

# Accumulus Synergy

*Cloud-based submissions and fostering reliance*

December 2025

# The Opportunity: Dossier Submission to Data Submission



*A strategic opportunity to shift the industry from document-based to data-driven regulatory submissions—unlocking upstream potential through a “single pane of glass” for real-time, eCTD-free data exchange.*

## Now:

- Submission of eCTD/CTD or dossiers in other formats individually to individual Health Authorities
- One-way document exchange (no real-time collaboration)
- Comprised primarily of static PDF documents
- +/- xml backbone



## Ongoing:

- Increase of databases at the Health Authority level (e.g., EMA workplan)
- Document management systems at the industry level
- ICH M4Q



## Future:

- A dynamic, interconnected ecosystem where stakeholders seamlessly share, access, and leverage data
- Real-time, actionable data that dramatically accelerates drug development, fuels regulatory intelligence, trend analysis, and predictive insights for faster decision-making
- Scalable, secure platforms that enable seamless collaboration, centralized data access, and streamlined interactions between regulators and industry in real time

# Critical regulatory challenges make it essential to transition to the Cloud



*Security and privacy concerns*

*Data harmonization*

*Data residency*

*Cross-border data sharing*

*Differing regional maturities*

*Compliance with regional regulations*

*Confidentiality / mutual recognition agreements*

*Regulatory autonomy*

*Regulatory convergence*

*Varying uses of dossiers*

*Reluctance to embrace cloud technology*

# There is a demonstrated appetite and willingness to pursue collaborative review



## Collaborative Review Examples

OPEN

ACCESS

ASEAN Joint  
Assessments

ORBIS

ICMRA



## Key Benefits



Encourages continuous improvement



Builds momentum and increases efficiency



Cultivates trust and transparency



Demonstrates success

# Learnings to date compel us to address the existing policy lag and pursue additional pilots



## Lessons Learned

- Despite these challenges, LSOs and NRAs are **willing to participate** in pilot projects.
- The more pilots that are done, the more we have **proven benefits**.

## Policy Lag

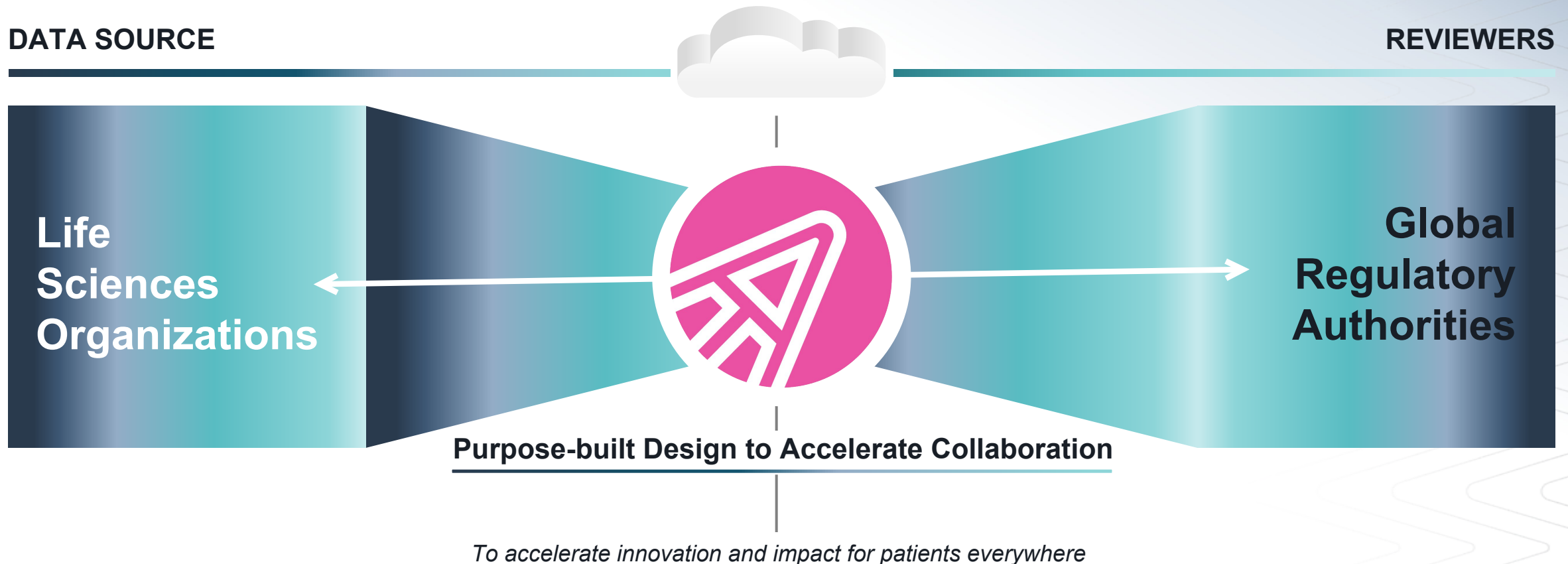
- Now is the time to address the **policy lag**.
- It isn't only about a specific platform, but rather about what global policy changes are needed to **enable change for the good of public health**.

## Call to Action

- Continue to **pursue additional pilots** and increase the comfort level of NRAs.
- **Embrace technology** as a friend and enabler.
- The more comfortable NRAs are with the process and experience, the **faster cloud projects and platforms can be widely implemented**.

# The Technology

A cloud-based SaaS platform **connecting** the regulatory ecosystem with intuitive tools that *streamlines data and information flow from origin to reviewers.*



# A Proven Platform with Global Reach

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

**70+**  
Agencies

across

**6**  
Continents

PURPOSE-BUILT SaaS PLATFORM + REGULATORY EXPERTISE

# The Value of Regulatory Connection

Ecosystem-wide impact, patient-focused outcomes

## SUBSCRIBERS



### TIME SAVING

Power faster approvals within a reliance framework

- Reduce timeline by up to 100-weeks

Streamline and expedite HAQs

- *Reduce duplicative questions*
- *Reduce number of questions*



### COST SAVING

Optimize facility capacity



### REDUCED MEDICINAL WASTE

Reduce Inventory

- *Transition to optimized product SKU*

## REGULATORS



### TIME SAVING

Instantaneous and simultaneous access

- Pulls review time forward
- Eliminates time to track down documentation
- Enables collaboration on questions



### TRANSPARENCY AND TRUST

Review the same content: documents, questions, etc.

- View the full dossier



### INNOVATION

Accelerate digital transformation strategies

## PATIENTS



Accelerate access to therapies globally

# Accumulus Platform Project Spotlight

Building Trust through Greater **Connectivity** and Transparency

## *Sample projects in the platform*

### **CMC Post Approval Change** (via reliance regulatory pathway)

- A single digital Dossier (eCTD)
- Assessment reports
- HAQ
- Decision tracking

### **Clinical Line Extension** (via reliance regulatory pathway)

- A single digital Dossier (eCTD)
- Assessment reports
- HAQ
- Decision tracking

### **Scientific Advice** (CEPI with 19 NRAS + 2 NGOs)

- Shared CMC best practices documents
- Inline comments and questions

***Coming Soon: AVAREF Pilots, IGAD Pilot, CTA Joint Review, Initial Application Review, and more!***

# Regional Regulatory led Pilots

## AVAREF

- Collaboration with CEPI, GATES Foundation to partner with AVAREF to establish a centralized clinical trials application process powered by the Accumulus platform for the African continent
  - First pilot starting October 20th, 2025
  - Participating countries include Uganda, Tanzania, Kenya, Ethiopia, Gambia, Rwanda, Nigeria, Senegal, Gabon, Burkina Faso, Ghana, Egypt
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## IGAD

- Call for public interest in dossier submission for pilot using Accumulus
  - Single dossier powered by Accumulus platform
  - Target start date: TBD
  - Participating countries include Djibouti, Eritrea, Ethiopia, Kenya, Somalia, South Sudan, Sudan and Uganda
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## Chile & LATAM

- Chile driving first ever joint assessment in Latin America in partnership with PAHO
- Single dossier biosimilar joint assessment powered by Accumulus platform
- Target start date: December 2025
- Participating countries include Argentina, Brazil, Colombia, Chile, Ecuador, El Salvador, Honduras, Costa Rica - and PAHO

# Responsible AI for Digital Equity

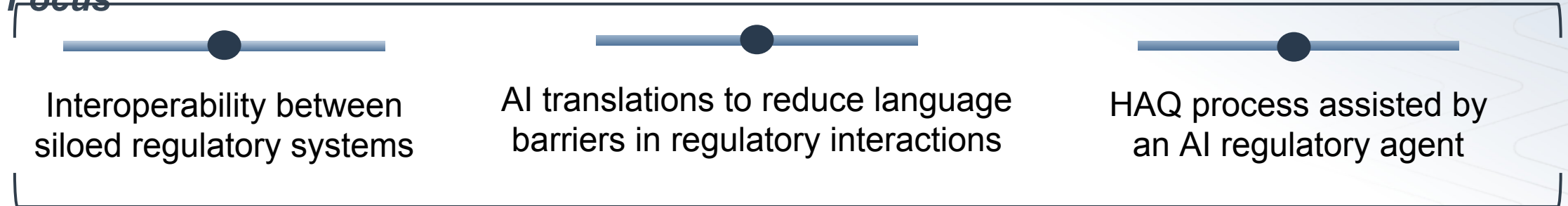
Breaking barriers for **connectivity** with AI translations and intelligent Q&A

At Accumulus Technologies, AI will be leveraged when and where it makes sense to solve the most pressing global challenges limiting access to therapies. Our approach is rooted in **responsibility, transparency, and equity.**

## Near-Term

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### Focus



*\*This information regarding Accumulus Technologies' near-term focus is not a commitment to deliver any material, code, or functionality. The development, release, and timing of any feature or functionality described for the Accumulus platform remains at the sole discretion of Accumulus Technologies.*

*AI to drive digital equity is **only** possible with a trusted platform where regulators, sponsors, and stakeholders come together to connect and collaborate*