

## Regulator Forum

Tuesday, July 18th, 2023

7 am EST / 4 am PST

### Attendance

#### Accumulus Synergy

|                       |              |             |
|-----------------------|--------------|-------------|
| Khushboo Sharma       | Dom Lagrave  | Bill Gibson |
| Jillian Wein Riley    | Dawn Russell | Amit Becker |
| Ashley Jones-Mitchell | Ali Hansford |             |

#### Regulators

|                                  |                          |                          |
|----------------------------------|--------------------------|--------------------------|
| Leonardo (ANVISA)                | Daniel Buijs (HC)        | Harriet Teare (MHRA)     |
| Jessica Kirby (MHRA)             | Mary-Ann Slack (FDA)     | Phil Gillibrand (MHRA)   |
| Tamiya (PMDA)                    | Ryo Saito (PMDA)         | Sorin Nastea (FDA)       |
| Stephan Jaermann<br>(Swissmedic) | Yoshihiro Matsuda (PMDA) | Naruhiko Hiramoto (PMDA) |

#### Operating Procedure Review

- *Accumulus Synergy (Accumulus) formed the Regulator Forum (the Forum) to consistently and efficiently capture health authority and regulating body perspectives pertaining to a myriad of topics, to include product vision, security, operations, and governance.*
- *It was reinforced that participation in the Forum is voluntary and does not serve as a form of endorsement to either Accumulus' organization or the platform.*

#### Accumulus Mission, Project Orbis, and Current Product Roadmap.

- Accumulus provided an overview of the core platform capabilities, which will support use cases such as Project Orbis, FDA Labeling Negotiations, CMC Post Approval Changes (PAC) Reliance, and Hybrid Inspections.
- Forum participants noted that it should be clear when certain features are turned on and off in the platform, and that there should be flexibility with disabling certain features based on the needs of the regulators. Forum participants also agreed that content needs to have traceability.

### **The Accumulus Business Model**

- Accumulus provided an overview of the Accumulus Business Model around Sponsorship, Membership, Subscription and Research Grants. Accumulus confirmed that membership will not be overly restrictive and will likely utilize a tiered approach.
- Participants asked questions around the intent of the membership model. Accumulus agreed to keep the Forum informed around the progress of membership.

### **Governance Model**

- Accumulus provided a summary of Governance objectives, current progress, and 2024 next steps.

### **Discussion and Next Steps**

- Regulators were asked if there were any objections to representatives from Coalition for Epidemic Preparedness Innovations (CEPI) and the Bill and Melinda Gates Foundation joining the Forum as observers; no objections were voiced. Regulators were also informed that Israel MoH will be joining the Forum.
- Forum attendees agreed it is critically important to ensure the platform works at all stages and maturities of the ecosystem.
- An update on Product Preview will be shared with the Regulators at a future Forum.

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