



2019 KoNECT-MOH-W-MFDS INTERNATIONAL CONFERENCE

September 18th (Wed) - 19th (Thu), 2019

[Pre-Workshop 17th (Tue)]

Conrad Seoul, Korea

**Accelerating Clinical Development,
Bringing Hope to Patients**

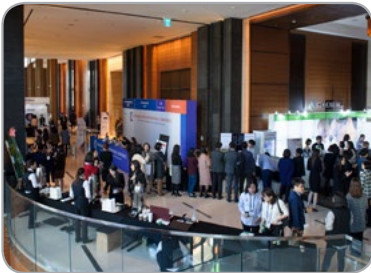
For Registration & Exhibition

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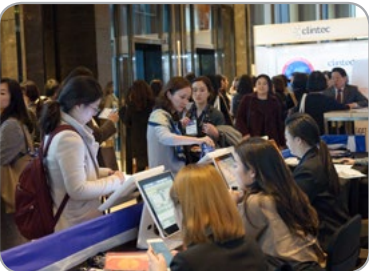
ORGANIZING COMMITTEE

Chair	Deborah Chee	Korea National Enterprise for Clinical Trials (KoNECT)
Member	Yil-Seob Lee	GSK
	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

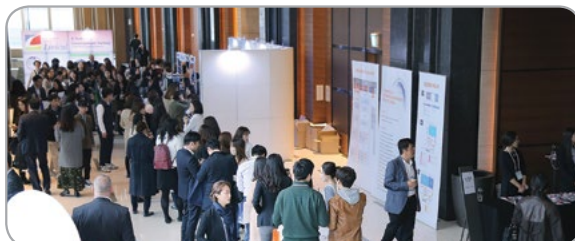
Chair	Yil-Seob Lee	GSK, Chair of KIC Program Committee
Member	Youngho Kim	Ministry of Health and Welfare (MOHW)
	Jeong Mi Kim	Ministry of Food and Drug Safety (MFDS)
	Min Soo Park	Korea Clinical Trials Global Initiative (KCGI)
	In Jin Jang	Seoul National University Hospital
	Sin Gon Kim	Korea University 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 Korea
	Yoon-Duk Han	Pfizer Korea
	TaeYoun Jo	MSD Korea
	Hye Won Song	Sanofi Korea
	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 Korea
	Sora Lee	Syneos Health
	Stewart Geary	Eisai Japan
	Jessica Liu	TigerMed China



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.

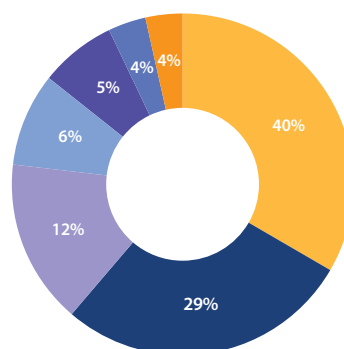
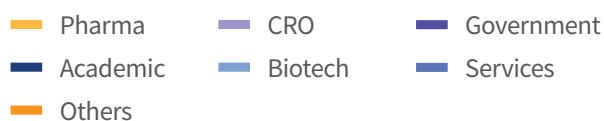
The program will be focusing on topics about new technologies and approaches in clinical trials, regulatory science, real-world studies, data-driven approaches, and the continuously evolving issues on ethics as well as patient-centric approaches in 3 parallel tracks with attendees from across government,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



OVERVIEW

Title	2019 KoNECT-MOHW-MFDS International Conference
Date	September 18 th (Wed) - 19 th (Thu), 2019 [Pre-Workshop 17 th (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



PROGRAM DETAILS

Pre-Conference Workshop: September 17 (Tue)

Time	Program	Speaker	Affiliation
Workshop 1. Biologics CMC for IND			
09:30~11:00	Biologics CMC for IND	Chair: Hyi-Jeong Ji, HyangWon (Harriet) Min	
09:30~10:00	Special Lecture - Process Control Strategy during Clinical Material Production	Jeongwon (Jason) Yun	Celltrion Inc.
10:00~10:30	CMC Data Requirement of IMPD for Earlier Phase Clinical Study Authorization : Learning from EMA and US FDA Regulations	Hyun Jung Kim	IQVIA
10:30~11:00	Regulatory Perspectives to Ensure the CMC Safety of Investigational Biotherapeutics	Jina Kim	MFDS
11:00~11:30	Coffee Break		
11:30~13:00	Experience Sharing with Key CMC Issues of Korea-IND	Chair: Yeo Wook Koh, Esther Bang	
11:30~12:00	Major CMC Issues in Biosimilar Development	Hoon Joo Kim	DGMIF
12:00~12:30	Manufacturer's Experience with Early Phase Studies	Yujin Jung	Lilly Korea Ltd.
12:30~13:00	CRO's Experience with MNC Global Development Studies	Kyunghwa Son	Mediheplline
13:00~14:00	Lunch		
Workshop 2. Risk-Based Quality Management			
09:30~11:00	Risk Management Planning	Chair: Carlo Maccarrone, Hye Jong Yoo	
09:30~10:00	Introduction of Risk Based Monitoring	Yoon-Duk Han	Pfizer
10:00~10:30	RBM Methodology	Sol Han	Sanofi
10:30~11:00	MOCK RACT Exercise Using Mock Protocol	Sol Han	Sanofi
11:00~11:30	Coffee Break		
11:30~13:00	Execution of RBM	Chair: Yoon-Duk Han, Hyewon Song	
11:30~11:50	On-Site Monitoring in the RBM Model	Eehwa Pae	Bristol-Myers Squibb
11:50~12:10	Central Monitoring Using RBM Tool	Ji Hee Kwon	AstraZeneca
12:10~12:30	Experience Sharing from Korean Company	Jin A Jung	Hanmi Pharm.Co., Ltd.
12:30~13:00	Panel Discussion	All Speakers	-
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	Chair: Stewart Geary, Seong Choon Choe	
14:00~14:15	Introduction: Current Issue in Safety Management	Stewart Geary	Eisai Co., Ltd.
14:15~15:10	Global Regulatory Framework for Clinical Safety	Ann Strauss	Merck
15:10~16:00	End to End Process on Clinical Safety/Safety Science in Clinical Trial	Dorina Bischof	Novartis
16:00~16:30	Coffee Break		
16:30~17:30	Safety Management in Clinical Development	Chair: Mariette Boerstoele-Streefland, Sungho Beck	
16:30~17:00	Challenges on Implementation of Global Standards and Our Future; 1) From Global Perspectives	Mariette Boerstoele-Streefland	Alexion
17:00~17:30	Challenges on Implementation of Global Standards and Our Future; 2) From Local Perspectives	SungMin Yoon	Celltrion, Inc.
Workshop 4. Maximizing Success in Immuno-Oncology Drug Development			
14:00~15:30	Strategy for Success in Immuno-Oncology Drug Development	Chair: Jin Hyoung Kang, Myung Ju Ahn	
14:00~14:30	Lessons from Success and Failure in Immuno-Oncology Drug Development	Dae Ho Lee	Asan Medical Center
14:30~15:00	Ensuring Clinical Trial Design for Immuno-Oncology Drug	Sun Young Rha	Yonsei University Hospital
15:00~15:30	Characteristics of Immune-Related AE and Their Management in Clinical Trials	Ji-Youn Han	National Cancer Center
15:30~16:00	Coffee Break		
16:00~17:30	Evolving Science in Immuno-Oncology	Chair: Woong-Yang Park, Yeul-Hong Kim	
16:00~16:30	Progress in Immune Checkpoint Biomarkers Beyond PD-L1 Antibody Development	Eunkyung Kim	Bristol-Myers Squibb
16:30~17:00	Multiparametric Approach through NGS for Immune-Oncology Therapy	Woong-Yang Park	Samsung Medical Center
17:00~17:30	Prediction of Immune-Oncology Drug Resistance for The Next Step	Kyong Hwa Park	Korea University College of Medicine

DAY 1: September 18 (Wed)

Time	Program	Speaker	Affiliation
08:00~09:00	Registraion		
Room A, B, C [3F ~ 5F]			
09:00~09:10	Opening Remarks	Deborah Chee	KoNECT
09:10~09:20	Welcome Remarks 1	TBD	MOHW
09:20~09:30	Welcome Remarks 2	Eui Kyung Lee	MFDS
09:30~09:50	Plenary Lecture 1	Chair: Yil-Seob Lee TBD	MOHW
09:50~10:10	Plenary Lecture 2	Chair: Yung-Jue Bang Young-ok Kim	MFDS
10:10~10:30	Coffee Break		
10:30~12:00	S1: Regulatory Updates in Clinical Development	Chair: Kyung Won Seo, Jessica Liu	
10:30~10:50	Impact of NMPA Reform in China	Xiaoyuan Chen	Tsinghua University
10:50~11:10	Regulatory Updates in Japan	Junko Sato	PMDA
11:10~11:30	Recent Changes of IND Review System in Korea	Chang-Won Park	NIFDS
11:30~12:00	Regulatory Updates in USA	Jiao Song	J&J
12:00~13:30	Lunch		
Room A [3F]			
13:30~15:00	S2: Successful Outsourcing Strategy in Clinical Development	Chair: Sora Lee, Chanil Moon	
13:30~14:00	Optimum Outsourcing Strategies to Fit Your Unique Needs	Chanil Moon	Gemvax & KAEI
14:00~14:30	How to Select the Right CRO for Your Clinical Programs	BokJin Hyun	HANDOK Inc.
14:30~15:00	Building Healthy Partnership between Sponsor and CRO to Achieve Joint Goals	Graham Birrell	Syneos Health
15:00~15:30	Coffee Break		
Room B [3F]			
13:30~15:00	S3: Improving Evidence Generation Using RWD	Chair: Hyo Min Lee, Min Soo Park	
13:30~13:55	Use of RWE for Clinical Development Support	Leo Anthony Celi	Harvard Medical School
13:55~14:20	New Clinical Trial Execution Using RWD: Pragmatic Clinical Trials	Bruce Crawford	Syneos Health
14:20~14:45	Access, Analytics and Acceptance: Three Examples of Real-World Innovations in Drug Development	Hywel Evans	IQVIA
14:45~15:10	Use of RWE for Regulatory Decision	David Martin	FDA
15:10~15:30	Coffee Break		
Room C [5F]			
13:30~15:00	S4: Expanding the Horizon of Clinical Trial to Combination Products	Chair: Hea-Young Cho, Soo Kyung Shin	
13:30~14:00	Global Medtech Market Trend and Hot Topics; Clinical & Regulatory Perspectives	Tan Wilson	IQVIA
14:00~14:30	Clinical/Regulatory Considerations on Combination Products	Jeong-Ja Oh	Synex Consulting Ltd.
14:30~15:00	Regulatory Perspectives on Combination Products in Korea	Jusun Nam	MFDS
15:00~15:30	Coffee Break		
Room A [3F]			
15:30~17:00	S5: Smart Technology in Clinical Trials	Chair: Howard Lee, Byung-In Yoon	
15:30~16:00	Utility of New Technology in Clinical Trial (AI, Block Chain)	Ruthanna Davi	Medidata Solutions
16:00~16:30	Trend of Information & Communication Technology (ICT) in Clinical Trials	Kwang Joon Kim	Yonsei University College of Medicine
16:30~17:00	Improving Clinical Trial Efficiency using HIS (Hospital Information System)	Kyungwon Kim	Asan Medical Center
Room B [3F]			
15:30~17:00	S6: IIT: Now is the time to pivot	Chair: Young-suk Lim, Sin Gon Kim	
15:30~16:00	Contribution of IIT to Clinical Practice Change	Tae-Won Kim	Asan Medical Center
16:00~16:30	Infrastructure of IIT in Japan including Government Support	Akira Myoui	Osaka University Hospital
16:30~17:00	New Government Initiative on IIT in Korea	Jin Hyoung Kang	Korean Cancer Study Group
Room C [5F]			
15:30~17:00	S7: Interpretation of Non-Clinical Findings for Better Clinical Trials	Chair: Se-Woong Oh, Joonghoon Park	
15:30~16:00	Non-Clinical Development of Lasertinib for NSCLC	Se-Woong Oh	Yuhan Corporation
16:00~16:30	Non-Clinical Development of Universal CAR-T	Enrico Pesenti	Accelera srl
16:30~17:00	Oncolytic Virus Immunotherapy: Pexa-Vec and Its Place in the Immuno-Oncology Combination Regimens	Francis Hyukchan Kwon	SillaJen Inc.

DAY 2: September 19 (Thu)

Time	Program	Speaker	Affiliation
08:00~09:00	Registration		
Room A,B,C [3F ~ 5F]			
09:00~09:30	Plenary Lecture 3	Chair: Deborah Chee Andy Lee	MSD
09:30~10:00	Patient Voice	Chair: Jin Hyoung Kang Youngtae Park	Patient
10:00~10:30	Coffee Break		
10:30~12:00	S8: Improving Patient Experience and Quality by Patient Facing Technologies in Clinical Trials	Chair: Yoon-Duk Han, Andy Lee	
10:30~11:00	Digitizing a Patient-Focused Clinical Trial Experience	Denise Reyes	TransCelerate Biopharma Inc.
11:00~11:30	The Future of Informed Consent	Ji Won Yun	Roche Korea Co.,Ltd.
11:30~12:00	Current Landscape and Tools for eLabel	Hyun Ju Lee	Sanofi
12:00~13:30	Lunch		
Room A [3F]			
13:30~15:00	S9: Advancing Patient Protection in Clinical Trials	Chair: Seung Min Kim, Jong Woo Chung	
13:30~13:55	A System to Secure the Safety of the Patients	Woo Seong Huh	Samsung Medical Center
13:55~14:20	Clinical Trial Liability Insurance and Compensation; Guidelines and Issues	Dae Ho Lee	Asan Medical Center
14:20~14:45	Benefit of HRPP in Clinical Development- Global Perspective	Elyse Summers	AAHRPP
14:45~15:00	Recognition Survey on Clinical Trials in Korea	Ryungwoo Kang	KoNECT
15:00~15:30	Coffee Break		
Room B [3F]			
13:30~15:00	S10: Pioneering the Fundamental, Gene & Cell Therapy	Chair: Hun Che Cho, So Ra Park	
13:30~14:00	Cell Gene Therapy Industry and Clinical Development Trend	So Ra Park	Inha University School of Medicine
14:00~14:30	Advanced Cellular Therapeutics Landscape & Key Considerations for Human Trials	David Kim	Cure Therapeutics Inc.
14:30~15:00	Commercial Trends and Clinical Challenges of Gene Therapies	Bryan Choi	Inha University College of Medicine
15:00~15:30	Coffee Break		
Room C [5F]			
13:30~15:00	S11: Creating Value through Clinical Development	Chair: Hyou-Young Rhim, Sung Chun Kim	
13:30~14:00	Investor Perspectives: What Makes Your Product (Asset) Value Increased	Sung Chun Kim	KDDF
14:00~14:30	Key Questions to Ask Yourself Throughout Clinical Development Process for Product Success	Toral Shah	Syneos Health
14:30~15:00	Case Study: Challenges and Success	Seokuee Kim	CJ HealthCare Corp.
15:00~15:30	Coffee Break		
Room A [3F]			
15:30~17:00	S12: Early Engagement of Biomarker in Drug Development	Chair: In Jin Jang, Hyun Cheol Chung	
15:30~16:00	Pharmacodynamic biomarkers in early POC studies	Hyeong-Seok Lim	Asan Medical Center
16:00~16:30	Target the right target: Aligned discovery to development of drug and companion diagnostics	Soonmyung Paik	Yonsei University College of Medicine
16:30~17:00	Biomarkers in Immuno-Oncology Drug Development	Jonathan Juco	Merck
Room B [3F]			
15:30~17:00	S13: Quality Planning and Management in Protocol Execution	Chair: SungJa Cho, Jun Li	
15:30~16:00	Risk Management Planning (Sponsor Perspective)	Hyongyong Ji	Lilly
16:00~16:30	Quality Management at site (audit, inspection preparation)	Jungmi Baik	Seoul National University Hospital
16:30~17:00	Central Monitoring – how do we detect the risk and deal with it?	Yumi Sugiura	Bristol-Myers Squibb
Room C [5F]			
15:30~17:00	S14: Success to NDA through Optimal Study Design	Chair: Hanlim Moon, Yong H Rho	
15:30~16:30	Acceleration of drug development from First-Time-in-Human	Martin Roessner	Parexel International
16:00~16:30	New initiatives to accelerate drug development using master protocol	William Reece	Covance
16:30~17:00	Statistical strategy accelerating drug development	Tomomi Kaneko	Novartis

REGISTRATION

Online registration is now available on our official website (www.konectintconference.org).
Pre-registration will close for September 6th, so Don't miss out this opportunity.

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

Registration Organization	Registration
Government	KRW 150,000
Academia	KRW 250,000
Industry	KRW 350,000

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

Registration Organization	Registration
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-MOHV-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	<ul style="list-style-type: none"> • One Electric Socket (220v 2ways) • 1 Information Desk, 2 Chairs, Tablecloth 	

PROGRAM BOOK ADVERTISEMENT OPPORTUNITIES

Opportunities		KRW (₩)
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VENUE: Conrad Seoul

Address: 10 Gukjegeumyung-ro Yeouido
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