

Meeting Summary for attendees

Meeting:	Industry Association Forum
Meeting date and time:	14 January 2025 1-2pm GMT
Accumulus Contact:	Ali Hansford (ali.hansford@accumulus.org)

Attendees

Accumulus

- Ali Hansford (Chair), Director of Regulatory Innovation Strategy and Policy, Europe
- Ashley Jones-Mitchell, Director of Regulatory Innovation Strategy and Policy, North America
- Cesar Vinces, Senior Director of Regulatory Innovation and Policy, International
- Jeff Schnack, Asia Regulatory Policy Lead
- Khushboo Sharma, Chief Regulatory Innovation Officer
- Maria Barhams Sagoua, Director of Regulatory Innovation
- Patrick Crooks, Program Manager, Regulatory Innovation

External organizations

- ABPI (Dan O'Connor)
- BIO (Steve Berman)
- JPMA (Ayako Okayasu)
- PhRMA (Rebecca Nebel)
- SAPI (Sandy Chan)
- IMC (Emily Roome)
- BioPhorum (Jane Worthington)
- Medicines for Europe (Beatriz Solanas)
- IFPMA (Janis Bernat)

Apologies

- Interfarma Brazil (Luciana Shimizu Takara)
- Interpharma Switzerland (Tanja Colin)

- Medicines Australia (Anne-Maree England and Tham Vo)
- SAPI (Kum Cheun Wong)
- EFPIA (Sini Eskola)
- Pistoia Alliance (Thierry Escudier)
- Medicines for Europe (Remco Munnik)

Introductions

Attendees were welcomed to the meeting, and everyone introduced themselves to the group.

Key updates and announcements from Accumulus

Press releases

Ali informed the group that CSL and Chugai Pharmaceuticals have joined Accumulus as members. Ali also shared a press release from 7th November 2024 announcing Sanofi's use of the Accumulus platform.

CEPI Partnership

Khushboo gave a brief overview of the new Accumulus and CEPI strategic partnership, including a planned pilot project focused on pandemic preparedness. The benefit of pre-reviewing various documentation leading to an expedited review process was discussed.

Evaluation data from health authorities

Ali reviewed data and outcomes from the Roche case study, which was Accumulus' first conducted pilot project. The group discussed whether the ability to gain such fast alignment across NRAs will be achievable in another project type such as a change in indication. Accumulus has an ongoing project related to a clinical line extension and will be able to share data from that project once completed.

Regulatory policy priorities for 2025 – Accumulus

Engagement Structure

Ali presented the structure for the regulatory innovation team's engagement with Sponsors. "Task Forces" are new to the structure and will be formed as and when required. Data Management will be a key policy focus area for Accumulus in 2025,

including data sharing, data ownership, and data residency. Ali and Ashley from Accumulus will be leading a Task Force in 2025 related to this topic.

Regional priorities

Accumulus regional policy leads (North America, Europe, Asia, and International) provided updates related to 2025 priorities:

- North America: Ashley discussed our previous and ongoing work with FDA.
- Europe: Ali reviewed 2025 goals across EMA/NCAs, Swissmedic and MHRA.
- Asia: Jeff reviewed 2025 goals across the Asia region.
 - Sandy Chan raised the importance of involving ACCESS Consortium countries in our engagement efforts.
- International: Cesar discussed ongoing work in the Africa, Latin America, and Middle East regions. Accumulus will be participating in a FIFARMA industry workshop in February 2025.

Regulatory policy priorities for 2025 – meeting attendees

- Jane Worthington (BioPhorum) highlighted their 2025 priorities on structured data and CMC regulatory intelligence.
- Dan O'Connor (MHRA) highlighted their work with MHRA on their new IT system, Regulatory Connect, including potential use of a self-service approach to regulation for Type IA variations.
- Janis Bernat (IFPMA) indicated a continuing prioritization of increased use of regulatory reliance in 2025.

Next steps & AOB

Accumulus will be attending DIA Europe in March. Please contact Ali if you are also attending and would like to connect at the conference.

The next Industry Association Forum meeting will be held on 15th April 2025, 1-2pm UK time and an invitation will be sent to attendees after this meeting.