

Accumulus Synergy Regulator Forum | Meeting Summary

11 March 2025 | 7:30am ET (1:30pm CET)

National Regulatory Authority (NRA) / NGO Attendees:

Ethan Chen (FDA)	Freddie Foo (HSA)	Mariam Almazrouei (UAE EDE)
Yen-Chen Chang (Taiwan FDA)	Desmond Neo (HSA)	Bandar Alhammad (Saudi FDA)
IshiKawa (PMDA)	Mark Wong (HSA)	Stephan Jaermann (Swissmedic)
Tang Xuhua (HSA)	Yasukawa (PMDA)	Deb Yeskey (CEPI)
Tamiya-Kenichi (PMDA)	Yoshihiro Matsuda (PMDA)	Olga Rovira (CEPI)
Mac Lumpkin (Gates Foundation)	Nektaria Varela (EMA)	Sorin Nastea (FDA)
Numasawa (PMDA)		

Accumulus Synergy Attendees:

Ashley Jones-Mitchell	Jillian Wein Riley	Ali Hansford
Cesar Vinces	Khushboo Sharma	Matteo Calgaris
Chanille Juneau	Melissa Facini	

Amgen Attendees:

Mike Abernathy		
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Accumulus Platform Key Features

- Accumulus provided an overview of the key features and core capabilities of the platform. These key features include:

Projects Supported by Accumulus

- Accumulus and CEPI provided an overview of the CEPI and Accumulus partnership for pandemic preparedness and the CEPI CMC best practice pilot. CEPI also provided an overview of the regulatory preparedness framework to prepare for future public health emergencies.

- Accumulus provided an overview of the various projects being supported by the Accumulus Platform.
- Mike Abernathy of Amgen provided a deep dive into the Amgen project, including the innovative digital regulatory transformations.
 - Mike showed the production live Accumulus Platform that is currently in-use for the Amgen project.
- Accumulus explained the Regulator pricing structure.

Integration Discussion

- The following questions were discussed among the attendees with regard to their current thinking on integration:
 - What is your current system of record for submissions?
 - Do you have an internally developed system or a system that was purchased?
 - Do you typically integrate or do you use disparate systems?
 - What challenges have you experienced in the past with integration?
 - Would your preference be to integrate the Accumulus Platform with an existing system or use the Platform as one way to transfer information in addition to your current submission process?