



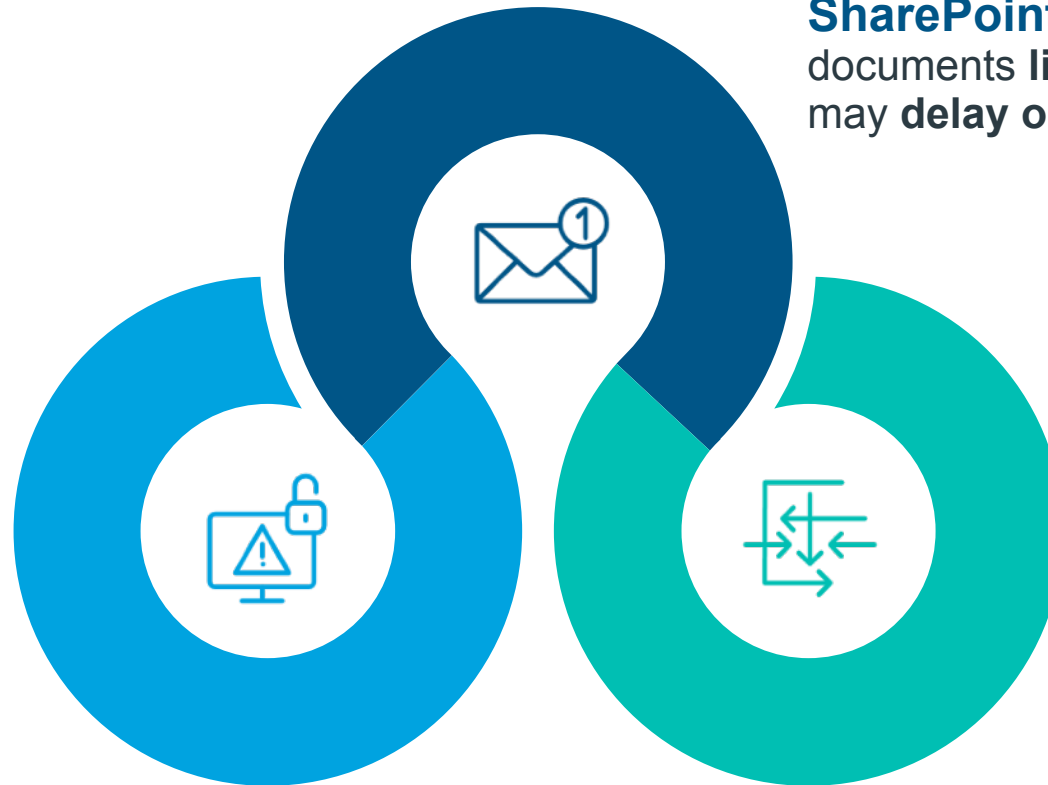
# **IQVIA RIM Smart Content Management**

*Collaboratively plan, author,  
review, and approve regulatory  
submission content*



# Content management challenges hinder quality of submissions

**Manual document management**, including reconciliation of renditions and relationships, is **inefficient** and may pose **compliance risks**



Using simple file share and **SharePoint solutions** to manage documents **limits collaboration** and may **delay outcomes**

**Poor synergy with publishing and labeling** may **duplicate efforts**, **increase costs**, and **complicate translations**



# Safe harbor statement

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# RIM smart content management is a modern, cloud content management solution

**Reduce costs, waste, and delays** from errors in content and submission production



**Foster collaboration** among colleagues to create higher-quality content efficiently



**Provide instant visibility** into progress with submission content, enabling proactive management



**Deliver peace of mind** by adhering to industry standards and ensuring GXP compliance



# Optimize regulatory deliverables with a modular workflow management solution using IQVIA RIM Smart

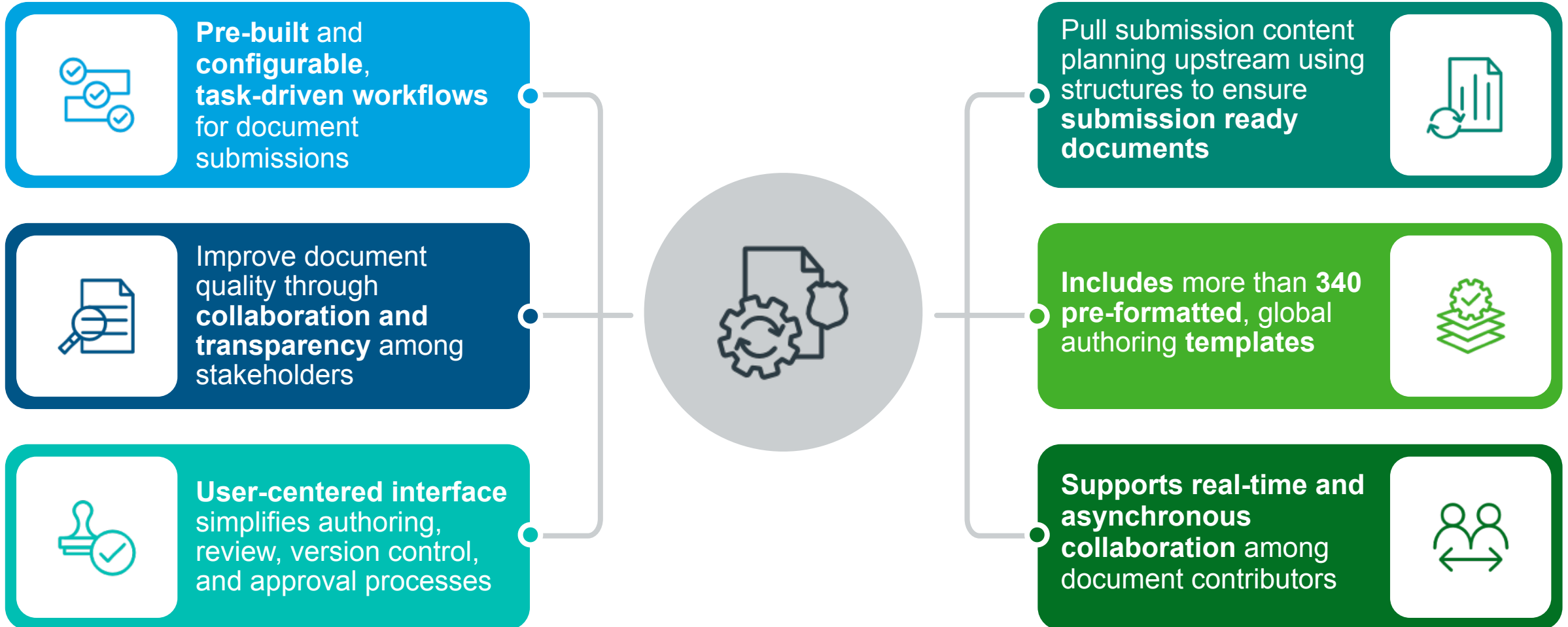


# Introducing IQVIA RIM smart content management

The screenshot displays the IQVIA RIM smart content management interface. The top navigation bar includes 'RIM Smart', 'Main', 'Requests', 'Tasks', 'Documents', 'Workflows', 'Reports', 'Dashboards', 'Audit Trail', and 'Administration'. The main area is titled 'Active Workflows (24)' and features a grid of workflow cards. A context menu is open over one of the cards, showing options: 'Edit', 'View Details', 'Put On Hold', 'Withdraw', and 'Notify Participants'. Below the workflow grid, there is a section for 'All Objects in Progress' with a table of documents. To the right, a 'My Task (4)' sidebar shows a list of tasks with due dates and status indicators.

Document Name	Version	Product	Document Status	Favorite
Company Core Data Sheets		IQVIATUM	Draft	☆
Annex II - Application 07082022		IQVIATUM	Draft	☆
N12-Company Core Data Sheet (for PSURs) -		IQVIATUM	Draft	☆
Company Core Data Sheets		DECAMETHONIUM IODIDE	Draft	☆
Annex II - Application 02207082		DECAMETHONIUM IODIDE	Draft	☆
N12-Company Core Data Sheet (for PSURs) -		ACLARUBICIN HYDROCHLORIDE	Draft	☆
Company Core Data Sheets		ACLARUBICIN HYDROCHLORIDE	Draft	☆

# Foster collaboration on high-quality regulatory documents



# Content management that supports submission publishing

Improve content consistency with more than **340 pre-formatted, authoring templates**

Pull submission content planning upstream using **structures to plan submission content**

**Auto classify** documents during creation for easy alignment to a **CTD structure**



Create **submission-ready PDF** renditions and **Where Used Reports** to improve efficiency

Strive for greater **document re-use** across regions and for **eCTD 4.0 enablement**

Use **regulatory and product data** to simplify and automate **submission publishing**



# Navigate document details using an intuitive interface

The screenshot displays the IQVIA software interface for document management. The top navigation bar includes 'RIM Smart', 'Main', 'Tasks', 'Workflows', 'Documents', 'Reports', 'Dashboards', 'Audit Trail', and 'Administration'. The main content area shows a document titled 'Regional Summary for Tylenol 4.1 mg' with a version of 'v 0.5' and a 'Draft' status. Below this, a table provides key document attributes:

Collection	Group	Document Type	Market	Current Version	Latest Version	Owner
Quality	Quality Overall Summ...	Regional Summary	GLOBAL	0.5	0.5	Gemma Vidal

The 'Details' section is expanded, showing a sidebar with options: Preview, Details (selected), Workflow, Versions, Relationship, Rendition, Permissions, Audit Trail, and Timeline. The 'Details' view includes sections for 'Document Classification', 'Regional Information', and 'Product Related Information'.

**Document Classification**

Collection *	Group *	Document Type *
Quality	Quality Overall Summary - Regional	Regional Summary

**Regional Information**

Market *	Country List	Language(s) *	CTD Section	File Tag	Module
GLOBAL	GLOBAL	English	2.3.R Regional Information	regional-information	Module 3

**Product Related Information**

Global Product: Tylenol 4.1 mg

Type	Generic Name	Therapeutic Area	Indication	Product Family
Global	Tylenol 4.1	Infections and Infectious Dis...	Depression	Anxiety disorder

Access all information about documents in one location

- Details
- Workflows
- Versions
- Relationships
- Renditions
- Permissions
- Audit trail and timeline

# Foster real-time and synchronous document collaboration

The screenshot displays the IQVIA RIM Smart interface for document collaboration. The document is titled "2.3 Introduction" and is currently in a "Working Copy" state. The document content includes a header with "ApplicantName" and "ProductName", a section title "2.3 INTRODUCTION", and a red placeholder text "[Enter text, Delete instructions and guidance notes]". Below this, there are two paragraphs of text. The interface also features a sidebar with navigation options like "Preview", "Details", "Workflow", "Versions", "Relationship", "Rendition", "Permissions", "Audit Trail", and "Timeline". The top navigation bar includes "RIM Smart", "Main", "Tasks", "Workflows", "Reports", "Dashboards", "Audit Trail", "Administration", "Documents", and "Labeling Requests".

- Present content in a feature-rich PDF viewer
- Document classification, full product metadata, and regional market info
- Predefine, create, name, and share document views
- Modify layouts and search documents to review
- Add, search for, reply to, and export annotations

# Orchestrate submission content efficiently and compliantly

## Control



**Manage regulatory documents** across the lifecycle including timelines, relationships, permissions, and renditions



**Monitor organizational usage** with metrics for document production, authors and reviewers, etc.



**Organize documents** based on Product, Application, Composition, Study data, etc.



## Compliance

**Regulatory-ready** with FDA's 21 CFR Part 11 requirements governing electronic records, audit trails, and digital signatures



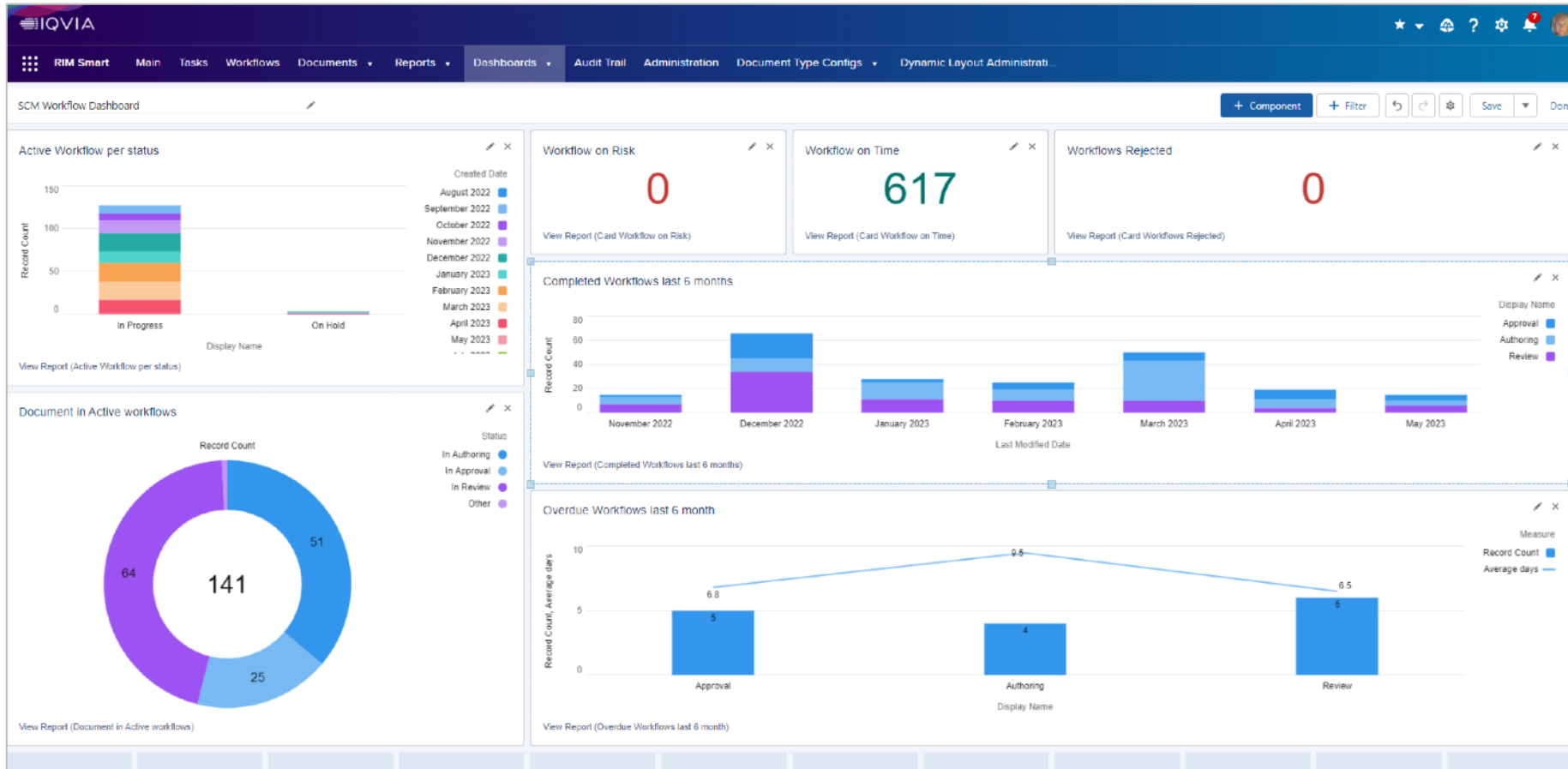
**Manage documents** in accordance with industry standard CTD and eCTD content structures



**Minimize the validation burden** with a cloud-based solution



# Provide teams with document oversight and traceability



- Submission by version, market, regulatory activity
- Contributors
- Task completion
- Risks to timeline



# Drive labeling and submission management in one platform



## SaaS solution

Software as a service architecture manages administration and future proofs with regular new capabilities



## RIM Smart platform

Built on common Salesforce platform that leverages core capabilities across the content lifecycle



## Single repository

Single source of truth that eliminates risk and generates higher quality documents



## Product metadata

Full relational metadata synchronized across RIM Smart including regional market and study details



## Publishing and labeling

Out of the box augmented submission assembly

# Minimize administration with a modern SaaS platform



**Three software releases per year**



**Hosting services included**



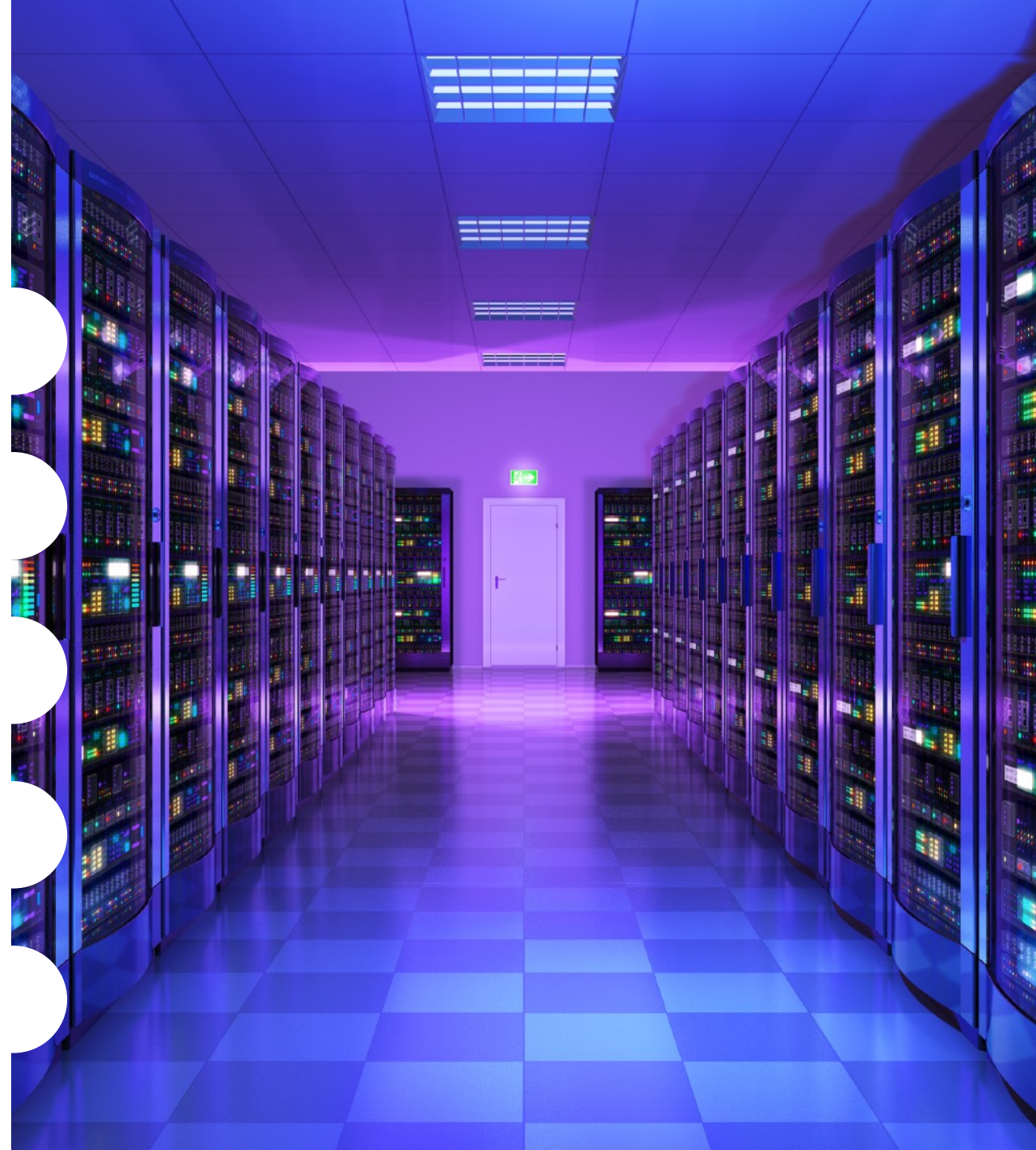
**Comprehensive support from IQVIA**



**Scalability for large regulatory workloads**



**Browser-only access for stakeholders**



# Support labeling and content management activities

The screenshot displays the 'Smart Labeling' application interface. At the top, there is a navigation bar with 'Smart Labeling' and various menu items like 'Dashboard', 'Documents', 'Requests', 'Products', 'Tasks', and 'Dashboards'. A search bar is also present. Below the navigation bar, the main content area shows a 'Labeling Change Request JB' with a 'For Review' status. Key details include: Estimated Submission: Mar 05, 2022; Current Stage: Global Impact Assessment; Stage Remaining: 3 Days; Priority: Expedited; ID: RID-0322-14543; Owner: Anne Anne. Action buttons for 'Actions', 'Put On Hold', and 'Change Owner' are visible.

Below this, the 'Planner' view is shown, which is a Gantt chart interface. It includes a sidebar with navigation options: Details, Products (1), Documents (1) (highlighted with a red box), Team (3), Tasks (2), Countries (1), Attachments (0), Planner (selected), Timeline, and Related Requests. The main planner area shows a table of tasks with columns for Plan Start Date, Actual Start Date, Plan End Date, Estimated End Date, Plan Duration, and Estimated Duration. The tasks are visualized as horizontal bars on a calendar grid from March 3rd to March 13th, 2022.

Stage/ Task Name	Start Date	Duration	Assigned To	Plan Start Date	Actual Start Date	Plan End Date	Estimated End Date	Plan Duration	Estimated Duration
Global Impact ...	Mar 03, ...	3d	AA	Mar 03, 2022	Mar 03, 2022	Mar 14, 2022	Mar 14, 2022	12 days	12 days
Label Request ...	Mar 03, 2...	1d	Anne Anne						
Label Request ...	Mar 04, 2...	1d	Anne Anne						
Label Request ...	Mar 05, ...	1d	Anne Anne						
Core Label Ap...	Mar 06, ...	8d	KA						
Target Product...	Mar 06, ...	8d	Koushik Anand						
Label Distributi...	Mar 14, 2...	1d	AA						

- Monitor label and artwork activities
- Approve planned documents prior to content development
- Manage stages and tasks alongside documents
- Manage translations and relationships to original source documents
- Notify submission coordinator upon approval of label content
- Initiate change cycles upon rejection of labeling assets

# Integrate with submission content planning and publishing

The screenshot displays the IQVIA RIM Smart Browser interface. The top navigation bar includes 'Applications > Submissions > Table of Contents > Staging Area'. The main window is divided into three panes:

- Left Pane (Navigation):** Shows a tree view of product families (e.g., 12productfamilytestv2, 13productfamilytest) and a selected product '13121 (131210)'. A 'Filters' dialog is open, showing '2 Selected' documents with checkboxes for 'Check All', 'Uncheck All', 'Collection', 'Product', 'Application', 'Studies', and 'CTD Section'.
- Center Pane (Table):** A table listing documents with columns for Name, Document Number, Size (KB), Version, Status, and Date Modified. The table contains 187 documents, with the first few rows visible.
- Right Pane (Table of Contents):** Shows a hierarchical view of the submission structure, including '0003 (In Publish)' and its five modules: 'Module 1. Administrative Information and Prescribing Information', 'Module 2. Common Technical Document Summaries', 'Module 3. Quality', 'Module 4. Nonclinical Study Reports', and 'Module 5. Clinical Study Reports'.

Name	Document Number	Size (KB)	Version	Status	Date Modified
TestNMV3 Additiona...	DID-0823-0959	126 KB	1.1	Draft	29-Aug-2023 01:25:00 PM
TestNMV2 Additiona...	DID-0823-0962	126 KB	0.1	Draft	28-Aug-2023 01:00:00 PM
TestNMV5 Additiona...	DID-0823-0960	126 KB	0.1	Draft	28-Aug-2023 01:00:00 PM
TestNMV4 Additiona...	DID-0823-0961	126 KB	0.1	Draft	28-Aug-2023 01:00:00 PM
Correspondence (N...	DID-0723-0817	121 KB	1.2	Draft	24-Aug-2023 10:14:00 AM
4Company Core Dat...	DID-0523-0581	51 KB	1.0	Approved	16-Aug-2023 02:28:00 PM
Copy of 6Company ...	DID-0823-0942	21 KB	0.1	In Autho...	16-Aug-2023 12:33:00 PM
Annex II - ANHYDRIC...	DID-0823-0922	121 KB	0.1	Draft	04-Aug-2023 01:58:00 PM
Annex II - ANHYDRIC...	DID-0823-0923	121 KB	0.1	Draft	04-Aug-2023 01:58:00 PM
Documentation Con...	DID-0723-0877	121 KB	2.1	In Review	04-Aug-2023 10:36:00 AM
Risk Communication...	DID-0723-0880	61 KB	1.0	Approved	02-Aug-2023 03:55:00 PM
Annex II - ANHYDRIC...	DID-0823-0918	14 KB	0.1	In Autho...	02-Aug-2023 02:28:00 PM
Annex II - ANHYDRIC...	DID-0823-0920	14 KB	0.1	Draft	02-Aug-2023 01:51:00 PM

- Search and filter documents in user-defined views
- Associate documents with the submission
- View reports about documents, properties, etc.
- Support hyperlink and bookmark creation documents
- Bind to specific version and rendition of a source file
- Enable and manage migration of bound documents between versions



# Advantages of RIM smart content management



Generate **high-quality** submission content **efficiently**



Gain **peace of mind** that regulatory content is compliant



Simplify workflows to **accelerate time to approval**



**Thank you!**

*(BD to insert contact info here)*

