

Be The Expert

EMPOWERING EFFICIENCY

02

Health Authority Interactions

Manual vs. AI/ML Automated Workflows





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24 years of Information Systems third tier experience supporting a wide array of technologies concurrent with 23 years Pharmaceutical and Biotechnology Regulatory industry experience.

Health Authority Interactions

Use Case – Manual Workflow

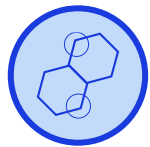
Effort Required



- ✓ Carefully read communication (could contain multiple questions to address)
- ✓ Save the communication
- ✓ Upload to regulatory technology platform
- ✓ Manually link documents to relevant datapoints
- ✓ Create tasks, assign ownership and route workflows
- ✓ Monitor workflows

25+

Est. minutes of manual effort to process and monitor each incoming health authority interaction



✓ 1 product – clinical trials / marketed



✓ 20 countries

Health Authority Interactions

Use Case: Efficiency Gains for Top 5 Global Pharma



Global pharma company
receives 6,000+ HAQs per day

MANUAL PROCESS

- FTEs per day – 275
- Processing time – 22 minutes per request
- Hours to manage HA interactions – 2,200 per day

AUTOMATED PROCESS (AI/ML)

- FTEs per day – 125
- Processing time – 22 minutes per request
- Hours to manage HA interactions – 1,000 per day

EFFICIENCY GAINS



45%

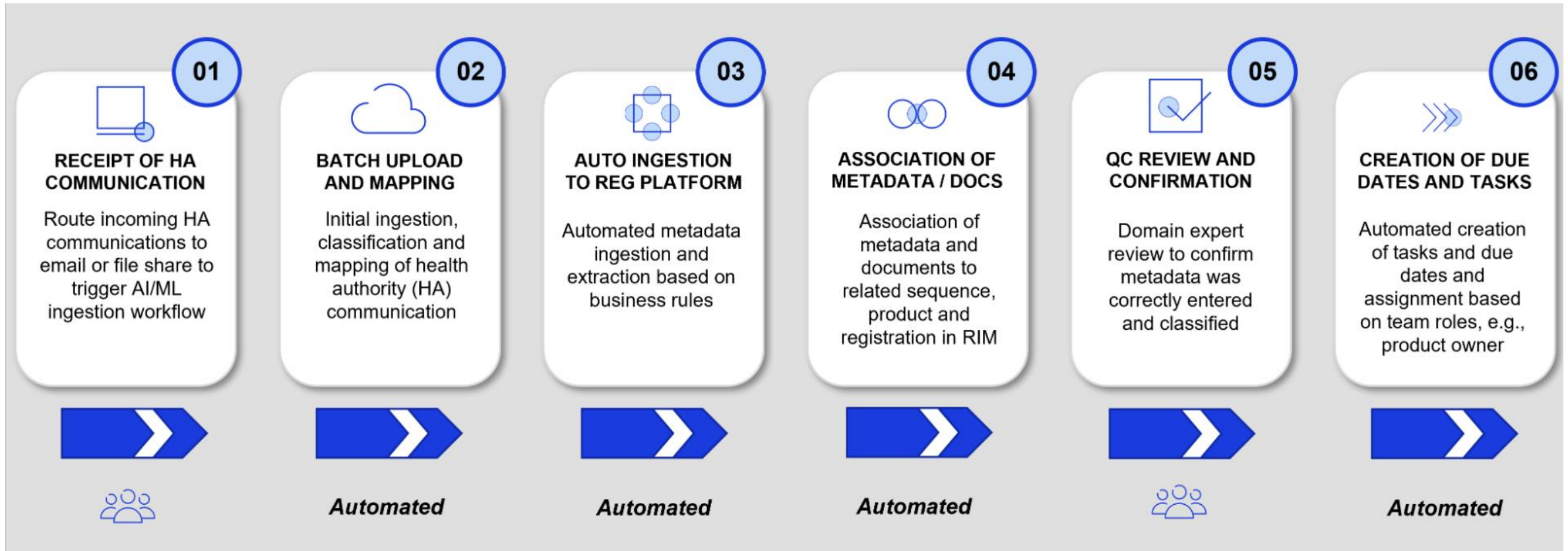
Overall efficiency generated
using AI/ML automation

12

Minutes per document times
savings automation vs. manual

Health Authority Interactions

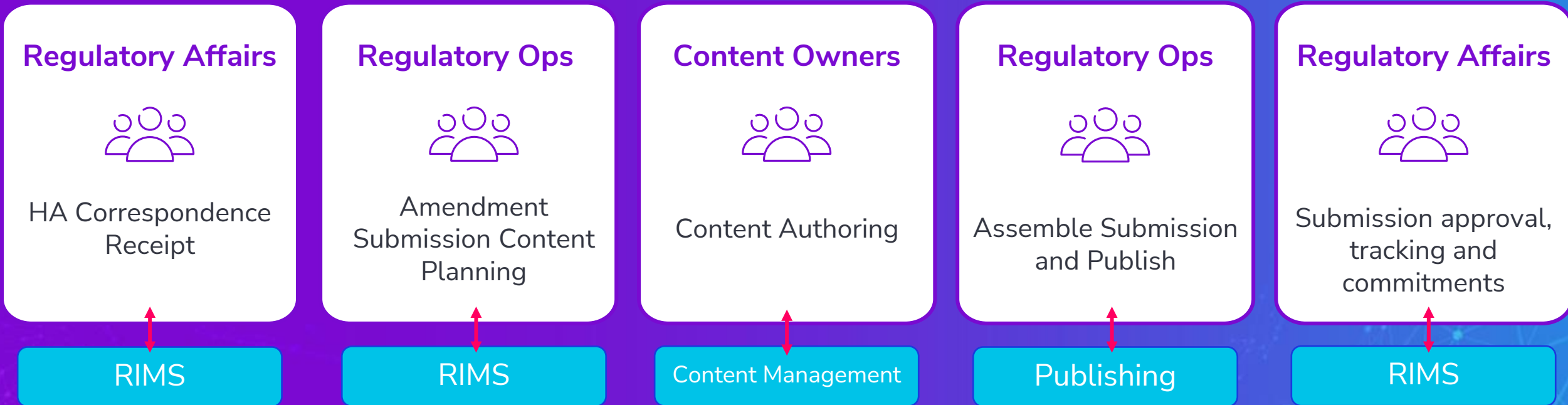
Use Case – Automated AI/ML Workflow



AI/ML driven workflow creates 45% efficiency gains

Responding to a Deficiency Letter on a Submission

Use Case – End-to-End Regulatory Platform Workflow Automation

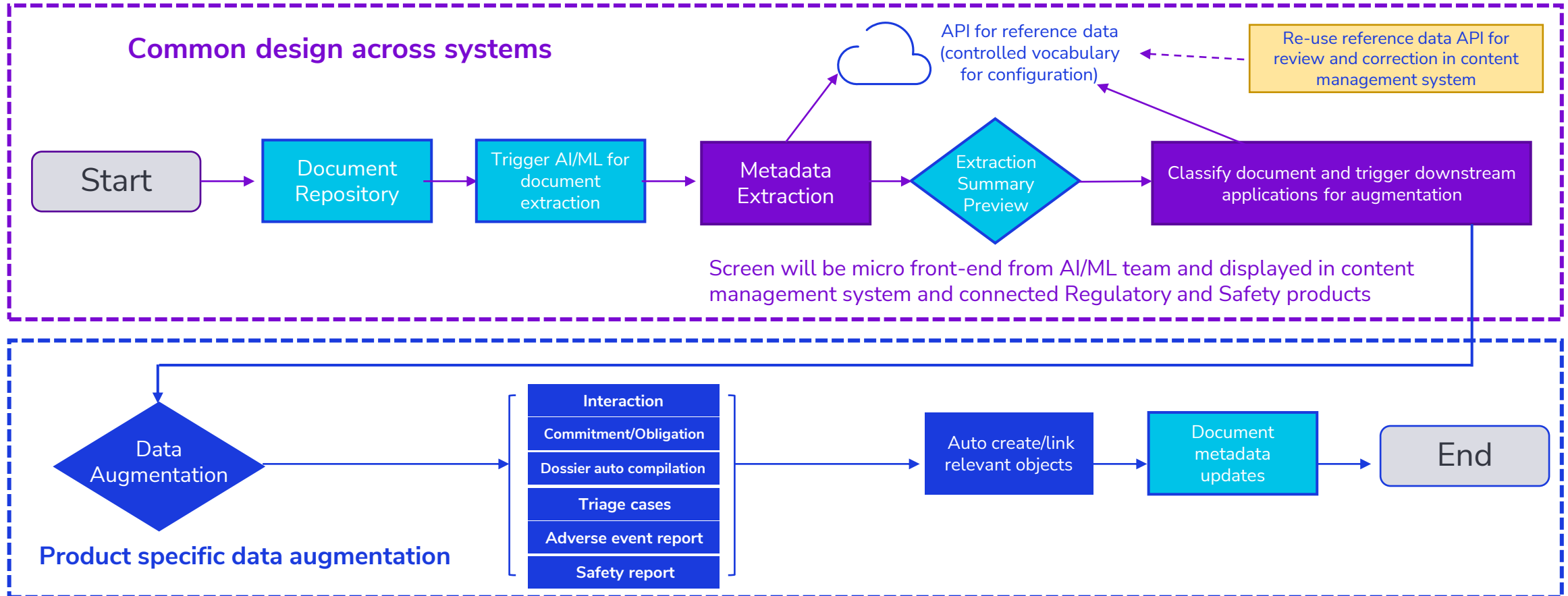


End-to-End Regulatory SaaS Platform

What is this a workflow of?

Automated Workflow Overview

AI/ML
Content Mgmt.
Reg/Safety



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THANK YOU!