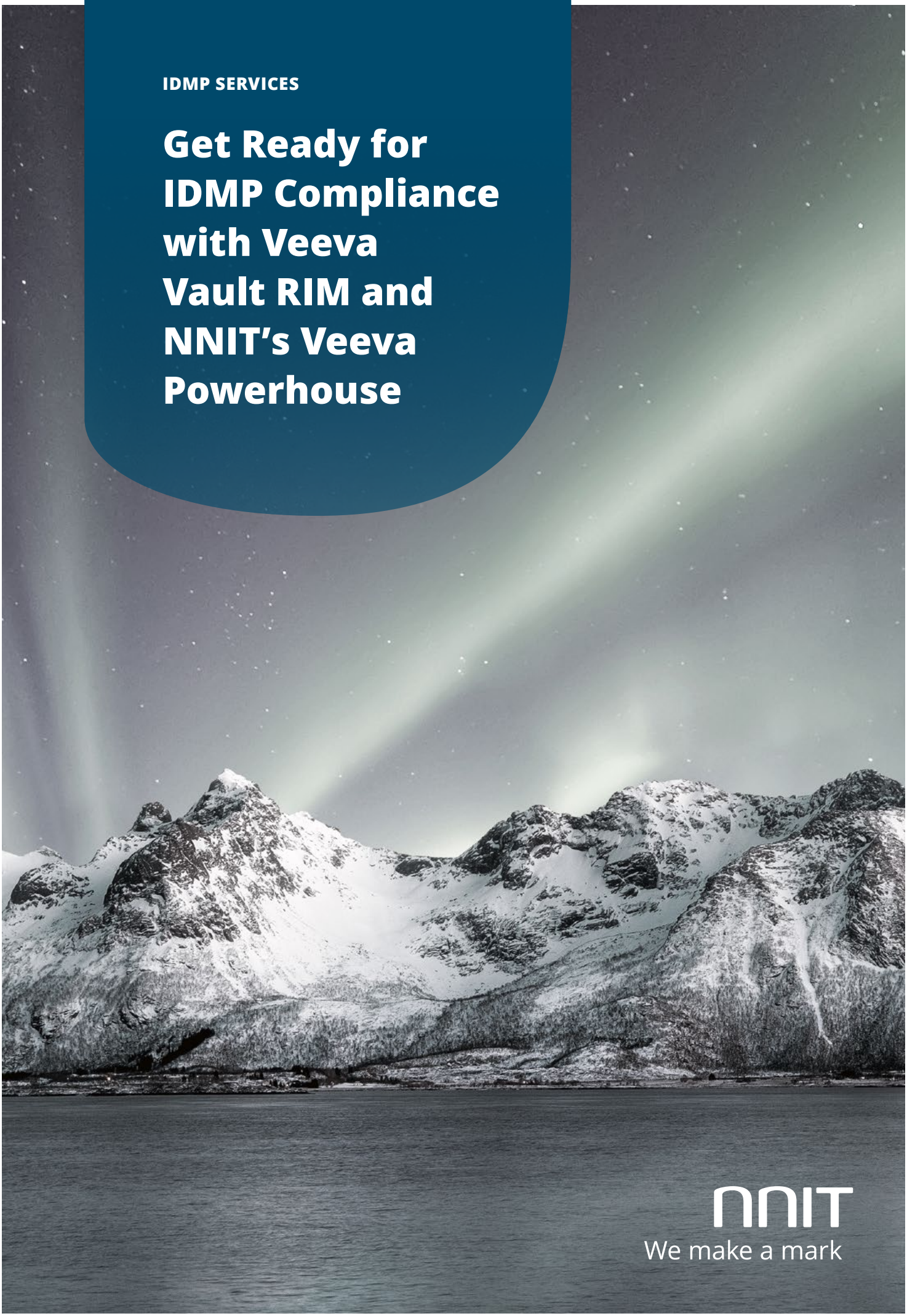
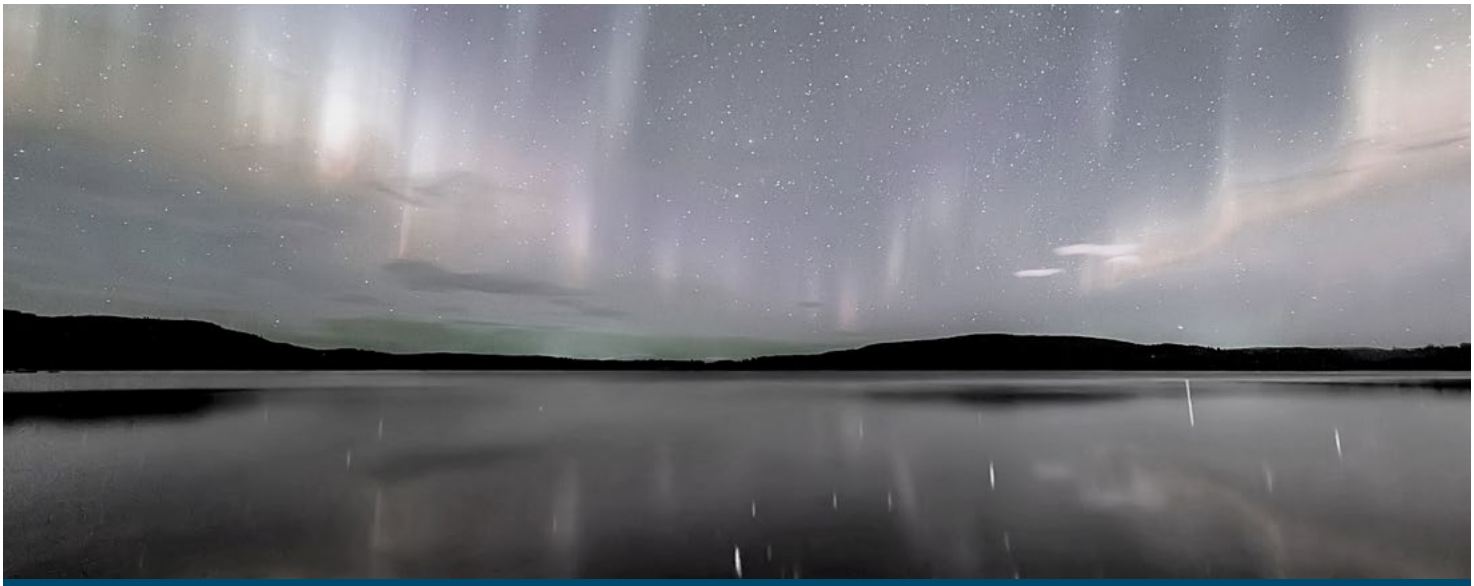
IDMP SERVICES

Get Ready for IDMP Compliance with Veeva Vault RIM and NNIT's Veeva Powerhouse



NNIT
We make a mark



Contents

Get Ready for IDMP Compliance with Veeva Vault RIM and NNIT's Veeva Powerhouse

At NNIT, we have developed a framework for data preparation and business process optimization, which together with the Veeva Vault RIM Suite, can be used as a best-practice approach for reaching IDMP compliance within EMA's timelines.

Managing regulatory information is a complicated task that demands system capabilities as well as knowledge of local requirements and regulatory processes. In Europe, the imminent enforcement of IDMP submissions adds an extra layer of complexity as large sets of data need to be submitted directly to the regulators during the assessment process.

Submission of regulatory data to health authorities has been an important task in regulatory affairs for years. Since 2012, companies holding Marketing Authorizations in the EU had to make structured regulatory data submissions to the xEVMPD (also known as Article 57 database). [1]

Over the past years, EMA has been planning the implementation of ISO IDMP (Identification of Medicinal Products) as part of their SPOR program. IDMP submissions based on ISO data standards will eventually replace xEVMPD submissions, as EMA launches the Product Management Service (PMS) for regulatory product information.

Currently, submission to PMS is expected to become mandatory by Q1 2023. With less than 2 years left, it is more important than ever to fully understand the impact of IDMP on your organization and how to tackle compliance.

As part of the submission to PMS, xEVMPD data will also be migrated to PMS; however, this will be handled by EMA, so sponsors will not have to concern themselves with this process.

Industry typically has immediate challenges in locating the required data for submission and ensuring data quality. As organizations align IDMP submissions with the usual dossier submission, they'll also need to understand the changes to their business processes. It's important to consider when data will need to be ready for submission to Health Authorities (HA) and for amendments as a result of HA reviews or unforeseen changes.

As an added benefit, ensuring your data is IDMP compliant, collected, and available early on in the process will enable digital transformation opportunities within your organization. Data and data identifiers can be used to establish the foundation for a data-driven regulatory affairs organization, where analytics, business intelligence and automation can become a reality.

NNIT VEEVA POWERHOUSE

How can Veeva & NNIT facilitate your compliance journey?

At NNIT, we have invested significantly in our partnership with Veeva to develop an accelerated, efficient and tailored approach to implementing a unified Veeva Vault RIM platform – the NNIT Veeva Powerhouse – which is an innovative approach to regulatory affairs transformation.

The Vault RIM Suite lets you address all your regulatory information needs within a single unified system built on the Veeva Vault platform. Therefore, you only store your information once, but are able to utilize it throughout the business.

Whether you are implementing Vault RIM or adding IDMP capabilities to your existing RIM solution, the NNIT Veeva Powerhouse is your partner in the process, helping you every step of the way. In close collaboration with Veeva, we use our expertise to guide you in getting the full value out of your Vault RIM investment, while continuously helping you prepare your IDMP data and processes. We can help you implement or enhance Vault RIM and make sure you are IDMP compliant at the same time.

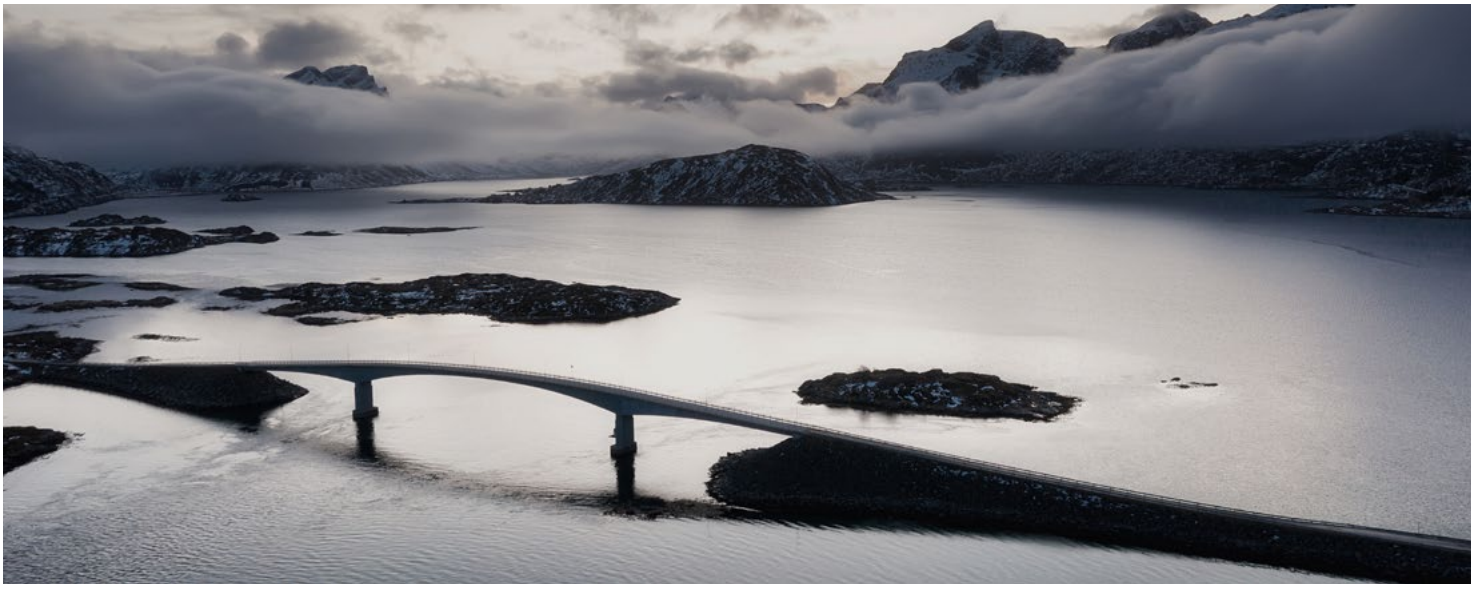
Benefits of the NNIT Veeva Powerhouse

While Veeva brings a unified platform to the table and guarantees that you are ready for technical go-live, NNIT provides you with the expertise and knowledge of the life sciences industry in general and regulatory affairs specifically to ensure you are ready for business go-live.
This is the essence of our **NNIT Veeva Powerhouse**.

With many years of experience as a service provider to the life sciences sector, we not only understand the complexities of drug product registrations and data management, but also the difficult process of being both agile and compliant.

At NNIT, we ensure that you are ready for business go-live by:

- making sure that your Vault RIM solution is optimized – from regulatory planning to tracking of lifecycle activities
- assisting you in setting up the application, processes and data needed to support IDMP data submission from your Vault RIM
- ensuring that your configuration needs are mapped and fitted into your Vault to support regulatory requirements and regulatory standards such as IDMP
- configuring reports to provide regulatory KPIs, product data required for the EMVO database (supporting the legal framework of Falsified Medicines Directive) or weekly reports on regulatory status – to mention a few
- performing gap assessments on your Vault RIM's capability to support new requirements and provide solution proposals
- establishing the data quality needed for IDMP
- updating existing procedures or establishing new ones to ensure governance is in place



The first step towards IDMP compliance

Veeva is continually investing in the Vault RIM Suite so users will be able to view, review, submit, and archive the larger IDMP data set defined by EMA. Even though it is not yet possible to submit to the PMS database until EMA is ready to receive the data, Vault RIM is ready to support it.

Furthermore, Veeva stated that "we already have several pieces of the IDMP framework in place including a data model, process automation, data view UI design, data record automation, and integration with the SPOR RMS database". [2] Therefore, it is important to take certain actions now to prepare for the challenges to come. [3]

NNIT can help you manage the IDMP-related releases as part of our Veeva services. Moreover, NNIT can help lay the strategy for populating the larger RIM data model with data from various sources and build interfaces as well as securing the data quality. After reaching an initial high level of data quality, maintaining the high quality also requires implementation of data governance in the organization including the creation of data policies and data management processes for generating, reviewing and correcting data.

Processes for preparing the data submissions and maintaining the data will have to be implemented, and existing submission processes need to be adjusted to incorporate the increasing requirements. Integrations with other source systems may have to be established. NNIT can take Veeva clients from A to Z in becoming IDMP compliant, from formulating the IDMP strategy to Veeva release management, integration, RA business knowledge and support of Vault RIM and data management tools.

NEXT STEP

Veeva Vault RIM is already in place – what is next?

If you have already implemented Vault RIM, you might not be aware of the possibilities provided by Veeva's product releases with regards to IDMP. Today, submitting XEVMPD is an integrated part of Vault RIM, providing a seamless data process for your regulatory data and a variety of possibilities for use of data throughout the business. IDMP is next and Vault RIM will be ready for Iteration 1.

A single data model supports XEVMPD and IDMP (as both are needed in the transition phase) as well as registration tracking and submissions, delivering a single authoritative source of regulatory data. [4] Veeva highlights that based on the newest guidelines from EMA, their "Vault RIM development team is currently building out functionality to support compliance while best serving our customers' ongoing needs." [5]

NNIT's IDMP Awareness and Training

Technology alone is not enough. Industry needs to get people onboard and make them ready for managing IDMP, too. To this end, NNIT offers various IDMP organizational change management packages with key elements to prepare clients for IDMP compliance. We offer awareness and training sessions to update you on the latest status of IDMP, with a special focus on Europe due to the publication of the EMA's Implementation Guide.

NNIT also offers data mapping, using our in-house developed data mapping tool, to assess the impact of IDMP on systems, processes, and data. The outcome is a consolidated report that highlights the gaps in the source fields of the required data for submission. This report provides the necessary foundation for choosing the best-fitting architectural solution and defining an implementation strategy.

The IDMP assessment provides the foundation for making the key decisions to ensure that systems, processes, and data are ready to become IDMP compliant. NNIT can leverage its knowledge and expertise to facilitate this decision-making process, develop an implementation strategy, and ensure a smooth and problem-free implementation of the chosen solution, including integration of the existing IT systems to form IDMP-compliant records. NNIT can also facilitate the training of team members to understand and maintain the solution and the data while ensuring smooth organizational change management throughout the implementation.

Thus, NNIT can help with everything from initial assessment to execution and maintenance.

Beyond compliance

Becoming IDMP compliant is a process that will evolve together with the staggered release of guidance by the EMA, which is why having timely access to regulatory updates is indispensable in planning your future transformation.

IDMP enables many regulatory use cases, but it is also a key driver for transformation of the industry most notably by providing some of the tools to achieve trust in data.

The much-coveted single source of truth is achievable by adopting robust data governance, breaking existing information silos and redesigning business processes with data in mind. Trust in data will open the door to data-driven decisions, data analytics and KPIs that would have not been possible in the past.

Facts about IDMP

- IDMP stands for Identification of Medicinal Products and consists of five standards developed by the International Organization for Standardisation (ISO).
- IDMP is eventually replacing xEVMPD and expands beyond with a new and larger data model and new submission requirements.
- Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26) dictates that European Union (EU) Member States, marketing authorization holders and the EMA should make use of the ISO IDMP standards. This will impact on many areas of the pharmaceutical regulatory environment, both in the EU and other regions. [6]
- The European Medicines Agency (EMA) is in the process of a phased implementation of the standards based on the four domains of master data: substance, product, organization and referential (SPOR) master data.
- Iteration 1 for PMS data would be mandatory from soon after February 2023. [7]
- Veeva has three software releases per year and is preparing the Vault RIM platform for EMA's Iteration 1 IDMP implementation.

Notes

1. Extended EudraVigilance medicinal product dictionary (XEVMPD) training
www.ema.europa.eu/en/human-regulatory/post-authorisation/data-medicines-iso-idmp-standards/extended-eudravigilance-medicinal-product-dictionary-xevmpd-training#xevmpd-e-learning-presentations-section

2. Supporting EMA's New IDMP Implementation Guide 2.0
www.veeva.com/supporting-emas-new-idmp-implementation-guide-2-0/#.YIF4ttupAho.linkedin

3. Supporting EMA's New IDMP Implementation Guide 2.0
www.veeva.com/supporting-emas-new-idmp-implementation-guide-2-0/#.YIF4ttupAho.linkedin

4. Veeva's Approach to IDMP
www.veeva.com/resources/veevas-approach-to-idmp/

5. Supporting EMA's New IDMP Implementation Guide 2.0
www.veeva.com/supporting-emas-new-idmp-implementation-guide-2-0/#.YIF4ttupAho.linkedin

6. Data on medicines (ISO IDMP standards) Overview:
www.ema.europa.eu/en/human-regulatory/overview/data-medicines-iso-idmp-standards-overview

7. Current date is February 22, 2023. This date is subject to change.

Contact

Niels Buch Leander
Global Head of Regulatory Affairs
nbln@nnit.com
+45 3075 5339

Brooke Casselberry
Head of Regulatory Affairs US
brcy@nnit.com
1-609-212-7833

Anna Pennington
Advisory Consultant, Regulatory Affairs
IDMP Service Manager
apng@nnit.com
+45 30779316

Stefan Peev, MTOPRA
Senior Advisory Consultant, Regulatory Affairs
IDMP Expert
sfpv@nnit.com
+41764874707

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.

Read more at **www.nnit.com**

nnit
We make a mark