

## Accumulus Synergy Regulator Forum | Meeting Summary

16 September 2025 | 7:30am ET (1:30pm CET)

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

Mei-Ling Chan (Taiwan FDA)	Mark Wong (HSA)	Yoshihiro Matsuda (PMDA)
Seoh Thin (HSA)	José Crisóstomo Landeros (ISP)	Takashi Misu (PMDA)
Stephan Jaermann (Swissmedic)	Debra Yeskey (CEPI)	Koichi Ishikawa (PMDA)
Seoh Thin (HSA)	Tasneem Keshavji (MHRA)	Kenichi Tamiya (PMDA)
Luljeta Nuraj (KMA)		

### Accumulus Synergy Attendees:

Ashley Jones-Mitchell	Khushboo Sharma	Patrick Crooks
Cesar Vinces		

### Accumulus Synergy Organizational Updates

- Khushboo Sharma and Ashley Jones-Mitchell provided an overview of the recent spinout creating two separate organizations: Accumulus Synergy and Accumulus Technologies.
  - Accumulus Synergy will continue to focus on building a broader collaborative ecosystem where emerging science and policy evolve together.
  - Accumulus Technologies will continue to focus on building, securing, and commercializing the Accumulus platform.

### Accumulus Synergy Policy Priorities

- € Ashley provided an overview of Accumulus Synergy's current priority topic areas:
  - ⊘ *Cross-border data transfer* (evaluating cross-border data sharing practices and developing policy recommendations)
  - ⊘ *Global dossier benchmarking* (benchmarking dossier alignment across regions and identifying areas of convergence)
  - ⊘ *Global analysis of NRA AI use* (assessing NRA AI utilization to develop insights to guide responsible and effective implementation of AI)

- ⊘ The attendees were asked to provide feedback on the priority topics for Accumulus Synergy as well as asked if any other topics should be considered for prioritization.
  - ⊘ ACTION: Accumulus Synergy will share an anonymous survey to gather additional feedback.

### **Data and Information Exchange Policy**

- ⊘ Ashley provided an overview of the Accumulus Synergy Data and Information Exchange Policy task force, which is dedicated to conducting research on the legal, regulatory, and technological frameworks surrounding international cross-border data transfers.
- ⊘ The primary goal of the task force is to examine key:
  - ⊘ Privacy laws
  - ⊘ Data residency requirements
  - ⊘ Data-sharing frameworks