2019 KoNECT-MOHW-MFDS International Conference

September 18th (Wed) - 19th (Thu), 2019
[Pre-Workshop 17th (Tue)]
Conrad Seoul, Korea

Accelerating Clinical Development, Bringing Hope to Patients

For Registration & Exhibition

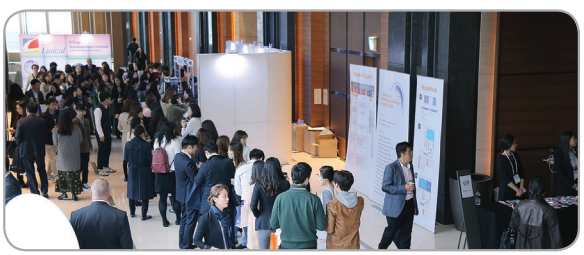
Website: www.konectintconference.org
Email: info-kic@konect.or.kr
Phone: +82-2-6000-7275

KONECT Korea National Enterprise for Clinical Trials
Ministry of Health and Welfare
Ministry of Food and Drug Safety

ABOUT CONFERENCE

2019 KoNECT-MOHW-MFDS International Conference, co-hosted by Ministry of Health and Welfare (MOHW) and Ministry of Food and Drug Safety (MFDS), is more special than ever.

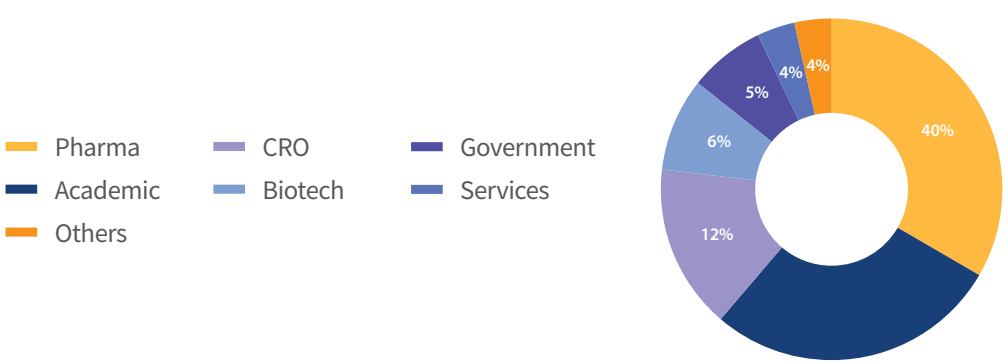
The program will be focusing on topics about new technologies and approaches in clinical trials, regulatory science, real-world studies, data-driven approaches, and the continuously evolving issues on ethics as well as patient-centric approaches in 3 parallel tracks with attendees from across government, academia and industry.



OVERVIEW

Title	2019 KoNECT-MOHW-MFDS International Conference
Date	September 18th (Wed) - 19th (Thu), 2019 [Pre-Workshop 17th (Tue)]
Venue	Grand Ballroom (3F) & Park Ballroom (5F), Conrad Hotel, Seoul, South Korea
Theme	Accelerating Clinical Development, Bringing Hope to Patients
Program	Pre-Workshops, Plenary Lectures, Sessions
Hosted by	KoNECT (Korea National Enterprise for Clinical Trials)
	MOHW (Ministry of Health and Welfare)
	MFDS (Ministry of Food and Drug Safety)

WHO ATTENDS



ORGANIZING COMMITTEE

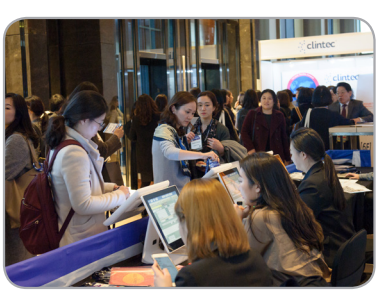
Chair	Deborah Chee	Korea National Enterprise for Clinical Trials (KoNECT)
Vice-Chair	Yil-Seob Lee	GSK
Member	In-Taek Lim	Ministry of Health and Welfare (MOHW)
	Young-ok Kim	Ministry of Food and Drug Safety (MFDS)
	Kyung Won Seo	National Institute of Food and Drug Safety Evaluation (NIFDS)
	Young-Whan Park	National OncoVenture
	HyunChul Jung	Korean Cancer Association (KCA)
	Hyunsang Muk	Korea Drug Development Fund Foundation (KDDF)
	Min Soo Park	Korea Clinical Trials Global Initiative (KCGI)
	Avi Benshoshan	Korean Research-based Pharmaceutical Industry Association (KRPIA)
	Jae-Wook Ko	Korean Society for Clinical Pharmacology and Therapeutics (KSCPT)
	In Jin Jang	The Korean Association of Clinical Trials Centers (KACTC)
	Seung Min Kim	Korean Association of Institutional Review Boards (KAIRB)
	Won-il Gal	Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA)
	Sung Ku Choi	The Korean Society of Pharmaceutical Medicine (KSPM)
	Hye-Jong Yoo	Korea Society for Clinical Development (KSCD)
	Dong-Yeon Kim	Korea Drug Research Association (KDRA)
	SeokHee Kang	Korea Biomedicine Industry Association (KOBIA)
	Jeong-Sun Seo	Korea Biotechnology Industry Organization (KoreaBio)
	Kwan-Soo Park	Korea Contract Research Organization Association (KCROA)
	Jungmi Baik	Korean Association of Clinical Research Coordinator (KACRC)
	Se-Woong Oh	The Korean Society of Non-Clinical Study (KSNS)

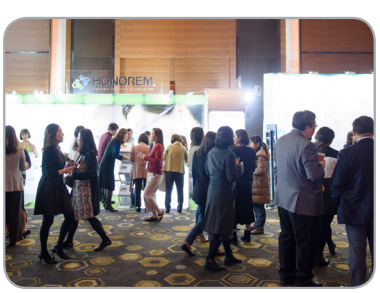




PROGRAM COMMITTEE

Chair	Yil-Seob Lee	GSK, Chair of KIC Program Committee
Member	Ju Young Kim	Ministry of Health and Welfare (MOHW)
	Jeong Mi Kim	Ministry of Food and Drug Safety (MFDS)
	Min Soo Park	Korea Clinical Trials Global Initiative (KCGI)
	In Jin Jang	Seoul National University Hospital
	Sin Gon Kim	Korea University College of Medicine
	Sun Young Rha	Yonsei University Hospital
	Hea-Young Cho	CHA University
	Young-suk Lim	ASAN Medical Center
	Hyo-Young Rhim	Yuhan
	KyoungHee Seo	Hanmi Pharm
	Geun Seog Song	CJ Healthcare
	SungJa Cho	Lilly
	Yoon-Duk Han	Pfizer
	TaeYoun Jo	MSD
	Hye Won Song	Sanofi
	Hye-Jong Yoo	Korea Society for Clinical Development (KSCD)
	Esther Bang	Korean Research-based Pharmaceutical Industry Association (KRPIA)
	Sung Chun Kim	Korea Drug Development Fund (KDDF)
	Hun Che Cho	Korea Drug Research Association (KDRA)
	Joonghoon Park	The Korean Society of Non-Clinical Study (KSNS)
	Byung-In Yoon	C&R Research
	Hanlim Moon	CUREnCARE Research
	Soo Kyung Shin	IQVIA
	Sora Lee	Syneos Health
	Stewart Geary	Eisai
	Jessica Liu	TigerMed





PROGRAM DETAILS

DAY 1: September 17 (Tue)

Time	Program
Workshop 1. Biologics CMC for IND	
09:30~11:00	**Biologics CMC for IND**
09:30~10:00	Special Lecture - Continuous Manufacturing for Bioproducts
10:00~10:30	CMC Data Requirement of IMPD for Earlier Phase Clinical Study Authorization: Learning from EMA and US FDA Regulations
10:30~11:00	Regulatory Perspectives, to Ensure the CMC Safety of Investigational Biotherapeutics
11:00~11:30	Coffee Break
11:30~13:00	**Experience Sharing with Key CMC Issues of Korea-IND**
11:30~12:00	Major CMC Issues in Biosimilar Development
12:00~12:30	Manufacturer's Experience with Early Phase Studies
12:30~13:00	CRO's Experience with MNC Global Development Studies
13:00~14:00	Lunch
Workshop 2. Risk-Based Quality Management	
09:30~11:00	**Risk Management Planning**
09:30~10:00	Introduction of Risk Based Monitoring
10:00~10:30	RBM Methodology
10:30~11:00	MOCK RACT Exercise Using Mock Protocol
11:00~11:30	Coffee Break
11:30~13:00	**Execution of RBM**
11:30~11:50	On-Site Monitoring in the RBM Model
11:50~12:10	Central Monitoring Using RBM Tool
12:10~12:30	Experience Sharing from Korean Company
12:30~13:00	Panel Discussion
13:00~14:00	Lunch
Workshop 3. How to Manage Safety in Clinical Development; Lessons Learned	
14:00~16:00	**Regulatory Updates in Clinical Development**
14:00~15:00	Global Regulatory Framework for Clinical Safety
15:00~16:00	End to End Process on Clinical Safety/Safety Science in Clinical Trial
16:00~16:30	Coffee Break
16:30~17:30	**Safety Management in Clinical Development**
16:30~17:00	Challenges on Implementation of Global Standards and Our Future; 1) From global perspectives
17:00~17:30	Challenges on Implementation of Global Standards and Our Future; 2) From local perspectives
Workshop 4. Immuno-Oncology	
14:00~15:30	**Maximizing Success in Immuno-Oncology Drug Development**
14:00~14:30	Lessons from Success and Failure in Immuno-Oncology Drug Development
14:30~15:00	Ensuring Clinical Trial Design for Immuno-Oncology Drug
15:00~15:30	Characteristics of Immune-Related AE and Their Management in Clinical Trials
15:30~16:00	Coffee Break
16:00~17:30	**Evolving Science in Immune-Oncology**
16:00~16:30	Progress in Immune Checkpoint Biomarkers Beyond PD-L1 Antibody Development
16:30~17:00	Multiparametric Approach through NGS for Immune-Oncology Therapy
17:00~17:30	Prediction of Immune-Oncology Drug Resistance for The Next Step

DAY 2: September 18 (Wed)

Time	Program
08:00~09:00	Registraion
Room A, B, C [3F ~ 5F]	
09:00~09:10	Opening Remarks
09:10~09:20	Welcome Remarks 1
09:20~09:30	Welcome Remarks 2
09:30~09:50	Plenary Lecture 1
09:50~10:10	Plenary Lecture 2
10:10~10:30	Coffee Break
10:30~12:00	**S1: Regulatory Updates**
10:30~10:50	Impact of NMPA Reform in China
10:50~11:10	Regulatory Updates on Japan
11:10~11:30	Regulatory Updates on Korea
11:30~12:00	Regulatory Updates on US FDA
12:00~13:30	Lunch
Room A [3F]	
13:30~15:00	**S2: Successful Outsourcing Strategy in Clinical Development**
13:30~14:00	Optimum Outsourcing Strategies to Fit Your Unique Needs
14:00~14:30	How to Select the Right CRO for Your Clinical Programs
14:30~15:00	Building Healthy Partnership between Sponsor and CRO to Achieve Joint Goals
15:00~15:30	Coffee Break
Room B [3F]	
13:30~15:00	**S3: Improving Evidence Generation Using RWD**
13:30~14:00	Use of Real World Evidence to Support Regulatory Decision Making
14:00~14:30	New Clinical Trial Execution Using RWD: Pragmatic Clinical Trials
14:30~15:00	Access, Analytics and Acceptance: Three examples of real-world innovations in drug development
15:00~15:30	Coffee Break
Room C [5F]	
13:30~15:00	**S4: Expanding the Horizon of Clinical Trial to Combination Products**
13:30~14:00	Global Medtech Market Trend and Hot Topics; Clinical & Regulatory Perspectives
14:00~14:30	Clinical/Regulatory Considerations on Combination Products
14:30~15:00	Challenges in Drug/Device Combination Products Trials
15:00~15:30	Coffee Break
Room A [3F]	
15:30~17:00	**S5: Smart Technology in Clinical Trials**
15:30~16:00	Utility of Smart Technology in Clinical Trials
16:00~16:30	Improving Clinical Trial Efficiency using HIS (Hospital Information System)
16:30~17:00	Utility of New Technology in Clinical Trial (AI, Block Chain)
Room B [3F]	
15:30~17:00	**S6: IIT: Now is the time to pivot**
15:30~16:00	Contribution of IIT to Clinical Practice Change
16:00~16:30	Infrastructure of IIT in Japan including Government Support
16:30~17:00	New Government Initiative on IIT in Korea
Room C [5F]	
15:30~17:00	**S7: Interpretation of Non-Clinical Findings for Better Clinical Trials**
15:30~16:00	Non-clinical development of Lasertinib for NSCLC
16:00~16:30	Non-clinical development of universal CAR-T
16:30~17:00	Non-clinical development of Pexa-Vec

DAY 3: September 19 (Thu)

Time	Program
08:00~09:00	Registration
Room A,B,C [3F ~ 5F]	
09:00~09:30	Plenary Lecture 3
09:30~10:00	Patient Voice
10:00~10:30	Coffee Break
10:30~12:00	**S8: Improving Patient Experience and Quality by Patient Facing Technologies in Clinical Trials**
10:30~11:00	Digitizing a Patient-Focused Clinical Trial Experience
11:00~11:30	The Future of Informed Consent
11:30~12:00	Current Landscape and Tools for eLabel
12:00~13:30	Lunch
Room A [3F]	
13:30~15:00	**S9: Advancing Patient Protection in Clinical Trials**
13:30~14:00	A system to secure the safety of the patients
14:00~14:30	Preparation of insurance contracts and insurance for victims
14:30~15:00	Benefit of HRPP in Clinical Development- Global Perspective
15:00~15:30	Coffee Break
Room B [3F]	
13:30~15:00	**S10: Pioneering the fundamental Gene & Cell Tharapy**
13:30~14:00	Cell gene therapy industry and clinical development trend
14:00~14:30	Advanced Cellular Therapeutics Landscape & Key Considerations for Human Trials
14:30~15:00	Gene Therapeutics R & D Trends and Key Considerations in Clinical Development
15:00~15:30	Coffee Break
Room C [5F]	
13:30~15:00	**S11: Creating Value through Clinical Development**
13:30~14:00	What makes your product(asset) value increased * Global Trend on deal making
14:00~14:30	Key Questions to Ask Yourselves Throughout Clinical Development Process for Product Success
14:30~15:00	Case Study: Challenges and Success ? big local pharma, small bio-tech
15:00~15:30	Coffee Break
Room A [3F]	
15:30~17:00	**S12: Early Engagement of Biomarker in Drug Development**
15:30~16:00	Pharmacodynamic biomarkers in early POC studies
16:00~16:30	Target the right target: Aligned discovery to development of drug and companion diagnostics
16:30~17:00	Biomarkers in Immuno-Oncology Drug Development
Room B [3F]	
15:30~17:00	**S13: Quality Planning and Management in Protocol Execution**
15:30~16:00	Risk Management Planning (Sponsor Perspective)
16:00~16:30	Quality Management at site (audit, inspection preparation)
16:30~17:00	Central monitoring ? how do we detect the risk and deal with it?
Room C [5F]	
15:30~17:00	**S14: Success to NDA through Optimal Study Design**
15:30~16:00	Acceleration of drug development from First-Time-in-Human
16:00~16:30	New initiatives to accelerate drug development using master protocol
16:30~17:00	Statistical strategy accelerating drug development

REGISTRATION

Online Registration is Available Now for Option A&B. (www.konectintconference.org)
Please register by June 30th 2019 to receive the early bird discount.

OPTION A. Conference (2 days, Sep 18th, 19th)

Registration / Organization	Early Bird (~2019. 06. 30)	Registration (2019. 07. 01 ~ 09. 06)
Government	KRW 100,000	KRW 150,000
Academia	KRW 200,000	KRW 250,000
Industry	KRW 300,000	KRW 350,000

OPTION B. Workshop + Conference (3 days, Sep 17th - 19th)

Registration / Organization	Registration (2019. 05. 01 ~ 09. 06)
Government	KRW 250,000
Academia	KRW 350,000
Industry	KRW 450,000

* Registration fee includes scientific programs, exhibition, lunch and coffee breaks.
* The on-site registration fee is the same as the standard registration.

EXHIBITION & AD

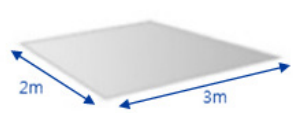
2019 KoNECT-MOHW-MFDS International Conference offers you an opportunity to join our Exhibition to promote your company, products and services to the participants from industry, academia, research institutes and government throughout the world. If you are interested in our Exhibition, please contact the conference secretariat.

Conference Secretariat

Email: info-kic@konect.or.kr
Phone: +82-2-6000-8191

- Date: September 18th – 19th, 2019
- Venue: Grand Ball Room Foyer and Park Ball Room Foyer, Conrad Seoul
- Booth location assignment is on a first come, first served basis

EXHIBITION BOOTH INFORMATION

Space Only Booth		
Type		
Rate	Early Bird (~ 2019. 06. 16)	KRW 3,000,000
	Standard (2019. 06. 17 ~)	KRW 3,500,000
Specification		· 1KW Electricity, One electric socket (220v 2ways) · 1 information desk, 2 chairs, tablecloth

Program Book Advertisement Opportunities

Opportunities		KRW (₩)
Program Book AD	Outside Back Cover	1,500,000
	Inside Front Cover	Completed
	Inside Back Cover	1,000,000
	Inner Ad Full Page	500,000

VENUE: Conrad Seoul

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