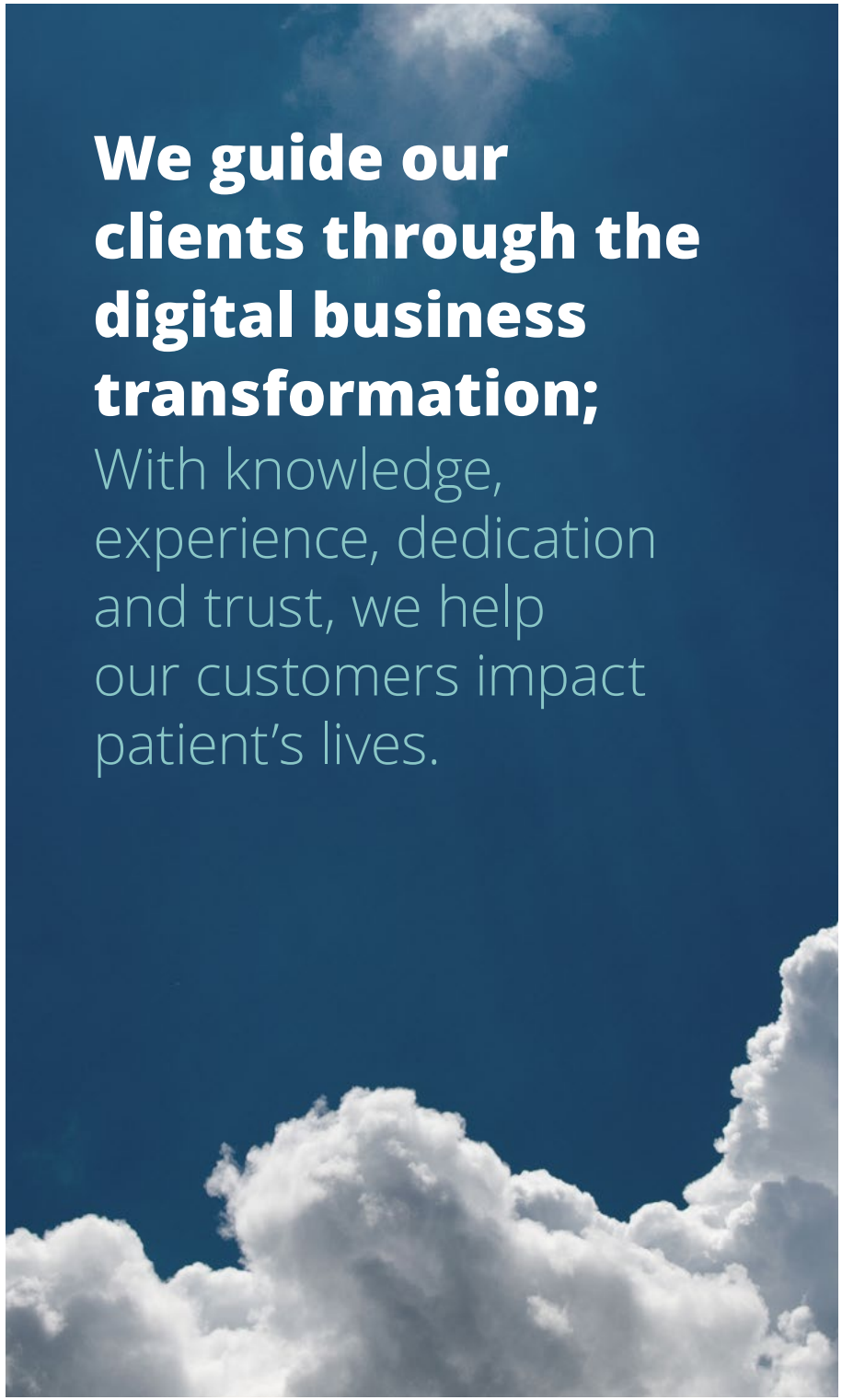
SERVICE CATALOG

NNIT Regulatory Affairs

We make a mark

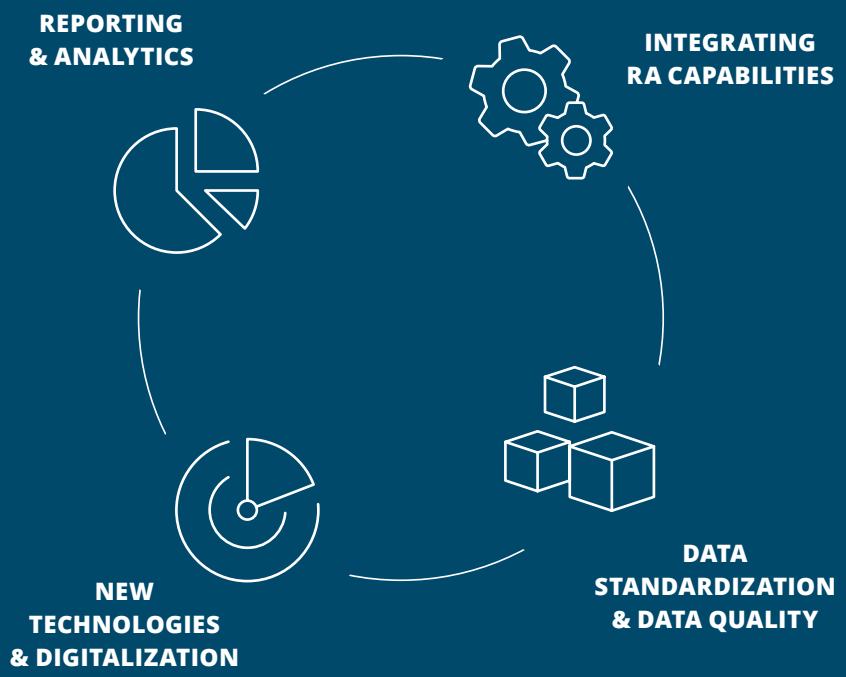


Contents

THE DIGITAL TRANSFORMATION OF REGULATORY AFFAIRS

Regulatory Affairs – Undergoing transformation

The regulatory landscape is constantly changing. It is becoming more complex and requirements from authorities are increasing, making the maintenance of systems that support changing business requirements quite challenging.



Regulatory Affairs departments have gained significant advantages in recent years by implementing EDMS, eCTD, RIMS, and labeling systems. However, the solutions often remain disconnected, slowing business processes and data sharing, and presenting vast potential for optimization.

We are moving away from point solutions and individual applications supporting individual processes with separate data and individual governance. Digital transformation of Regulatory Affairs offers unified processes and data by breaking silos, standardizing data and optimizing business processes.

There are many benefits of transforming Regulatory Affairs. Moving from spreadsheets and manual processes to data-driven processes enables and leverages optimized submission flows.

This change then paves the way for agile data-sharing between internal and external stakeholders to support processes and collaboration. Moreover, the transformation enables you to leverage advanced analytics and reporting to significantly improve business insights.

THE DIGITAL TRANSFORMATION OF REGULATORY AFFAIRS

NNIT is a leading partner in digital transformation of Regulatory Affairs

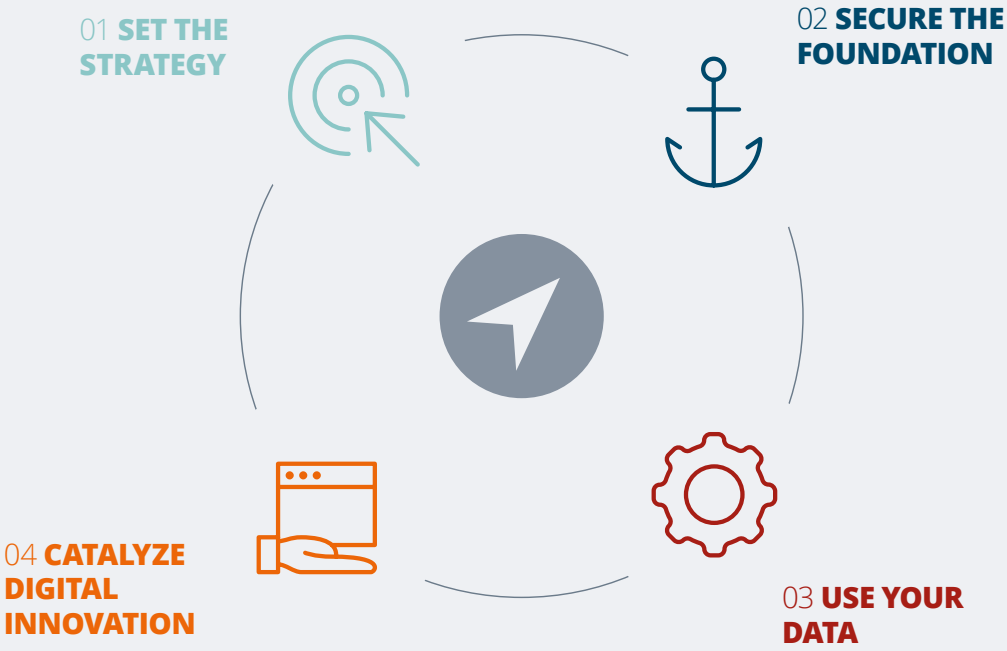
At NNIT, we aspire to transform Regulatory Affairs into an influential, strategic and data driven organization.

We leverage our deep domain knowledge and the newest technology with implementation excellence and successful maintenance services. With in-depth knowledge of the regulatory agenda, health authority requirements and processes, and a proven Digital Transformation framework, we build and implement high-quality and compliance-driven digital solutions to help RA become a data-driven organization.

NNIT has continuously been a trusted partner to life sciences companies for +25 years. With 30+ of RA implementations behind us, 100+ dedicated regulatory affairs consultants, and a strong advisor knowledge hub, NNIT is one of the leading partners in the industry to drive the transformation of RA.

Whether your starting point is establishing a vision for your transformation, drawing up the RA architecture, or laying out a roadmap, we can assist you with your strategy. We develop the digital transformation strategy with you, and deliver the implementation, host and support your solutions.

There are four key areas to focus on to develop and execute digital transformation of Regulatory Affairs into an influential, strategic and data-driven organization

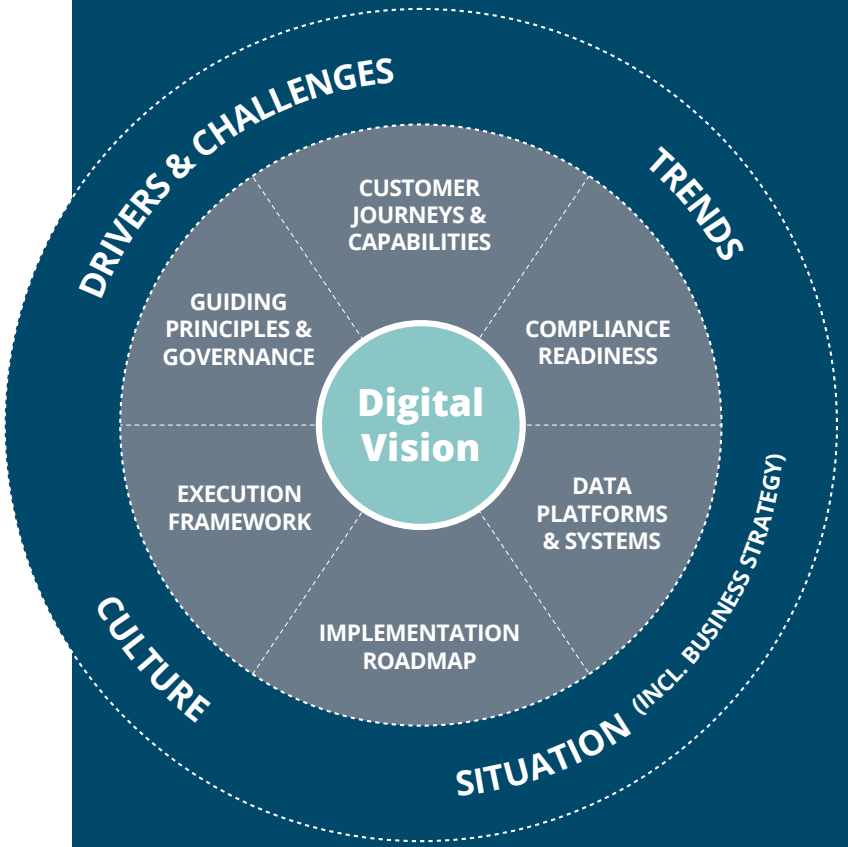


01 **SET THE STRATEGY**

Digital Transformation Strategy

It is of strategic importance to the RA/R&D organization to identify the need for **digital transformation** to adopt new technologies, improve efficiency and compliance, accelerate time to market, increase profit margins and drive strategic decisions.

NNIT advises and drives the process of building a digital transformation strategy and setting the goals for your organization. This is to ensure a solid foundation to take ownership of the digital transformation and reap the benefits in R&D – within Clinical, Safety and Regulatory Affairs. With enterprise architects dedicated to RA and R&D, we also define and draw up the target architecture linked to key capabilities for RA and demonstrating dependencies to other business areas.



Digital Vision
The digital vision is the core element that communicates the desired state by the end of the strategy period. It is established at the very beginning of the strategy project but is continuously revisited throughout the process to ensure it remains relevant as the project unfolds.

Strategy Roadmap
Guided by the vision, the strategy deliverables are developed through an analysis of as-is compared to aspirations and possibilities, which are consolidated in a to-be design. A key deliverable is the strategy roadmap, which includes prioritized activities to accelerate the organization's journey towards the vision.

Internal and External Drivers
Both internal and external factors affect and act as boundaries for the strategy. These factors are taken into consideration as a frame for the strategy work.

The NNIT project methodology covers an analysis of these key areas from both an as-is and a to-be perspective.

02 **SECURE THE FOUNDATION**

Technological and organizational aspects

The technological and organizational aspects of RA go hand in hand for successful **data-driven** RA. A digital transformation of Regulatory Affairs cannot focus solely on technology and data – the key to being successful is to consider the foundation from **different perspectives**.

Here, it is relevant to consider both the people and processes affected by the changes. You simply cannot besuccessful in one area without considering the other. At NNIT, we focus on the technological and organizational aspects illustrated here because we believe these are key to securing the proper foundation for digital transformation and to become a data-driven organization.

Technological aspects

Data Quality | Data Migration | System Architecture

Data Management

Organizational aspects – readying the organization

Business Processes | Data Governance | Organizational Change Management

02 **SECURE THE FOUNDATION**

Data Management

When we discuss data management, it is always key to remember that it is possible to do **data management** without doing **master** data management – but not the opposite!

Data are becoming increasingly important:

- IT is no longer a support function but an enabler
- Processes are converging
- Move from documents to structured data
- Importance of data is increasing in business
- Silos are breaking down
- Need for data driven decision making

Key drivers for change in the life sciences industry

INTERNAL

- Silo architecture with costly integrations
- Poor access to data
- Data driven decisions needed
- Increasing volume of data
- Rising costs of data quality & governance
- Digital services & therapies introduced

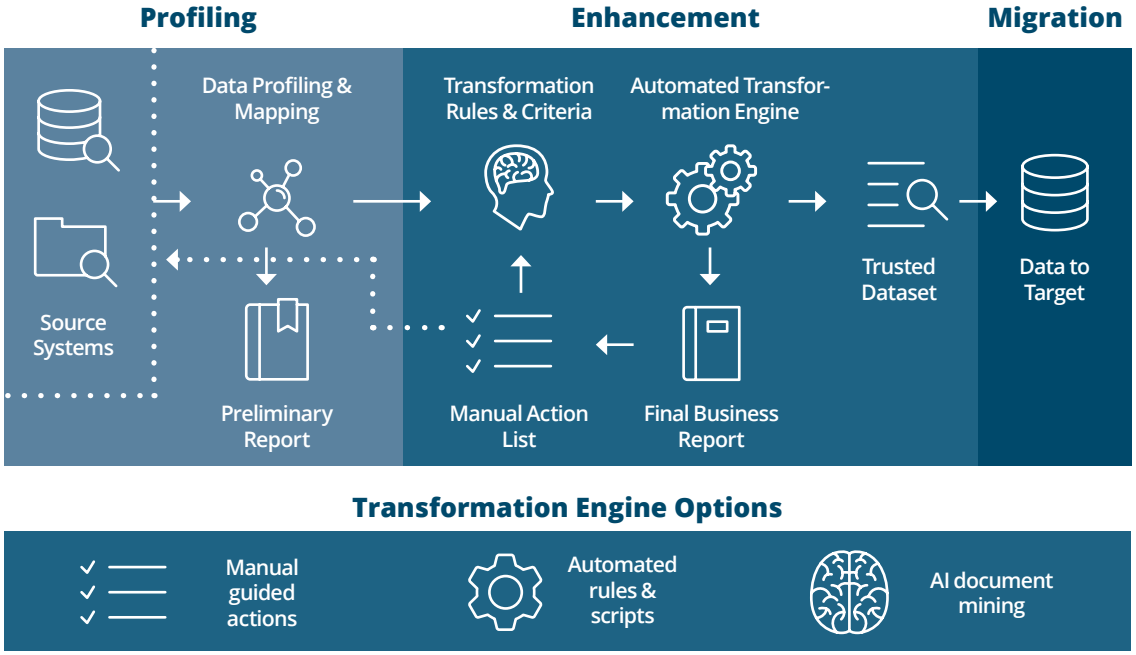
EXTERNAL

- Data standardization requirements are introduced
- Move from structured documents to structured data
- Regulators introducing MDM initiatives
- Processes converge

02 **SECURE THE FOUNDATION**

Data quality & migration

Data quality is a key focus in the life sciences industry as a result of increasing regulatory requirements and the need business integration to ensure corporate efficiency and savings.



NNIT's Data Quality Services

When moving from legacy systems to new solutions, it is essential to consider data quality and migration readiness because we are looking into new data models with modern data structure and consistency requirements. NNIT's Data Quality Services offer a solution for improving data quality before migration to ensure that the new system gets properly up and running.

By using AI and ML on a cloud platform to read and extract business information, Data Quality Services offer value by ensuring the visibility of the data quality concerns and baseline, measured according to industry standards, and NNIT knowledge of good data for Regulatory Affairs, delivering actionable data insights with guidance for correction, and ensuring confidence in the data. Finally, we offer natural language processing, making it possible to extract structured data fromdocuments to compare with structured data, prepare documents for migration, and provide a better overview of documentation, for example, spotting duplicates.

Data Migration

NNIT's group company Valiance is Veeva's most experienced migration partner in the regulatory space, with mid-sized to large enterprise migrations for Vault Registrations, Vault Submissions, and Vault Submissions Archives. Vault RIM systems tend to address complex global environments where the "Source of Truth" is often in a number of places distributed over the globe and must be harmonized before being migrated into Vault. These migrations tend to address one or two central RIM systems, with many outliers in a variety of locations, which need to be brought together in one new "Source of Truth."

Valiance is experienced in working with global clients who often discover new sources of data during Phase 0 stages of their Vault implementation and migration projects, and must consider how to realign, to deploy the new processes they are trying to develop with Vault. The combination of migrating data (Vault Registrations) and content (Submissions and Submissions Archive) may be challenging, when implementing changes across the globe. Valiance adds significant value to Veeva and NNIT by helping clients to address these changes while moving to the new Vault environment.

02 **SECURE THE FOUNDATION**

System Architecture

During the last decade, Regulatory Affairs' individual applications have attained maturity, providing solid document management capability for EDMS systems, submission capability for eCTD systems, regulatory tracking for RIMS systems, and for labeling systems.

However, these RA systems have rarely been connected and increasingly, this challenges RA process flow and overviews. However, with new technologies, Regulatory Affairs now has an opportunity to transform its business by bringing these systems together, which may improve both compliance and operational effectiveness.

EDMS
Document management is a core imperative of all life sciences companies. Given the ever-increasing number of regulated documents, a robust and user-friendly EDMS is indispensable for efficiently preparing documents for submission or labeling.

RIMS
A modern RIM system serves to break down existing data "silos" and take advantage of synergies in process alignment and standardization by bringing planning, tracking, and reporting into a unified platform. With over 20 years of experience as a Regulatory Affairs integration partner, NNIT understands the regulatory processes and how to bring digital transformation to RA. NNIT will advise you on RA systems, data, and organization, and help you to implement a unified platform with RIMS at the core in RA.

eCTD
There is an increasing need to connect or even combine EDMS, eCTD, and Labeling systems, for both efficiency and cost control. NNIT helps to draw EDMS and eCTD closer together through smarter interfaces, or by moving to a unified platform, where the link between documents and submissions may be preserved. This improves transparency, control, and the reuse of documents.

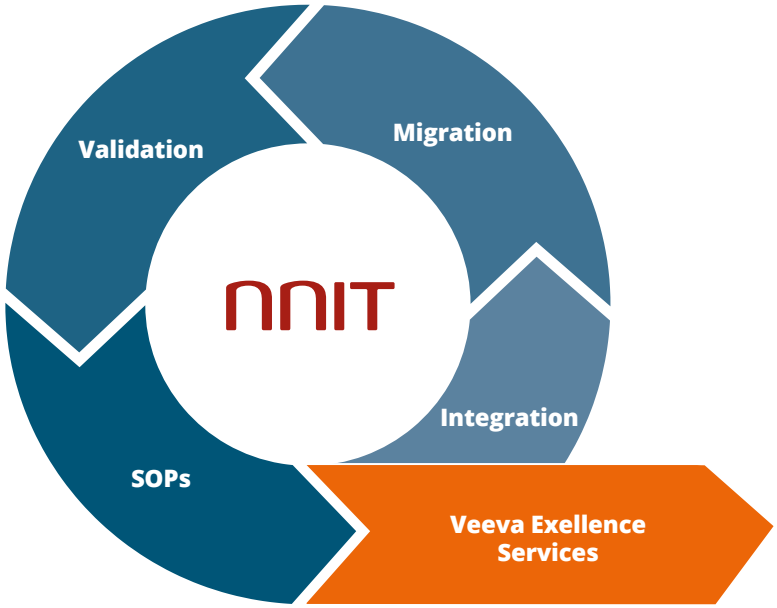
IDMP
IDMP will have a broad impact on preparing and planning submissions and maintaining data at life sciences companies; from manufacturing data and structured substance information to registration information for the life cycle of a medicinal product.

Labeling
Labeling is a complex and resource-heavy process. To support this, NNIT focuses specifically on structured labeling. By structuring content as data, changes in the data will automatically and correctly update the associated documents, eliminating the need to rewrite several documents. This significantly reduces both the risk of errors and the amount of time involved.

02 **SECURE THE FOUNDATION**

NNIT's Veeva Powerhouse for Vault RIM

Veeva Implementation Services		Veeva Excellence Services
	INTEGRATION SERVICES	
	MIGRATION SERVICES	
	VALIDATION SERVICES	
	PROFESSIONAL SERVICES	



Veeva Implementation Services

- **Integration Services:** NNIT has built more than 50 integrations to and from Veeva Vault with more than 25 of those integrations being in Veeva Vault RIM. We are able to accelerate the integration workstream with our existing assets.
- **Migration Services:** NNIT offers extensive knowledge on regulatory data standards such as IDMP, xEVMPD, SPL and the target Veeva data model.
- **Validation Services:** the NNIT validation concept supports automation in the User Acceptance Test (UAT)/Performance Qualification (PQ), guided by professionals with experience in validating a multi-tenant cloud platform.
- **Professional Services:** NNIT has a dedicated Veeva Project Management team and SMEs within Regulatory Affairs who support Business Process Optimization and Change Management & Rollout.

Veeva Exellence Services

NNIT's Veeva Exellence Services ensure continuous improvement with release management by managing the release backlog. Ensuring that the fully implemented solution is validated and compliant results in fundamental tasks to extract maximum value from the Veeva Vault.

How can Veeva & NNIT facilitate your compliance journey?

Whether you are implementing Vault RIM or adding IDMP capability to your existing RIM, the NNIT Veeva Powerhouse will help you every step of the way. We collaborate closely with Veeva, and our expertise ensures that you get full value from your Veeva Vault RIM investment.

Veeva's Vault RIM is being prepared for IDMP, and NNIT can help you manage the IDMP-related releases as part of our Veeva services. We can take you from A to Z in becoming IDMP compliant, from formulating the IDMP strategy to Veeva release management, integration, RA business knowledge, and the support of Veeva RIM and data management tools.

02 **SECURE THE FOUNDATION**

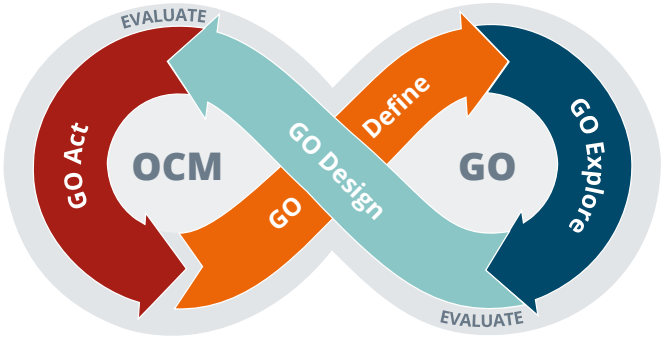
Organizational aspects

Business process re-engineering
Regulatory transformation projects often entail a change in the way we work. This naturally influences our processes and how they are executed. The advantage of this is that these transformations offer a clear-cut opportunity to improve process lead-times, whereby the RA function must strive for operational excellence to meet increasing demands with often reduced resources.

The future RIM landscape must reduce regulatory submission costs through automation and improved processes. To ensure you attain the potential advantages of business process transformation, NNIT dives deep into the current process-work, to grasp the AS-IS processes, and the connections between them. This allows us to establish a baseline and connect to the current processes and ways of working.

The TO-BE processes will be based on high-level process diagrams and act as input for the future process landscape. The changing regulatory requirements that must be complied with and the coming, mandatory IDMP data submissions make a process setup that is correctly designed from the outset crucial for providing the necessary agility and speed.

SUBMISSION PLANNING ▶ **AUTHOR & APPROVE** ▶ **ASSIGN DOCS TO SUBMISSION** ▶ **PUBLISH & SUBMIT** ▶ **ARCHIVE & VIEW** ▶ **TRACK & MANAGE LIFE CYCLE**



NNIT truly understands the complexity of driving change within life science
A deep understanding of regulated industries is a vital part of NNIT's DNA. We have developed our own OCM framework – OCM GO – that consists of four key phases. These phases are repeated iteratively during client engagements. Overall deliverables are the OCM Strategy where the key components are the Case for Change & Desired Outcomes, Stakeholder Analysis, Communications & Engagement Approach and Training Approach. For the execution of the strategy, we prepare an OCM Plan that describes the deliverables and activities needed to drive successful change for digital transformations of RA.

Even though no projects or customers are alike, we have identified some accelerators when working with OCM based on our knowledge about life sciences. For instance, we have identified what the typical Regulatory Affairs stakeholder landscape looks like for a technology-driven project like a RIM implementation or for a cross-organisational compliance-driven project like IDMP. This serves as a good starting point for interaction with our clients as we are able to hit the ground running. In addition to offering OCM implementation, we also offer general advice on OCM regardless of the drivers within our customers' organization.

02 **SECURE THE FOUNDATION**

Aura-X – Automated Regulatory Data Extraction

The global movement toward structured data submissions such as the Identification of Medicinal Products (IDMP) is founded on Regulatory data. Much of this critical data currently exists in Regulatory submission documents and supporting document collections.

Regulatory teams have begun reviewing documents such as the Summary of Product Characteristics (SmPC) and the Package Insert (PI) to extract key data and get ready for data submission requirements. These teams spend significant amounts of time manually searching, reviewing, and extracting data.

A New Approach
NNIT Aura-X is a Data Extraction solution that includes:

- AI-driven technology that automates data extraction
- Regulatory domain knowledge that is built into the technology
- Regulatory expertise that augments the technology to increase accuracy

NNIT Aura-X wraps powerful artificial intelligence (AI) with robust professional services to extract critical Regulatory data while improving speed, accuracy, and compliance.

Benefits
Aura-X provides intelligent capabilities that help organizations quickly locate, extract, and use Regulatory data that resides in unstructured format in documents.

- Frees up Regulatory resources to do more meaningful work (One hour of automated extraction is the equivalent of 50 hours of review time by an SME)
- Regulatory domain knowledge built into the tool
- Offers 98% data accuracy
- Supports 72 different languages
- Positions Regulatory teams for the future of data submissions, including IDMP
- Use cases include IDMP, xEVMPD, RIM migrations, and M&A system integrations

02 **SECURE THE FOUNDATION**

One Regulatory Intelligence

As Life Sciences teams grow and expand into new markets, they must be aware of local and regional regulatory requirements. These requirements change frequently so teams have the added burden of identifying the changes and assessing the impact to their current operations. This complex task requires rigor and diligence.

Automation and Expertise

NNIT views this business challenge as requiring a solution that includes automation and expertise. One without the other, will not allow organizations to realize their potential. That's why NNIT developed our Regulatory Intelligence Solution.

Our cross-functional team of Regulatory Affairs Consultants, Power Platform Developers, Migration Specialists, and AI Data Scientists use artificial intelligence (AI) and the Microsoft Power Platform to offer a Regulatory Intelligence Solution that helps Life Sciences teams CAPTURE, CURATE, and ACCESS global and local requirements.

NNIT's Regulatory Intelligence Solution

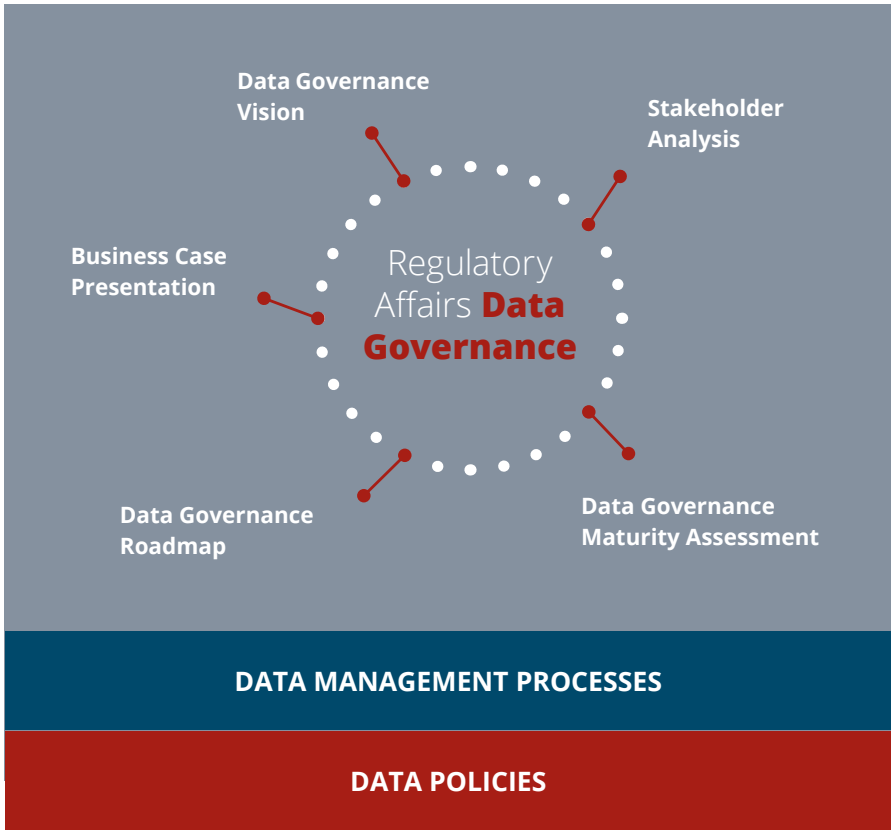
The NNIT Regulatory Intelligence Solution offers:

- A single source of truth that incorporates requirements and lessons learned in one global database
- Timely updates that are automatically delivered to team desktops for review and implementation without extensive efforts to manually identify and track
- Broader access to more timely requirements information
- Automated workflows that are integrated with other Microsoft Applications, MS Teams
- Improved data quality based on user permissions, audit history, version control, and other compliance controls
- Phased implementation that addresses quick wins early to speed adoption across the organization

03 **USE YOUR DATA**

Ensure appropriate data governance

A key element of NNIT's Data Management framework is **Data Governance**, which provides the guidance that ensures that data are accurate and consistent to meet business goals.



Data governance implementation framework

There are three key steps to implementing data governance.

ORGANIZATIONAL STRUCTURE → **OPERATIONAL PLAN** → **PROCESS & DECISION-MAKING**

The **organizational structure** covers the establishment of data governance structure to ensure representative groups at leadership, implementation and execution and end user levels have authority to make collective decisions.

The **operational plan** covers how the work of data governance will be developed after the initial steps of its implementation and the transition to the execution phase has been completed.

Once the initial transition to the execution phase has occurred and the operational data governance structure has been established, the data governance committee will begin planning as required, to fully establish the **processes and decisions** necessary for actual data management.

03 **USE YOUR DATA**

IDMP – build data-driven submissions

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 your organization 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

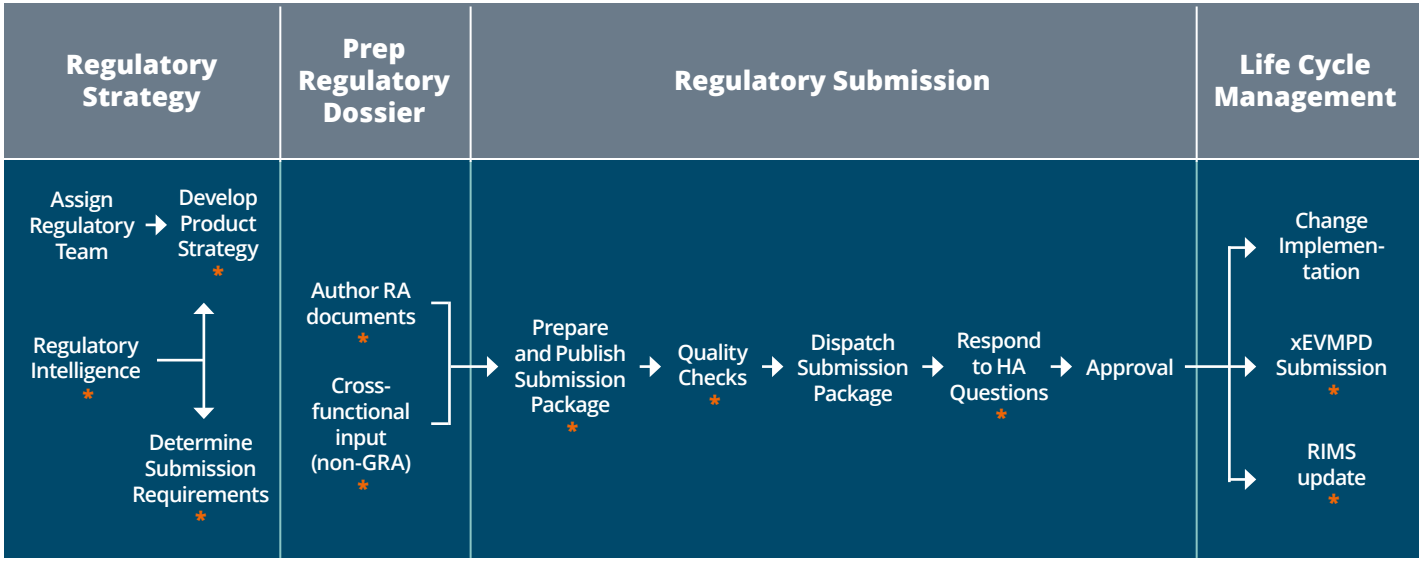
03 **USE YOUR DATA**

IDMP – Business Processes & SOPs

How does IDMP affect processes within Regulatory Affairs?

Detailed efficiencies expected from 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	AS-IS to TO-BE	SOPs and WIs
• Updates from the regulators • Advice on industry practices • Insight into dependencies such as CTIS, FMD • On-demand IDMP consultation	• AS-IS process map, including dependent processes • IDMP impact assessment • Set of decisions and actions to be made • TO-BE process design subject to decisions and actions made	• Recommendations for approaches to updating SOPs and WIs • Final draft SOPs and WIs for review and approval


“We have advisory and implementation experts with both technical and business skills”
NNIT Regulatory Affairs

04 **LIGHT THE DIGITAL INNOVATION**

What is Regulatory Affairs Digital Transformation?

Many RA departments wish to transform their business through new technology, such as AWS, MS, PowerBI, and Leapwork, and to reap the benefits of innovation and IT optimization. The challenges are how this is governed and how to define the roadmap for this transformation.

NNIT can drive your RA digital transformation journey by defining key business challenges and then determining how to best utilize technology to realize use cases for **Automation**, **Robotics**, **Artificial Intelligence** (AI), and **Machine Learning** (ML).

Improve operational efficiency
Technological advancements enable efficient processes through automation – e.g. for submission-generation and dossier compilation – which drives operational excellence, especially for life cycle management activities.

Improve response searches
AI/robotics can allow RA to conduct intelligent searches of previous responses to questions from Health Authorities (Gens & Associates)

Visualize data
Maximize the use of data in decision-making processes by streamlining the use of Power BI, e.g. for Regulatory Operations KPI dashboards.

Reduce manual labor and improve efficiency
Automating manual activities in RA can greatly improve operational efficiency and free up resources for development. Example use cases are notifications for renewals, adverse events alerts, data entry in systems and automatic data extracts from Excel to a database.

Improve quality and compliance
Automation can improve document upload and quality control, and the validation of RA systems.

Data Management
Data can support fast, valuable insights and facilitate intelligent forecasting and timely decision-making – also in RA. A solid foundation, with suitable governance, management, quality, and metadata, is key to apply useful data intelligence or analytics.

Knowledge management & affiliate collaboration
Automation can facilitate faster and better knowledge management, for example, sharing local country requirements between affiliates and HQ.

Improve transparency & compliance
Facilitate advanced reporting and decision-making by ensuring a controlled process that applies RPA technologies to make certain that every action performed is tracked.

Data that drive regulatory intelligence
Advanced analytics, ML, and AI unlock data potential like never before, but require solid master data management and governance.

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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.

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

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We make a mark