

Summary of the 7th Asian Network Meeting

1. Overview

- The 7th Asian Network Meeting (ANM) was held in Tokyo, Japan on 23rd April 2025, attended by 34 participants from 9 countries.
- The meeting was co-hosted by China, India, Japan and Singapore.

2. Regulatory updates by each country

- Each regulator made presentation for regulatory updates since the last meeting.
- Common issues observed were related to adjusting regulation to technological development:
 - Utilization of new technology in regulation (e.g. Digitalization)
 - Securing rapid patient access to innovative products
 - Introduction of “reliance” in the regulatory process (including ATMP)
- Other significant recurring themes included:
 - Regulatory measures to avoid shortages and ensure a stable supply chain
 - Participation in international regulatory harmonization activities

3. Presentation and Discussion

In sessions 5 and 6, several countries made presentations followed by panel discussion. Major points highlighted in each session were as follows:

Session 5: Clinical Trial Challenges: How to overcome existing challenges?

- Challenges for both regulators and academia/medical institutes were identified.
- Some of the practices/actions for regulators to overcome those challenges included:
 - Capacity building for assessment of submitted clinical trial documents.
 - Incorporation of reliance and/or risk-based assessment for timely assessment of clinical trial documents (including protocol).
 - Encouragement of sponsors to use consultation at pre-submission phase to reduce issues in protocols.
 - Proper GCP inspection and training on GCP for clinical trial sites for quality control of clinical trials.
 - Information exchange and development of guidelines for adopting new technologies in clinical trials.
- Some of the practices/actions for academia/medical institutes to develop fundamental environment for conducting clinical trials included:
 - Education and communication with patients and care givers, education to healthcare providers (medical doctor, nurse, pharmacist, etc)
 - Development of key opinion leaders
- Other challenges identified were such as financial/funding to clinical trial sites and reducing cost for clinical trial operation.

Session 6: Sharing Best Practices: Reliance and Convergence

- Efficiency benefits are a key driver for reliance and convergence. However, current challenges remain given differences between various regulatory agencies' approaches.
- Major actions were proposed included:
 - Accelerating trust-building processes between Asian regulatory agencies
 - Facilitating reliance mechanisms by considering other management approaches:
 - Participating in Joint assessments with regulatory authorities
 - Utilizing WHO Collaborative Registration Procedure (CRP)
 - Maximizing the use of trainings by APEC Centre of Excellence for regulatory staffs in Asia
 - Facilitate cross-agency exchanges to understand different systems

4. Others

- The 8th ANM will be held in Tokyo, Japan, around the 4th week of April 2026, back-to-back with APAC like 7th ANM, to obtain synergy effect as this year.
- Co-hosting countries will jointly prepare for the next meeting contents.

5. Outcome

Based on the presentations and discussion held during the meeting, the outcome of the 7th ANM was summarized as follows:

- Clinical trial challenges for both regulators and academia/medical institutes were identified. Some of the practices/actions were shared and participating countries agreed to promote clinical trials through ANM and work together to address challenges.
- To further promote reliance and convergence in Asia, participating countries recognized that trust building, adopting and understanding best practices from each other, and building stronger international cooperation are needed.