2017 Joint International Conference on Clinical Trials

- 3rd KoNECT International Conference
- 1st DIA Korea Conference

November 1-2 | Conrad Hotel, Seoul

DIA | KONECT Korea National Enterprise for Clinical Trials

PROGRAM CHAIR

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We are pleased to invite you to a two(2)-day conference held in Seoul, South Korea jointly hosted by Korea National Enterprise for Clinical Trials (KoNECT) and Drug Information Association (DIA). The joint conference brings regulators, industry, patient advocates and academia together to discuss and share both Korea and Global up-to-date clinical trial topics and will host 600+ health care professionals.

Our sessions will cover a wide range of topics including advances in patient-centric clinical trials with special emphasis on the 4th industrial revolution and its impact on the clinical development, strategic cooperation required for clinical trials of innovative new drug development and regulatory science. In addition, it will be the best opportunity to connect with heath care development domestic and international professionals in Korea.

Topic Highlights

- Bio-Health Innovation Plan for Korea
- Patient Centric Clinical Development
- Updates on Regulatory Science (Focus on Korea, China and Japan)
- Real World Evidence and Clinical Development
- Holistic Approach in Drug Development
- Precision Medicine and Clinical Development
- Medical & Social Value of Clinical Trials
- 4th Industrial Revolution and Clinical Development
- More Unseen Than Seen
- Evolving Ethical Topics in Clinical Trials
- Clinical Operational Excellence with New Technologies
- Data Driven Approaches in Clinical Development
- Adaptive Design in Clinical Trials: When and How to Apply

Program Highlights

The Joint conference is the largest clinical trial conference in Asia, known as a forum of knowledge exchange that fosters innovation. We drive proactive thought leadership through the conference and connect global community of clinical trial.

- Two (2) Plenary sessions
- Eleven (11) tracks and Two (2) workshops on RBM and PV/RMP
- Exhibition
- One-on-One Partnering Meetings
- Networking Reception

Program Committee

Joo-young Kim
Ministry of Health and Welfare (MoHW)

Nam-hee Lee
Ministry of Food And Drug Safety (MFDS)

Dae Cheol Kim
Ministry of Food And Drug Safety (MFDS)

Yeul Hong Kim
Korea University College of Medicine

Min Soo Park
Korea Clinical Trials Global Initiative (KCGI)

In Jin Jang
Seoul National University College of Medicine

Young Suk Park
Samsung Medical Center

Sin Gon Kim
Korea University College of Medicine

Sung-ho Beck
ASAN Medical Center

Jeewoong Son
LG Chem

Seoung-Choon Choe
Boryung Pharmaceutical Company

Kyung-Mi Park
CKD Pharm

Jongho Ahn
MSD Korea

Sung Chun Kim
Korea Drug Development Fund (KDDF)

Eunhwa Kim
Korean Research-based Pharmaceutical Industry Association (KRPIA)

Seung In Um
Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA)

SungJa Cho
Janssen Korea

TaeYoun Jo
MSD Korea

Hun Che Cho
Korea Drug Research Association (KDRA)

Jung Tae Park
Korea Biomedicine Industry Association (KOBIA)

Seok-Min Yoon
ADM Korea

MiSook Hyun
QuintilesIMS Korea

Stewart Geary
Eisai Japan

Ling Su
Shenyang Pharmaceutical University

AGENDA | Day 1 | Wednesday, November 1

8:30	**Registration**
09:00 – 09:10	**Opening Remarks**
	Deborah Chee KoNECT **Barbara Lopez Kunz** DIA
Welcome address	
09:10 – 09:20	**Congratulatory Remark**
	Sung Il Yang MOHW
09:20 – 09:30	**Congratulatory Remark**
	Won Sik Lee MFDS
09:30 – 10:00	**Plenary Lecture 1**
	Chair **Yil-Seob Lee** GSK, Korea Speaker **Joo-young Kim** MOHW, Korea
10:00 – 10:30	Coffee Break
10:30 – 12:00	**S1: Patient Centric Clinical Development**
	Chair **Yeul Hong Kim** Korea University College of Medicine, Korea **Carlo Maccarrone** GSK, Australia Voice of Patients on Clinical Trials **Ji Yeon Lee** The Patient Award in Clinical Trials Experience, Korea Is Patient Centricity the right approach to engagement? **Trish Caruana** President/CEO Rare Disease Solution, USA Digital Enabled Tactics to Improve Engagement, Retention and Adherence **David Hou** Quintiles, Singapore Patient Centric Recruitment, Lesson Learned from Study **Mariah Baltezegar** INC Research, USA
12:00 – 13:20	Lunch
13:20 – 15:00	**S2: Updates on Regulatory Science**
	Chair **Dae Cheol Kim** Ministry of Food And Drug Safety (MFDS), Korea **Yoshiaki Uyama** Pharmaceuticals and Medical Devices Agency (PMDA), Japan Regulatory Science Initiatives at FDA to Streamline Early Clinical Drug Development **Hae-Young Ahn** FDA, USA Update on MRCT Guideline (ICH E17) **Yoshiaki Uyama** Pharmaceuticals and Medical Devices Agency(PMDA), Japan Expedited Pathways for Biopharmaceuticals in Korea **Kyungtak Nam** Ministry of Food And Drug Safety(MFDS), Korea Update on China Reform in Regulatory Science **Jessica Liu** Tigermed Co. Ltd / DreamCIS, INC., China
13:30 – 15:00	**S3: Real World Evidence and Clinical Development**
	Chair **Sung Ja Cho** Janssen, Korea **Sung Chun Kim** Korea Drug Development Fund (KDDF), Korea
Parallel Sessions	How to Use Real World Study Data for Drug Development **Bart Vannieuwenhuyse** J&J, Belgium What are Opportunities and Barriers for Real World Study **Sumitra Shantakumar** GSK, Singapore Real-World Study Cases : from Preclinical to Clinical Trials **Hae-Sim Park** Ajou University School of Medicine, Korea
15:00 – 15:30	Coffee Break

AGENDA | Day 1 | Wednesday, November 1

15:30 – 17:10	**S4: Holistic Approach in Drug Development: Bridging the Gap**
	Chair **Hanlim Moon** CUREnCARE Research, Korea **Hyunsang Muk** Korea Drug Development Fund (KDDF), Korea
Parallel Sessions	Joining Preclinical and Clinical Development: Discovery with IND in Mind **Seonggu Ro** PiMedBio, Korea
	Critical Points to Consider in Clinical Development Plan in Early Stage **Jeewoong Son** LG Chem, Korea
	Strategy for Asian Clinical Development in Global CDP in Multinational Company **Sam Lim** AstaZeneca, China
	How to Choose the Comparator with Rapidly Changing Standard of Care (Oncology Example) **Hanlim Moon** CUREnCARE Research, Korea
15:30 – 17:00	**S5: Precision Medicine and Clinical Development**
	Chair **Young Suk Park** Samsung Medical Center, Korea **Soonmyung Paik** Severance Biomedical Science Institute, Korea
	N of One Trial in Clinical Development **Young Suk Park** Samsung Medical Center, Korea
	Companion Diagnostic and Clinical Development (Example of Keytruda) **Sally Bai** MSD, Singapore
	Clinical Development in Breast Cancer **Soonmyung Paik** Severance Biomedical Science Institute, Korea

Day 2 | Thursday, November 2

8:30	**Registration**
9:00 – 9:30	**Plenary Lecture 2: Medical & Social Value of Clinical Trials**
	Chair **Min Soo Park** KCGI, Korea
	Speaker **Kathy Rouan** GSK, USA
9:30 – 10:20	**S6: 4th Industrial Revolution and Clinical Development**
	Chair **Sin Gon Kim** Korea University College of Medicine, Korea **Jongho Ahn** MSD, Korea
	4th Industrial Revolution Health Care Industry **Wonjae Lee** Yozma asia, Korea
	4th Industrial Revolution, Medical Care and Drug Development **Alice Landis-McGrath** IBM Watson Health, USA
10:20 – 10:50	Coffee Break
10:50 – 12:10	**S7: Clinical Trials: More Unseen Than Seen**
	Chair **Choong Heon Lee** Medical Journalist of KBS, Korea **Jeong Rim Moon** 19th National Assembly Member of the Republic of Korea, Korea
	Public Awareness & Perception of Clinical Trials **Sung-ho Beck** ASAN Medical Center, Korea
	PMDA's Initiative for Introducing Innovative Medical Products **Masayoshi SHIBATSUJI** Pharmaceuticals and Medical Devices Agency(PMDA), Japan
	Social Value of IIT on Public Health **Young-suk Lim** ASAN Medical Center, Korea
	Successful Cases of Public IIT - Development of Optimal Busulfan Dosing Based on Pharmacokinetic Modeling **Hyoung Jin Kang** Seoul National University Hospital, Korea
12:10 – 13:30	Lunch

AGENDA | Day 2 | Thursday, November 2

13:30 – 15:00 **S8: Evolving Ethical Topics in Clinical Trials**

Chair
Min Soo Park
Korea Clinical Trials Global Initiative (KCGI), Korea
Barbara Bierer
Multi-Regional Clinical Trials Center of BWH and Harvard, USA

Parallel Sessions

Patient Protection Activities in Clinical Trial
Seung Min Kim
Korean Association of Institutional Review Boards(KAIRB), Korea

Building Human Research Protections Programs in Korea: AAHRPP Perspective
Elyse Summers
Association for the Accreditation of Human Research Protection Programs(AAHRPP), USA

Emerging Ethical Issues in Clinical Trials
Barbara Bierer
Multi-Regional Clinical Trials Center of BWH and Harvard, USA

13:30 – 15:00 **S9: Clinical Operational Excellence with New Technologies**

Chair
Soo Kyung Shin
QuintilesIMS, Korea
Jae Gook Shin
Inje University Busan Park Hospital, Korea

The application of Digital healthcare to Clinical Trial - Not to prove, but to improve
Kwang Joon Kim
Yonsei University College of Medicine

Informed Consent Entering the Digital World: The TransCelerate eConsent Initiative
Nozomi Sakurai
Janssen, Japan

EMR Data Quality and Standardization
Mi Ra Kang
Mi Ra Kang Samsung Medical Center, Korea

15:00 – 15:30 Coffee Break

15:30 – 17:00 **S10: Data Driven Approaches in Clinical Development**

Chair
In Jin Jang
Seoul National University College of Medicine, Korea
Hun Che Cho
Korea Drug Research Association(KDRA), Korea

Parallel Sessions

Harnessing Big Data for Clinical Trial Design
Dustin Owen
PPD, Singapore

Data Driven Approaches in Clinical Development
Jerome Armellini
QuintilesIMS, Singapore

How Big Data and Analytics are Changing Clinical Trials
Eunho Shin
Medidata, Korea

15:30 – 17:00 **S11: Adaptive Design in Clinical Trials: When and How to Apply**

Chair
Howard Lee
Seoul National University College of Medicine, Korea
Hye-Jong Yoo
AstraZeneka, Korea

Principle of Adaptive Design & Regulatory Requirement for Adaptive Clinical Trials
Howard Lee
Seoul National University College of Medicine, Korea

Practical Aspects of Designing and Implementing Adaptive Design Trials in Immune Oncology
Naftali Bechar
COVANCE, USA

Infrastructure and Processes Required for Optimal Delivery of Adaptive Clinical Trials
Jerry Wang
Merck Serono, China

AGENDA | WORKSHOP SESSION

Wednesday, November 1

Risk Based Monitoring Workshop

13:30 – 15:10	**RBM**
	Chair **Carlo Maccarrone** GSK, Australia **Nam-hee Lee** MFDS, Korea
	What is RBM, and how it is working? **SunKyung Hur** ICON, Korea
	How central monitoring is working? **Yumi Sugiura** BMS, Japan
	RBM guidelines **T.B.D.** MFDS, Korea
15:10 – 15:30	Coffee Break
15:30 – 17:00	**How RBM will change our daily life?**
	Chair **Yunni Lim** Roche, Korea **Seok-Min Yoon** ADM Korea, Korea
	From Project management perspectives **Ashley Yoo** BMS, Korea
	From site management perspectives **HeeJung Yang** ICON, Korea
	From site perspectives **HyeYoung Lee** Severance Hospital, Korea
	From quality management perspectives **Michelle Ho** INC Research, Singapore

Thursday, November 2

PV Workshop : Principles and Practices in Global Drug Development

13:30 – 14:50	**PV Workshop 1**
	Chair **Stewart Geary** Eisai, Japan **Seong-Choon Choe** Boryung Pharmaceutical Company, Korea
	Introduction to principles of Pharmacovigilance throughout product lifecycle (clinical development through marketing) including terminology **Stewart Geary** Eisai, Japan
	International reporting requirements, risk management plans around the world **Rei Maeda** Lilly, Japan
14:50 – 15:20	Coffee Break
15:20 – 17:00	**PV Workshop 2**
	Chair **Stewart Geary** Eisai, Japan **Seong-Choon Choe** Boryung Pharmaceutical Company, Korea
	Periodic Reports: the DSUR and PSUR/ PBRER, how to prepare and interpret them **Asha Liju** Parexel, India
	Signal detection and safety databases **Andrew Bate** Pfizer, UK
	Discussion

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Event I.D. 83517 | November 1~2, 2017 | Conrad Hotel Grand Ballroom, Seoul, Korea

VENUE:
Conrad Hotel Grand Ballroom
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The conference secretariat
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For more information
http://www.konect-diaconf.org/sub04/sub01.html

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For more details, please visit www.DIAglobal.org
www.KoNECT-DIAconf.org

REGISTRATION FEES FOR TWO DAYS CONFERENCE

(*Registration fee includes refreshment breaks and luncheons.)*

	BASIC RATE (UDS)
Early Bird (ON OR BEFORE OCTOBER 13TH, 2017)	$270 ❑
Normal	$310 ❑

Booth	
EARLY BIRD (ON OR BEFORE SEPTEMBER 30TH, 2017)	$2,600 ❑
NORMAL	$3,000 ❑

For Booth and delegate Registration
www.KoNECT-DIAconf.org / info@KoNECT-DIAconf.org

Program Book (Ads1)	
Outside Back Cover	$2,100
Inside Front Cover	$1,700
Inside Back Cover	$1,300
Inner Ad full Page	$900
Website (Ads2)	
Online Banner	$1,700

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ACADEMIA/GOVERNMENT REGISTRATION
Registration discount available for academia and government participants.
Please check it at http://www.konect-diaconf.org/sub03/sub01.html

CTC TOUR
On 3rd Nov. There will be Free CTC Tour for global companies.
You can also register through
http://www.konect-diaconf.org
Please contact : suji.yoo@konect.or.kr

DELEGATE REGISTRATION PAYMENT
Beneficiary : Korea National Enterprise for Clinical Trials
Bank name : Shinhan Bank
Account No. : 100-030-871971
Swift Code : SHBKKRSE
Address : 136, MAPO-DAERO, MAPO-GU, SEOUL

EXHIBITION & AD
Please contact youngshin.lee@diaglobal.org

DIA Bank Information

Beneficiary: Drug Information Association INC
Bank Name: TD Bank NA
ABA No.:036001808
ACCOUNT No: 366930337
SWIFT CODE: NRTHUS33XXX

FOREIGN CURRENCY (IF NOT SENDING USD)

Beneficiary: Drug Information Association INC
Bank Name: TD Bank NA
ABA No: 036001808
ACCOUNT No: 366930337
SWIFT CODE: TDOMCATTTOR

CANCELLATION POLICY: ON OR BEFORE OCTOBER 20, 2017

- Cancellation must be in writing and received by October 20, 2017. Registrants who do not cancel in writing by that date and do not attend the event will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations.
- Cancellation received after the deadline will not be eligible for a refund.

FULL MEETING CANCELLATION

- All refunds will be issued in the currency of the original payment