# 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

### Program Committee

**Xiaoyuan Chen, PhD**
Tsinghua University

**Yifei Chen, PhD**
Shanghai Center for Drug Evaluation and Inspection

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Johnson & Johnson Pte. Ltd.

**Qiang Li, PhD**
Boehringer Ingelheim

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**In-sook Park, Ph.D.**
Korea Regulatory Science Center

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Yuhan Pharm inc.

**Juyoung Shin, PhD**
Sungkunkwan University

**Jin Shun, MBA**
DIA Global Forum

**Danny Soon, MBBS**
Consortium for Clinical Research and Innovation

**Yuji Kumagai, MD, PhD**
Kitasato University Kitasato Institute Hospital

**Yoshiaki Uyama, PhD**
Pharmaceuticals and Medical Devises Agency

**Catherine Jun Xie, MD, MPH**
Pharmacovigilance Caidya

**Kum Cheun Wong, PharmD**
Novartis Asia Pacific Pharmaceuticals Pte.Ltd.

**Young Joo Park, PhD**
Korea, Singapore, and Southeast Asia, DIA

**The Drug Information Association, Inc.**
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## AGENDA | September 25, 2024 | ALL TIMINGS IN KST

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|---|---|
| 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 |
| 9.10 – 9.30 am | **Key Note Speech: Key Strategy to Advance in Regulatory Science** |
| | **TBD**, MFDS, Korea |

Session Chair

**Yil-Seob Lee**
Professor
CHA Bundang Medical Center

| | |
|---|---|
| 9.30 – 11.35 am | **Session 1.**<br>**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.<br>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

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|---|---|
| 9.30 – 9.55 am | Recent Changes on Regulatory Science in US |
| | **FDA, US** |
| 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,** MFDS, Korea |
| 10.45 - 11.10 am | Regulatory Agency Speaker from China |
| | **SHFDA** |
| 11.10 - 11.35 am | Regulatory Science: Singapore's Experience in Supporting Advanced Therapies |
| | **John CW Lim**, Executive Director, CoRE, Duke-NUS Medical School |
| 11.35 am - 12.35 pm | **Lunch & Networking** |

## AGENDA | September 25, 2024 | ALL TIMINGS IN KST

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| 12.35 – 2.40 pm | **Session 2.**<br>**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

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|---|---|
| 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, MD, PhD** 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,** Chair of relevant division of EFPIA |
| 2.40 - 3.10 pm | **Coffee Break & Networking** |
| 3.45 – 5.50 pm | **Session 3.**<br>**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**
Yuhan Pharm inc.

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

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|---|---|
| 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 |
| | **Denisov Sergey,** 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,** PhD, General Manager of Japan, ICON plc |
| 4.50 – 5.15 am | Unblocking the AI in Medicine - the Dynamic Regulatory Evolution |
| | **Vicky Han,** Senior Director, Johnson&Johnson |

**REGISTRATION FORM :** Register online or forward to DIA
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## Aisa Meeting 2024

**Event #24302 • 25 September, 2024** | The-K Hotel Seoul, Korea

## REGISTRATION

Register online at the link below or complete this registration form and email to our Korea Office

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**DIA will send participants a confirmation letter within 10 business days after receipt of their registration.**

**Registration Fees** If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes refreshment breaks and reception (if applicable), and will be accepted by mail, fax, or online.

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*Please note that the discount is only available when registering for both events at the same time. **Before WEB registration, please contact** Korea@diaglobal.org**"**

| Exploring DIA-KRSC Workshop 2024 Click Here | | | REGISTRATION FEE (KRW) | |
|---|---|---|---|---|
| | **Early Bird (until 13 Sep, 2024)** | | 25. SEP ASIA MEETING | 26. SEP DIA - KRSC WORKSHOP |
| MEMBER | **Academic** | **Early Bird** | ❑200,000 | ❑130,000 |
| | | **After 14 Sep, 2024** | ❑250,000 | ❑180,000 |
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| | | **After 14 Sep, 2024** | ❑250,000 | ❑180,000 |
| | **Industry** | **Early Bird** | ❑300,000 | ❑200,000 |
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| | **Government** | **Early Bird** | ❑250,000 | ❑180,000 |
| | | **After 14 Sep, 2024** | ❑350,000 | ❑230,000 |
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## CONTACT INFORMATION

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**Administrative fee that will be withheld from refund amount: the administrative fee that will be withheld from refund amount is 25 % of the delegate fee**

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid.

Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but **membership is not transferable**. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

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