

Accumulus Synergy Regulator Forum | Meeting Summary

03 June 2025 | 7:30am ET (1:30pm CET)

National Regulatory Authority (NRA) / NGO Attendees:

Rim Mahmoud (EDA)	Christelna Reynecke (SAHPRA)	Takashi Yasukawa (PMDA)
Wael Adel Elsisy (EDA)	Desmond Neo (HSA)	Yoshihiro Matsuda (PMDA)
Mei-Ling Chan (FDA)	Mark Wong (HSA)	Takashi Misu (PMDA)
Seoh Thin (HSA)	Varela Nektaria (EMA)	Koichi Shikawa (PMDA)
Bandar Alhammad (Saudi FDA)	Claire Harrison (MHRA)	Kenichi Tamiya (PMDA)
Stephan Jaermann (Swissmedic)	Shinichi Okudaira (PMDA)	Koji Numasawa (PMDA)

Accumulus Synergy Attendees:

Ashley Jones-Mitchell	Chanille Juneau	Kevin Charest
Cesar Vinces	Khushboo Sharma	Patrick Crooks

Projects Supported by Accumulus

- Accumulus provided an overview of the current pilot project with CEPI.
- Accumulus also provided an update on current sponsor / industry pilots.
- Accumulus provided an overview of early learnings from regulators, including findings from regulators related to time savings, transparency and trust, and innovation / digital transformation.

Clinical Data Discussion

- ⌘ Chanille Juneau, Accumulus Chief Product Officer, provided an overview of Accumulus' vision toward data-driven submissions.
- ⌘ Attendees inquired whether there are any specific criteria to be involved in a pilot related to clinical data.
 - Accumulus confirmed that there are no specific criteria to be involved. NRAs that are interested in participating should reach out to Accumulus.
- ⌘ Attendees had the opportunity to answer several poll questions related to the clinical data discussion.

- Accumulus will share anonymized results of these poll questions before and/or during the next Regulator Forum meeting.

Any Other Business

- Attendees inquired whether Accumulus intends to incorporate additional notifications in the Platform.
 - Accumulus confirmed that modifications and enhancements related to notifications are on Accumulus' product roadmap.
- The next Regulator Forum meeting has been rescheduled to September 16th in order to accommodate summer holidays.