FACT SHEET

RIM Smart Submission Management

Intelligence. Automation. Integration.

The ever-dynamic global biopharmaceutical regulatory operations landscape exerts increased pressure on sponsor companies to optimize and maximize product approval success rates and timelines.

Situation

Rising costs, evolving regulatory mandates, guidelines, and expectations drive organizations to implement better tools and technologies. These innovations enable teams to prepare submission dossiers more efficiently while ensuring full compliance with the applicable requirements of the regional health authorities.

Our solution

RIM Smart Submission Management, part of IQVIA's end-to-end Regulatory Information Management (RIM) solution, provides the industry's most advanced solution for **managing Pharmaceutical and Medical Device regulatory product registration activities globally**. RIM Smart delivers a single, fully integrated, extensible solution developed on cloud architecture to ensure scalable, effective and compliant management of regulatory applications, positioning organizations to complete regulatory activities more efficiently and cost-effectively.

With RIM Smart Submission Management, organizations can **efficiently assess, plan, forecast and coordinate the end-to-end processes** involved in assembling, publishing and dispatching regulatory dossiers to international health authorities within a single integrated platform.

RIM SMART SUBMISSION MANAGEMENT

Built with IQVIA's deep industry knowledge and experience, led by a large team of professionals with practical business and technology competence

Supports the entire regulatory submission management lifecycle, from early investigational stages to marketing and post-approval activities

Enables full transparency of actions, data in-use and project timelines across all involved regulatory groups

Supports all mandatory pharma (eCTD, NeeS) and MedTech (eCopy) submission formats

Intuitive and easy to use, enabling efficient tasks completion with familiar tools and functions throughout the system

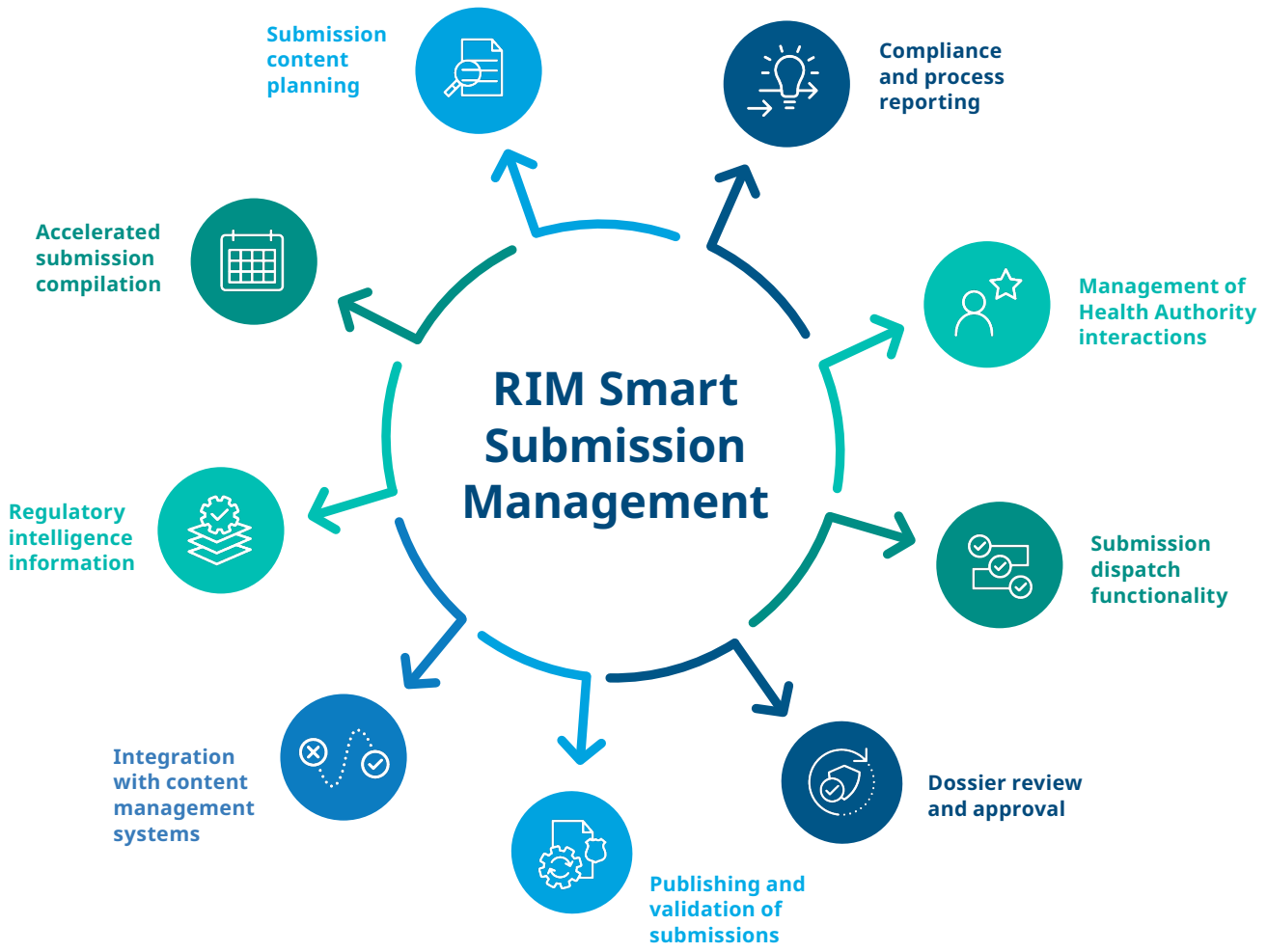
Drives operational efficiency enabling re-use of integrated PDF tools across workstreams, countries and regions

RIM Smart improves submission production efficiency/productivity and shortens the time to approval.

Key capabilities

- **Global forecasting, planning and tracking** of regulatory submission activities
- **Submission content planning**, including task assignments and scheduling
- **Accelerated submission compilation** via automated content plan-to-submission sequence building
- **Embedded access to regulatory intelligence information**, including country-level reporting requirements
- **Publishing and validation of submissions** based on current regional and international regulations and standards
- **Integrated dossier review and approval functionality**, including peer comments and communications
- **Complete management of Health Authority interactions**, including correspondence and commitment tracking
- **Integration with multiple content** and document **management systems**
- **Efficient submission dispatch functionality** via integrated business-to-business gateway
- **Compliance and process reporting**, including dashboards

RIM Smart Submission Management allows teams to get safe and effective products to market faster, and keep them there.



A fully automated, technology-led, intelligent management of the complete regulatory lifecycle.

Our Vision

IQVIA's vision and solutions focus on **intelligent simplification and automation** of complex business processes enabling Life Science organizations to spend more time on **value-adding activities** and less on operations. RIM Smart Submission Management is a vital component of this vision, which is **built upon three core foundations:**

CONNECTED INTELLIGENCE	RIM Smart Submission Management immerses users within an environment to provide complete awareness with actionable insights that are never more than one click away.
END-TO-END FUNCTIONALITY AND INTEGRATION	RIM Smart Submission Management provides customers with best-in-class electronic dossier compilation, publishing and validation capabilities, advanced planning and tracking features, and business process automation functionality to eliminate repetitive tasks and enable faster, more efficient, and compliant regulatory applications.
REGULATORY INSIGHT	RIM Smart Submission Management uncovers strategic, regulatory and compliance updates in real-time; actively monitoring and alerting users to changes or emerging trends.

Delivering sustainable business improvement requires more than technology. IQVIA also offers **transformational consulting services** to define and implement **smarter ways of working**, **reduce workload and cycle times**, and maintain exceptional quality.

IQVIA TECHNOLOGIES

2400 Ellis Road | Durham | NC 27703 | United States
RegulatoryTechnology@iqvia.com
iqvia.com/contactus