

Accumulus Synergy Regulator Forum | Meeting Summary

09 December 2025 | 7:30am ET

National Regulatory Authority (NRA) / NGO Attendees:

Mei-Ling Chan (Taiwan FDA)	José Crisóstomo Landeros (ISP)	Takashi Misu (PMDA)
Stephan Jaermann (Swissmedic)	Bandar Al Hammad (SFDA)	Loh Seoh Thin (HSA)
Seoh Thin (HSA)	Tasneem Keshavji (MHRA)	Kenichi Tamiya (PMDA)
Luljeta Nuraj (KMA)	Adiela Saldana (ISPCH)	Ake Dennis (NAFDAC)
Alessandro Lazdins (CEPI)	Desmond Neo (HSA)	Mark Wong (HSA)

Accumulus Synergy Attendees:

Ashley Jones-Mitchell	Khushboo Sharma	Patrick Crooks
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Additional Speaker Attendees:

Debra Yeskey (CEPI)	Craig Anderson (Pfizer)	
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Regulatory Preparedness Framework and Pilot

- Debra Yeskey from CEPI provided an overview of CEPI's Regulatory Preparedness Framework.
 - Debra Yeskey provided an overview of a recently conducted Regulatory Preparedness Pilot, which was a scientific advice-like collaborative review using cloud-based technology.
 - In total, 19 NRAs and 2 regulatory organizations participated in the pilot.
- With any additional questions or feedback, Regulator Forum attendees are encouraged to reach out to Debra (CEPI) or Ashley Jones-Mitchell (Accumulus Synergy).

2027 and the Path to Real-Time Data Submission

- ∄ Craig Anderson from Pfizer provided a presentation related to the path to real-time data submission.
 - ∄ Craig Anderson provided an overview of UMC's global PhPID system, FHIR standards for APIX exchange, ePI, CMC, health authority questions/response, and AI agents.

- ⊘ Craig Anderson also discussed how best to accelerate implantation to achieve critical mass quickly and overcome change management obstacles.
- ⊘ Regulator Forum attendees will be provided with a copy of Craig's presentation.
- ⊘ With any additional questions or feedback, Regulator Forum attendees are encouraged to reach out to Craig (Pfizer) or Ashley Jones-Mitchell (Accumulus Synergy).

Wrap-up and Closing

- ⊘ Today's meeting is the last Regulator Forum meeting in 2025.
- ⊘ Currently, the next planned Regulator Forum meeting is scheduled for March 3, 2026.