Korea Regulatory Science Center

DIA Korea Annual Meeting 2026

NIFDS-DIA-KRSC Workshop

From Regulation to Reality: Shaping the Next Era of Clinical Development

15-16 April, 2026
Kim Koo Museum & Library, Seoul, Korea

Program Overview

The DIA Korea Annual Meeting 2026 will bring together global experts, regulators, industry leaders, and academic researchers to exchange the latest insights and developments across the life sciences ecosystem. Guided by the theme “From Regulation to Reality: Shaping the Next Era of Clinical Development,” this year’s program is designed to bridge regulatory frameworks with real-world implementation, ultimately advancing clinical development and patient access.

The program will highlight critical regulatory updates and perspectives from leading authorities, including the FDA, EMA, PMDA, NMPA, and MFDS. Key sessions will explore evolving regulatory and scientific frameworks across clinical trial operations, digital innovation, trial statistics, real-world evidence (RWE), alternatives to animal testing in regulatory science, and patient centricity, including medical communication. In addition, cross-regional dialogues will underscore Asia’s expanding role in global regulatory harmonization and innovation.

Beyond regulatory and scientific updates, the meeting emphasizes practical case studies, collaborative models, and partnerships among industry, academia, and government. Through a balanced mix of plenary lectures, panel discussions, and interactive networking opportunities, participants will gain actionable insights that can be translated into real-world impact.

The second day of the meeting will feature a joint conference co-organized by the Ministry of Food and Drug Safety (MFDS), DIA, and the Korean Regulatory Science Center (KRSC). This joint session will provide a unique platform for in-depth dialogue on regulatory science, policy alignment, and collaborative approaches to strengthening Korea’s clinical development ecosystem within the global landscape.

DIA Korea Annual Meeting 2026는 생명과학 전반에 걸친 최신 인사이트와 동향을 공유하기 위해 글로벌 전문가, 규제기관 관계자, 산업계 리더, 학계 연구자들이 한자리에 모이는 자리입니다.
올해 회의는 “From Regulation to Reality: Shaping the Next Era of Clinical Development”라는 주제 아래, 규제 프레임워크를 실제 현장 적용과 연결함으로써 임상 개발의 발전과 환자 접근성 향상을 도모하도록 구성되었습니다.
본 프로그램에서는 FDA, EMA, PMDA, NMPA, MFDS 등 주요 규제 당국의 관점을 포함한 핵심 규제 업데이트와 인사이트를 중점적으로 다룰 예정입니다. 주요 세션에서는 임상시험 운영, 디지털 혁신, 임상 통계, 실사용근거(Real-World Evidence, RWE), 규제과학 분야에서 동물실험 대체 접근법, 의료 커뮤니케이션을 포함한 환자 중심성 등 다양한 영역에서 진화하는 규제 및 과학적 프레임워크를 심도있게 논의합니다. 또한, 아시아가 글로벌 규제 조화와 혁신에서 차지하는 역할이 확대되고 있음을 조명하는 지역 간 협력 및 논의 세션도 마련됩니다.
규제 및 과학적 업데이트를 넘어, 본 회의는 실제 적용 가능한 사례 연구, 산업·학계·정부 간의 협업 모델과 파트너십을 강조합니다. 기조 강연, 패널 토론, 그리고 인터랙티브 네트워킹 세션이 균형 있게 구성되어, 참가자들은 실질적인 인사이트를 얻고 이를 현실적인 임상 개발과 규제 전략에 적용할 수 있을 것입니다.
회의 둘째 날에는 식품의약품안전처(MFDS), DIA, 한국규제과학센터(KRSC)가 공동으로 주관하는 합동 컨퍼런스가 개최됩니다. 이 공동 세션은 규제과학과 정책 정합성, 그리고 글로벌 환경 속에서 한국의 임상 개발 생태계를 강화하기 위한 협력적 접근 방안을 심도 있게 논의하는 독보적인 소통의 장을 제공할 예정입니다.

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DIA Korea Annual Meeting 2026

From Regulation to Reality: Shaping the Next Era of Clinical Development

15-16 April, 2026 | Kim Koo Museum & Library Seoul, Korea

Program at a Glance

DAY 1 - 15 April, 2026		
9.00 – 9.10 am	Opening	
9.10 – 10.00 am	S1. Keynote Speeches: Shaping the Future of Clinical Development: Global Transformation and Korea's Path Forward	
10.00 – 10.30 am	Break	
10.30 – 12.40 pm	S2. Regulatory Updates and Implications for Clinical Development	
12.40 – 1.40 pm	Luncheon Seminar/ Lunch	
1.40 – 3.00 pm	S3. What's new in ICH guidelines? (1)	S4. Medical Communication Interfaces: Bridging Science, Patients, and Practice
3.00 – 3.30 pm	Break	
3.30 – 5.00 pm	S3. What's new in ICH guidelines? (2)	S5. Bridging Regulation and Reality: Decentralized Trials for Broader Participation

DAY 2 - 16 April, 2026		
9.00 – 9.10 am	Opening	
9.10 – 10.40 am	S6. Use of AI in the Regulation of Medical Products	
10.40 – 11.10 am	Break	
11.10 – 12.30 pm	S7. Advancing Clinical Development Efficiency with AI	
12.30 – 1.30 pm	Luncheon Seminar/ Lunch	
1.30 – 3.10 pm	S8. Global Regulatory Trends and Standardization Strategies for Next-Generation Alternative Technologies	S9. Practical Implementation of Next-Generation Post-Marketing Safety Studies
3.10 – 3.40 pm	Break	
3.40 – 5.00 pm	S10. From Insights to Impact: Delivering Truly Patient-Focused Clinical Development	S11. Innovative Biostatistical Approaches to Real-World Data

Program Chair

Yil-Seob Lee, MD, PhD, CHA University

Program Committee

JoonWoo Bahn, MD, PhD
Asan Medical Center
Youngju Choi, PhD
National Institute of Food and Drug Safety Evaluation, Ministry of Food & Drug Safety
Juhye Kang, PhD
National Institute of Food and Drug Safety Evaluation, Ministry of Food & Drug Safety
Esther Bahng, MSc
AstraZeneca Korea
HyungJin Jung, MD, MBA
Lundbeck Korea
Sora Lee, RPh, M Pharm, MBA
Syneos Health Inc.
Minjung Lim, RPh, M Pharm
MediSafe
Yunni Lim, RPh
Korea Clinical Development Association | Roche
In-sook Park, PhD
Juyoung Shin, PhD
Sungkunkwan University
Hyejong Yoo, RPh
AstraZeneca Korea
Kyung-Sang Yu, MD, PhD, MBA
Seoul National University, ARICTT
Amy(Hyunjoo) Lee, RPh, MBA
MSD Korea
Deborah Chee, MD, PhD, MBA
Gateway Sciences
Hyo Young Rhim, MD
Young Joo Park, MPH, PhD
DIA Korea, Singapore, and SEA

Facilitator

Jeehyun Oh, AstraZeneca Korea
Haelim Jeong, PharmaResearch
Mikyung Cho, Syneos Health Inc.
Minai Lee, Novartis Korea

AGENDA | 15 April 2026 | Day 1 | ALL TIMINGS IN KST

The title and speaker(s) are subject to change.

9.00 – 9.03 am	**Opening Remarks**
	Young Joo Park, MPH, PhD, Vice President, Korea, Singapore, and SEA, DIA
9.03 – 9.10 am	**Welcome Remark & Congratulatory Remark**
	Yil-Seob Lee, MD, PhD, Program Chair of Korea Annual Meeting 2026, CHA University **Eun-young Jung,** Director General, Bureau of Health Industry Policy, Ministry of Health and Welfare **Christopher Hansung Ko, PhD.** President of KoreaBio
9.10 – 10.00 am	**Session 1. Keynote Speeches** **Shaping the Future of Clinical Development: Global Transformation and Korea's Path Forward**
	As a keynote session of the DIA Korea Annual Meeting 2026, this session will feature a keynote speech by a DIA global CEO titled "Navigating Global Changes in Drug Development: The Way Forward for Korea." This presentation will provide insights into the evolving global drug development landscape and discuss strategic directions for Korea in response to these changes. This will be followed by a keynote address from the Ministry of Health and Welfare, Bureau of Health Industry Policy, entitled "Clinical Development in Korea: Past Progress and Strategies for Sustainable Growth," highlighting the history, achievements, and future strategies for Korea's clinical development ecosystem.
Session Chair	**Yil-Seob Lee, MD, PhD,** Program Chair of Korea Annual Meeting 2026, CHA University
9.10 – 9.35 am	Navigating Global Changes in Drug Development: The Way Forward for Korea
	Marwan A. Fathallah, President & CEO, DIA Global
9.35 – 10.00 am	Clinical Development in Korea: Past Progress and Strategies for Sustainable Growth
	Eun-young Jung, Director General, Bureau of Health Industry Policy, Ministry of Health and Welfare
10.00 – 10.30 am	**Coffee Break and Network**
10.30 am – 12.40 pm	**Session 2** **Regulatory Updates and Implications for Clinical Development**
	This session will feature regulatory updates from major global health authorities, including the FDA, EMA, PMDA, NMPA, and MFDS. Delegates from each agency will present recent and emerging regulatory developments relevant to clinical development within their respective jurisdictions. Each presentation will highlight key regulatory changes, current policy directions, and practical implications for clinical trial design, conduct, and regulatory strategy. By bringing together perspectives from multiple regulatory agencies, this session aims to enhance participants' understanding of the evolving global regulatory landscape and its impact on clinical development across regions.
Session Chairs	**Xiaojun Wendy Yan, MD** Strategic Advisor to the Borad of Directors, DIA **Jeewon Joung, PhD,** Director General, Pharmaceutical and Medical Device Research Department, NIFDS, MFDS
10.30 – 10.50 am	Regulatory Updates from FDA
	Sarah Ibrahim, B.Pharm, PhD, Acting Deputy Center Director, Regulatory Programs of the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER)
10.50 – 11.10 am	Regulatory Updates from EMA
	Sarra Massimiliano, PhD, Pre-clinical and clinical assessor, European Medicines Agency (EMA)
11.10 - 11.30 am	Regulatory Updates from PMDA
	Maki Mizukami, Clinical Compliance Inspector, Office of Clinical and Non-clinical Compliance II, PMDA
11.30 – 11.50 am	Regulatory Updates from NMPA
	Xiaoyuan Chen, Professor, Tsinghua University School of Basic Medicine

11.50 – 12.10 pm	Regulatory Updates from MFDS
	Jooyeon Jung, Division Director, Clinical Trial Dossier Evaluation Division, NIFDS, MFDS
12.10 – 12.40 pm	Q&A + Panel discussion
	Regulatory delegates from FDA, PMDA, NMPA and MDFS
12.40 – 1.40 pm	**Lunch and Network / Lunch Symposium - Sponsored Presentation**
Parallel Session / ROOM A - Session 3	
1.40 – 4.50 pm	**Session 3 (Parallel with Session 4 & 5)** **What's new in ICH guidelines?**
	This session will provide updates on recently revised or newly adopted ICH guidelines that are relevant to clinical development. Speakers who have been directly involved in guideline development or implementation will highlight key changes, underlying regulatory intent, and practical implications for clinical trial design, conduct, and regulatory strategy. By focusing not only on what has changed but also on why these changes were made, the session aims to help participants better interpret and apply the guidelines in real-world clinical development settings. This update session is designed to support regulators, industry professionals, and researchers in staying aligned with evolving global regulatory standards.

Session Chairs

Yoshiaki Uyama, PhD.
Associate Executive Director, Pharmaceutical and Medical Devices Agency (PMDA) Regulatory Science Center

Janis BERNAT
Director, Scientific & Regulatory Affairs, IFPMA

1.40 – 2.00 pm	ICH E6(R3): Good Clinical Practice
	Nihan Burul Bozkurt, Health Policies Director, Association of Research Based Pharmaceutical Companies (AIFD), Türkiye
2.00 – 2.20 pm	ICH E17: General planning and design of Multi-Regional Clinical Trials - Practical implementation of MRCT
	Osamu Komiyama, Senior Manager, Statistical Research & Data Science, Pfizer Japan
2.20 – 2.40 pm	ICH E20: Adaptive designs for clinical trials
	Xiaoni Liu, PhD. Executive Director, Head of Analytics China, GDD China Data & Digital Head, Group Head for China Hematology Biostatistics Team, Novartis
2.40 – 3.00 pm	Q&A, Discussion
3.00 – 3.30 pm	**Coffee Break and Network**

Session Chairs

Kelly (MyoungHee) Kim
Senior Director, Clinical Operations, IQVIA Korea

Na Young Lee, BPharm, MBA
Vice President, Commercial APAC, Parexel

3.30 – 3.50 pm	ICH M11: Clinical electronic Structured Harmonized Protocol (CeSHarP)
	Nan Wang, PhD, Head, Asia Medical Writing, GSK
3.50 – 4.10 pm	ICH M14: Use of real-world data for safety assessment of medicines
	BongKyoo Choi, ScD MPH RPh, Senior Research Fellow/Head/Vice President, AI & Data Science Center, R&D Department, GC Biopharma
4.10 – 4.30 pm	ICH E22: General Consideration for Patient Preference Studies
	Young Su Noh, PhD, Director, Head of Clinical Research and Development, Hanmi
4.30 – 4.50 pm	Q&A, Discussion
4.50 – 5.00 pm	**Closing**

AGENDA | 15 April 2026 | Day 1 | ALL TIMINGS IN KST

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Parallel Session / ROOM B - Session 4 & 5	
1.40 – 3.00 pm	**Session 4 (Parallel with Session 3)** **Medical Communication Interfaces: Bridging Science, Patients, and Practice**
	Effective medical communication extends far beyond the delivery of scientific data. In today's healthcare environment, pharmaceutical companies must navigate complex interfaces - between industry and physicians, patients, and broader stakeholders - while ensuring accuracy, transparency, and accessibility. This session will explore four critical dimensions of communication, highlighting regulatory requirements, practical challenges, and innovative approaches. Through real-world examples, we will discuss how to bridge gaps and create meaningful impacts in patient care.
Session Chairs	
Juyoung Shin, PhD Professor, Sungkunkwan University	**Seunghoon Han, MD, PhD** AIMS BioScience, CEO
1.40 – 2.00 pm	Enhancing Medical Communication through Additional RMM: Ensuring Effective Risk Communication across Stakeholders
	Yoonsun Oh, Country Head of Global Patient Safety, Amgen Korea,
2.00 – 2.20 pm	Scientific Accuracy and Compliance in Promotional Activities
	Shinkeol Kim, MedInfo and Channels Lead, Eli Lilly
2.20 – 2.40 pm	Empowering the Informed Patient: Why Plain Language Summaries are the Future of Medical Communication
	Kwangil Oh, MA, MBA, Science Communication Consultant, Media Aloud
2.40 – 3.00 pm	When Influence Replaces Evidence: Regulating Viral Health Information in the Digital Era
	Jae Hyun Lee, DDS, JD, Vice President, JNPMEDI
3.00 – 3.30 pm	**Coffee Break and Network**
3.30 - 4.50 pm	**Session 5 (Parallel with Session 3)** **Bridging Regulation and Reality: Decentralized Trials for Broader Participation**
	Decentralized Clinical Trials (DCTs) use digital and remote technologies to conduct parts of a study outside traditional sites, supporting more patient-centered and efficient operations. Wearables, mobile tools, and e-consent help collect real-world data, though some methods face country-specific regulatory limits. In South Korea, interest is growing but adoption remains slower than in the US and Europe. A collaborative group across academia, industry, and regulators is working to advance Korea's DCT ecosystem.
Session Chairs	
Kyung-Sang Yu, MD, PhD, MBA Professor, Seoul National University College of Medicine and Hospital	**Amy(Hyunjoo) Lee, RPh, MBA** Executive Director, Country Research Director MSD Korea Ltd
3.30 – 3.50 pm	DCT recommendations and guidelines
	Jun Gi Hwang, MD, PhD, Associate Professor, Chungbuk National University College of Medicine and Hospital
3.50 - 4.10 pm	Case studies of DCT elements
	Yoonjin Kim, MD, Department of Clinical Pharmacology and Therapeutics, Seoul National University
4.10 - 4.30 pm	Decentralized Clinical Trials - Implementation and Insight in Japan (PMDA experience)
	Mikiko Kubo, Inspector, Office of Non-clinical and Clinical Compliance, PMDA
4.30 – 4.50 pm	Panel Discussion: Making It Real- Practical Applications of Decentralized Trial Elements
	Yoomin Song, Clinical Research Lead, Eli Lilly and Company **Hyun Bae,** Associate Director, Clinical Research Manager, MSD Korea Ltd. **Sophia (OkSun) Im,** Local Head of CD&O, HP, Boehringer Ingelheim Korea Ltd. **Stella Ha,** Sr. Director, Clinical Operations Korea, Gilead Sciences
4.50 – 5.00 pm	**Closing**

AGENDA | 16 April 2026 | Day 2 | ALL TIMINGS IN KST

The title and speaker(s) are subject to change.

9.00 – 9.03 am	**Opening Remarks**
	Seogyoun Kang, Director General, NIFDS, MFDS
9.03 – 9.10 am	**Welcome Remark & Congratulatory Remark**
	Marwan A. Fathallah, President & CEO, DIA Global **Jaeho Oh, PhD,** Director General, KRSC
9.10 – 10.40 am	**Session 6** **Use of AI in the Regulation of Medical Products**
	This session explores how AI is being applied to enhance efficiency and improve the quality of outputs in the preparation and regulatory assessment of extensive documentation for pharmaceuticals, medical devices, and other regulated products. Through presentations from industry and regulators, we will examine practical use cases and gain insights into the real-world impact of AI in regulatory workflows.
Session Chairs	**Youngju Choi** Director General NIFDS, MFDS **Esther Bahng** Director of Market Access and Regulatory Affairs AstraZeneca
9.10 - 9.30 am	The use of AI and its application to review report in MFDS
	Kyung Hun Son, PhD, Director, Drug Research Division, Pharmaceutical and Medical Device Research Development , NIFDS, MFDS
9.30 - 9.50 am	MHRA's experience in the application of AI in regulatory activities and dossier review
	Charlotte McIntyre, MD, PhD, Strategy advisor to the CEO, Medicines and Healthcare products Regulatory Agency(MHRA)
9.50 - 10.10 am	Case study: Experience with Swissmedic
	Nicolás Pérez González, PhD, Data Scientist Swissmedic
10.10 - 10.30 am	Case study: The use of AI in industry
	Priti Shah, MS, Bio Pharmacy, Vice President, International Regulatory Affairs, AstraZeneca
10.30 - 10.40 am	Q&A
10.40 - 11.10 am	**Coffee Break and Network**
11.10 – 12.30 pm	**Session 7** **Advancing Clinical Development Efficiency with AI**
	Translate AI promise into measurable operational outcomes across the lifecycle—design optimization, site and patient identification, enrollment forecasting, real-time operational analytics for proactive decision making, and submissions. Learn responsible AI implementation patterns, vendor collaboration models, and change management that meet regulator expectations. Walk away with a roadmap to scale AI with ethics, transparency, and reproducibility.
Session Chairs	**Yunni Lim, RPh** Country Head of Global Clinical Operations, Roche Korea President, KCDA **Hyejong Yoo** Executive Director, AstraZeneca
11.10 - 11.30 am	AI Implementation in Clinical Operations and Beyond: What to Avoid and What to Emphasize (practical overview of key considerations - ethics implications, regulatory updates such as the EU AI Act, use cases)
	Piotr Maślak, MSc, Senior Director, Head of Emerging Technologies, AstraZeneca
11,30 - 11.50 an	Smarter Trials Design - AI Powered Clinical Design and Protocol Optimization
	Hye Jin Choi, R.Ph, Head, Drug Development & Regulatory Strategy JAPAC Operations, IQVIA

11.50 – 12.10 pm	AI-driven Site Identification and Patient Recruitment
	Lars Hulstaert, Director of Data Science, Johnson & Johnson Innovative Medicine
12.10 – 12.30 pm	Transforming Clinical Monitoring with AI-Powered Data Intelligence
	YuJin Lee, Solution consultant, Medidata Solutions
12.30 - 1.30 pm	**Lunch and Network / Lunch Symposium - Sponsored Presentation**
Parallel Session / ROOM A - Session 8 & 10	
1.30 – 3.10 pm	**Session 8 (Parallel with Session 9)** **Global Regulatory Trends and Standardization Strategies for Next-Generation Alternative Technologies**
	This session examines how New Approach Methodologies (NAMs) are evolving beyond the 3R concept to become essential, human-relevant tools for toxicity and safety assessment. We will discuss pathways to achieve regulatory acceptability of NAMs in drug development and quality control, focusing on practical regulatory science solutions. By reviewing global regulatory trends and requirements for data reliability and standardization, the session aims to show how NAMs can be effectively integrated into development and QC systems.
Session Chairs	**In-sook Park, PhD,** Former Director General, KRSC **Sangaeh Park, PhD,** Director General, Toxicological Evaluation and Research Department, NIFDS, MFDS
1.30 – 1.50 pm	Beyond 3Rs : Transitioning to Human-Centric Toxicity Platforms through Regulatory Science Integration of NAMs
	Joohwan Kim, Deputy Director, Nonclinical Resource Research Division, NIFDS, MFDS
1.50 – 2.10 pm	Catalyzing MPS as Drug Development Tools and Combinatorial NAMs Towards Regulatory Acceptance and Global Utility
	Danilo TAGLE, PhD. Director, Office of Special Initiative, NIH
2.10 - 2.30 pm	Regulatory trends related to alternative methods to animal testing in Canada and Europe
	Dean Smith, PhD, Advisor to the Director & Sr. Evaluator, Centre for Vaccines, Clinical Trials & Biostatistics, Health Canada
2.30 - 2.50 pm	Global Trends in NAMs and Industry Perspectives on Key Challenges
	Ran Noh, MS in Pharmacy, Team manager, Korea Biomedicine Industry Association (KoBIA)
2.50 - 3.10 pm	Panel Discussion
	Joohwan Kim, NIFDS, MFDS **Danilo TAGLE,** NIH **Dean Smith**, Health Canada **Ran Noh,** KoBIA **Jaeok Kim** Director, Biologics Division, NIFDS, MFDS
3.10 - 3.40 pm	**Coffee Break and Network**
3.40 - 5.00 pm	**Session 10 (Parallel with Session 11)** **From Insights to Impact: Delivering Truly Patient-Focused Clinical Development**
	This session, "From Insights to Impact: Truly Patient-Focused Clinical Development," highlights how global pharma, global CROs, Korean industry, and leading hospital sites each translate patient insights into practical impact. Speakers will cover embedding patient needs across the drug-development lifecycle, designing trials that amplify the patient voice, applying patient-centric lessons in global and local contexts, and implementing site-level operational strategies that enhance the patient experience
Session Chairs	**Joonwoo Bahn, MD, PhD** Professor, Asan Medical Center **Sora Lee** Vice President, General Manager, Syneos Health Inc

3.40 - 4.00 pm	Embedding Patient Insights Across the Clinical(Drug) Development Lifecycle
	Victoria DiBiaso, Head of Patient Informed Development & Health Value Translation, Sanofi
4.00 - 4.20 pm	Designing Trials with the Patient Voice: From Concept to Protocol
	Conrado Jr Vidad, Sr Director, Oncology Therapeutic Strategy and Innovations, Clinical Solutions, Syneos Health
4.20 - 4.40 pm	Industry Perspectives on Patient-Centric Development: Global Lessons
	SooKyung Shin, MSc, Head of Medical Division, GC Biopharma
4.40 - 5.00 pm	Enhancing Patient Experience at Sites: Operational Strategies and Localization Insights
	Kyu-pyo Kim, MD, PhD. Department of Oncology, Asan Medical Center
5.00 pm	**Closing**
	Yil-Seob Lee, MD, PhD, Program Chair of Korea Annual Meeting 2026, CHA University

Parallel Session / ROOM B - Session 9 & 11

1.30 – 3.10 pm	**Session 9 (Parallel with Session 8)** **Practical Implementation of Next-Generation Post-Marketing Safety Studies**
	This session will deeply explore next-generation post-marketing safety evaluation strategies leveraging Real-World Data (RWD). Key topics include the current status of database studies in Japanese Post-Marketing Surveillance (PMS) and a case study of a pharmaceutical company's use of RWD in its RMP-based post-marketing safety study. We will also share necessary preparations and recommendations for pharmaceutical companies to effectively conduct RWD safety research. Furthermore, a panel discussion involving industry, academia, and regulatory agencies will provide a platform for an in-depth discussion on the future development and direction of post-marketing safety study using RWD.
Session Chairs	**Minjung Lim** CEO, MediSafe **Seongsik Kang, MD** Senior Vice President, HANDOK, Inc
1.30 – 1.50 pm	Current Status of RWD-Based Safety Studies (Database Studies) in Japanese PMS
	Fuminori Okubo, Director, Strategic Excellence Department, Real World Data Solutions Division, CMIC Co.,Ltd
1.50 – 2.10 pm	Case Study: RWD-Based Safety Study in RMP – Korea
	Hye Young Kim, MD, PhD, VP, Head of Medical Affairs, SK bioscience
2.10 - 2.30 pm	Proposal for Conducting RWD-Based Safety Studies in RMP
	Seong-jun Byun, PhD, Director, DreamCIS
2.30 - 3.10 pm	Panel discussion
	Fuminori Okubo, CMIC **Hye Young Kim,** SK Bioscience **Seong-jun Byun,** DreamCIS **Seung Hee Jeong, PhD,** RWE Generation Lead, Pfizer **Jung Ae Kim, PhD,** Professor, Department of Pharmaceutical Engineering College of biomedical science & health, Inje University **Kim So Hee, PhD**. Director, Cardiovascular & Neurology Products Division, NIFDS, MFDS
3.10 - 3.40 pm	**Coffee Break and Network**

3.40 - 5.00 pm	**Session 11 (Parallel with Session 10)** **Innovative Biostatistical Approaches to Real-World Data**
	This session explores innovative epidemiologic and biostatistical approaches to accelerate drug development using real-world data (RWD). It first addresses key challenges—including heterogeneous data quality, limited standardization, and variable database accessibility—and discusses strategies to improve data accessibility and reliability. The session then reviews the concepts and applications of estimands in real-world evidence studies and clinical trials with ICH E9(R1). Finally, it introduces emerging design along with target trial emulation and briefly highlights the relevance of the newly established ICH M14 guideline in guiding high-quality RWD-based evidence generation.

Session Chairs

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

Hyoyoung Rhim, MD

3.40 - 4.00 pm	Data accessibility and availability in Asia and Global
	Dony Patel, PhD, Senior Director of Epidemiology and Database Studies, IQVIA
4.00 - 4.20 pm	Estimands in real-world evidence studies
	Sohee Kim, PhD, Executive Officer, Clinical Statistics Team, YUHAN
4.20 - 4.40 pm	When Observational Data Behave Like Clinical Trials: The Target Trial Emulation Framework under ICH M14
	Hojoon Lee, MD, MPH, DrPH, Head, JAPAC Data & Analytic Center Epidemiology, Amgen
4.40 - 5.00 pm	Q&A
5.00 pm	**Closing**
	Young Joo Park, MPH, PhD, Vice President, Korea, Singapore, and SEA, DIA

REGISTRATION FORM : Register online (Click HERE) or forward to korea@DIAglobal.org

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REGISTRATION

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

Online Registration For Payment via Credit Card, please access here

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

Registration Fee(USD) 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.

◆ ***Full Pass (2 Days)***

MEMBER	Academia	Early Bird (until 14 March)	☐ 230
		After 15 March	☐ 280
	Government	Early Bird (until 14 March)	☐ 220
		After 15 March	☐ 275
	Industry	Early Bird (until 14 March)	☐ 255
		After 15 March	☐ 320
NON-MEMBER	Academia	Early Bird (until 14 March)	☐ 300
		After 15 March	☐ 370
	Government	Early Bird (until 14 March)	☐ 285
		After 15 March	☐ 360
	Industry	Early Bird (until 14 March)	☐ 330
		After 15 March	☐ 420
Students/ Patient / Patient Advocacy Groups			☐ 130
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	Government	☐ 235
	Industry	☐ 275
Please check the date you wish to attend.	**April 15th** ☐	**April 16th** ☐

Please check the applicable category:

☐ Academia ☐ Government ☐ Industry

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First Name

Degrees ☐ Dr. ☐ Mr. ☐ Ms.

Job Title

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City State Zip/Postal Country

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