Accumulus™ TECHNOLOGIES

Operationalizing Modern CMC Lifecycle Management

The Digital Infrastructure Behind Collaborative Regulatory Execution

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July 28, 2026

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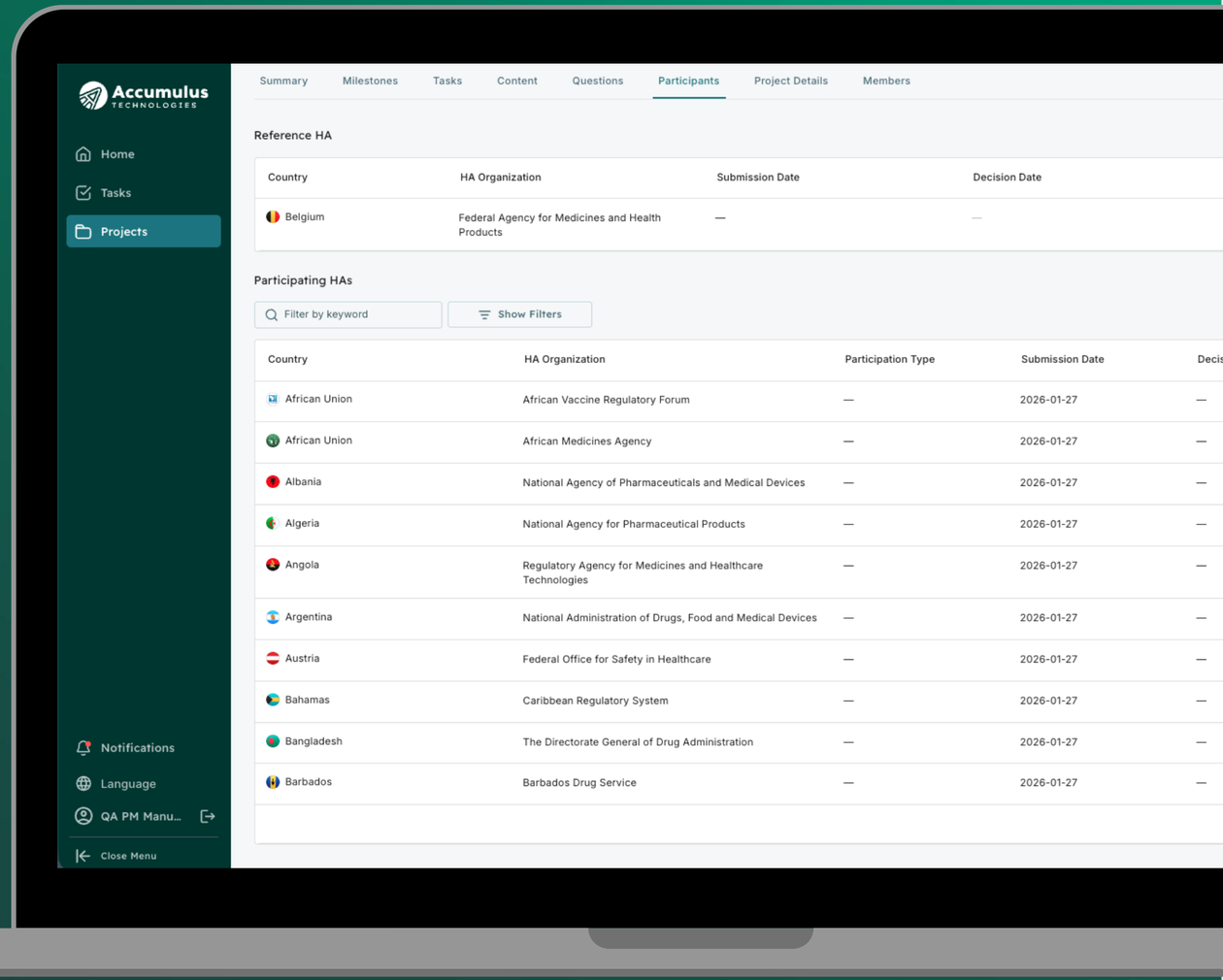


An Outdated Model

Global approvals follow a slow, sequential pattern known as the 'wave model', with each country reviewing in turn

01

Regulatory exchange is document-centric and fragmented

02

Submissions, reviews, and responses are sequential and linear.

03

Work is redundant and duplicated across every market worldwide.

The Last Approval

Manufacturing changes cannot be implemented until the last market approves, often 2-5 years after the first submission.

Manufacturing

01. Duplicate Manufacturing

Running in parallel

Multiple production processes run in parallel across market while approvals catch up.

Inventory

02. Stockpiled & Excess Inventory

Capital tied up

Companies build, hold, and manage inventory while waiting for regulatory approvals.

Supply

03. Products Pulled Off the Market

Availability at risk

Products withdrawn or unavailable until changes are approved, impacting continuity and supply.

Shared pressures across a two-sided ecosystem

01 Acceleration

02 Data & Complexity

03 Sustainability

04 Digital Transformation

Global Momentum

Expanding global momentum toward more efficient regulatory pathways is evidence of increasing alignment, adoption, and efficiency worldwide

~100

Agencies participating in regulatory reliance pathways[1]

48%

Life Sciences companies surveyed plan to use cloud technology for regulatory collaboration this year[2]

71%

Life Sciences companies surveyed believe that cloud technology will innovate ways of working with regulators[2]

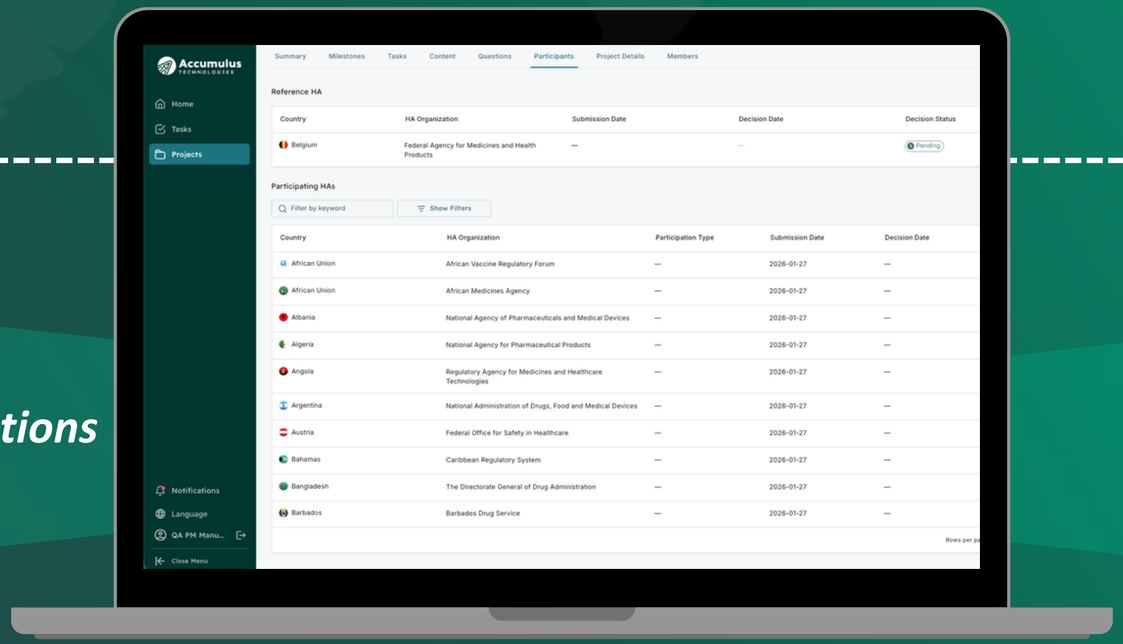
1 European Medicines Agency. (2025). Reliance for post-authorisation changes: Pilots for the pharmaceutical industry.

2 Gens & Associates. (n.d.). Regulatory operational excellence and World Class RIM℠.

A connected regulatory ecosystem

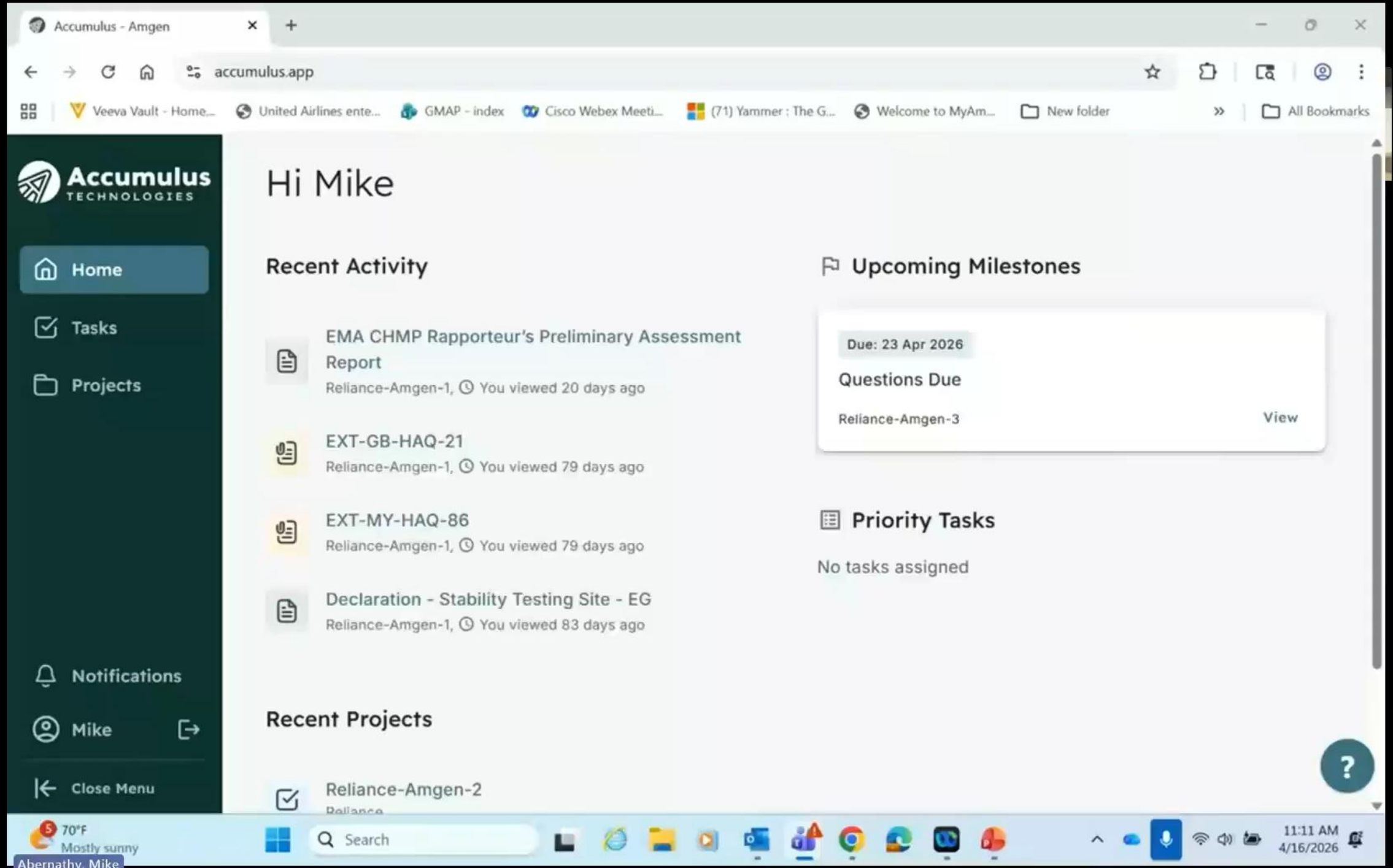
DATA SOURCE

REVIEWERS



Life Sciences Organizations

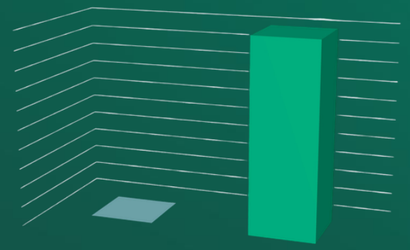
National Regulatory Authorities


Accumulus - Amgen
accumulus.app
Veeva Vault - Home...
United Airlines ente...
GMAP - index
Cisco Webex Meeti...
(71) Yammer : The G...
Welcome to MyAm...
New folder
All Bookmarks
Accumulus TECHNOLOGIES
Home
Tasks
Projects
Notifications
Mike
Close Menu
Hi Mike
Recent Activity
EMA CHMP Rapporteur's Preliminary Assessment Report
Reliance-Amgen-1, You viewed 20 days ago
EXT-GB-HAQ-21
Reliance-Amgen-1, You viewed 79 days ago
EXT-MY-HAQ-86
Reliance-Amgen-1, You viewed 79 days ago
Declaration - Stability Testing Site - EG
Reliance-Amgen-1, You viewed 83 days ago
Upcoming Milestones
Due: 23 Apr 2026
Questions Due
Reliance-Amgen-3
View
Priority Tasks
No tasks assigned
Recent Projects
Reliance-Amgen-2
70°F
Mostly sunny
Search
11:11 AM
4/16/2026
Abernathy, Mike

Accelerated Collaborative Review

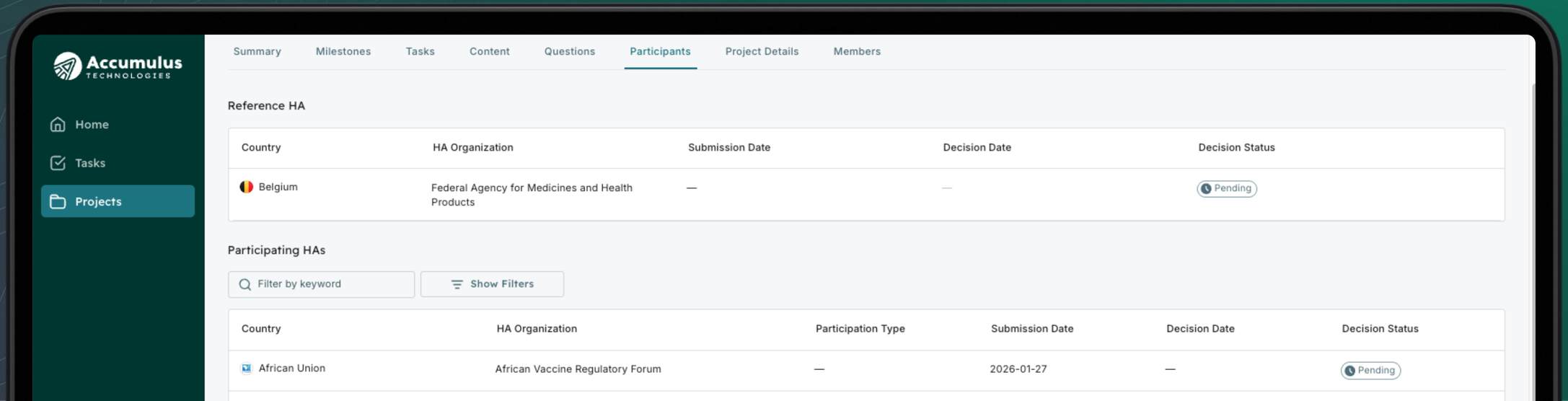
Instant | Simultaneous | Transparent

90% Acceleration



$10M-$100M Savings

75% Efficiency



Global Reach

Powering connection to a rapidly growing network of life science organizations and national regulatory authorities

75 +

Agencies

6

Continents

Case Studies

Case Study

ROCHE – 100 week reduction in global approval time leveraging the Accumulus platform to power a reliance pathway in a Roche-led submission

KEY OUTCOMES

87%
Approvals Granted

- In just 7 months, Roche received 87% of approvals

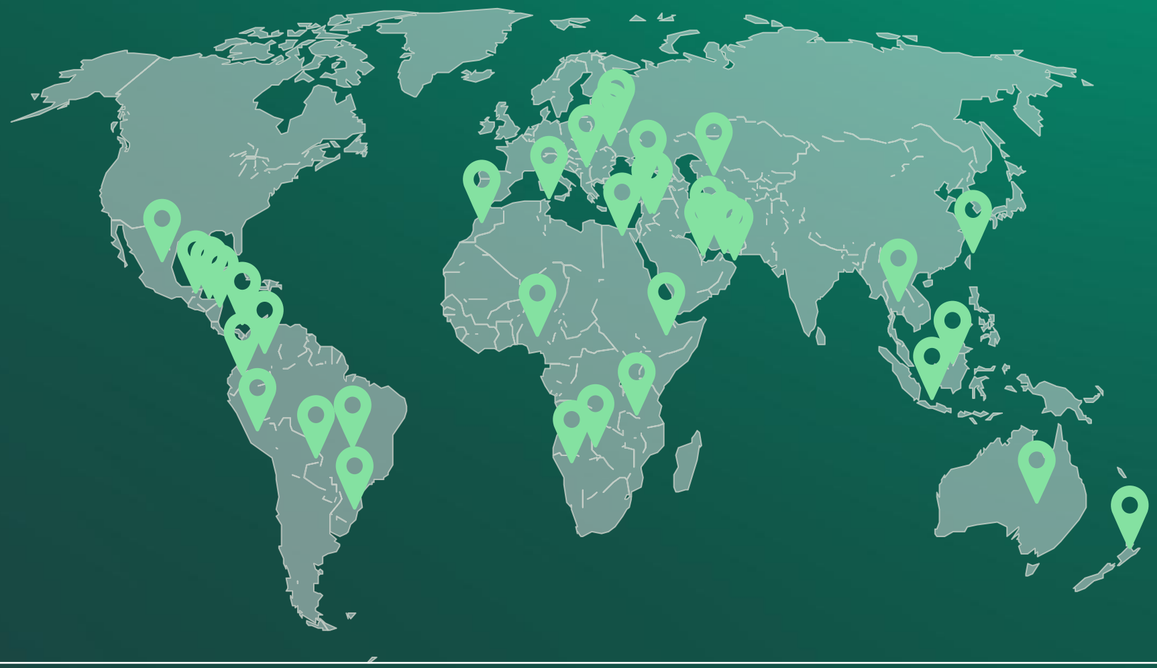
80%
Cycle Time Reduction

- The global approval timeline decreased from an average of 2.5 years to under 6.5 months

70%
Without Questions

- The percent of regulators who granted approvals with zero independent questions

48 Regulators - **6** Continents



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Case Study

AMGEN – Reducing cycle times by 90% and delivering up to $100M cost benefit per submission

OVERVIEW

Powered by the Accumulus platform, Amgen, Inc. streamlined global regulatory exchange and submitted a single dossier simultaneously to nearly two dozen countries.

Regulators worldwide accessed the same dossier in parallel, enabling:

- simultaneous, shared visibility
- real-time collaboration
- transparency

… while maintaining individual regulatory autonomy.

An unprecedented opportunity to accelerate global patient access.

RESULTS

Savings

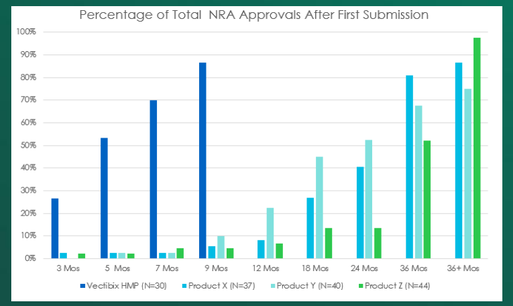
Increased Manufacturing Capacity

Up to $100M

$10M-100M estimated cost benefit per significant post-approval variation

Acceleration

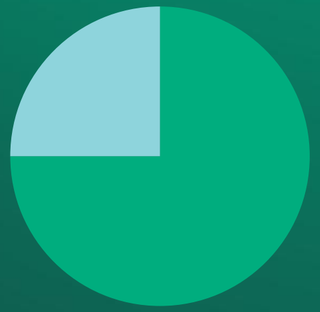
Timeline and Patient Access



90% acceleration: faster approvals, accelerated access to optimized product

Efficiency

Operational Gains



75% efficiency gain: *single global submission,* parallel reviews, a single view of all regulators, fewer questions;

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Thank you!

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