



Phuse SDE Kobe

December 8, 2023

Disclaimer

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Agenda

- Accumulus Mission, Vision, and Approach
- Product Update
- Regulatory Engagement Strategy
- Subscription and Membership

OUR MISSION

To dramatically accelerate critical therapies to citizens of the world



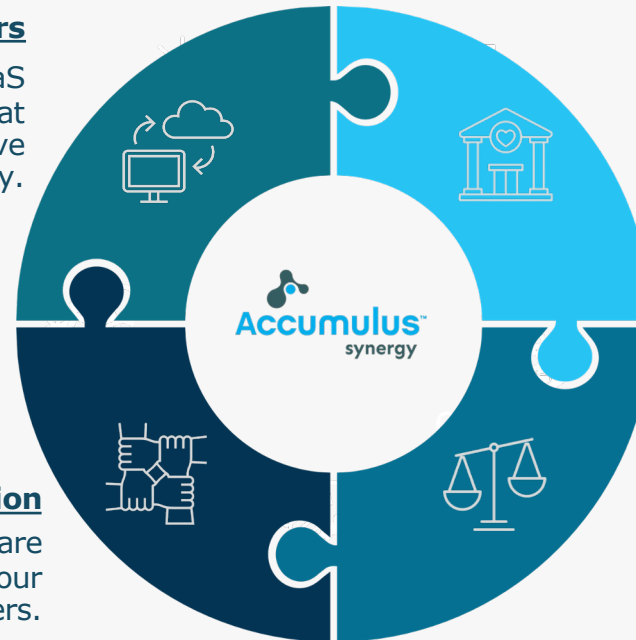
Who We Are

Technology Developers

Via the development of a data exchange, SaaS platform, we are pushing the boundaries of what is currently possible to create transformative changes and improvements in industry.

An Industry Association

As an Industry Association, our primary goals are to represent and advocate for the interests of our stakeholders and members.



A Nonprofit

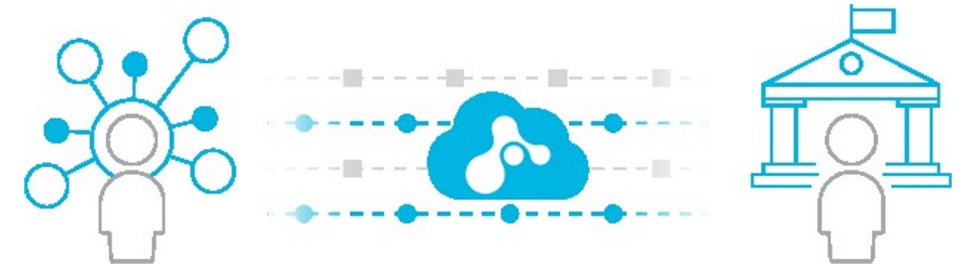
Accumulus Synergy is registered in the United States as a 501(c)(6) nonprofit organization and therefore has no shareholders or financial interest beyond advancing its purpose to improve efficiency and innovation in regulatory processes.

Regulatory Influencers

It is through deep Regulatory subject matter expertise that Accumulus is able to engage with Health Authorities, influence policy, and positively impact public health.

PRODUCT VISION

To propel the industry toward a fully data-driven, global dossier in the cloud



global dossier

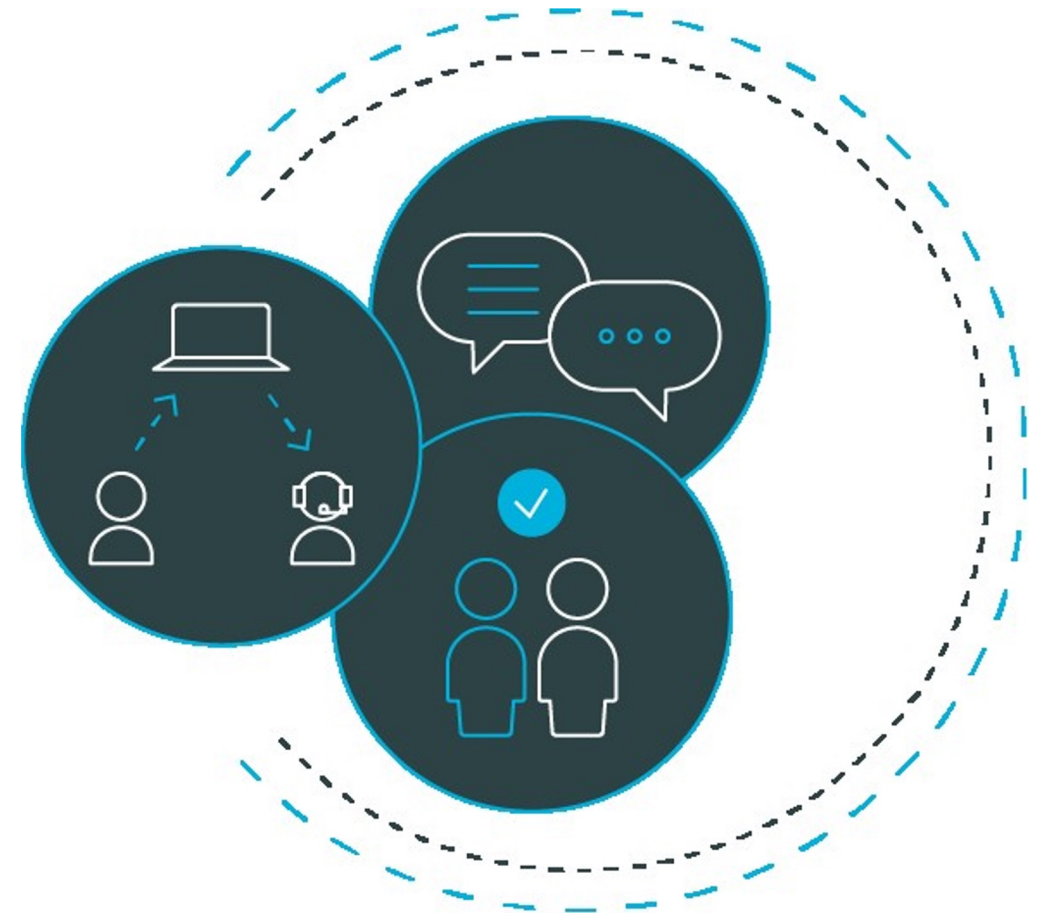
: lifecycle data management for a drug product from pre-clinical to post-approval

| Life Sciences Organizations generate data and content for a *dossier* once and use it repeatedly for filings around the world, with several Health Authorities at the same time

PRODUCT STRATEGY

A first-of-its-kind Data and Information Exchange Platform to support any interactions between Life Sciences Organizations and Global Health Authorities

- *Built for both the process needs of today and the evolving digital regulatory landscape of the future –*



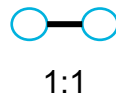
Interaction Capabilities



Interaction Support

“Get everyone in the **same room** together”

Key Paradigm Shift



Key Capabilities



Real-Time
Collaboration



Two-Way
Communication

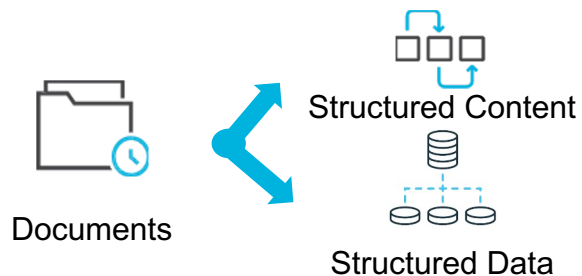
Data and Information Exchange Capabilities



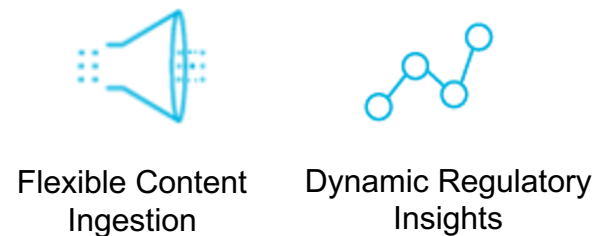
Data and Information Exchange

“Give everyone in the room **documents, data, or visuals** to collaborate on”

Key Paradigm Shift



Key Capabilities



Example Content

Project Specific Documents
Orbis Assessment Aid
Orbis Global Submission Plan
FDA Label
CMC PAC HAQs

How We Increase Value Over Time

As the platform expands to support **more varied content**,
the sophistication of the **information exchanges** grows,
so the magnitude, impact, and **value of the collaborations**
increases.

Accumulus Platform Capabilities

Collaboration

- Sponsor – health authority
- Sponsor – 2+ health authorities
- Health authority – health authorities

Health Authority Invitation

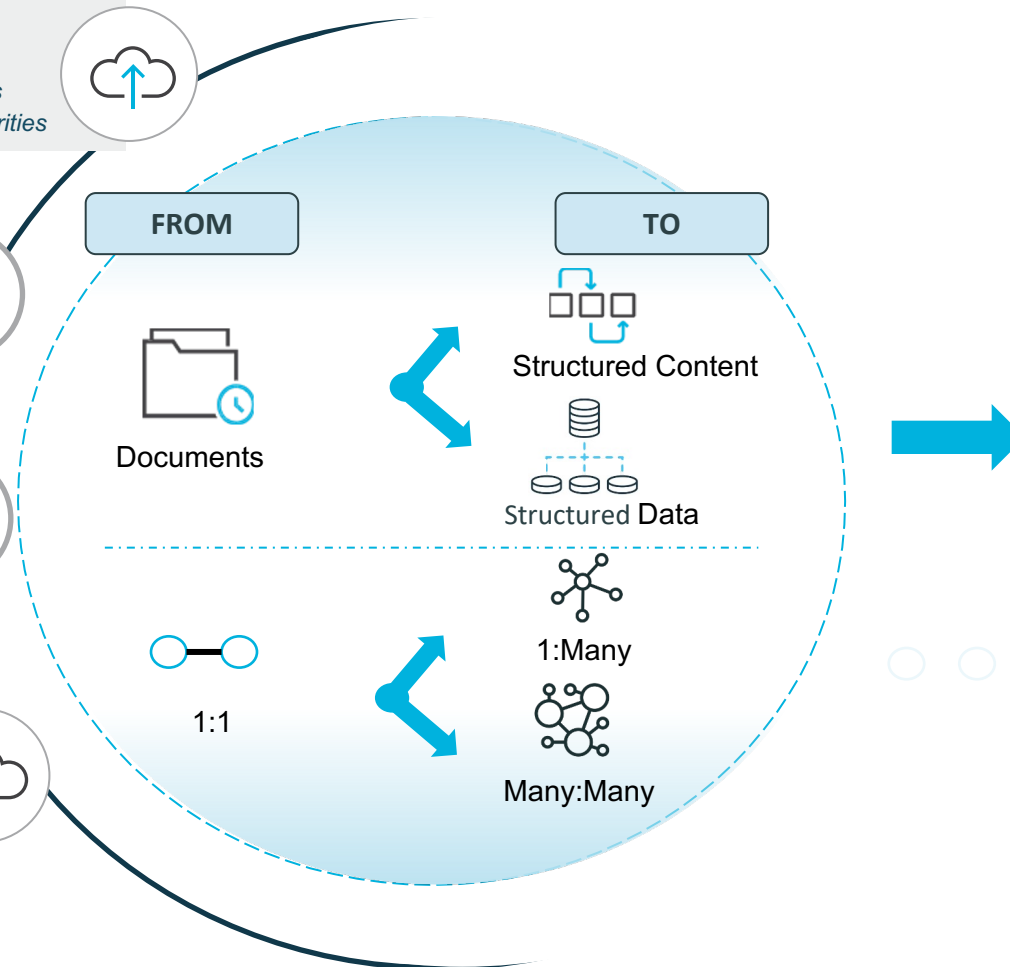
- Scalable process
- Electronic forms
- Electronic submission

Health Authority Question Library

- Reduced effort
- Searchable repository
- Increased visibility

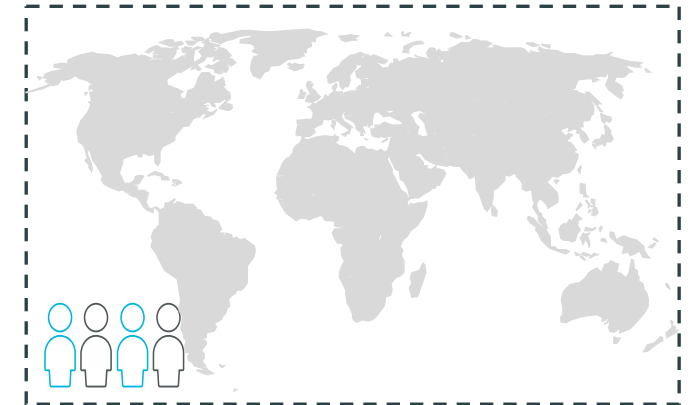
Structured Content

- Transformation of unstructured content
- Flexible output – documents or data
- Content upload and parsing



Regulatory Convergence

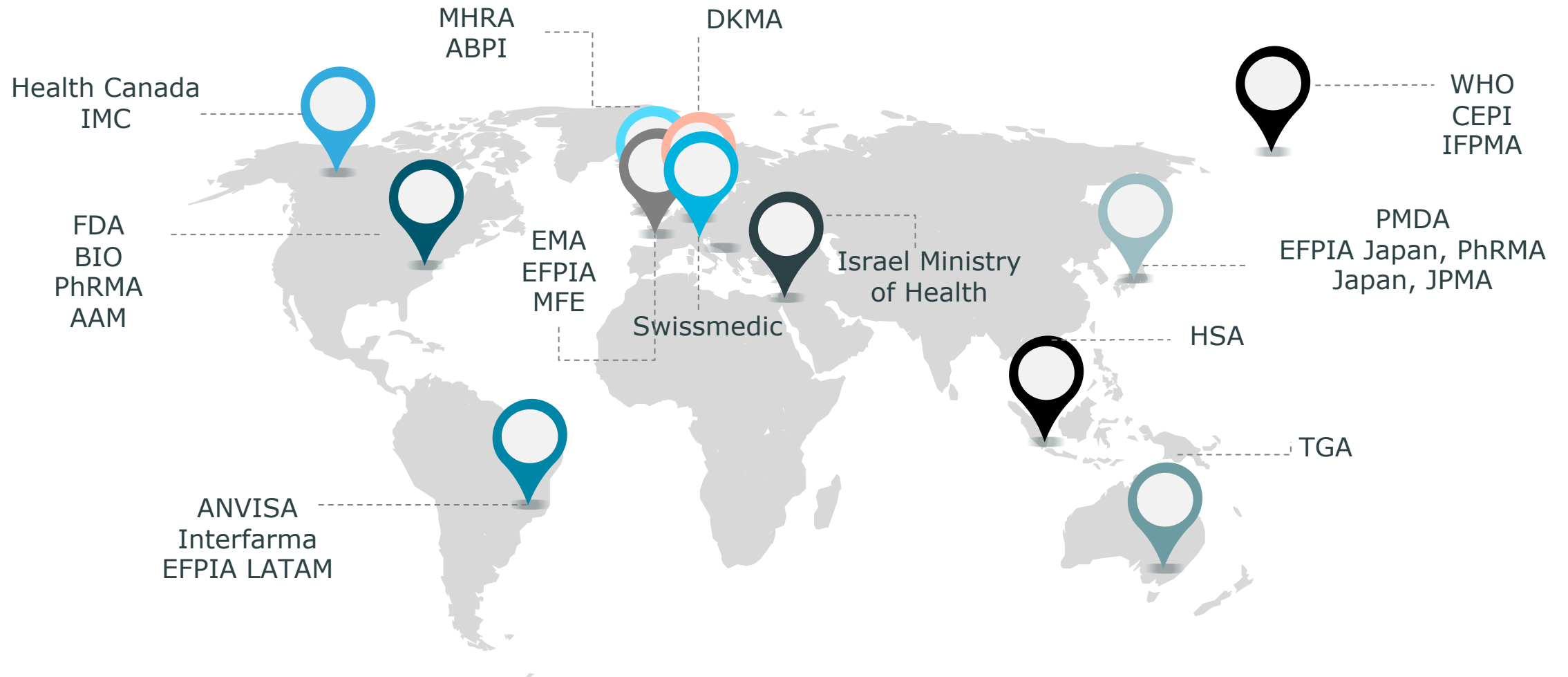
**Jurisdictional autonomy will be maintained*



Organizational Sovereignty
Secure & Private by Design | Distributed | Multi-Tenant

Current Health Authority & Trade Association Engagement

Accumulus is focused on broadening stakeholder engagements worldwide to develop and deepen relationships.



The Accumulus Associate Membership Model

MEMBERSHIP

Engage with organizations in broader life sciences ecosystem; collaborate to support and raise awareness around policies that help advance digital transformation

Associate Membership Model Objectives

- Build a community within the global regulatory ecosystem to collaborate, support, and raise awareness around policies that help advance digital transformation
- Establish greater regard with Health Authorities by engaging a wider range of industry participants beyond our platform subscribers and Sponsors
- Advance our mission to accelerate therapies to patients around the world

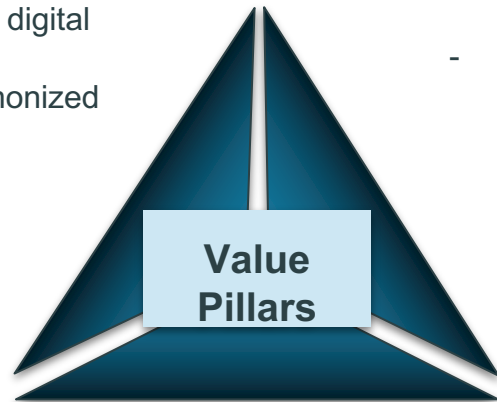
Our Unique Value for Associate Members

Policy Influence

- Enable regulatory harmonization and convergence through digital transformation
- Promote adoption of harmonized global data standards

Digital Transformation Preparation

- Prepare for a cloud-based digital transformation
- Incorporate people, process, and technology progression



Global Reach

- Access global HA perspectives
- Engage with diverse stakeholders in global regulatory system

2024 Introductory Member Benefits

Global network

- Participate in semi-annual dynamic discussion on global HA work and priority policy areas
- Access global community of diverse industry leaders within the regulatory ecosystem

Regulatory policy strategy

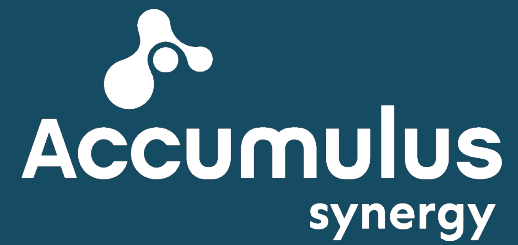
- Participate in Regulatory Policy subcommittees
- Receive updates from the quarterly Accumulus Regulator Forum
- Access timely analysis on regulatory policy activities

Digital transformation preparation

- Participate in Regulatory Operations subcommittee
- Access to digital transformation considerations, including: people, process, technology

Accumulus update

- Receive annual update on Accumulus progress, priorities, and product roadmap



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