

Achieving Responsible
Alignment of Label Content
with Drug Packaging Now
and in the Future.

Cham Williams, Associate Director, Safety, Regulatory and Quality Solutions, IQVIA



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#### **Presenter**



**Cham Williams** 

Associate Director, Safety,
Quality and Regulatory
Customer Engagement, IQVIA



#### Who is to blame?

GG

...had to recall two batches of Robaxin® 750mg Tablets 100, owing to an error in the amount of dosage...

GG

...had to recall
Laxocodyl because
of a certain medicine
for adults that was
instead labeled as
being for children...

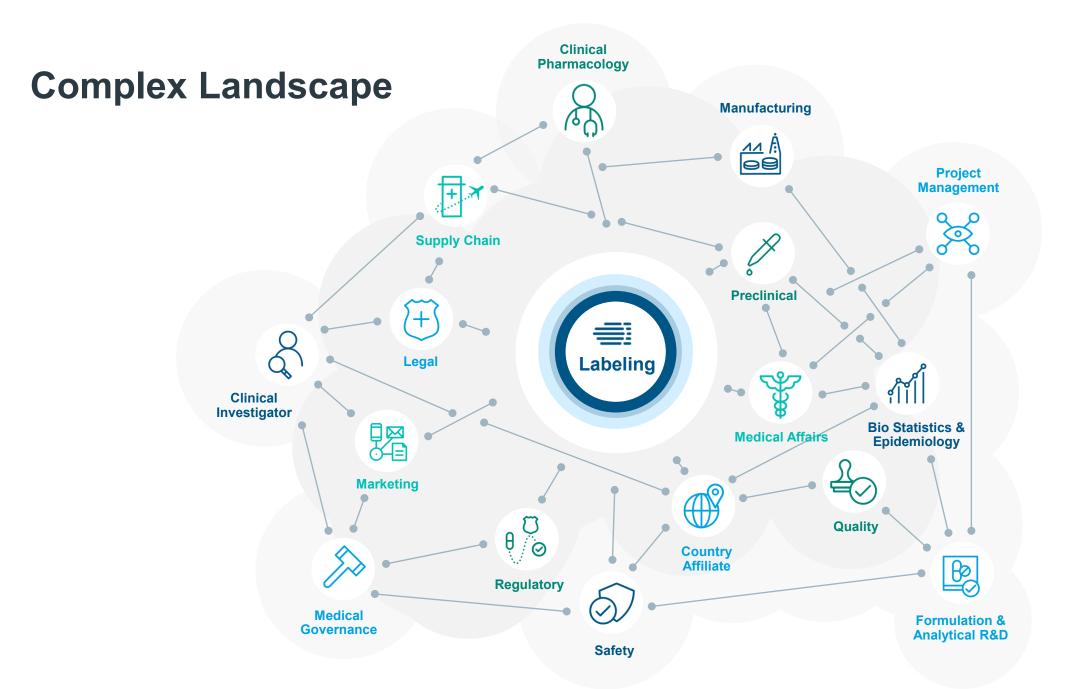
GG

asthma treatment sold in US retail outlets were recalled because the product carton label failed to include a range of information about when treatment should be stopped and a doctor consulted...

GG

...is recalling a batch of Clopidogrel Oral Solution 75mg in 5ml due to a discrepancy with the product labelling that could result in an incorrect volume to be administered to the patient...







## **Labeling Information Management**







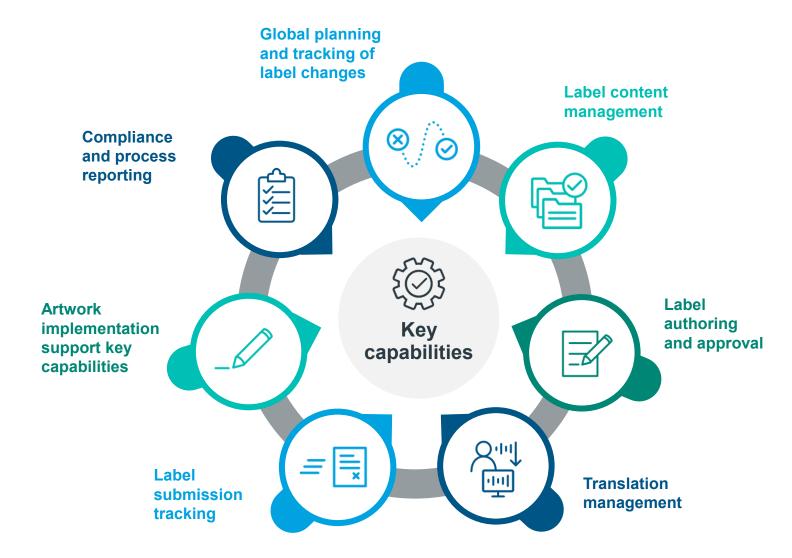
### **Key Labeling Management Capabilities**

Orchestrate label management workflow from change request through implementation

Ensure consistency and accuracy of core and regional labels through structured content management

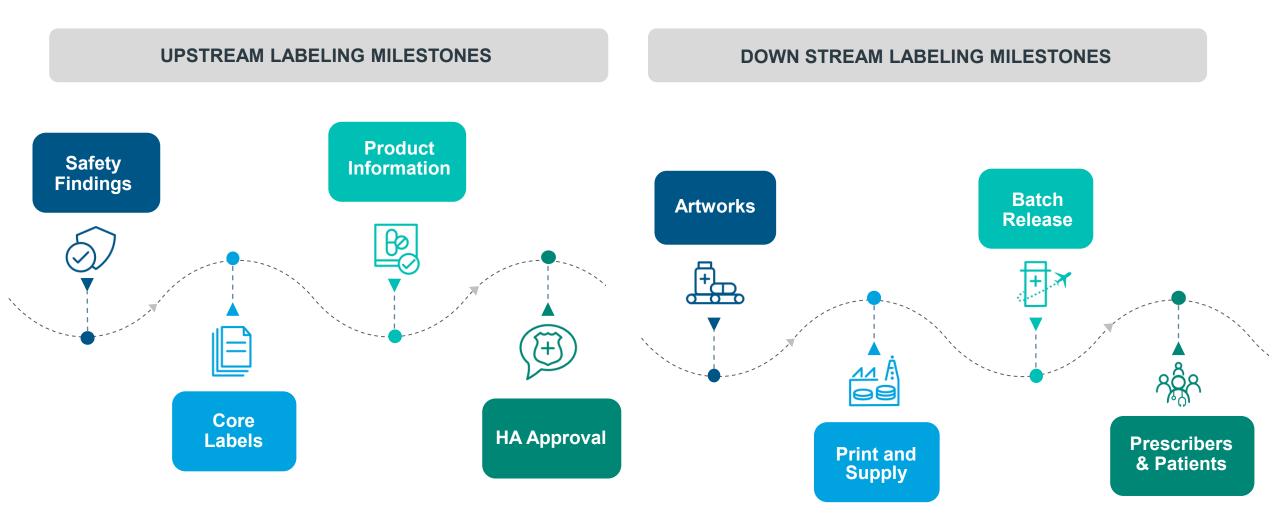
Enjoy end-to-end visibility across markets with integrated reporting and dashboards

Leverage regulatory intelligence to drive label, translation and artwork implementation

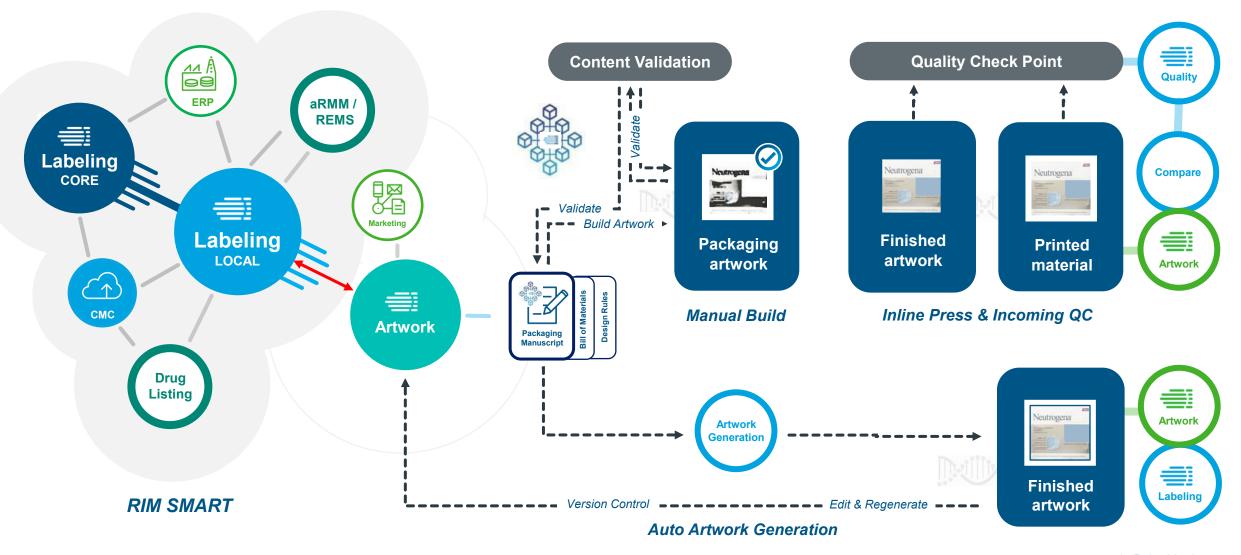




### **Implementation Tracking**

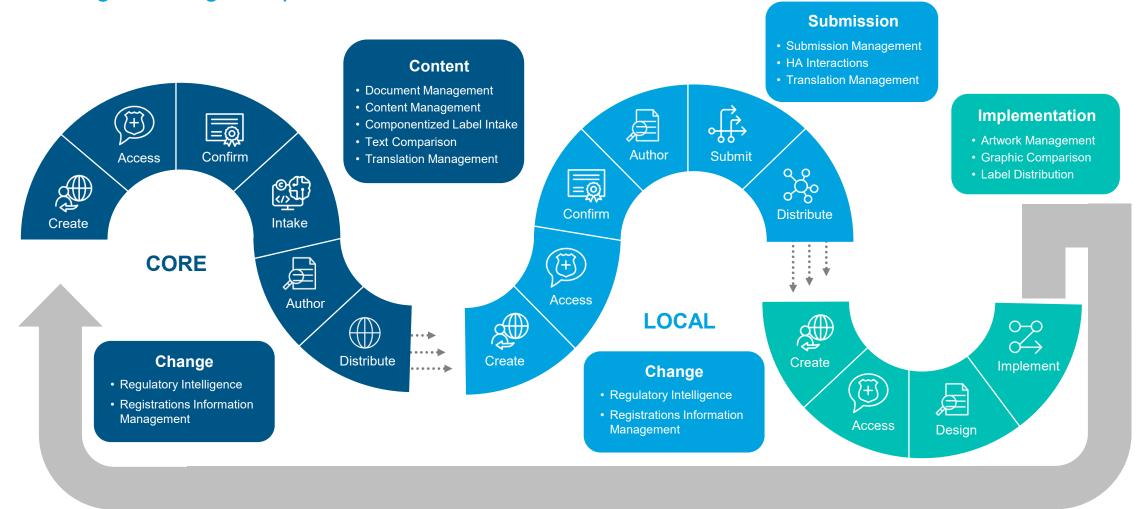


### **Beyond Label Approval**



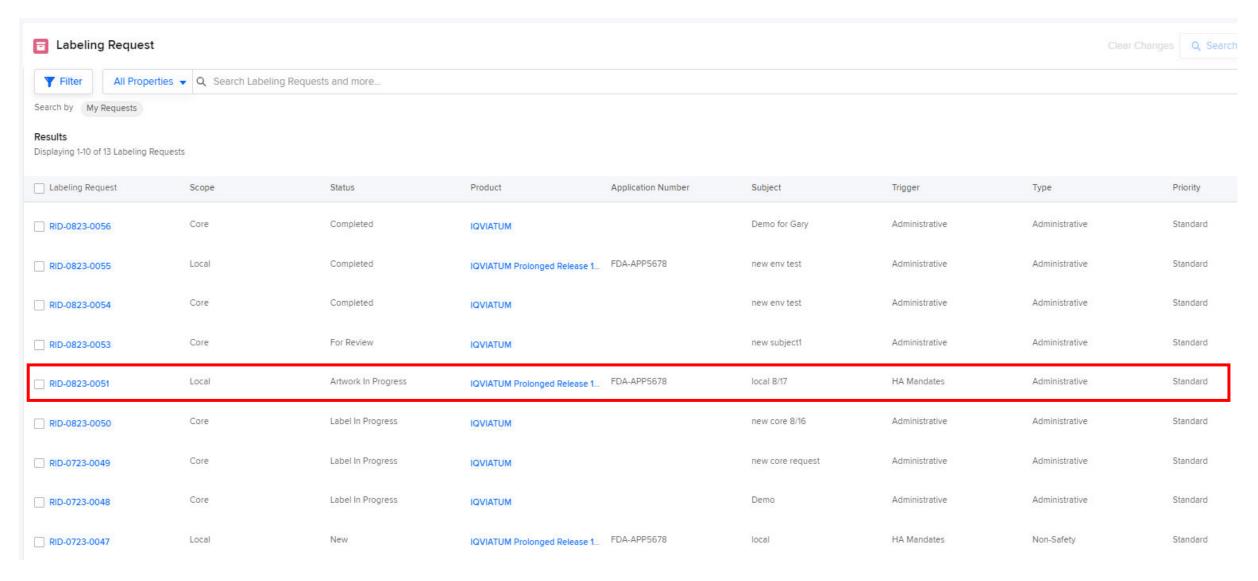
#### A Smart Approach to Labeling

Achieving Labeling Compliance

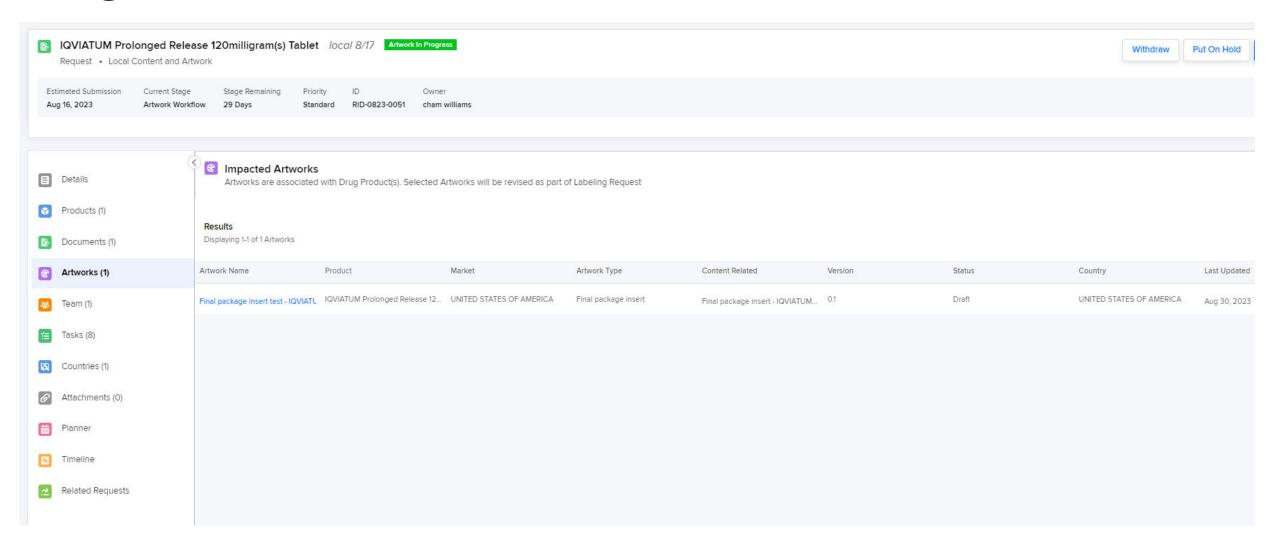




#### **Label Change Requests**



#### **Aligned Artwork**





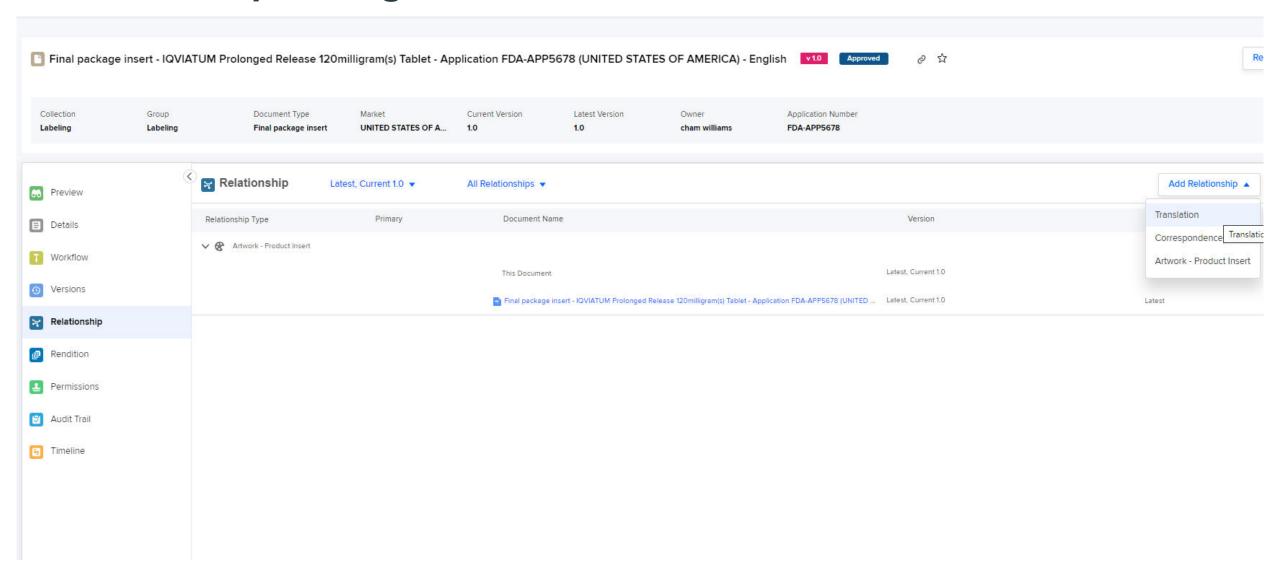
## **Change Planning and Tracking**

Planner

Plan Start D Aug 16, 202		Plan End Date Sep 13, 2023	Estimated End Date  Aug 17, 2023	Plan Duration 29 days	Estimated Duration  1 day					
Stage /	/ Task Name	ID	Risk	Status	Start Date	End Date	Duration	Related to	Priority	Assigned to
✓ Local I	mpact Assessment		<b>O</b>	Completed	Aug 16, 2023	Aug 16, 2023	1			
	Label Request Creation	1	<b>O</b>	Completed	Aug 16, 2023	Aug 16, 2023	1	5	Normal	cham williams
	Label Request Assessment	2	<b>Ø</b>	Completed	Aug 16, 2023	Aug 16, 2023	1	1	Normal	Impact Assessor
	Label Request Confirmation	3	<b>Ø</b>	Completed	Aug 16, 2023	Aug 16, 2023	1	2	Normal	cham williams
✓ Local L	abel Workflow		<b>O</b>	Completed	Aug 16, 2023	Aug 15, 2023	0			
	Final package insert - IQVIATU	4	<b>Ø</b>	Completed	Aug 16, 2023	Aug 15, 2023	NA	3	Normal	cham williams
<b>∨</b> Submis	ssion Preparation		<b>O</b>	Completed	Aug 16, 2023	Aug 16, 2023	1			
	Label Submission Preparation	5	<b>Ø</b>	Completed	Aug 16, 2023	Aug 16, 2023	1	4	Normal	cham williams
✓ HA Sul	bmission		<b>Ø</b>	Completed	Aug 16, 2023	Aug 16, 2023	1			
	Final HA Submission	6	<b>Ø</b>	Completed	Aug 16, 2023	Aug 16, 2023	1	5	Normal	cham williams
✓ HA De	cision		<b>Ø</b>	Completed	Aug 16, 2023	Aug 29, 2023	14			
	Receive HA Decision	7	<b>Ø</b>	Completed	Aug 16, 2023	Aug 29, 2023	14	6	Normal	cham williams
Artwor	k Workflow		0	In-Progress	Aug 29, 2023	Sep 26, 2023	29			
	Final package insert test - IQVI	) 8	0	In-Progress	Aug 29, 2023	Sep 26, 2023	30	7	Normal	cham williams



#### **Relationship Management**



## Q&A



# Thank you! Please contact us for more information.

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