Accumulus Synergy Regulator Forum | Meeting Summary
09 July 2024 | 7:30am ET (1:30pm CET)

National Regulatory Authority (NRA) / NGO Attendees:

Ethan Chen (FDA)	Desmond Neo (HSA)	Gabriela Zenhausern (Swissmedic)
Mark Wong (HSA)	Phil Gillibrand (MHRA)	Kenichi Tamiya (PMDA)
Takashi Misu (PMDA)	Sorin Nastea (FDA)	Tas Keshavji (MHRA)
Tracy Drabble (MHRA)	Yoshihiro Matsuda (PMDA)	Michael McDonald (HPRA)
Sean d'Art (HPRA)		

Accumulus Synergy Attendees:

Ashley Jones-Mitchell	Jillian Wein Riley	Kevin Charest
Bill Gibson	Khushboo Sharma	Patrick Crooks
Chanille Juneau		

Roche Pilot Overview
- Accumulus provided an update on the Roche Chemistry, Manufacturing, and Controls Post-Approval Change (CMC PAC) Reliance pilot supported by the Accumulus Platform.

Accumulus Product Updates
- Chanille Juneau, Accumulus Chief Product Officer, provided an update related to the Accumulus product roadmap.

Security Updates
- Kevin Charest, Accumulus Chief Information Security Officer, provided an update related to the Accumulus security roadmap and team structure.

Industry Reliance Survey
- Accumulus reviewed a recent Centre for Innovation in Regulatory Science (CIRS) Industry survey regarding key enablers and barriers of adopting reliance.
- Members and observers of the Regulator Forum were invited to give feedback on the CIRS Industry survey, offering insights into the enablers and barriers to adopting reliance from their perspectives.

Next Steps
NRAs

- NRAs interested in participating as a reference Health Authority in a reliance project should contact Accumulus for next steps.
- If there are specific areas of their work where NRAs 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 later this year.
- The next Regulator Forum meeting is currently scheduled for **September 24, 2024**.