

DIA

DIA Asia Track - Oct 19th 2026

Asia Leading the Next Era of Global Drug Development:
Harmonization, Innovation and Patient-focus

Online



Overview

The Asia Track, in conjunction with the DIA Japan Annual Meeting, is designed to provide a collaborative platform for key stakeholders across Asia, including regulatory authorities, industry, academia and patients, to exchange insights and advance the future of global drug development.

Under the theme “Asia Leading the Next Era of Global Drug Development: Harmonization, Innovation and Patient-Focus,” the program highlights the increasingly important role of Asia in shaping the global pharmaceutical landscape. As the Asia region continues to grow in scientific capability, regulatory maturity, and market significance, there is a strong need for enhanced collaboration and alignment across countries.

The Asia Track aims to promote regulatory harmonization, encourage innovative approaches in drug development, and emphasize the importance of integrating patient perspectives throughout the healthcare and product lifecycle. By fostering open dialogue and knowledge sharing among stakeholders, the program provides valuable opportunities to address challenges that are particularly relevant to Asia, identify common priorities, exchange experiences and best practices across the region, and articulate shared Asian perspectives to help inform and shape global discussions in regulatory science.

Through this initiative, the Asia Track aspires to contribute to a more coordinated and forward-looking ecosystem in Asia, ultimately enabling faster access to innovative medicines and improved health outcomes for patients across the region.

Simultaneous Translation by AI system is available



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Drug Information Association

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DIAglobal.org

Monday October 19

9:00-9:05 Opening: Marwan Fathallah

9:05-9:10 Welcome Remark: Yoshiaki Uyama

9:10-10:40 SESSION 1

Regulatory Science in Asia: Advancing Drug Development with Collaboration in Asia

Session Chair: Masao Iwagami, Joonwoo Bahn

This session will explore current initiatives and collaborative mechanisms that are strengthening regulatory science in Asia. The session will begin with an overview of the OPEN Collaborative Procedure and proposed initiatives for its further advancement, highlighting how international regulatory cooperation can accelerate access to innovative medicines. This will be followed by a discussion on Asian Clinical Trial network as a strategic platform for promoting drug development in Asia, emphasizing their role in harmonizing evidence generation and facilitating efficient drug development. The session will also examine emerging Real-World Data (RWD)-driven collaborations in Asia, presenting current examples and discussing future opportunities to leverage real-world evidence in regulatory decision-making and post-market evaluation.

The session will conclude with a panel discussion featuring experts from regulatory authorities, academia, and industry to explore the future vision of a Asia regulatory system.

9:10-9:30
(20m)

Topic 1

OPEN Collaborative Procedure and Proposed Initiative for Further Advancement

Hodei Cuenca Grao (European Medicines Agency)

9:30-9:45
(15m)

Topic 2

ATLAS (Asian Clinical Trial Network for Cancer Project) as a Platform to Accelerate Innovative Drug Development from Asia

Kenichi Nakamura (National Cancer Center)

9:45-10:00
(15m)

Topic 3

Real-World Data (RWD)-Driven Collaboration in Northeast Asia: Current Cases and Future Directions

Judy Shin (Sungkyunkwan University)

10:00-10:40
(40m)

Panel discussion

Future: Toward an Asia Regulatory System

All speakers +

Ling SU (DIA Fellow, backup) or National Medical Products Administration o delegate

Yil-Seob Lee (CHA Medical Center)

Ayumi Endo (Pharmaceuticals and Medical Devices Agency)

Ines Lenic (AstraZeneca)

10:40-11:15 (35 min) Networking break

11:15-12:45

SESSION 2a

Beyond E17 - Holistic Implementation of E5 and E17 to Lead Global Drug Development from Asia**Session Chair: Masafumi Yokota, MFDS invited**

This session discusses the holistic and integrated implementation of ICH E5 and E17 to lead global drug development from Asia. Building on the principles of the guidelines, the discussion will focus on practical challenges such as determining the appropriate sample size for each participating country and interpreting the results derived from multi-regional clinical trials (MRCTs).

We will explore specific pathways to overcome differences in regional requirements and construct efficient, scientifically robust development strategies from a pan-Asian perspective. Through this session, participants are expected to gain practical insights for achieving true global harmonization and optimizing clinical development in the Asian region.

11:15 – 11:30
(15m)**Topic 1****Scientific Principles Bridging E5 and E17: Trial Design Focusing on Effect Modifiers**

Shuji Kamada (Pharmaceuticals and Medical Devices Agency)

11:30 – 11:45
(15m)**Topic 2****Beyond Consistency Assessment: Statistical and Regulatory Considerations for Integrated Evidence Evaluation from China Perspective**

Yan Hou (Peking University)

11:45 – 12:00
(15m)**Topic 3****Asia-led Simultaneous Global Development Strategy: Case Studies**

Hyejong Yoo (AstraZeneca)

12:00 – 12:15
(15m)**Topic 4****Leveraging Asia in Global Development Planning through E17/E5 Implementation**

William Wang (Merck US)

12:15 – 12:45
(30m)**Panel discussion****Strategic Recommendations to Improve Patient Access in Asia, leveraging E5/E17 Implementation**

All speakers + (Pharmaceuticals and Medical Devices Agency / Program Chair)

Janet Lu (Shanghai Zhiqiaohang Medical Consulting Co.)

12:45-14:15 (90 min) Lunch Break

14:15-15:45

SESSION 2b

Transformation in Quality Management Approach for Global Clinical Trials - Strategic E6(R3) Implementation to Realize "Flexible" GCP Leveraging CTQ Factors

Session Chair: Izumi Oba, NaYoung Lee

This session highlights the transformation in quality management approaches driven by ICH E6(R3) and discusses the realization of "flexible" GCP operations in global clinical trials. The focus will be on the importance of identifying Critical to Quality (CTQ) factors that are directly linked to protocol objectives during the planning stage and continuously reviewing them throughout the trial.

Furthermore, we will examine practical connections with other guidelines, such as using Estimands (ICH E9(R1)) to identify potential CTQ factors and determining how to communicate priority risk management issues across all participating countries and sites (ICH E17). Through this session, participants will comprehensively learn about next-generation quality management strategies leveraging a risk-proportionate approach.

14:15 – 14:30
(15m)

Topic 1

Paradigm Shift Driven by ICH E6(R3): Realizing 'Flexible' GCP Leveraging CTQ Factors

Osamu Komiyama (ex E8(R1) Expert)

14:30 – 14:45
(15m)

Topic 2

Quality by Design from a Statistical Perspective: Identification and Management of CTQ Factors Using Estimands

Yang Zhao (Nanjing Medical University)

14:45 – 15:00
(15m)

Topic 3

Practical Challenges and Solutions for CTQ Factor Management in MRCTs within Asia

BokJin Hyun (Handok)

15:00 – 15:15
(15m)

Topic 4

Expectations for GCP Renovation Implementation: Opportunities in Asia from a Global Development Perspective

Rebecca Stanbrook (RESaltas GmbH)

15:15 – 15:45
(30m)

Panel discussion

From Asian Practice to Global Practice: Considerations for Realizing Flexible GCP

All speakers

15:45-16:45 (60 min) Networking Break

16:45-18:20

SESSION 3

Advancing Patient-Focused Drug Development: From Clinical Trials to Real-World Medication Use

Session Chair: Ling Su, Dorothy Toh

Patient focus is increasingly recognized as a critical component of drug development and medication use. Integrating patient perspectives can improve the relevance of clinical research, reduce participation burden, and support better treatment adherence and health outcomes.

This session will discuss practical approaches to implementing patient-focused strategies across the drug development lifecycle. It will include patient-centric clinical trial design to reduce burden, such as simplified protocols, decentralized trials, and digital tools that facilitate participation and data collection. The investigator's perspective on how to collect patient voice will be addressed. Discussion will explore how patient preference studies may inform drug development, risk-benefit assessment, regulatory submission and evaluation. The session will also discuss considerations in promoting patient-centric product information (PCPI) worldwide. Through examples and discussion, participants will gain insights into how patient-focused approaches can strengthen evidence generation, improve real-world use of medicines and better empower patients.

16:45 - 17:05
(15m)

Topic 1

Advancing Patient-Centric Product Information (PCPI) across Regions: Enhancing Understanding, Adherence and Patient Empowerment

Rie Matsui (Pfizer R&D Japan G.K.)

17:05 - 17:25
(15m)

Topic 2

Patient Focus from the Investigator's Point of View - How to Collect Patient Voice

Kyu-pyo KIM (AMC)

17:25 - 17:45
(15m)

Topic 3

Decentralized Clinical Trials in Asia: From Innovation to Implementation

Wenjing Zhou (University of Hong Kong, Shenzhen Hospital Clinical Trial Centre)

17:45 - 18:15
(30m)

Panel discussion

Advancing Patient-Focused Drug Development Across the Product Lifecycle: From Patient Voice to Real-World Impact

All speakers + Representative from Patient group

18:15-18:20 Closing: TBD (next hosting country)

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