



February 24, 2023

European Medicines Agency  
Domenico Scarlattilaan 6  
1083 HS Amsterdam  
The Netherlands

**RE: Accelerating Clinical Trials in the European Union, Priority Action 3 concept paper: an EU multi-stakeholder platform for improving clinical trials**

To Whom It May Concern:

Accumulus Synergy (Accumulus) appreciates the opportunity to provide feedback on the Accelerating Clinical Trials in the European Union (ACT-EU) concept paper aimed at improving clinical trials through the establishment of a multi-stakeholder platform. Accumulus supports the ACT-EU initiative and its goals of advancing innovative clinical research and modernizing clinical trial strategies. The multi-stakeholder platform approach offers the potential to increase engagement opportunities, leverage knowledge among participants, and enhance the efficiency and effectiveness of clinical trials.

Accumulus shares the goals of this initiative and is developing a data exchange platform to promote collaboration and enable enhanced efficiencies in how regulatory interactions occurs among stakeholders in the regulatory ecosystem. Technological solutions are needed to drive change in clinical trial innovation.

Digital health technology, including artificial intelligence, data analytics, and digital tools, can improve the discovery, development, manufacturing, evidence generation, assessment, supply and use of medicines. Enabling the integrated use of cloud technology that is aligned across regulatory regions allows for the structured sharing of data and reduces the need for multiple submissions of the same information to different global health authorities. It also allows for receiving, storing, managing, and analysing large data sets that are increasing in prominence with more complex medical product development programs. In addition, expanded use of real-world data (RWD) can help address some of the current limitations of clinical trials. Through enhanced technological solutions, RWD can be effectively applied to generate complementary evidence across the product life cycle.

The ACT-EU concept paper acknowledges that a broad scope of key stakeholders are needed for the platform, including regulators, sponsors, patients, policy makers, and health technology assessment bodies. Accumulus is working towards a cloud-based platform that has the potential to include many of these different stakeholders for enhanced collaboration and data and information exchange. Accumulus would like to be included as a member of this platform and offer our support to enable clinical trial transformation and to help address the challenges facing the European healthcare ecosystem.



Accumulus Synergy is a non-profit trade organization formed in 2020 to create a cloud-based platform to transform data sharing between the life science and global health authorities. The cloud platform approach aims to improve efficiencies in the regulatory process by leveraging advanced technology, including data science and AI, as well as tools for secure data exchange to improve patient safety, help reduce the cost of innovation, and ultimately bring patients safe and effective medicines faster. Accumulus will work with key stakeholders to build and sustain a platform that meets regulatory, cybersecurity, and privacy requirements spanning clinical, safety, chemistry and manufacturing, and regulatory interactions.

Accumulus appreciates the efforts being implemented by the European Commission, Heads of Medicines Agencies, and the EMA to improve and modernize clinical trials, as well as the efforts to bring stakeholders together to advance these initiatives. Accumulus would like to be a partner in this effort and welcomes the opportunity to discuss our comments further.

Sincerely,

Khushboo Sharma  
Chief Regulatory Innovation Officer  
Accumulus Synergy