



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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DIAglobal.org

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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Asan Medical Center

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AstraZeneca Korea

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Gateway Sciences

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National Institute of Food and Drug Safety Evaluation, Ministry of Food & Drug Safety

HyungJin Jung, MD, MBA

Janssen Korea

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So Hee Kim, PhD

National Institute of Food and Drug Safety Evaluation, Ministry of Food & Drug Safety

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Korean Society of Pharmaceutical Medicine
Seoul CRO

Won Sik Lee, MD, PhD

Idience

Minjung Lim, RPh, M Pharm

MediSafe

Yunni Lim, RPh

Korea Clinical Development Association | Roche



Program Chair

Yil-Seob Lee, MD, PhD

CHA University

Dong Hee Na, PhD

Chung-Ang University

Kyuho Oh

KCRO Association

Hyesook Park

CMIC Korea

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Korea Regulatory Science Center

Misun Park, PhD

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Hyejong Yoo, RPh

AstraZeneca Korea

Kyung-Sang Yu, MD, PhD, MBA

Seoul National University, ARICTT

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 Annual Meeting 2025 coordinators

E-mail: korea@DIAGlobal.org

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

9.00 – 9.05 am	Opening Remarks
	Marwan Fathallah , President & CEO, DIA Global
9.05 – 9.15 am	Congratulatory Remark
	Seogyoun Kang , Director General, NIFDS Jae-Kook Lee , Vice President, KPBMA In-sook Park, PhD , Director General, KRSC
9.15 – 9.55 am	Keynote speech : Needs for new treatment modality for unmet medical needs
	James Wabby , Head, Global Regulatory Affairs, Emerging Technologies, Combination Products, and Devices, Vice Chair for RAPS, AbbVie Chair : Yil-Seob Lee, MD, PhD , CHA University
9.55 – 10.20 am	Coffee Break and Network
10.20 am – 12.00 pm	Session 1 Trends and Hot Topics in CGT Development 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.
Session Chairs Deborah Chee, MD, PhD, MBA Partner Gateway Sciences Sora Lee 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
	Joungee BAEK, PhD , Senior Scientific Officer, Cell and Gene Therapy Product Division, NIFDS, MFDS
10.45 – 11.10 am	Regulatory Focus for Expediting CGT Development with the Selection of Key Partners
	James Wabby , Head, Global Regulatory Affairs Emerging Technologies, Combination Products, and Devices, Vice Chair for RAPS, AbbVie
11.10 – 11.35 am	Bottlenecks and Solutions of CAR-T Therapy Manufacturing Process
	Yongzeng (James) Wang, PhD , CTO, Juventas Cell Therapy Corp.
11.35 am– 12.00 pm	Considerations in CGT Early Clinical Development
	Byungwook Kim, MD, PhD , Assistant Professor, Kangwon National University
12.00 – 1.30 pm	Lunch and Network / Lunch Symposium - Sponsored Presentation by perceptive
1.30 – 3.10 pm	Session 2 (Parallel with Session 3) Patient Diversity, Equity and Inclusion in Clinical Trials and Regulatory Insights 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 Yunni Lim, RPh Clinical Operations Portfolio Leader, Roche Korea President, KCDA Hyejong Yoo Executive Director AstraZeneca, Korea, Republic of	

1.30 – 1.55 pm	FDA Diversity Plan Implementation and Consideration
	Vanessa Cahee , VCahee Consulting LLC
1.55 – 2.20 pm	Advancing Patient Diversity in Clinical Trials: Academic Perspective on Patient Diversity
	Seonghae Yoon, MD, PhD , Seoul National University Bundang Hospital
2.20 – 2.45 pm	Sponsor strategies and toolkit for Diversity, Equity and Inclusion of Participants in Clinical Trials
	Monica Eason , Genentech
2.45 – 3.10 pm	What is the regulatory implication for Korea ?
	Pei-Chieh Fong , VP, Medical International, Astrazeneca
3.10 – 3.40 pm	Coffee Break and Network
1.30 – 3.10 pm	Session 3 (Parallel with Session 2) Can RWE Replace Conventional Clinical Trials in Regulatory Decision-Making? 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.
Session Chairs <div> Juyoung Shin, PhD Professor Sungkunkwan University </div> <div> HyungJin Jung, MD, MBA Sr. Director, Medical Affairs Janssen Korea </div>	
1.30 – 1.55 pm	From Past to Future: Integrating Real-World Evidence into Regulatory Practices
	Taehyun Jung, PhD , Senior Statistical Reviewer, FDA
1.55 – 2.20 pm	The Challenges of RWE: Navigating Uncertainty in Regulatory Decision-Making
	Hojoon Lee, MD, MPH, Dr.PH , Amgen Korea
2.20 – 3.10 pm	Panel Discussion + Q&A
	Chair : Juyoung Shin, PhD , Sungkunkwan University Sohee Kim, PhD , Clinical Statistics, Yuhan Corporation So Hee Kim, PhD , NIFDS, MFDS JiYoon Ahn , IQVIA <div> Taehyun Jung, PhD, FDA Hojoon Lee, MD, MPH, Dr.PH, Amgen Korea Kyu-pyo Kim, MD, PhD, Asan Medical Center </div>
3.10 - 3.40 pm	Coffee Break and Network
3.40 - 5.20 pm	Session 4 (Parallel with Session 5) Drug Development with innovative Technology 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&D processes. 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.
Session Chairs <div> Hyesook Park Head, General Manager CMIC Korea </div> <div> Kyuhoo Oh Vice President KCRO Association </div>	

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

3.40 – 4.05 pm Harnessing AI for Success: Revolutionizing Drug Discovery and Development

Hyunjin Shin, PhD, President, MOGAM Institute for Biomedical Research

4.05 – 4.30 pm The future of AI drug discovery: vanguard of quantum era?

EunSung Cho, PhD, Founder and CEO, 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 Going with the (Digital Data) Flow : The Why, How and What of Transcelerate DDF

Donald G Jennings, MS, MBA, Senior Advisor of Systems Engineering, Eli Lilly and Company

3.40 – 5.20 pm

Session 5 (Parallel with Session 4)

Challenges and Opportunities for the Environmental Changes in Clinical Trials

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.

Session Chairs

Won Sik Lee, MD, Ph.D
CEO
Idience

Daehee Lee
CEO, Seoul CRO
President, Korean Society of Pharmaceutical Medicine

3.40 – 4.05 pm Major global environment changes which may impact Korean clinical trial execution

Marwan Fathallah, President & CEO, DIA Global

4.05 – 4.30 pm Major Korea environment changes which may impact Korean clinical trial execution

Sanghee Kim, PhD, Head of Centralised Monitoring and RBQM, Novotech

4.30 – 5.20 pm

Panel Discussion

Chair : **Won Sik Lee**, Idience
Marwan Fathallah, DIA Global
Youngshin Lee, KRPIA

Sanghee Kim, Novotech
Junwoo Bahn, Asan Medical Center
Daehee Lee, KSPM

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

9.00 – 9.10 am The 2nd Young Regulatory Scientist Awards

Presenters: **NIFDS and KRSC**

9.10 – 9.30 am **Plenary speech | WHO, Regulatory Reliance**

9.10 – 9.30 am Regulatory Reliance as a Catalyst for Harmonization and Convergence: Increasing Efficiency in National Decision-Making

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

9.30 – 11.10 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

9.30 - 9.55 am EMA's Perspectives on promoting regulatory reliance

Victoria Palmi-Reig, Scientific administrator, EMA

9.55 - 10.20 am The latest trends and future plans of global regulatory reliance pathways and mutual recognition agreements operated or participated in by ANVISA

Bianca Zimon, Health Regulation Expert, ANVISA

10.20 - 10.45 am MFDS' Perspectives on promoting regulatory reliance pathways

Jaeok Kim, Director, NIFDS, MFDS

10.45 - 11.10 am Strengthening the Use of International Collaborative Regulatory Assessments to Accelerate Regulatory Convergence and Patient Access

Irene Chan, Executive Director, Global Regulatory Policy and Strategy – Asia Pacific, Eli Lilly and Company

11.10 - 11.30 am **Networking and Break**

11.30 - 12.10 pm **Panel Discussion | Preparing for Regulatory Reliance from Korea – Strategies for Overcoming Challenges**

Chairs : **Youngju Choi**, NIFDS, MFDS
Esther Bahng, AstraZeneca

Irene Chan, Eli Lilly and Company
Jaeok Kim, NIFDS, MFDS
Moon Jeong Ko, RA Lead, MSD Korea

12.10 pm – 1.30 pm **Lunch and Network / Lunch Symposium - Sponsored Presentation by InHandPlus**

1.30 – 3.10 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
Professor
College of Pharmacy, Seoul National University

Youngshin Lee
CEO
Korean Research-based Pharma Industry Association

1.30 – 1.55 pm	Regulatory update in the US on utilizing innovative technologies: KASA system in FDA to review approval dossier
	Vada A. Perkins, DRSc, MSc, MS , Vice President, Boehringer Ingelheim Pharmaceuticals, Inc.
1.55 – 2.20 pm	AI for medicines regulation at the Swedish Medical Products Agency
	Gabriel Westman, MD, PhD, MScEng , Head of Artificial Intelligence Swedish Medical Products Agency
2.20 - 2.45 pm	Regulatory update in MFDS on utilizing innovative technology
	Jung Hun Ju, PhD , Cardiovascular & Neurology Products Division, NIFDS, MFDS
2.45 - 3.10 pm	Machine Learning Applications in Pharmaceutical Manufacturing - a safe space to deploy AI (?)
	Gert Thureau, PhD , Head of Manufacturing Innovation in CMC Reg Policy, Roche

1.30 – 3.10 pm	Session 8 (Parallel with Session 7) Improving patient access to clinical trials through decentralization (DCT)
	<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>

Session Chairs

Kyungsang Yu, MD, PhD

Professor
Seoul National University Hospital (SNUH)

Hea-Young Cho, PhD

Professor
College of Pharmacy, CHA University

1.30 – 1.55 pm	Clinical Policy Direction of the Ministry of Food and Drug Safety: Focusing on DCT and Clinical Trial Participants
	Kyung Jin Han , Clinical Trials Policy Division, Pharmaceutical Safety Bureau, MFDS
1.55 – 2.20 pm	Case studies of DCT elements: Direct-to-patient delivery of digital therapeutics
	Sungjee Kang, MD, MPH, PhD , CEO & Co-founder, WELT
2.20 - 2.45 pm	Clinical trials with decentralized elements: operating models and implementation strategies
	Ki Young Huh, MD, PhD , Clinical Trials Center, Seoul National University Hospital
2.45 - 3.10 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
	Kouta Funakoshi, MD , Assistant Professor, Center for Clinical and Translational Research, Kyushu University Hospital
3.10 - 3.40 pm	Networking and Break

3.40 - 5.20 pm	Session 9 (Parallel with Session 10) Risk Communication Strategy for Patient Safety
	<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>

Session Chairs

Joonwoo Bahn

Professor
Asan Medical Center

Minjung Lim

CEO
MediSafe

3.40 - 4.05 pm	Management of Core Safety Information - From development to post-approval, learn how to handle core safety information
	Andrew Erdman, MD , Vice President Global Head of Early Development Safety, Genentech
4.05 - 4.30 pm	Drug Safety Communication Tools in Korea; Maximize the use of existing communication methos in Korea for enhanced patient safety
	Hyun-Joo Jung, PhD , Department of Drug Safety Information, Korea Institute of Drug Safety & Risk Management
4.30 - 4.55 pm	Innovative Safety Communication Methods: Explore various ways to communicate safety information beyond traditional product labels, including electronic materials and interactive communication
	Rie Matsui , Senior Director, International Labeling APAC , Pfizer Japan Inc. Craig Anderson , Director, International Labeling, Pfizer
4.55 - 5.20 pm	Global Risk Communication Strategies: Gain insights into the current status and future plans for enhancing the safe use of medicines worldwide.
	Viola Macolic Sarinic , Scientific Officer, EMA
5.20 - 5.30 pm	Closing
	Yil-Seob Lee, MD, PhD , Program Chair of Korea Annual Meeting 2025, CHA University
3.40 - 5.20 pm	Session 10 (Parallel with Session9) CMC and non-clinical studies <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>
Session Chairs <div> Donghee Na, PhD Professor Chung-Ang University </div> <div> In-sook Park, PhD Director General KRSC </div>	
3.40 - 4.05 pm	Reducing the number of animals in safety studies with virtual control groups
	Thomas Steger-Hartmann, PhD , Senior Project Lead Innovative Health Initiative, VP, Bayer AG
4.05 - 4.30 pm	CMC Regulation for IND
	Ohseok KWON, PhD , Recombinant Protein Products Division, Ministry of Food of Drug Safety
4.30 - 4.55 pm	Case study of CMC for the success of Biologics
	Jaewoon Son, PhD , MSAT/DP Team leader, GC Pharma
4.55 - 5.20 pm	Nonclinical study for the success of new drug development
	Sukmo Kang, DVM, PhD , Director Biototech, BTT Group
5.20 - 5.30 pm	Closing
	Young Joo Park, MPH, PhD , Vice President, Korea, Singapore, and SEA, DIA

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DIA Korea Annual Meeting 2025

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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

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