Insight Brief

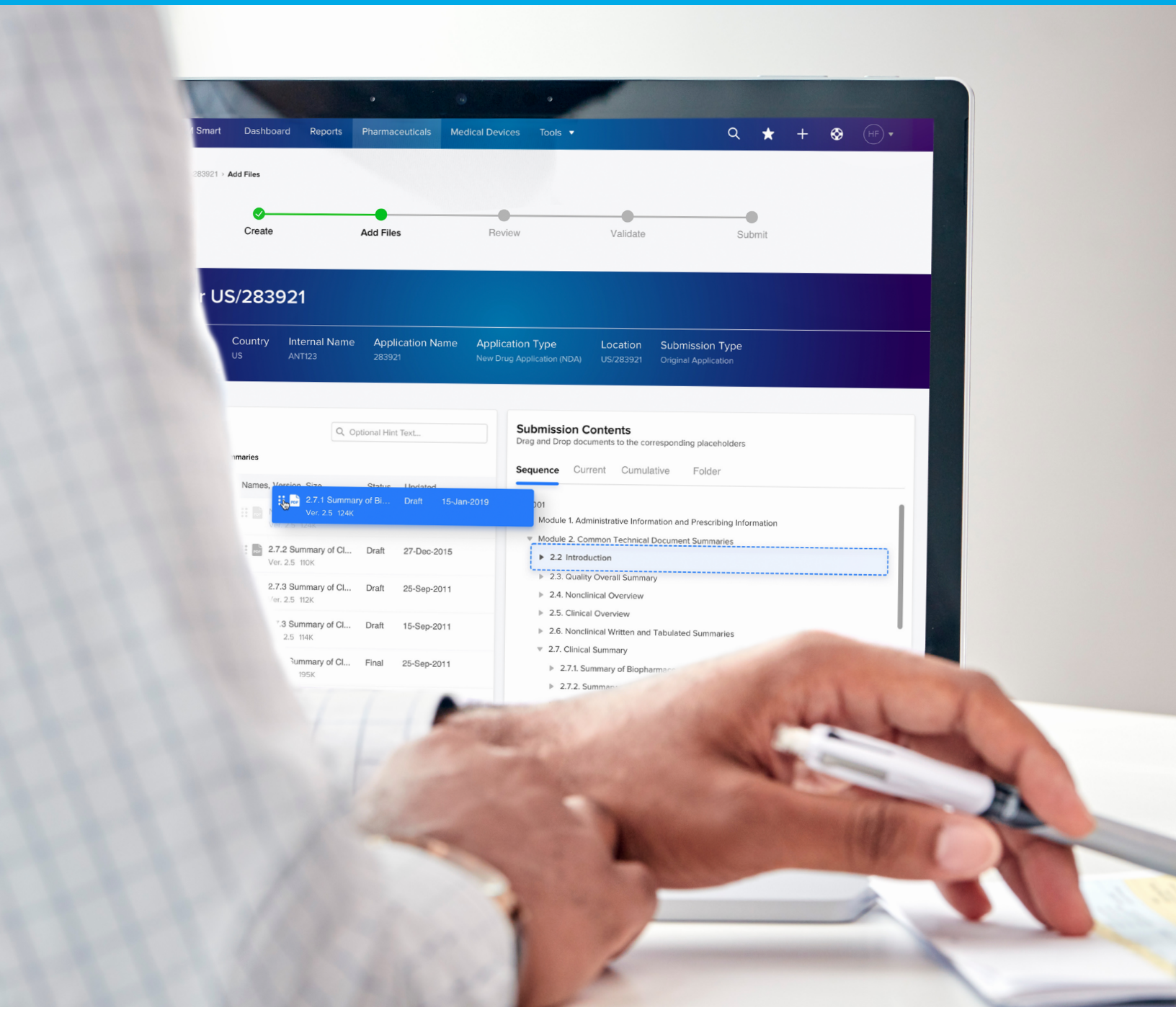
Meet the Challenges of Regulatory Information Management

IQVIA

Take your RIM knowledge to the next level

Richard D'Mello, PhD
Sr. Director, Commercial Strategy and Operations, IQVIA Integrated Global Compliance

Shylendra Kumar
Director, Product Offering and Development, IQVIA, Technology Solutions



Regulatory information management (RIM) has always been an essential but burdensome function within the life sciences industry. Managing product information and keeping up with submissions, often to multiple regulatory agencies, is repetitive and time-consuming work. The explosion of novel products, new data and changing regulatory requirements across multiple geographies is adding new complexities to these tasks, making it difficult for regulatory departments to stay current.

In the past 22 years, the US Food and Drug Administration alone has released more than 2,000 new or modified regulations while in the past two years, China has exceeded that number. Keeping up-to-date with the evolving global regulatory landscape is a constant challenge that is putting a strain on regulatory teams. In large life sciences companies, regulatory departments often have hundreds of staff who spend more than half of their time completing important but low-level manual tasks.

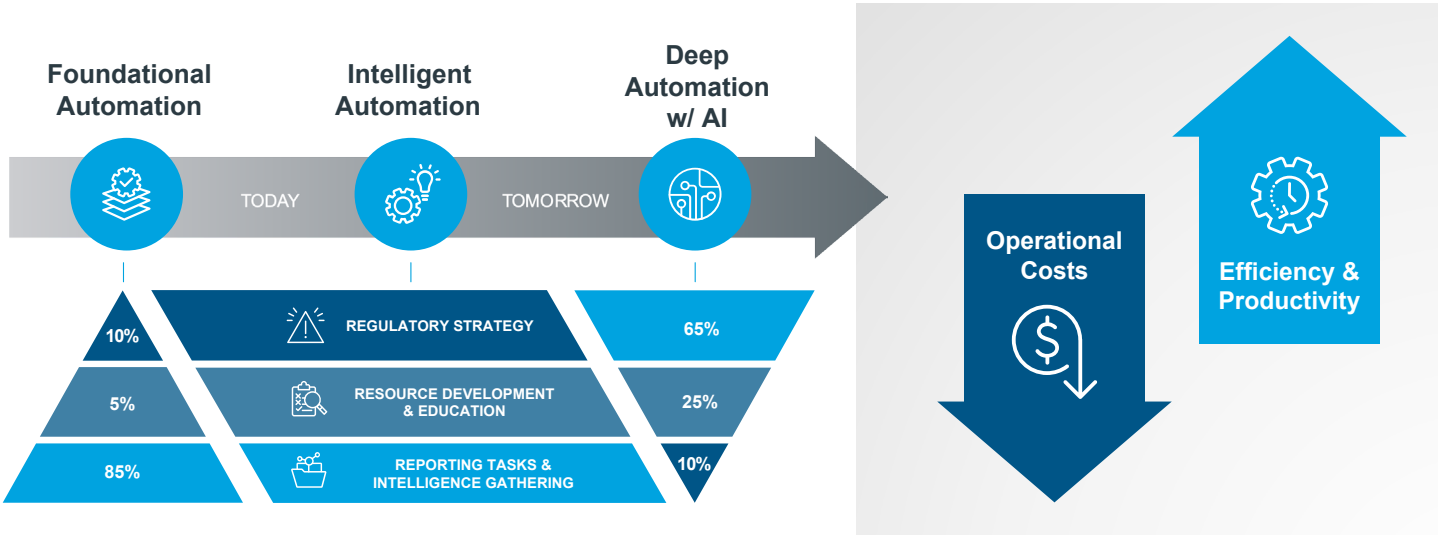
The complexity and quantity of work is not going away but is in fact increasing, which means life sciences companies have to change how they handle regulatory information management. They need more efficient tools to manage these steps, and many are turning to regulatory information management (RIM) technology as the solution.

RIM technology dramatically reduces the time and cost associated with achieving compliance.

One of the key benefits of this technology is that it automates many of the manual aspects of regulatory information management. The most advanced systems are able to automatically capture compliance-related data from across multiple business units and databases, then organize and analyze it for easy access and review. This dramatically reduces the time regulatory professionals spend overseeing these tasks, while reducing the time and cost associated with achieving compliance.

Technology not only accelerates the entire planning and submission process, it also increases data accuracy as well as regulatory team productivity, allowing regulatory staff to focus more on value-added, strategic activities.

Figure 1: Automation drives regulatory management transformation



RIM digital transformation

The RIM software marketplace has been steadily evolving to meet the needs of overburdened regulatory teams for years. The latest iterations of these systems are beginning to leverage artificial intelligence (AI) and machine learning (ML) to reduce the need for human intervention and expand their capabilities across the regulatory lifecycle.

However, many life sciences companies still rely largely on manual workflows, or piecemeal RIM tools that may solve individual reporting tasks but fail to provide a coherent workflow across all information management activities.

In the least mature organizations, compliance data is captured in spreadsheets and through shared files that may only be accessible to a handful of individuals – who are unlikely to be data management experts. This creates the potential for data to be lost or mishandled and can create gaps in information that may not be discovered until the data is requested by regulators.

In some cases, companies may not even realize they need to maintain certain data until they attempt to file a New Drug Application (NDA). If it isn't available, it can set them back months as they attempt to capture or recreate the necessary information after the fact.

More mature companies have implemented point solutions that capture data and complete certain regulatory tasks within a specific department or category. Deploying these tools can be a useful first step towards transitioning to a more automated RIM workflow. However, if the individual point solutions aren't designed to work collaboratively or to share data, it creates silos of data, which can reduce efficiencies, increase the risk of errors, and make it difficult to scale.

Figure 2: Regulatory intelligence proactively drives RIM automation

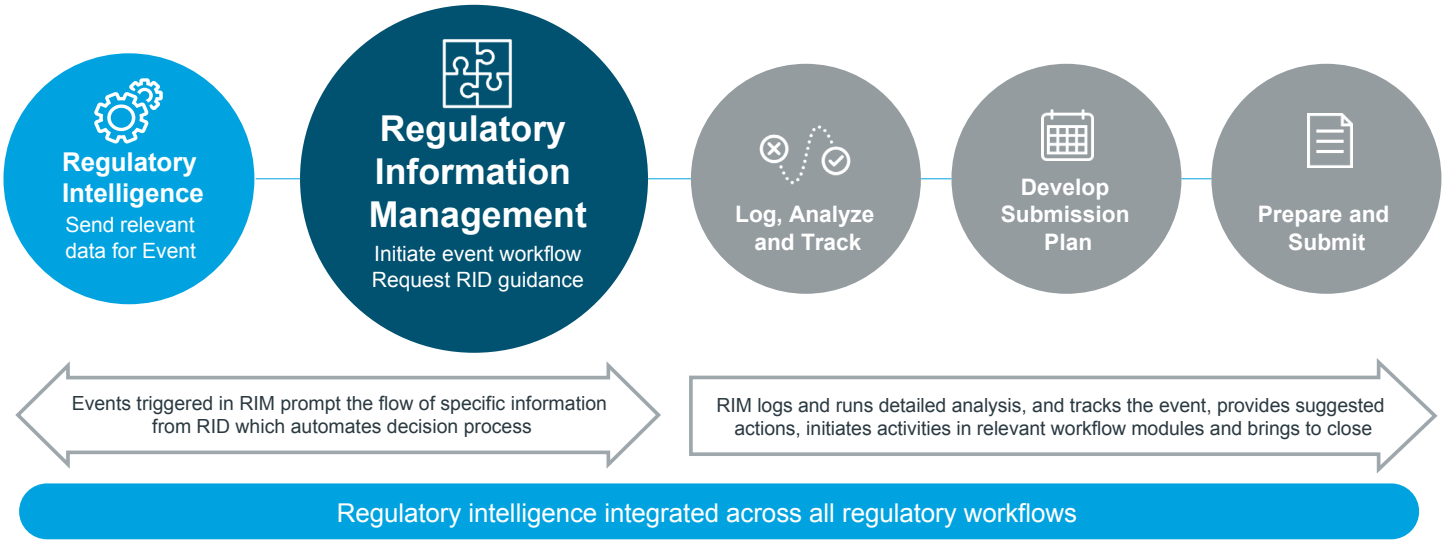
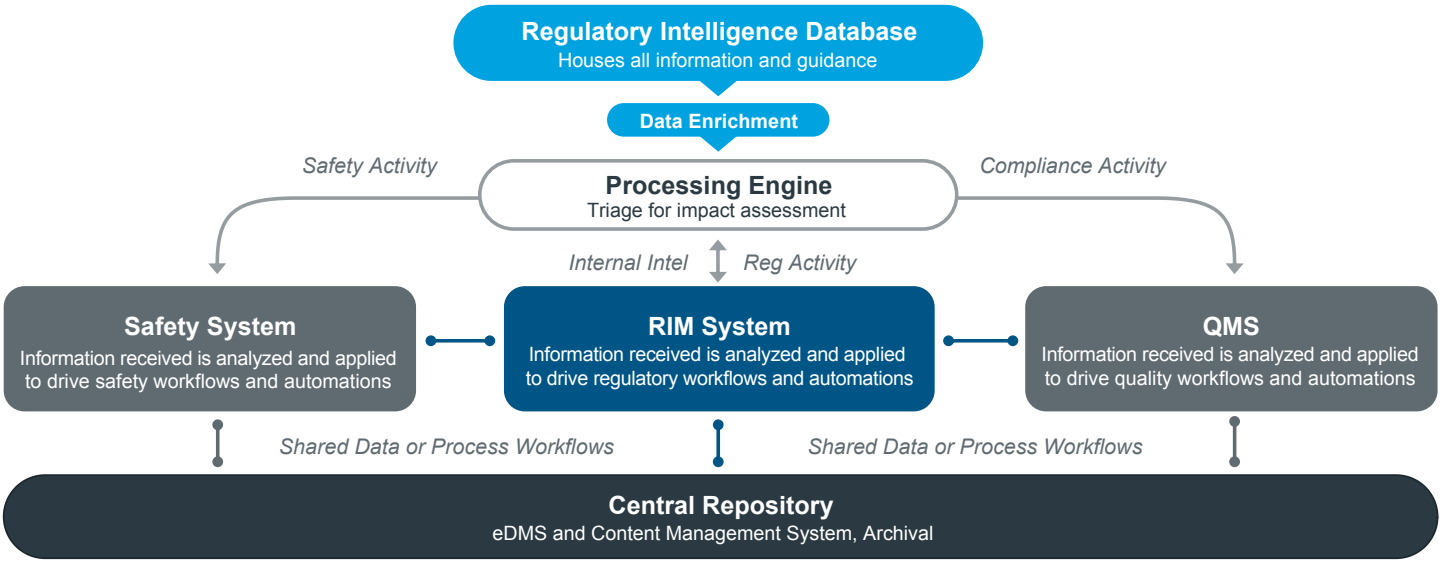


Figure 3: Building bridges within organizations by using existing technology more efficiently



A RIM system integrated across regulatory functions boosts speed and efficiency while reducing the risk of common mistakes that can occur with other approaches. For example, it is not uncommon for a submission to be ready to go to regulatory agencies, only to have a last-minute change made to the document. Pages may be added or deleted, or there may be a change to a single sentence or word.

Many regulatory departments have deployed RIM systems, but not all RIM systems are created alike.

With more traditional approaches to information management, changes may be missed, or conflicting documents can result in added delays. But end-to-end RIM systems have built-in intelligence that can scan the entire data environment, to identify the necessary changes in the revised document, and automatically migrate links and bookmarks from the previous version. This saves time and makes it possible to finalize the revised submission, publish it, and send it to reviewers for approval in a matter of minutes.

Such seamless cross-functionality and automation is achieved through two innovative developments in RIM software. The first is the use of a common central document and content management repository, accessible by every module in the RIM solution. When a software system stores all regulatory data in a single centralized repository, every time a regulatory task is required, content is pulled from the same data source, and once the task is completed the finalized content is archived back into the repository. This ensures every task is based on the most up-to-date information available.

The second development involves employing automated regulatory intelligence, which sends the data through a processing engine that leverages artificial intelligence (AI) and natural language processing (NLP) to automatically assess the impact of changes, determine outcomes, and route information to the relevant destination. In the most advanced solutions, and when appropriate, the processing engine can even initiate activities and workflows.

The right RIM system for you

When organizations are considering which RIM solution to deploy, decision-makers should look for a system that can adapt to their current regulatory needs while also offering intelligent automation tools to streamline tasks and eliminate redundancy.

The most advanced platforms can automate tasks across the workflow, including:

- **Correspondence and commitments**:
  When health authorities make requests or provide comments, an automated system should be able to quickly respond with appropriate data or materials, then archive and track all communications for future review.
- **Submission planning**:
  The software should be able to prepare submissions, manage the workflow, and provide tools for dossier planning, and resource and time management.
- **Publishing and validation**:
  It should provide flexible tools to create, edit and validate submissions using electronic Common Technical Documents (eCTD), Non-eCTD electronic Submissions (NeeS) and paper submissions.
- **Product and registration tracking**:
  It should also offer universal, portfolio-wide multi-level tracking, reporting capabilities to accommodate any regulatory submission requirement across geographies and therapy areas.
- **Intelligent automation of labeling**:
  This will be able to utilize structured content authoring, automated comparisons, collaborative authoring and review, change request and deviation management to provide a ‘content-to-carton’ solution.

The best solutions will also meet all of the most up-to-date, country-level reporting requirements to align with the creation of compliant, submission-ready content that is synchronized with master data management (MDM).

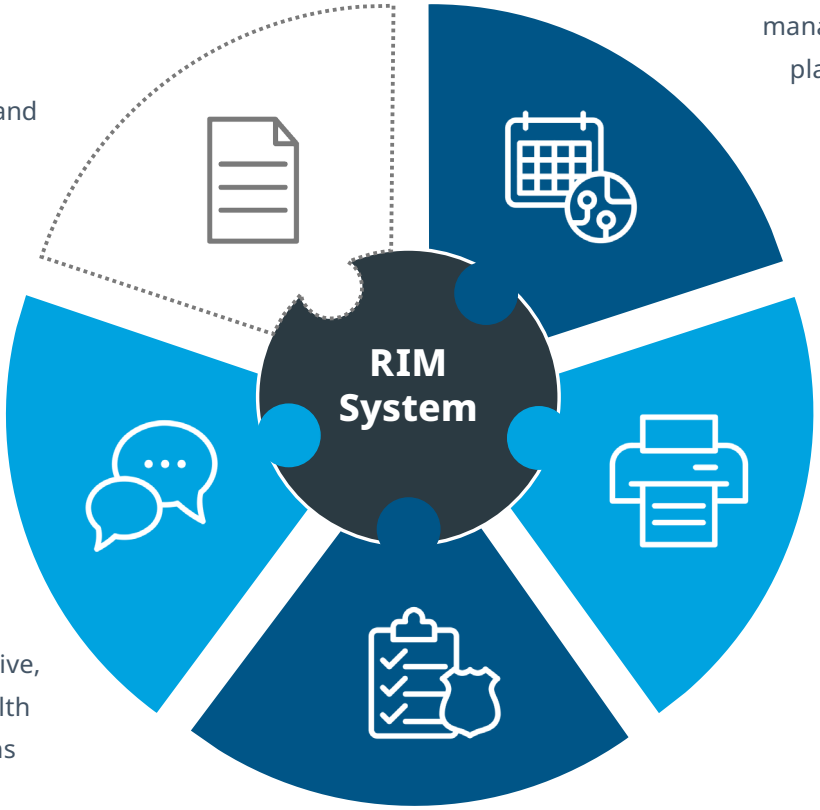
While end-to-end RIM solutions may seem complex, the benefits are clear and immediate. We regularly see companies experience measurable time and cost savings within weeks of deploying our RIM Smart solution. For example, we recently worked with a fast-growing biotech company that had previously been relying on outsourcing point solutions and spreadsheets to manage compliance data and reporting for its two marketed products. To manage this small but growing portfolio, the regulatory team had to manually organize seven separate tracking hierarchies of products, indications, countries and clinical trials.

Once they deployed RIM Smart they saw significant cost savings through the elimination of multiple development, validation and production servers. They also eliminated redundant tasks, reduced on-boarding time for new regulatory staff from one week to one day, and saw improvements in knowledge management and talent development across these teams.

Figure 4: IQVIA RIM Smart modules

Labeling
"Content-to-carton" transparency, utilizing component authoring, automated comparisons and deviation management

Submission Planning
Preparation, workflow, management tools for dossier planning and resource/time management



Correspondence & Commitments
Quickly, efficiently e-archive, track and respond to health authority communications

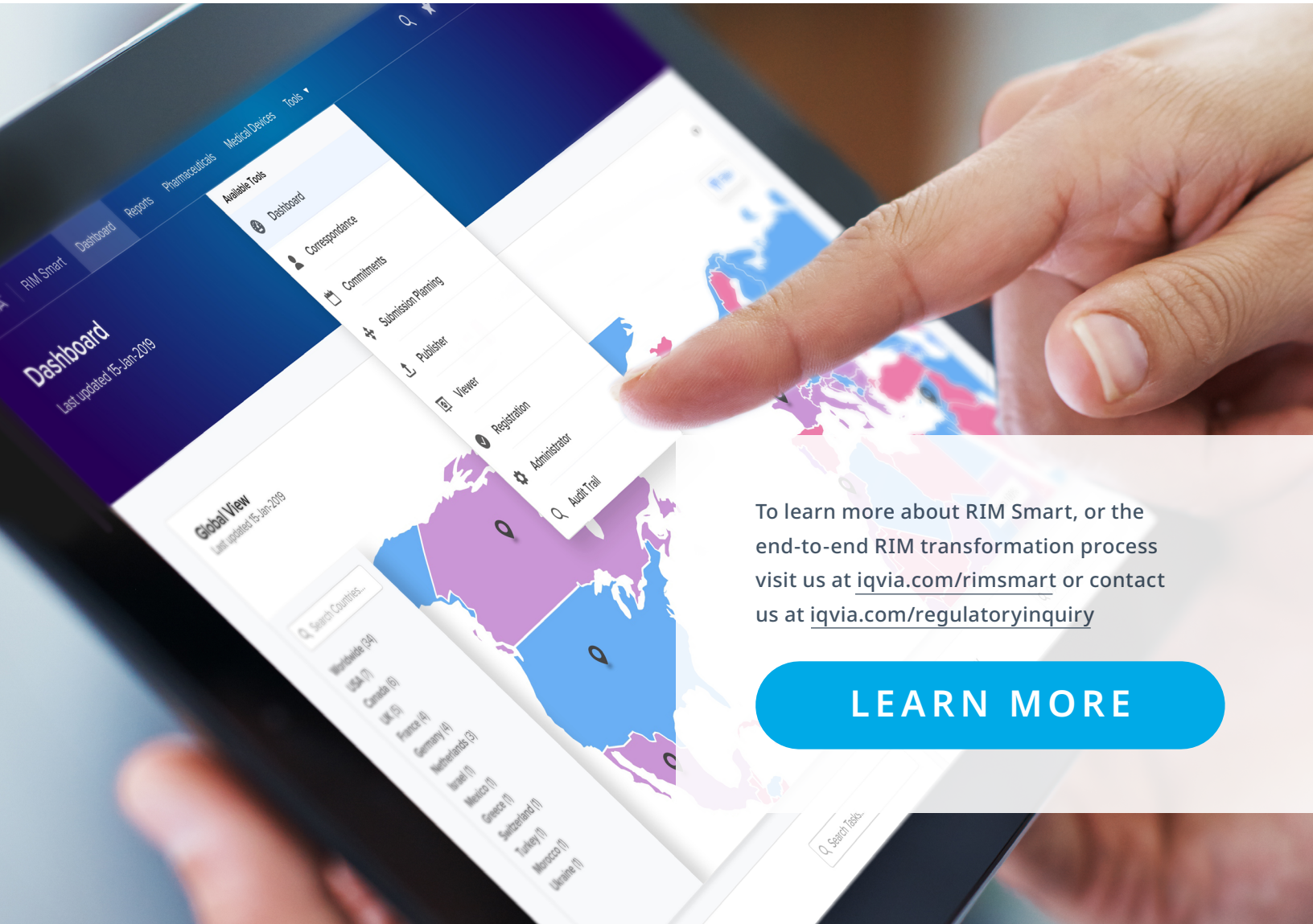
Publishing & Validation
Create, edit and validate eCTD, NeeS and paper submissions

Product & Registration Tracking
Universal, portfolio-wide multi-level tracking, reporting capabilities

Conclusion

Along with significant time and cost savings, end-to-end RIM solutions deliver greater agility in terms of handling regulatory activities. They make it possible to respond more quickly to requests from regulatory agencies across the globe, ensuring consistency and quality in every regulatory exchange, from early clinical development through end of market life.

The transition doesn't have to be overly disruptive. When companies choose end-to-end RIM technology, they can easily transition their regulatory tasks to a single automated environment, regardless of where they are in the transformation process. Whether they choose to start with one or several modules, or the entire solution, each step will generate measurable time and financial savings. They can scale the solution on their own timeline, according to their needs, knowing that each of these tools will work in concert even with other third-party software, with little customization required.



To learn more about RIM Smart, or the end-to-end RIM transformation process visit us at iqvia.com/rimsmart or contact us at iqvia.com/regulatoryinquiry

LEARN MORE

Authors' biographies

SHYLENDRA KUMAR,
Director, Product Offering and Development, IQVIA Technology Solutions

As Director of Product Offering and Development, Shylendra Kumar is responsible for leading the design, development and delivery of regulatory technology solutions for IQVIA. He focuses specifically on strategic, innovative solutions that drive efficiency through intelligence and automation.

Kumar received his MPH (Epidemiology and Biostatics) degree from Boston University and an MA (Social Sciences) degree from Bangalore University.

RICHARD D'MELLO,
Sr. Director, Commercial Strategy and Operations, IQVIA Integrated Global Compliance

As Senior Commercial Strategy and Operations Director for IQVIA Integrated Global Compliance, Richard D'Mello is responsible for driving the growth of IQVIA's Safety, Regulatory, Quality and Commercial Compliance business. This includes establishing and governing strategic initiatives and identifying innovative technology and services solutions that meet the needs of customers.

D'Mello obtained his PhD in Neuroscience from University College London and a Bachelor of Science (Hons) in Biomedical Science from King's College London.

CONTACT US
4820 Emperor Boulevard
Durham,
NC 27703
United States
iqvia.com/rimsmart