

Regulatory Data and Information Management

Are you extracting maximum operational and strategic value from your RIM Processes and Systems?

Benefits

Optimized and Harmonized Regulatory Data and Information Management:

- Harmonized processes and systems which are Compliant and support the expanded scope of the latest regulations
- Processes and governance understood by all; inspection ready
- Improved oversight due to meaningful, accurate, and timely metrics and KPIs
- Operationally efficient – minimal rework, supports cross-functional and cross-geography collaboration
- Generates strategic value for the rest of the organization, beyond compliance
- Supports IDMP readiness

Ineffective management of regulatory data and information leads to many challenges in managing the lifecycle of product information and maintain a 'single version of truth'. This results in loss of productivity, rework, increased cycle times, non-compliance and inability to harness the strategic value which resides within our regulatory information, to better inform our regulatory and development strategies and stay competitive.

Navitas Life Sciences provides an integrated approach leading to impactful results

Phase I Rapid Assessment

Process and data mapping to understand current gaps in processes, data and system landscape

Governance fit-for-purpose assessment: process governance, data governance and system governance

Industry validated RIM Maturity Model looking at: Process, Governance, Data, Technology and Culture

Phase II Implementation of priority recommendations

Support to redesign and implement process, system and governance recommendations

Streamline data flows, maximize re-use and minimize re-entering of data
Optimize integration between disparate systems, connecting feeder and consumer systems, minimize point solutions

- Leveraging our insights from our Regulatory networks **rimnet** and **labelnet**

Deliverables

- Detailed mapping of data flow and process flow
- Integrated system architecture designed to support, not dictate, desired data and process flow
- Governance structure for process, data and systems
- Overall technology vision and roadmap
 - Detailed implementation plan
 - Rollout and training plans
 - Metrics and KPI to measure performance

About Navitas Life Sciences

As a partner for the industry, Navitas Life Sciences leverages industry insights, consulting and technology capabilities to deliver full service clinical, regulatory and safety solutions and desired outcomes to clients. As the dedicated life sciences brand of TAKE Solutions, Navitas harnesses the combined knowledge and experience of three legacy brands—Ecron Acunova, Navitas, and Intelent—to provide end-to-end services and solutions. Navitas helps clients address their most critical problems by bringing together the capabilities of a full-service CRO, a technology-led life sciences services provider across clinical, regulatory and safety, and a life sciences big data services and analytics provider. Operating from 7 countries across the globe, Navitas works with over 150 customers in Life Sciences.

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A TAKE Solutions Enterprise