



# DIA



Korea Regulatory  
Science Center

## DIA Korea Annual Meeting 2025

NIFDS-DIA-KRSC Workshop

Learn and Work 'Accelerating Innovative  
Pharmaceutical Development and  
Advancing Regulatory Reliance'

22-23 April, 2025

Kim Koo Museum & Library, Seoul, Korea



### Overview

DIA Korea Annual Meeting 2025, under the theme “Learn and Work: Accelerating Innovative Pharmaceutical Development and Advancing Regulatory Reliance” holds significant meaning from both clinical development and regulatory science perspectives. In an era of rapid technological advancements and growing healthcare needs, innovative approaches in clinical development are essential to deliver safe and effective therapies to patients faster. This event will serve as a crucial platform to discuss cutting-edge strategies, novel methodologies, and emerging trends that can enhance the efficiency, quality, and success of clinical trials.

From the perspective of regulatory science, DIA Korea Annual Meeting 2025 highlights the importance of fostering regulatory reliance to streamline approval processes and reduce duplication of effort across regions. Regulatory reliance encourages collaboration and mutual trust among global regulatory authorities, enabling faster decision-making and facilitating patients' timely access to innovative medicines. It is an essential strategy for harmonizing global regulatory standards while addressing local and international healthcare challenges.

The joint workshop on the second day, co-hosted by NIFDS (National Institute of Food and Drug Safety), DIA, and KRSC (Korea Regulatory Science Center), carries significant importance. This workshop demonstrates a unified effort to bridge gaps between regulators, industry professionals, and research organizations. By encouraging open dialogue and shared expertise, it aims to address key challenges in regulatory science, such as enhancing approval efficiency, aligning standards, and ensuring bio-pharmaceutical quality and safety.

This collaborative approach is critical for advancing regulatory frameworks that can support innovation while maintaining high standards of safety and efficacy. The workshop will foster mutual learning, encourage the adoption of best practices, and strengthen Korea's role as a leader in the global bio-pharmaceutical regulatory landscape. DIA Korea Annual Meeting 2025, with its focus on innovation and cooperation, is poised to accelerate clinical development and advance regulatory reliance, benefiting patients and stakeholders in Korea and Asia.

# DIA

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# DIA Korea Annual Meeting 2025

Learn and Work 'Accelerating Innovative Pharmaceutical Development and Advancing Regulatory Reliance'

22-23 April, 2025 | Kim Koo Museum & Library Seoul, Korea



## Program Chair

**Yil-Seob Lee, MD, PhD**

CHA University

## Program Committee

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**Yuni Lim, RPh**

Korean Society for Clinical Development | Roche



## Program Chair

**Yil-Seob Lee, MD, PhD**

CHA University

**Dong Hee Na, PhD**

Chung-Ang University

**Kyuho Oh**

KCRO Association

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CMIC Korea

**In-sook Park, PhD**

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**Young Joo Park, MPH, PhD**

DIA Korea, Singapore and SEA

DIA Korea Annual Meeting 2025 Website

Please kindly read the details of this meeting

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[For inquire]

DIA KOREA

DIA Korea Annual Meeting 2025 coordinators

## AGENDA | 22 April 2025 | Day 1 | ALL TIMINGS IN KST

8.30 – 9.00 am	Registration
9.00 – 9.05 am	<b>Opening Remarks</b>
	<b>Marwan Fathallah</b> , President & CEO, DIA
9.05 – 9.10 am	<b>Congratulatory Remark</b>
	<b>Seogyoun Kang</b> , Director General, NIFDS
9.10 – 9.50 am	<b>Keynote speech</b> : Needs for new treatment modality for unmet medical needs
	Chair : <b>Yil-Seob Lee, MD, PhD</b> , CHA University   <b>CBER or CDER delegate</b>
9.50 – 10.20 am	<b>Coffee Break and Network</b>
10.20 am – 12.00 pm	<b>Session 1</b> <b>Trends and Hot Topics in CGT Development</b>  Cell and Gene Therapy (CGT) is a revolutionary field in medicine, offering potential cures for genetic and acquired diseases by addressing their root causes. This session will highlight the latest trends in CGT development, including regulatory updates, strategies for innovations in manufacturing and process, and considerations in early clinical development. By bringing together experts from regulatory bodies, industry, and academia, the session aims to foster collaboration and drive innovation in CGT development. Attendees will gain valuable insights into the challenges and opportunities in CGT, promoting a deeper understanding of this transformative field.
<b>Session Chairs</b> <b>Deborah Chee, MD, PhD, MBA</b> Partner Gateway Sciences  <b>Sora Lee</b> Vice President, General Manager Korea Syneos Health Inc	
10.20 – 10.45 am	Regulatory Update for CGT Development in Korea - Focus on the Guideline for the Development of Personalized Neoantigen-Targeted Therapy Products
	<b>Jounghee BAEK, PhD</b> , Senior Scientific Officer, Cell and Gene Therapy Product Division NIFDS, MFDS
10.45 – 11.10 am	Regulatory Focus for Expediting CGT Development
	<b>FDA speaker</b>
11.10 – 11.35 am	Manufacturing and process innovation in CGT Development
	<b>Yongzeng (James) Wang, PhD</b> , CTO, Juventas
11.35 am– 12.00 pm	Considerations in CGT Early Clinical Development
	<b>Byungwook Kim, MD, PhD</b> , Professor, Seoul National University College of Medicine and Hospital
12.00 – 1.30 pm	<b>Lunch and Network / Lunch Symposium</b>
1.30 – 3.10 pm	<b>Session 2 (Parallel with Session 3)</b> <b>Patient Diversity, Equity and Inclusion in Clinical Trials and Regulatory Insights</b>  Patient Diversity, Equity and Inclusion of Participants in Clinical Trials (DEICT) is an important topic to ensure the benefits of trials are shared by everyone. The sponsors have been working to improve the representation of patient populations in clinical trials for which the studies drugs are intended to be prescribed and used. Now we're also focused on the inclusion of racial and ethnic underrepresented populations in clinical trials. In this session, speakers will share the new insights and considerations to inform operational strategies and identify how practically implement diversity plans. And it would be a good opportunity to understand US regulatory landscape in terms of Diversity of Participants in Clinical Trials and consider future engagement with other Health Authorities.

### Session Chairs

**Yuni Lim, RPh**  
Clinical Operations Portfolio Leader, Roche Korea  
President, KSCD

**Hyejong Yoo**  
Director  
AstraZeneca Korea

1.30 – 1.55 pm	FDA Diversity Plan Implementation and Consideration
	<b>FDA speaker</b>
1.55 – 2.20 pm	Europe Diversity Plan in Clinical Trials – Regulatory Perspective
	<b>Europe speaker - EMA or Industry/Association</b>
2.20 – 2.45 pm	Sponsor strategies and toolkit for Diversity, Equity and Inclusion of Participants in Clinical Trials
	<b>MSD, Speaker (TBD)</b>
2.45 – 3.10 pm	What is the regulatory implication for Korea ?
	<b>Pei-Chieh Fong</b> , VP, Medical International, Astrazeneca

1.30 – 3.10 pm	<b>Session 3 (Parallel with Session 2)</b> <b>Can RWE Replace Conventional Clinical Trials in Regulatory Decision-Making?</b>
	<p>This session will explore the potential of Real-World Evidence (RWE) to complement or even replace traditional clinical trials in regulatory decision-making processes. With advancements in data science and healthcare technologies, RWE has emerged as a valuable tool in drug development, offering insights from real-world settings outside the controlled environment of clinical trials. However, key questions remain about whether RWE can fully substitute conventional trials and how regulatory bodies are adapting to its growing role. Experts will present on the definition, current use, and challenges of RWE, comparing it to traditional clinical trials in terms of reliability, generalizability, and regulatory acceptance and in-depth panel discussion will be followed with the experts from diverse sectors.</p>

<b>Session Chairs</b> <b>Juyoung Shin, PhD</b> Professor Sungkunkwan University		<b>HyungJin Jung, MD, MBA</b> Sr. Director, Medical Affairs Janssen Korea
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1.30 – 1.55 pm	From Past to Future: Integrating Real-World Evidence into Regulatory Practices
	<b>FDA invited</b>
1.55 – 2.20 pm	The Challenges of RWE: Navigating Uncertainty in Regulatory Decision-Making
	<b>Hojoon Lee, MD, MPH, Dr.PH</b> , Amgen Korea
2.20 – 3.10 pm	<b>Panel Discussion + Q&amp;A</b>
	<b>Sohee Kim, PhD</b> , Clinical Statistics, Yuhan Corporation <b>Sohee Kim, PhD</b> , NIFDS, MFDS <b>JiYoon Ahn</b> , IQVIA
	<b>FDA invited</b> <b>Hojoon Lee, MD, MPH, Dr.PH</b> , Amgen Korea <b>Kyu-pyo Kim, MD, PhD</b> , Asan Medical Center

3.40 – 5.20 pm	<b>Session 4 (Parallel with Session 5)</b> <b>Drug Development with innovative Technology</b>
	<p>Pharmaceutical research is being revolutionized by innovative technologies like AI, machine learning, and digital platforms, transforming drug development through faster target identification, enhanced screening, and improved efficiency in R&amp;D processes.</p> <p>This session unites industry leaders and researchers to discuss technological breakthroughs in bio-pharmaceutical research, AI implementation, and solutions to drug development challenges, while fostering interdisciplinary collaboration.</p>

<b>Session Chairs</b> <b>Hyesook Park</b> Head/General Manager CMIC Korea		<b>Kyuhoo Oh</b> Vice President KCRO Association
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3.40 – 4.05 pm	Harnessing AI for Success: Revolutionizing Drug Discovery and Development
	<b>Hyunjin Shin, PhD</b> , President, MOGAM Institute for Biomedical Research

AGENDA | 22 April 2025 | Day 1 | ALL TIMINGS IN KST

4.05 - 4.30 pm	The future of AI drug discovery: vanguard of quantum era?	
	EunSung Cho, PhD, Incerebro	
4.30 - 4.55 pm	AI-Driven New Drug Combination (NDC) Development For Orphan Diseases	
	Ji-Hyun, Lee, PhD, CEO, DR.NOAH Biotech	
4.55 - 5.20 pm	Digital Data Flow: Modernizing Clinical Trials Through Digitized Protocol Information	
	Donald G Jennings, Lilly	
3.40 - 5.20 pm	<div>Session 5 (Parallel with Session 4) Challenges and Opportunities for the Environmental Changes in Clinical Trials</div> <p>In this session we will carefully review global and Korean macro-environment changes and identify possible factors which may impact on planning and execution of clinical trial in Korea. To add more detail, invited panel speakers will provide their opinion on which to deal with and which to maximize with these opportunities.</p>	
Session Chairs		
	Won Sik Lee, MD, Ph.D CEO idience	Daehee Lee CEO, Seoul CRO President, Korean Society of Pharmaceutical Medicine
3.40 - 1.55 pm	Major global environment changes which may impact Korean clinical trial execution	
	Marwan Fathallah, President, DIA Global	
1.55 - 2.20 pm	Major Korea environment changes which may impact Korean clinical trial execution	
	Sanghee Kim, Novotech	
2.20 - 3.10 pm	Panel Discussion + Q&A	
	Marwan Fathallah, DIA Global Yil-Seob Lee, CHA University Youngshin Lee, KRPIA	Sanghee Kim, Novotech Junwoo Bahn, Asan Medical Center Daehee Lee, KSPM

## AGENDA | 23 April 2025 | Day 2 | ALL TIMINGS IN KST

8.30 – 9.10 am **Plenary speech | WHO, regulatory Reliance**

**Samvel AZATYAN, MD, PhD**, RCN, REG, RPQ, World Health Organization  
Chair : **Young Joo Park, MPH, PhD**, Vice President, Korea, Singapore, and SEA, DIA

9.10 – 10.30 am

### Session 6 International Regulatory Collaborative Frameworks based on Regulatory Reliance

This session will feature on how regulatory authorities are working together to accelerate the approval of innovative medicines and drive regulatory efficiency. Speakers in regulatory authorities will present their latest trends and future plans for collaboration via work sharing/reliance programs(e.g., Project Orbis, Access Consortium, OPEN initiatives and MRA). Industry will present their experiences participating in these programs and their perspectives on them. In the following panel discussion regulators will discuss the challenges they face in participating in International regulatory collaborative pathways and what prerequisites are needed.

#### Session Chairs

**Youngju Choi**  
Director General  
NIFDS, MFDS

**Esther Bahng**  
Senior Director of Market Access and Regulatory Affairs  
AstraZeneca

9.10 – 9.30 am

EMA's Perspectives on promoting regulatory reliance pathways : Latest trends and future plans including OPEN program and mutual recognition agreements(MRA) etc.

**Victoria Palmi-Reig**, EMA

9.30 – 9.50 am

The latest trends and future plans of global regulatory reliance pathways and mutual recognition agreements operated or participated in by HSA

**HSA Speaker (TBD)**

9.50 – 10.10 am

MFDS' Perspectives on promoting regulatory reliance pathways

**Jaeok Kim**, Director, NIFDS, MFDS

10.10 – 10.30 am

Industry's perspectives on participation in global regulatory reliance pathways

**Irene Chang**, Eli Lilly and Company

10.30 – 10.50 am

**Networking and Break**

10.50 – 11.30 am

**Panel Discussion |** Preparing for Regulatory Reliance from Korea – Strategies for Overcoming Challenges

**Session 6 Chairs, Speakers**

11.30 am – 12.30 pm

**Lunch and Network / Lunch Symposium**

12.30 – 2.20 pm

### Session 7 (Parallel with Session 8) Transforming Regulatory Science: Global Trends and Innovative Technology Applications

This session brings together experts from global regulatory authorities to discuss the latest advancements and trends in regulatory field. The focus will be on the integration of innovative technologies across regulatory processes, including the use of AI and digital tools. Presenters will share insights into emerging strategies and frameworks shaping the future of drug approval and review processes. Join us to hear from leading authorities on the evolving regulatory landscape and its impact on the pharmaceutical industry.

#### Session Chairs

**Younjoo Park (TBD)**

**Seung-In Um, PhD**  
Vice President  
KPBMA

12.30 – 12.50 pm

Regulatory update in the US on utilizing innovative technologies: KASA system in FDA to review approval dossier

**FDA Speaker, TBD**

12.50 – 1.10 pm

AI for medicines regulation at the Swedish Medical Products Agency

**Gabriel Westman, MD, PhD, MScEng**, Head of Artificial Intelligence Swedish Medical Products Agency

1.10 - 1.30 pm	Regulatory update in MFDS on utilizing innovative technology
	<b>Jung Hun Ju, PhD</b> , Cardiovascular & Neurology Products Division, NIFDS, MFDS
1.30 - 1.50 pm	AI Machine Learning in Pharmaceutical Manufacturing
	<b>Gert Thureau, PhD</b> , Head of Manufacturing Innovation in CMC Reg Policy, Roche
12.30 – 2.20 pm	<b>Session 8 (Parallel with Session 7)</b> <b>Improving patient access to clinical trials through decentralization (DCT)</b> <p>Decentralized Clinical Trials (DCTs) are a type of clinical trial that selectively incorporates decentralized components through the use of digital and remote technologies. This approach enables patient-centric trial operations and enhances efficiency in the long term. By leveraging tools such as wearable devices, mobile devices, and electronic consent systems, DCTs facilitate the effective collection of clinical data in real-world settings. However, certain methods, such as direct-to-patient shipping and remote procedures, may face challenges in implementation due to regulatory constraints specific to each country.</p> <p>Decentralized components can be applied not only to conventional pharmaceuticals but also to innovative therapies like digital therapeutics. In South Korea, interest in DCTs is growing, yet their adoption remains slower compared to the United States and Europe. To address this issue, a collaborative working group comprising academic, industrial, and regulatory stakeholders is actively working to develop the DCT ecosystem in Korea.</p>
<b>Session Chairs</b> <div> <b>Kyungsang Yu, MD, PhD</b>  Professor  Seoul National University Hospital (SNUH) </div> <div> <b>Hea-Young Cho, PhD</b>  Professor  College of Pharmacy, CHA University </div>	
12.30 – 12.50 pm	Clinical Policy Direction of the Ministry of Food and Drug Safety: Focusing on DCT and Clinical Trial Participants <b>Kyung Jin Han</b> , Clinical Trials Policy Division, Pharmaceutical Safety Bureau, MFDS
12.50 – 1.10 pm	Case studies of DCT elements: Direct-to-patient delivery of digital therapeutics <b>Sungjee Kang, MD, MPH, PhD</b> , WELT
1.10 - 1.30 pm	Clinical trials with decentralized elements: operating models and implementation strategies <b>Ki Young Huh, MD, PhD</b> , Clinical Trials Center, Seoul National University Hospital
1.30 - 1.50 pm	DCT implementation in Japan, particularly from an academic perspective: A comprehensive comparison between FDA guidance and Japanese regulations on DCT, along with insights into PMDA's stance on decentralized trials <b>Kouta Funakoshi, MD</b> , Assistant Professor, Center for Clinical and Translational Research, Kyushu University Hospital
1.50 - 2.20 pm	<b>Networking and Break</b>
2.20 - 4.00 pm	<b>Session 9 (Parallel with Session 10)</b> <b>Risk Communication Strategy for Patient Safety</b> <p>This session will cover essential topics for safety communication. We will discuss considerations for managing key safety information from drug development to post-approval, and how to maximize the use of existing drug safety communication tools. Additionally, we will explore innovative methods of delivering safety information, including traditional labeling and new electronic communication methods, to ensure that patients and healthcare professionals can easily access key safety information. Finally, we will provide insights into the current status and future plans of risk communication strategies aimed at enhancing the safe use of medicines worldwide.</p>
<b>Session Chairs</b> <div> <b>Joonwoo Bahn</b>  Professor  Asan Medical Center </div> <div> <b>Minjung Lim</b>  CEO  MediSafe </div>	
2.20 – 2.45pm	Management of Core Safety Information - From development to post-approval, learn how to handle core safety information <b>Andrew Erdman, MD</b> , Vice President Global Head of Early Development Safety, Genentech



2.45 - 3.10 pm	Drug Safety Communication Tools in Korea; Maximize the use of existing communication methods in Korea for enhanced patient safety
	<b>Hyun-Joo Jung, PhD</b> , Department of Drug Safety Information, Korea Institute of Drug Safety & Risk Management
3.10 - 3.35 pm	Innovative Safety Communication Methods: Explore various ways to communicate safety information beyond traditional product labels, including electronic materials and interactive communication
	<b>Pfizer Regulatory (TBD)</b>
3.35 - 4.00 pm	Global Risk Communication Strategies: Gain insights into the current status and future plans for enhancing the safe use of medicines worldwide.
	<b>EMA(TBD)</b>
2.20 - 4.00 pm	<b>Session 10 (Parallel with Session9)</b> <b>CMC and non-clinical</b> <p>CMC and non-clinical data: What is the gap for the success in IND and NDA/BLA? How can we ensure success? The success of an Investigational New Drug (IND) and New Drug Application (NDA) or Biologics License Application (BLA) is deeply influenced by a comprehensive approach to Chemistry, Manufacturing, and Controls (CMC) and non-clinical data. Toxicology modeling plays a critical role in assessing the safety of a drug candidate, ensuring that animal studies are properly aligned with regulatory expectations. Efforts to harmonize CMC guidelines across the US, Japan, Europe, and Korea have become essential to streamline global drug development and facilitate regulatory approvals. A robust CMC strategy for biologics must address challenges in manufacturing, stability, and scalability while ensuring compliance with global standards. For non-clinical studies, the integration of reliable data on pharmacokinetics, pharmacodynamics, and safety signals is vital for advancing to clinical trials and ultimately securing market authorization. In this session, we will explore the efforts to harmonize CMC regulations across regions, including Korea, and discuss efficient examples of toxicology modeling. We will also learn about CMC strategies for success in biologics and examine CMC case studies in non-clinical studies.</p>
<b>Session Chairs</b> <div> <div> <b>Donghee Na, PhD</b>  Professor  Chung-Ang University </div> <div> <b>In-sook Park, PhD</b>  Director General  KRSC </div> </div>	
2.20 - 2.45pm	Contemporaries and future trend of Toxicology Modelling
	<b>CMC toxicologist AstraZeneca global, speaker TBD</b>
2.45 - 3.10 pm	CMC Regulation for IND
	<b>Ohseok KWON, PhD</b> , Advanced Drug Quality Division, Ministry of Food and Drug Safety
3.10 - 3.35 pm	Case study of CMC for the success of Biologics
	<b>Jaewoon Son, PhD</b> , GC Pharma
3.35 - 4.00 pm	Nonclinical study for the success of new drug development
	<b>Sukmo Kang, DVM, PhD</b> , Biototech, BTT Group
4.10 - 4.20 pm	<b>Closing</b>
	<b>Yil-Seob Lee, MD, PhD</b> , Program Chair of Korea Annual Meeting 2025



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## DIA Korea Annual Meeting 2025

Event #87125 • 22-23 April 2025 | Kim Koo Museum & Library, Seoul, Korea

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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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### CONTACT INFORMATION

**Joshua Choi**

Event Manager, Korea & Singapore, DIA

Phone: +821090149582

Email: [joshua.choi@diaglobal.org](mailto:joshua.choi@diaglobal.org)

**DIA**

tel: +821090149582

email: [Korea@DIAglobal.org](mailto:Korea@DIAglobal.org)

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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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