

Accumulus Synergy Regulator Forum | Meeting Summary

09 April 2024 | 7:30am ET (1:30pm CET)

Health Authority / NGO Attendees:

Bill Wilson (Health Canada)	Rosette Tobias (Israel MOH)	Nelio Aquino (ANVISA)
Sorin Nastea (FDA)	Michal Hirsch (Israel MOH)	Deb Yeskey (CEPI)
Ethan Chen (FDA)	Kenichi Tamiya (PMDA)	Murray Lumpkin (Gates Foundation)
Tas Keshavji (MHRA)	Naruhiko Hiramoto (PMDA)	Samvel Azatyan (WHO)
Hilmar Hamann (EMA)	Christelna Reynecke (SAHPRA)	Deusdedit Mubangizi (WHO)
Stephan Jaermann (Swissmedic)		

Accumulus Synergy Attendees:

Ashley Jones-Mitchell	Jillian Wein Riley	Kevin Charest
Cesar Vinces	Khushboo Sharma	Patrick Crooks
Chanille Juneau	Maria Sagoua	

Roche Pilot Overview

- An update on the Roche CMC PAC Reliance pilot supported by the Accumulus Platform was provided.

Accumulus Platform Demonstration

- A demonstration of the Accumulus Platform with a focus on PAC Reliance capabilities was conducted.
- After the demonstration, Forum participants asked questions around how the Platform will integrate with eCTD and existing Health Authority technologies. Accumulus confirmed that as the Platform continues to evolve, it is being designed to be flexible and interoperable.
- Forum participants inquired about what governs confidential information in the Platform. Accumulus explained the approach employed during the Roche pilot. In the future, Accumulus envisions having direct relationships with Health Authorities when they subscribe to use the Platform.
- Forum participants discussed data storage and governance as well as how Accumulus will ensure information security. Accumulus explained that its approach is centered

around meeting the needs of the Regulatory community. As the Platform evolves, product security will continue to evolve as well.

- At the July 2024 Regulator Forum meeting, Accumulus' Chief Information Security Officer, Kevin Charest, will provide a deep dive on product security. Accumulus confirmed that Kevin is the appropriate contact for future questions related to security (kevin.charest@accumulus.org).
- Forum participants emphasized that security certifications are critical to the long-term success of the Platform.

Other Discussion Items

- Forum participants raised the topic of governance and funding as it will apply to WHO and regulators in low-income countries. Accumulus and Forum participants agreed that this requires further discussion to ensure Forum participants understand and feel comfortable with Accumulus' model.

Next Steps

Health Authorities

- Health Authorities interested in participating as a reference Health Authority in a reliance project should contact Accumulus.
- If there are specific areas of their work where Health Authorities could see improvement from leveraging a cloud-based technology platform, they are encouraged to reach out to Accumulus to brainstorm / discuss.

Accumulus Synergy

- Lessons learned from the Roche pilot will be shared once it is complete.
- More reliance programs with other Sponsors are coming in the next several months.
- The next Regulator Forum meeting is scheduled for **July 09, 2024**.