Beyond Borders: Scaling Regulatory Reliance Through Operational-Excellence and Cloud-Based Collaboration

Practical lessons from executing Teva's first global reliance pilot

Kavita Aiyer, Ph. D
Head of Biologics/ Vaccines Regulatory Affairs- CMC, Innovative Medicines
Teva Pharmaceuticals

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Today's Roadmap

From Concept to Practice- Lessons from Teva's First Global Regulatory Reliance Pilot

1

Why Reliance ?

Opportunity- and why execution remains challenging

- Promise of reliance
- Why it matters
- Implementation gap

2

Building the Operating Model

Designing our end to end approach

- Platform integration
- Dossier alignment
- Affiliate and regulatory authority engagement

Enabled by cross-functional governance

3

Executing the Pilot

Putting the model into practice

- Parallel workstreams
- Country specific approaches
- Real-time operational decisions

4

Scaling Beyond the Pilot

What we learned- and where we go from here

- Parallel workstreams
- Country specific approaches
- Real-time operational decisions

> *"It felt like building the ship while sailing."*
>
> We weren't inventing regulatory reliance—we were developing our own operating model while executing our first global pilot.

What is Regulatory Reliance

(WHO Good Reliance Practices)

WHO Definition

"The act whereby the regulatory authority in one jurisdiction **takes into account and gives significant weight** to assessments performed by **another regulatory authority or trusted institution**, or to any other authoritative information, in reaching its own decision. The relying authority remains **independent**, **responsible** and **accountable** for the decisions taken, even when it relies on the decisions, assessments and information of others."

World Health Organization | WHO Good Reliance Practices for the Evaluation of Medicinal Products

Key Principles

Uses trusted science
Builds on assessments already performed by trusted regulatory authorities

Independent decisions
Each authority retains full responsibility for its own decisions

Reduces duplication
Avoids repeating the same scientific assessment

Better efficiency
Supports more timely decision making

Reliance is an established regulatory concept. The challenge is operationalizing it at scale.

teva

Why Digital, Cloud- Enabled Regulatory Reliance Matters

Benefits for Regulatory Authorities, Industry and Patients

Trusted science enabled through secure digital collaboration

Faster Patient Access

- Enables more timely regulatory decisions
- Reduces review timelines
- Facilitates global availability

Secure Digital Collaboration

- Secure sharing of questions and assessments
- Real time information exchange on a common platform

accumulus — Enabled through the Accumulus® cloud-based collaborative review platform

Efficient Resource Utilization

- Reduces duplication of assessments
- Allows focus on high value activities
- Optimized capacity and expertise

Scientific Confidence

- Leverages trusted scientific assessments
- Promotes consistency across evaluations
- Supports informed regulatory decisions

Regulatory reliance defines the approach. | **Digital collaboration enables the execution.**

Our Pilot Journey

Executing a post approval CMC reliance pilot across multiple regulatory authorities

1 Project Selection

Defined pilot scope

2 Pilot Preparation

Three coordinated workstreams

- Affiliate & Stakeholder Readiness
- Platform Readiness (Accumulus)
- CMC & Dossier Readiness

3 Regulatory Authority Engagement

Customized authority engagement

4 Local submission

Existing submission pathways

5 Collaborative Review via Reliance

Active collaborative assessment

Pilot Scope

Product
AJOVY®
(fremanezumab)

Change
Post- approval
CMC change (PAC)

Approach
A common global
PAC evaluated through
regulatory reliance

Pilot Participation

11 Health Authorities Invited

Active participation
(via Accumulus)

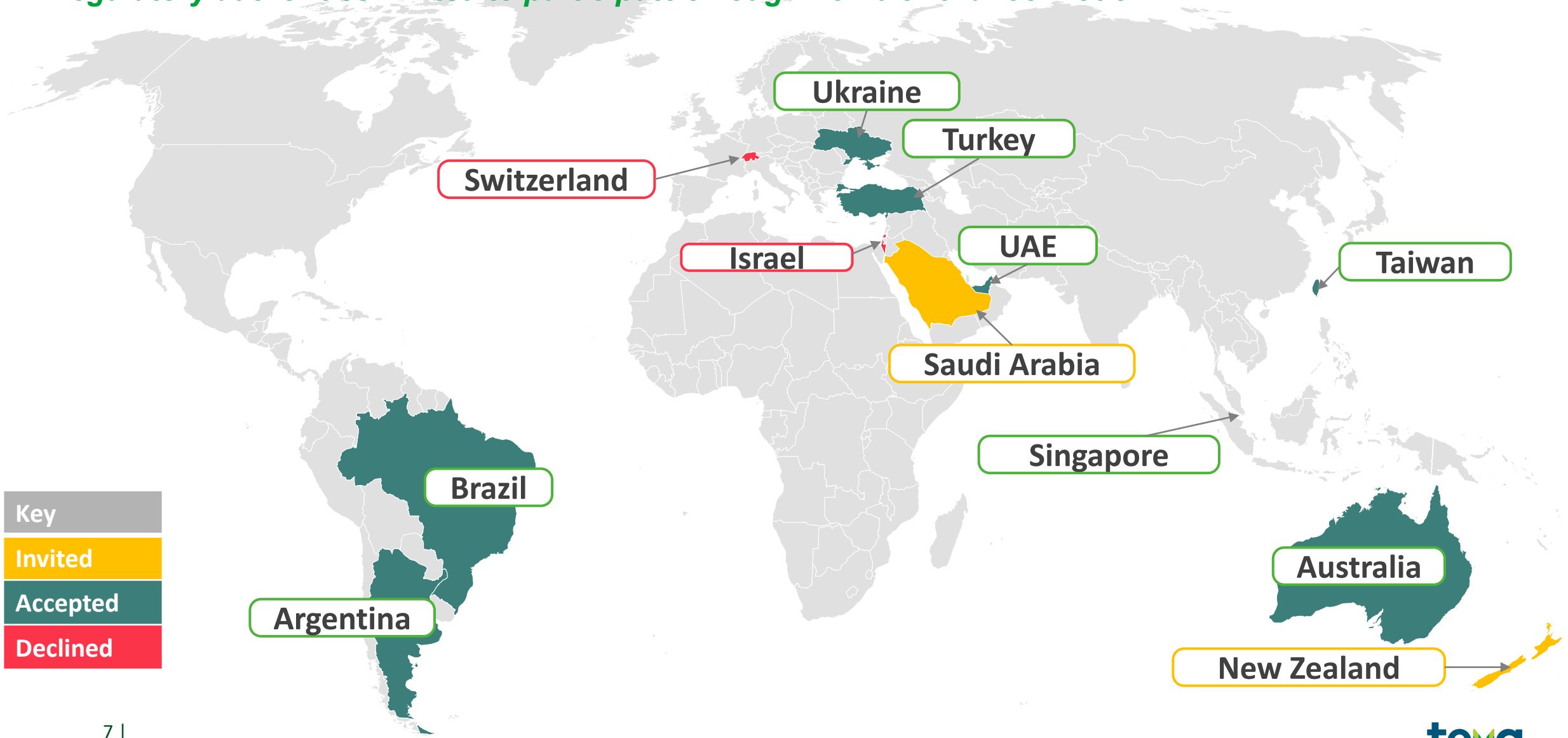
Observer participation
(via Accumulus)

Reliance pathways outside Accumulus
(e.g. direct exchange)

Every phase required simultaneous coordination across regulators, affiliates, digital platforms and internal stakeholders.

Global Regulatory Authority Engagement

11 regulatory authorities invited to participate through flexible reliance model



Global Reliance Landscape

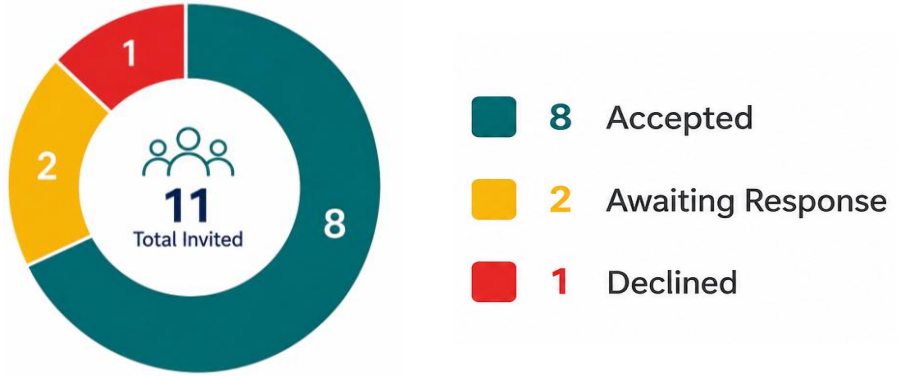
Participating authorities represented diverse levels of existing reliance adoption, providing a unique opportunity to evaluate collaborative review across a broad regulatory landscape.

11
Authorities Invited

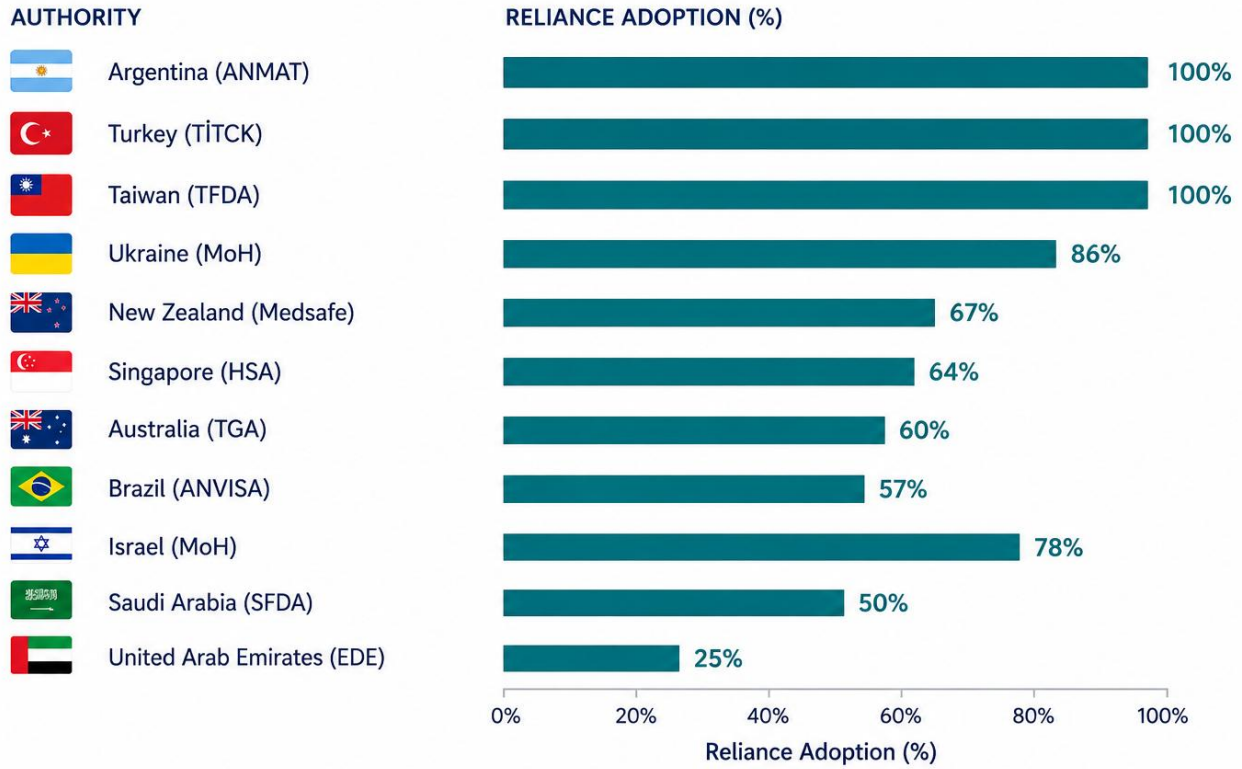
8
Accepted Participation

73%
Participation Rate

Participation Status



EXISTING RELIANCE ADOPTION*

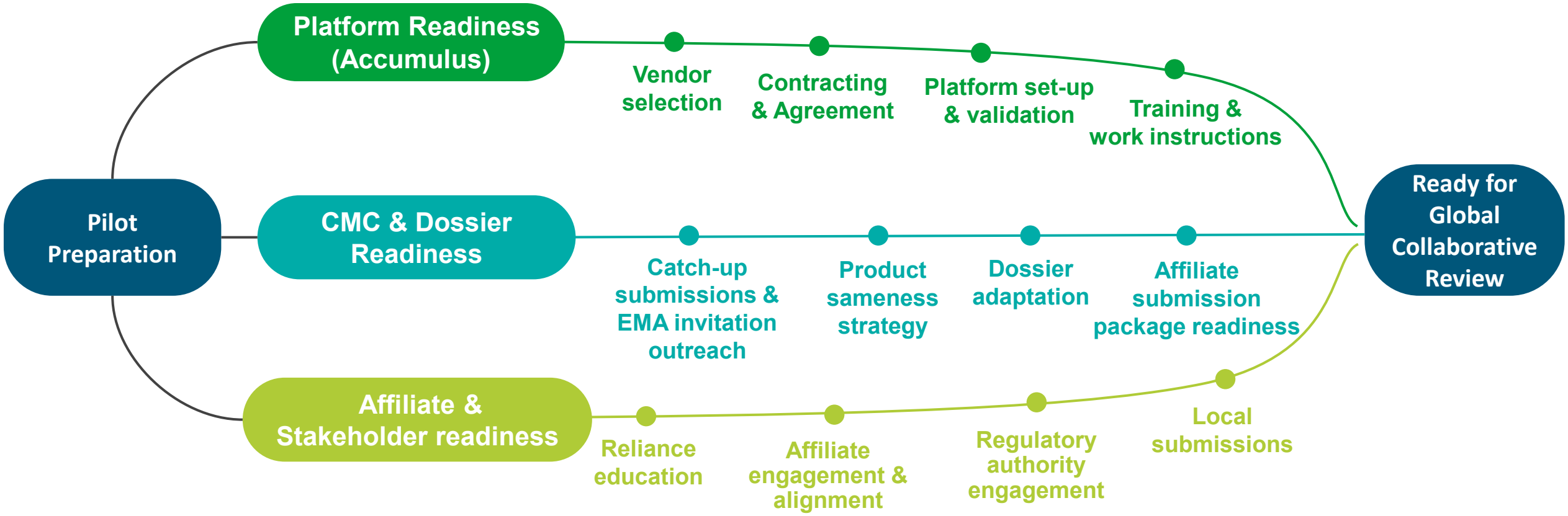


Key Observation | **Participating authorities spanned both emerging and well-established reliance environments, demonstrating broad interest in collaborative review across diverse regulatory settings.**

** Reliance adoption based on IFPMA published data (January 2026)*
Swissmedic elected to pursue reliance outside the collaborative review pilot and is not included in participation status

Building the Operating Model

Pilot preparation initiated three coordinated workstreams that progressed in parallel throughout pilot execution.



Continuous coordination across all three workstreams was essential to pilot success.

Affiliate and Stakeholder Readiness

Preparing affiliates and stakeholders to confidently execute a global regulatory reliance pilot

Educate

- Regulatory reliance principles and benefits
- Accumulus overview and collaborative review
- Published literature, industry case studies and experience sharing
- Training sessions and knowledge sharing

Align

- Governance and executive sponsorship
- Defined roles and responsibilities
- Pilot timelines and expectations
- Alignment across Regulatory CMC, Operations and affiliates

Enable

- Draft Q&A document
- Draft NRA emails
- EMA invitation letter
- Accumulus overview and user guides
- NRA standard communication toolkit

Execute

- Country specific engagement strategies
- Regular discussions and follow up
- Local submission support
- Ongoing troubleshooting and escalations

Key Takeaway

Regulatory reliance is enabled through people, preparation, and partnership—not just process. Early alignment, standardized resources, and continuous execution support were just as essential to successful implementation as the technical aspects of the pilot.

Platform Readiness

Establishing a secure and validated digital environment for collaborative review

Establish

- Vendor selection (Accumulus selected)
- Contracting and agreements
- Governance model and decision rights

Configure

- Platform setup and configuration
- Project structure and workflows
- User roles and permissions
- Integration and coordination with internal systems

Validate

- System validation and testing
- Work instructions
- Business process definition
- Quality and IT compliance

Deploy

- User training
- Pilot go- live (June 2026)
- Operational support
- Continuous improvement

Key Takeaway

Know your internal processes – they can become the critical path for implementation. Onboarding and validating a collaborative review platform requires significant cross-functional collaboration, disciplined governance and careful planning.

CMC and Dossier Readiness

Building a common scientific foundation for collaborative review

Assess

- Catch- up submissions and outstanding items
- Gap assessment against reference dossier
- Internal CMC alignment and readiness review

Harmonize

- Scientific and life cycle consistency
- Dossier sameness assessment
- Dosser adaptation
- Reference dossier content alignment

Compile

- Common core CMC submission dossier
- Common administrative document alignment
- Cover letter templates and annexes
- Submission dossier compilation and QC

Enable

- Affiliate handover and briefing
- Submission readiness confirmation
- Filing support and coordination
- Response planning and support

Key Takeaway

A collaborative review begins with common scientific foundation. Developing a harmonized dossier required significant planning, scientific alignment, and coordination before engaging with regulatory authorities

Preparing the Scientific Foundation

Historical lifecycle differences across participating markets were reconciled before collaborative review

63
Lifecycle Changes

Catch- up submissions completed

11
Participating Markets

Aligned to the EU reference dossier

~8
Months

Preparation efforts to establish common scientific baseline

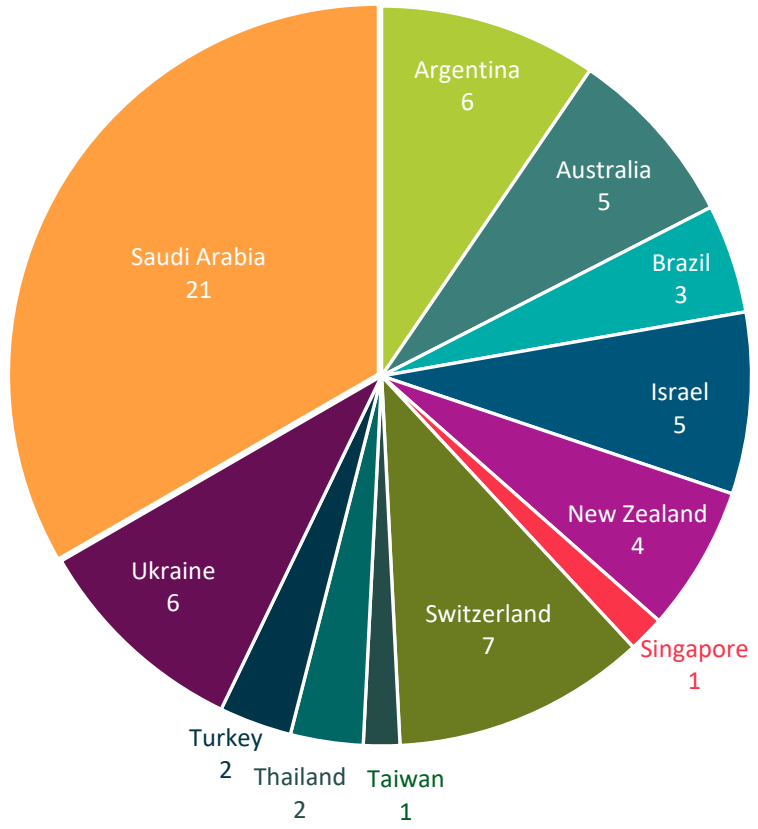
Why It Was Needed

Participating markets were at different lifecycle positions, with country- specific gaps between local dossier and EU reference dossier

What We Did

Executed 63 catch-up submissions across 11 markets over ~8 months aligning country dossier to a common EU reference dosser and enabling collaborative review

Catch-up Submissions by Market



Key Takeaway

Establishing a common scientific baseline is a critical prerequisite for collaborative review and often requires substantial upfront effort to reconcile historical lifecycle differences.

Regulatory Authority Engagement

Tailored engagement strategies to each regulatory authority's regulatory environment.

Engagement Approach

Engage Early

- Initiate dialogue
- Introduce pilot and goals

Listen and Understand

- Authority specific processes
- Identify expectations, and concerns
- Clarify governance and participation options

Adapt the Approach

- Tailor participation model to local framework
- Flexible pathways (active, observer, outside Accumulus)
- Country specific strategy and communication

Support Execution

- Ongoing communication and alignment
- Address questions and facilitate access
- Submission support

Different Engagement Scenarios

Singapore (HSA)

- Initially declined
- Follow-up discussions addressed questions
- Participation secured after targeted dialogue

Lesson: *Address concerns through dialogue*

Taiwan (TFDA)

- Early engagement identified newly established pathway
- Followed recommended process (ExPress)
- Accepted after 46 days

Lesson: *Discover and leverage emerging regulatory pathway*

Brazil (ANVISA)

- Initially declined
- Follow-up discussions revealed misalignment with current framework
- Hybrid participation model developed

Lesson: *Adopt model to fit local regulatory framework*

Turkey (TITCK)

- Executive engagement established participation pathway
- Preliminary Assessment Unit approval required

Lesson: *Navigate authority-specific governance required*

Key Takeaway

No one-size-fits all engagement strategy. **Early dialogue**, understanding each authority's unique regulatory environment and **adapting the approach were critical** to successful participation.

Lessons for Scaling Regulatory Reliance

Our experience demonstrated that scaling regulatory reliance extends well beyond scientific assessment—it requires coordinated operational excellence across multiple dimensions.

 1 **Scientific Readiness**	A common scientific foundation requires upfront dossier harmonization and lifecycle alignment.
 2 **Organizational Readiness**	Preparing affiliates and cross-functional teams is as important as preparing the submission itself.
 3 **Regulatory Partnership**	Early dialogue builds trust, uncovers opportunities, and enables authority-specific approaches.
 4 **Digital Enablement**	Digital platforms enable collaboration, but governance enables adoption.
 5 **Operational Excellence**	Operational excellence connects science, people, processes, and technology into one coordinated operating model.

 **Key Takeaway**

Scaling regulatory reliance is not a scientific challenge alone – it is operational transformation requiring trusted collaboration across regulators, industry and technology partners.

From Pilot to Practice:

Questions We Need to Solve Together

Building on pilot learnings, how do we make collaborative review routine, scalable, and sustainable?

1

Engagement Model

How can we **standardize engagement** while preserving regulatory flexibility?

Can common engagement principles Improve predictability?

2

Scientific Alignment

What constitutes an acceptable **common scientific baseline**?

How much dossier alignment is enough for collaborative review?

3

Digital Collaboration

How can digital collaboration become part of **routine regulatory review**?

What capabilities are needed to support trusted collaboration?

4

Governance Models

What **governance** enables scalable collaborative review?

How do we preserve independent decision-making while collaborating?

5

Scaling Adoption

How do we **scale collaborative review** across diverse regulatory environment?

How do we move from pilot to routine Practice?

THE FUTURE

The next phase of regulatory reliance will be shaped by continued collaboration among regulators, industry and technology partners.

Stronger Partnerships

Shared Data, Shared Insight

Trusted Process

Global Impact

THANK YOU

Scaling Regulatory Reliance Through Operational-Excellence and Cloud-Based Collaboration

Questions & Discussions

The Journey Continues……

IMPLEMENTATION
Pilot designed and executed across participating authorities

PILOT REVIEW (In Progress)
Collaborative review underway across participating authorities

OUTCOME ANALYSIS
Evaluation of pilot impact and performance

> We look forward to returning with a comprehensive evaluation of the pilot outcomes and sharing real-world evidence on the value of collaborative review.

Stronger Together
Better Decisions
Better Access