

# From Fragmentation to Global Control: Global Regulatory Affairs, Simplified

Powered by *SmartSolve*<sup>®</sup> RIM

## The challenge

- Fragmented submissions, variations, and registrations across markets
- Limited visibility across dossiers, HA interactions, and commitments
- Duplicate data across eCTD, labeling, and registration systems
- Disconnected tools increase compliance and inspection risk

## A better way forward

### SmartSolve<sup>®</sup> RIM

*A unified, AI-enabled RIM platform to streamline submissions, ensure data integrity, and scale globally*

### What you gain



#### Trusted data

Single source of truth for registrations, dossiers (eCTD), and labeling



#### Seamless execution

Manage IND/CTA through post-approval variations with full traceability



#### Built-in compliance

Visibility into HA interactions, submission history, and commitments



#### Actionable insight

Track status, timelines, and risks across markets

## The impact

- Reduce regulatory risk across submissions, variations, and HA interactions
- Strengthen inspection readiness with traceability and audit trails
- Improve data integrity across dossiers, registrations, and labeling
- Accelerate global execution across markets and evolving requirements (IDMP/SPOR)

**About SmartSolve<sup>®</sup>:** SmartSolve is an AI-enabled, Microsoft Azure-based platform that helps Life Sciences organizations streamline and automate global quality management and regulatory compliance.

**SmartSolve<sup>®</sup> eQMS** centralizes enterprise-wide quality processes, from design and manufacturing to post-market surveillance, while **SmartSolve<sup>®</sup> RIM** manages regulatory submissions, product registrations, and health authority interactions. Built on industry best practices, SmartSolve connects teams, data, and workflows in a single platform to drive an optimized focus on patient safety, product quality and commercial performance.

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