

## Regulator Forum

13 October 2023

9:00am ET; 6:00am PST

### Health Authority Attendees:

Karl Hamilton - EMA	Helen Saccone - FDA	Mary Ann Slack - FDA
Sorin Nastea - FDA	Murray (Mac) Lumpkin - Bill and Melinda Gates Foundation	Billy Wilson - Health Canada
Daniel Buijs - Health Canada	Michael McDonald - HPRA	Sean d'Art - HPRA
Michal Hirsch - IMoH	Rosette Tobias - IMoH	Glenn Wells - MHRA
Phil Gillibrand - MHRA	Hiramoto Naruhiko - PMDA	Ryo Saito - PMDA
Tamiya Kenichi - PMDA	Stephan Jaermann - Swissmedic	

### Accumulus Synergy Attendees:

Khushboo Sharma	Ashley Jones-Mitchell	Amit Becker
Russell Burt	Marvin Larry	Bill Gibson
Kaarin Gordon	Jillian Wein Riley	

#### Introductions

- Accumulus Representatives were introduced and all attending regulators and observers were welcomed.

#### Technology and Security

- Accumulus provided an overview of technology architecture, application and data security and privacy, and compliance.
- Accumulus provided clarity around data sharing between regions.
- Accumulus addressed questions from the attending regulators around how data is shared and replicated within the platform and amongst the regulator's space.
- Accumulus provided clarity to Forum participants around work sharing within the platform, as well as how it differs from record keeping.

## **Business Model Update**

- Accumulus provided an overview of the current thinking around the subscription model for Life Science Organizations (LSOs) and HAs, as well as a description of the Accumulus non-voting Membership model.
- Forum participants agreed that Accumulus should develop business continuity plans to mitigate risks (i.e., the ability to export documents from the platform).

## **Product Update**

- Forum participants were provided an overview of the Accumulus product vision and strategy, as well as a description of the platform capabilities around interaction support and data and information exchange.
- Forum participants were presented with a product update for calendar year 2024 and 2025.
- Accumulus provided updates around the scope and timing of the Product Preview.
- Accumulus shared that the first release will be CMC Post Approval Changes (PAC) Reliance, which is anticipated for early 2024. In parallel, Accumulus is continuing to work on the Project Orbis use case.

A **Discussion** and **Q&A** session was held.

- A question was raised around who will have permissions to collaborate on a shared document within the platform; it was clarified that only participants invited to collaborate within each project will have access to the shared document.

*A final version of the meeting summary will be shared with attendees and publicly on Accumulus's website no later than mid-December.*