No interface with EMA

Data Hub

Pros

- Flexibility for the new regulations (EMA, US, RoW)
- Data improvement and extended business capabilities

Cons

- Custom-built submission process
- Time-consuming process build

IDMP Application

Pros

- Management and tracking of submissions
- Standard applications available

Cons

- Capabilities limited to IDMP
- No improvement to company data strategy

Layered Architecture

Pros

- Implementation in phases
- Company-wide data governance
- Tailored to specific use
- Highest degree of futureproofing

Cons

- New processes, training, and support
- High cost

IDMP aims to improve patient safety regarding medication and will soon become mandatory for every Marketing Authorization Holder operating within the EU.

Contact

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Together we make a mark in business and society; bringing digital transformation to life

The NNIT Group provides a wide range of IT and consulting services to the global life sciences industry and has been a trusted partner to life sciences companies for +25 years.

We are a leading global RA advisory and consultancy unit committed to digitally transform Regulatory Affairs into an influential strategic and data driven business unit. We leverage thought leadership knowledge and the newest technology, with implementation excellence and successive maintenance service.

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