

## Accumulus Synergy Regulator Forum | Meeting Summary

24 September 2024 | 7:30am ET (1:30pm CET)

### National Regulatory Authority (NRA) / NGO Attendees:

Ethan Chen (FDA)	Desmond Neo (HSA)	Yoshihiro Matsuda (PMDA)
Mark Wong (HSA)	Sorin Nastea (FDA)	Tas Keshavji (MHRA)
Takashi Misu (PMDA)	Alessandro Lazdins (CEPI)	Stephan Jaermann (Swissmedic)
Mei-Ling Chan (FDA)	Murray Lumpkin (Gates Foundation)	Naruhiko Hiramoto (PMDA)
Rosette Tobias (IL MOH)	Samvel Azatyan (WHO)	

### Accumulus Synergy Attendees:

Ashley Jones-Mitchell	Jillian Wein Riley	Kevin Charest
Bill Gibson	Khushboo Sharma	Patrick Crooks
Ali Hansford		

### Roche Attendees:

Francesca Mangia	Susanne Ausborn	
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### Upcoming Reliance Pilots Supported by Accumulus

- Accumulus provided an update regarding upcoming reliance pilot projects that will be supported by the Accumulus platform.

### Roche Pilot Supported by Accumulus (presented by Roche)

- Roche provided an overview of their reliance pilot project supported by the Accumulus platform, including feedback from National Regulatory Authorities (NRAs) on their experience using the Accumulus platform.

### Questions and Discussion

#### *Privacy and Confidentiality*

- Jillian Wein Riley (Accumulus General Counsel) addressed a question about the nature of the confidentiality agreements that are put in place for projects in the Accumulus platform.
- Kevin Charest (Accumulus Chief Information Security Officer) provided an overview of the Accumulus platform's key security safeguards to ensure data protection and security.

### *Product*

- A participant asked a question about whether there is a space in the platform that is limited to interactions among NRAs only. A representative confirmed that there is a regulator-only space in the platform to which sponsors do not have access.
- In response to a question received prior to the meeting, Bill Gibson (Accumulus Chief Technology Officer) confirmed that while Accumulus is actively exploring the use of AI / large language models (LLMs) for incorporation in the Accumulus platform in 2025 and beyond, there are no immediate plans to implement these tools in the near-term Accumulus product roadmap.

### **Next Steps**

- Accumulus intends to participate in the upcoming ICH PQKM Task Force RFI process.