DIA Asia Meeting 2024

Accelerating Drug Development with Advanced Innovation for Asian Patients

25 September 2024
The-K Hotel Seoul, Korea

Overview

This Asia meeting 2024 will bring together industry, regulatory authorities, and academia to address pressing challenges in public health and drug development in Asia. The event will feature sessions where speakers will discuss recent advancements in regulatory science and the use of innovative tools to expedite clinical development and pharmacovigilance (PV).

One key topic will focus on regulatory agencies' perspectives, highlighting recent advances in regulatory science and how the medical and regulatory landscapes are evolving. Speakers will also explore areas ripe for innovation in regulatory science.

Another topic will delve into the impact of real-world data (RWD) on regulatory decision-making, featuring case studies showcasing RWD's role in indication expansion, new drug approvals, and post-marketing studies. Speakers will assess data quality, integration, analysis methods, and practical considerations.

Additionally, experts from the pharmaceutical industry will discuss the latest developments and practical applications of AI in clinical development. Topics will include indication selection, patient enrichment, AI-supported diagnosis, operational excellence, and AI-powered medical writing.

Lastly, This event will explore the integration of AI technologies in safety surveillance, signal detection, and risk management in pharmaceuticals. Attendees will gain insights into leveraging AI for enhanced patient safety outcomes through collaboration and knowledge-sharing.

Program Chair

Yil-Seob Lee, MD, PhD
CHA Bundang Medical Center

Program Co-Chair

Hironobu Saito, PhD
Tottori University

Wendy Yan, MBA
BeiGene

Jing Ping Yeo, PhD, MBA
George Clinical Singapore Pte Ltd

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AGENDA | September 25, 2024 | ALL TIMINGS IN KST

8.30 – 9.00 am	Registration
9.00 – 9.05 am	**Opening Remarks**
	Young Joo Park, Vice President, Korea, Singapore, and Southeast Asia, DIA
9.05 – 9.10 am	**Congratulation Remark**
	Yu-Kyoung Oh, Minister, MFDS, Korea
9.10 – 9.30 am	**Keynote Speech: Key Strategy to Advance in Regulatory Science**
	Seogyoun Kang, Director General, NIFDS, MFDS, Korea

Session Chair

Yil-Seob Lee
Professor
CHA Bundang Medical Center

9.30 – 11.35 am	**Session 1.** **Recent Advances in Regulatory Science**
	In this session, regulatory agency speakers will address regulatory agencies' perspectives on key areas of recent advances in regulatory science in their respective agencies. Speakers will present and discuss how the medical and regulatory environments will change in the future, and what are areas that are being prepared for advance in regulatory science or how Asia can contribute to the future global drug development. By the end of the session, the audience will be updated on regulatory science in Asia and US.

Session Chairs

Eui-Kyung Lee, PhD
Professor
Sungkunkwan University

Hironobu Saito, PhD
Appointed Professor
Tottori University

9.30 – 9.55 am	Recent Changes on Regulatory Science in US
	Radha Goolabsingh, Global Regulatory Strategy and Engagement Leader, Scientific Affairs, DIA
09.55 – 10.20 am	PMDA Initiative for Advancing Regulatory Science in Japan
	Yoshiaki Uyama, PMDA, Japan
10.20 – 10.45 am	Recent Regulatory Updates in Korea
	Heesung Kim, Director of Pre-Submission Consultation Division, MFDS, Korea
10.45 - 11.10 am	Regulatory Science in China-a perspective from Shanghai
	Yifei Chen, Manager of the Innovation and Regulatory Science Development Department, Shanghai Center for Drug Evaluation and Inspection
11.10 - 11.35 am	Regulatory Science: Singapore's Experience in Supporting Advanced Therapies
	John C W Lim, Executive Director, CoRE, Duke-NUS Medical School
11.35 am - 12.35 pm	**Lunch & Networking**

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12.35 – 2.40 pm	**Session 2.** **Regional Collaboration for the Development of Innovative Products using RWD**
	This session covers into the latest trends and showcases case studies that demonstrate the impact of RWD on regulatory decision-making in China, Japan, Korea, and Singapore. Each presenter will introduce their RWD framework and use cases including drug approval and post-marketing examples. EMA speaker will introduce RWD/E to support EU regulatory decision-making, and share their experiences how to collaborate for better decision.

Session Chairs

Juyoung Shin, PhD
Professor,
Sungkunkwan University

Qiang Li
Regional Epidemiology Lead Asia,
Boehringer Ingelheim, China

12.35 – 1.00 pm	Research Strategy and Future Plan for using RWE toward Regulatory Decision Making
	Seongjun Yang, MFDS, Korea
1.00 – 1.25 pm	RWD and RWE to Support Drug Development and Approval in China.
	Xiaoyuan Chen, Professor, Tsinghua University, China
1.25 – 1.50 pm	Utilizing RWD through a Drug Life-cycle in Clinical Trial and Post-marketing Study for Better Benefit/Risk Assessment
	Yuji Kumagai, Professor, Kitasato Clinical Research Center, Kitasato University Hospital
1.50 - 2.15 pm	Use of EMR Federated Data to Support RWE in Oncology Studies Across Asia Pacific
	Huren Sivaraj, CEO Oncoshot
2.15 - 2.40 pm	Real-World Data/Evidence to Support EU Regulatory Decision-making: Experience of EU Collaboration and Suggestion for Asian Region
	Álmath Spooner, The Chair of the Integrated Evidence Generation and Use working group at EFPIA, Abbvie
2.40 - 3.10 pm	**Coffee Break & Networking**
3.45 – 5.50 pm	**Session 3.** **How to Leverage Innovative Tools to Accelerate Drug development for Asian Patients**
	The session aims to address the latest advancements, challenges, and opportunities associated with the innovative technologies in drug development and safety surveillance within the pharmaceutical landscape. By knowledge-sharing and fostering collaboration, the meeting seeks how to leverage the innovative tools to accelerate drug development for patients

Session Chairs

Hyou Young Rhim, MD
Vice President
Yuhan Pharm inc.

Jing Ping Yeo, PhD, MBA
Global Head, Project Operations & Head, Transformation
George Clinical Singapore Pte Ltd

3.10 – 3.35 pm	Roles of C3TI and It's Future Direction
	Meghana Chalasani, FDA/CDER/OND Associate Director for Clinical Trial Innovation, US
3.35 – 4.00 pm	Proactive AI-Powered Vigilance for Tomorrow's Challenges
	Sergey Denisov, Sr. ML Engineer, Seltasquare, Korea
4.00 – 4.25 pm	Revolutionizing Pharmacovigilance: AI and RPA Unlocks the Future of AE Handling
	Henry Wu, Sr. Director, Regional Lead-China, HK and Eurasia, R&D, Global Patient Safety Global Markets, AZ
4.25 – 4.50 pm	Innovations to Accelerate Clinical Drug Development
	Atsushi Ogawa, General Manager of Japan, ICON plc
4.50 – 5.15 pm	Unblocking the AI in Medicine - the Dynamic Regulatory Evolution
	Vicky Han, Senior Director, Johnson&Johnson
5.15 - 5.20 pm	Closing Remark
	Jing Ping Yeo, Chair person of Asia meeting 2025

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