2018 KoNECT International Conference

"Embracing Change and Beyond in Clinical Development"

일시: 2018년 10월 31일(수) ~ 11월 2일(금)

장소: 여의도 콘래드 호텔

(재)한국임상시험산업본부(KoNECT)는 올해로 4회째를 맞이하는 아시아 최대 규모의 임상시험 국제회의인 2018 KoNECT International Conference 를 10월 31일(수) – 11월 2일(금), 보건복지부의 후원으로 여의도 콘래드 호텔에서 개최합니다. 특히, 올해는 "Embracing Change and Beyond in Clinical Development"의 주제로 임상시험 분야의 최신 트렌드를 공유하고, 임상시험과 신약개발의 새로운 도전과 비전 그리고 협력을 논의하는 자리로 만들고자 합니다.

한국을 대표하는 임상시험 컨퍼런스이자 전세계 16개국 800여명의 전문가들이 한자리에 모이는 협력의 장인 KoNECT International Conference 에 함께하여 자리를 빛내 주시기 바랍니다.

*WHY KIC? The Reasons to Attend KoNECT International Conference

1. **임상시험의 최신 이슈 및 글로벌 동향**

   KIC 국내외 관·산·학계 임상시험 전문가들을 연자로 모시고, 글로벌 최신 이슈를 다루는 매우 심도 있고 실용적인 논의의 장입니다. 특히, 빠르게 변화하는 임상시험 규제환경을 다루는 Recent Regulatory Updates 세션 등을 통해, 여러 국가의 규제현황 및 한국에서의 허가, 임상시험 전략에 대한 정보를 얻을 수 있습니다.

   - Recent **Regulatory Update** in Clinical Trials
   - **Real World Data** for Clinical Development
   - **Data Driven Approaches** in Drug Development?
   - Trends in **Gene & Cell Therapy**
   - Clinical Trials in **Rare Disease**

2. **임상개발에 바로 적용 가능한 실무적인 논의의 장**

   Clinical Operation Team 에게 실무에 바로 적용 가능한 실용적인 이슈 및 임상시험의 최신 지견을 숙지하여 **임상개발에 도움**을 줄 수 있습니다.

   - Are You Ready for Implementation of **RBM**?
   - New Approaches to **Pharmacovigilance** & Their Applications to Clinical Development?
   - Changing **Ethics** in Clinical Trials
   - Securing **Quality and Compliance** in Clinical Trials
   - **Adaptive design** of Clinical Trials in Oncology Drug Development

2018 KoNECT International Conference

"Embracing Change and Beyond in Clinical Development"

일시: 2018년 10월 31일(수) ~ 11월 2일(금)

장소: 여의도 콘래드 호텔

3. **임상개발에 필요한 최신 접근방법 및 정보의 접점**

   Medical Affairs 의 임상개발 트랜드와 지식 공유, **최신 접근방법** 뿐만 아니라 국내 연구자, 국내 임상시험 센터의 **임상 계획 등 최신 정보**를 접할 수 있습니다.

   - **Real World Data** for Clinical Development
   - **Data Driven Approaches** in Drug Development
   - Clinical Development Strategy for **Precision Medicine**
   - Building **Industrial Capabilities** in Early Phase Development
   - A Step Forward in **IIT**
   - Trends in **Gene & Cell** Therapy
   - Answering Clinical Questions Using Medical Big Data

4. **국내외 주요제약사, CRO, 바이오텍 및 유관사를 한 자리에서** 만나 볼 수 있으며, 특히, 국내 임상CRO Fair를 운영하는 이번 KIC 2018에서는 한국 주요 임상CRO들을 한자리에서 만나볼 수 있고, 네트워킹 할 수 있는 장이 마련되어 있습니다.

5. 미국FDA, 독일식품의약품안전청을 비롯한 해외 정부기관 및 글로벌 유관기관에서 참여하는 연자들을 통해 최신지견 습득 및 **글로벌 네트워크를 구축**할 수 있습니다.

6. 컨퍼런스 기간 중, **비즈니스 파트너링 미팅룸이 별도로 제공**되며 누구나 자유롭게 이용하실 수 있습니다. KIC 웹페이지에서 사전에 참석자를 검색하여 미팅을 요청할 수 있는 **시스템이 마련**되어 있어, 효율적이고 빠른 의사소통이 가능합니다.

7. 이 컨퍼런스는 **임상시험등 종사자 직능공통 심화, 보수교육**으로 인정되는 교육과정입니다.

2018 KoNECT International Conference 참가문의

등록 및 문의: info-kic@konect.or.kr , +82-70-4711-9999

공식웹사이트: www.konectintconference.org

참가비용

	Early Bird (~2018.9.7.)	Standard Registration (2018.9.7.~ On-stie)
Government	☐ KRW 150,000	☐ KRW 200,000
Academia	☐ KRW 250,000	☐ KRW 300,000
Industry	☐ KRW 350,000	☐ KRW 400,000

2018 PROGRAM AT A GLANCE

	October 31 (WED)				November 1(THU)				November 2 (FRI)			
	Grand Ballroom A	Grand Ballroom B	Park Ballroom	Lobby	Grand Ballroom A	Grand Ballroom B	Park Ballroom	Lobby	Grand Ballroom A	Grand Ballroom B	Park Ballroom	Lobby
08:00~09:00	Registration			EXHIBITION	Registration			EXHIBITION	Registration			EXHIBITION
09:00~09:30	Opening Ceremony				PL2				S15 How Smart Will Clinical Trials Centers Be? [KCGI]	S16 Securing Quality and Compliance in Clinical Trials	S17 Trends in Gene & Cell Therapy	
09:30~10:00	PL1				Patient Voice							
10:00~10:30	Coffee Break				Coffee Break				Coffee Break			
10:30~12:00	S1 Recent Regulatory Updates in Clinical Trials [MFDS]				S8 Data Driven Approaches in Drug Development				S18 Adaptive Design of Clinical Trials in Oncology Drug Development	S19 Answering Clinical Questions Using Medical Big Data [MIT]	S20 Clinical Trials in Rare Diseases	
12:00~13:30	Lunch				Lunch							
13:30~15:00	S2 Facing ICH-E17 in North East Asia [KRPIA]	S3 Are You Ready for Implementation of RBM? [KSCD]	S4 Non-Clinical Studies Enabling Successful Clinical Development [KSNS]		S9 Patient Centric Clinical Development	S10 Clinical Development Strategy for Precision Medicine	S11 Changing Ethics in Clinical Trials [KAIRB]					
15:00~15:30	Coffee Break				Coffee Break							
15:30~17:00	S5 Real World Data for Clinical Development	S6 Patient Journey in Clinical Trials - From Enrollment to Trial Completion	S7 New Approaches to Pharmacovigilance & Their Applications to Clinical Development?		S12 Building Industrial Capabilities in Early Phase Development [KSPM]	S13 Role of Clinical Trial Centers in Global Collaboration [KSCTC]	S14 A Step forward in IIT					

PROGRAM DETAILS

October 31(WED)

Time	Program	Speaker	Affiliation
08:30	**Registration**		
			Grand Ballroom A·B & Park Ballroom (3F, 5F)
09:00~09:05	**Opening Remarks**		
09:00~09:10			
09:10~09:15	**Introduction**		
09:20~09:25	**Congratulatory remark**		
09:30~10:00	**Plenary Lecture 1.**	**Chair : Yil-Seob Lee**	
		Ju Young Kim	MOHW
10:00~10:30	Coffee Break		
			Grand Ballroom A·B & Park Ballroom (3F, 5F)
10:30~12:00	**S1: Recent Regulatory Updates in Clinical Trials (MFDS session)**	**Chair : Na Kyung Kim, Hea-Young Cho**	
10:30~11:00	Clinical Trial Regulation Implementation in Germany	Claudia Riedel	BfArM
11:00~11:30	Regulatory Update for Clinical Trials in China	Ling Su	Shenyang University
11:30~12:00	Regulatory Update for Clinical Trials in Korea	Byung Sam Kim	MFDS
12:00~13:30	Lunch		
			Grand Ballroom A (3F)
13:30~15:00	**S2: Facing ICH-E17 in North East Asia (KRPIA session)**	**Chair : Don Woong Choi, Helen Cho**	
13:30~14:00	Experience on Exploratory Analysis/Designing a Clinical Trial Which Will be Applied to E17 Guideline, from Implementation Group Perspectives	Akira Wakana	MSD
14:00~14:30	Academic Perspective	In Jin Jang	Seoul National University
14:30~15:00	Industry Perspective	Hwei-Gene Wang	BMS
			Grand Ballroom B (3F)
13:30~15:00	**S3: Are You Ready for Implementation of RBM? (KSCD session)**	**Chair : TaeYoun Jo**	
13:30~14:00	What is RBM and How to Adopt It More Effectively?	Masato Kobayashi	TransCelerate
14:00~14:30	Key Role of Central Monitoring in RBM	Yumi Sugiura	BMS
14:30~15:00	What Other CRA Capability Should be Required in a New RBM Process?	Barbara Grassi	GSK
			Park Ballroom (5F)
13:30~15:00	**S4: Non-Clinical Studies Enabling Successful Clinical Development (KSNS session)**	**Chair : Joonghoon Park, Dong Hwan Kim**	
13:30~14:00	Translation of Non-Clinical Studies to Clinical Trials	Dong Hwan Kim	Konyang University
14:00~14:30	PKPD Considerations for New Drug Development	Hyun Joo Shim	Dong-A ST
14:30~15:00	Accelerating Clinical Development Using Cutting Edge Preclinical Technologies and E data Submission	Takayuki Anzai	Showa University School of Medicine
15:00~15:30	Coffee Break		
			Grand Ballroom A (3F)
15:30~17:00	**S5: Real World Data for Clinical Development**	**Chair : Rae Woong Park, Chang-Won Park**	
15:30~16:00	Effective Clinical Trial Planning Using Real World Data	Andrew Roddam	GSK
16:00~16:30	Utilization of RWD in Korea	Nam-Kyong Choi	Ewha Womans University
16:30~17:00	Enhancing Clinical Development through the Use of RWD	Bruce Crawford	Syneos Health
			Grand Ballroom B (3F)
15:30~17:00	**S6: Patient Journey in Clinical Trials - From Enrollment to Trial Completion**	**Chair : Hailey Chae, Catherine Yi-San. Lee**	
15:30~16:00	Clinical Research Access & Information Exchange Assets		TransCelerate
16:00~16:30	Patient-Centric, Patients-First Approach to Enrollment Feasibility	Gaurav Bhatnagar	PPD
16:30~17:00	Mobile and Digital Interaction with Patients	Catherine Yi-San. Lee	Pfizer
			Park Ballroom (5F)
15:30~17:00	**S7: New Approaches to Pharmacovigilance & Their Applications to Clinical Development?**	**Chair : Stewart Geary, Soo Yeon Jung**	
15:30~16:00	ICH E19 Guideline on Optimization of Safety Data Collection	Mary T. Thanh Hai	FDA
16:00~16:30	Pharmacovigilance for Oncology Combination Studies with Checkpoint Inhibitors	Stewart Geary	Esai
16:30~17:00	Process Improvements and Innovative Technology for Case Intake to Enable Better Data Analysis	Jamie Portnoff	Foresight

PROGRAM DETAILS

November 1(THU)

Time	Program	Speaker	Affiliation
08:30	**Registration**		
			Grand Ballroom A·B & Park Ballroom (3F, 5F)
09:00~09:40	**Plenary Lecture 2.**	**Chair : Deborah Chee**	
		Andreas Koester	J&J
09:40~10:00	**Patient Voice**	**Chair : SungJa Cho**	
		Won Young Jang	Korea Blood Cancer Association
10:00~10:30	Coffee Break		
			Grand Ballroom A·B & Park Ballroom (3F, 5F)
10:30~12:00	**S8: Data Driven Approaches in Drug Development**	**Chair : Soo Kyung Shin**	
10:30~11:00	Practical Application of New Solutions for Drugs' Development: From Strategic Development Decisions to Patient's Perspective	Kate Lawrey	IQVIA
11:00~11:30	Healthcare Big Data	Kyu-pyo Kim	Asan Medical Center
11:30~12:00	Block Chain Health Care in Clinical Development	Seyoung Jung	Seoul National University Bundang Hospital
12:00~13:30	Lunch		
			Grand Ballroom A (3F)
13:30~15:00	**S9: Patient Centric Clinical Development**	**Chair : Jessica Liu**	
13:30~14:00	Patient Centric Protocol Design		
14:00~14:30	Clinical Trial Quality Management System Set Up for Patient Centricity	Fuqu Wang	J&J
14:30~15:00	Tissue Chips for Personalized Medicine in Risk Assessment during Drug Life Cycle Management	Tagle Danilo	NIH
			Grand Ballroom B (3F)
13:30~15:00	**S10: Clinical Development Strategy for Precision Medicine**	**Chair : Young Suk Park, Hyerim Lee**	
13:30~14:00	Application of NGS in Clinical Trials, Clinical Research and Practice	Kyoung-Mee Kim	Samsung Medical Center
14:00~14:30	Innovative IO Strategy in the Era of Precision Medicine	Hyerim Lee	MSD
14:30~15:00	Refractory Cancer Basket Trials and Cancer Genomics	Hyo Song Kim	Yonsei Cancer Center
			Park Ballroom (5F)
13:30~15:00	**S11: Changing Ethics in Clinical Trials (KAIRB session)**	**Chair : Sun Young Rha**	
13:30~14:00	Understanding Common Rule	Jerry Menikoff	HHS
14:00~14:30	Opportunities and Challenges of Single IRB vs Central IRB	Yong-Jin Kim	Kyungpook National University
14:30~15:00	Proper Handling of COI	Dae Ho Lee	Asan Medical Center
15:00~15:30	Coffee Break		
			Grand Ballroom A (3F)
15:30~17:00	**S12: Building Industrial Capabilities in Early Phase Development (KSPM session)**	**Chair : SungJa Cho, Sam Muk**	
15:30~16:00	How to Start Phase I Study: Starting Dose in FIH, Minimum Anticipated Biological Effect Level (MABEL) for Selection of First Human Dose, Endpoint	Joseph Kim	PAREXEL
16:00~16:30	How to Design Clinical Trial with Considering Statistical Methodology	Byung-Ho Nam	Herings Global
16:30~17:00	How to Combine Companion Diagnosis and What Are Huddles?	Brian Lamon	BMS
			Grand Ballroom B (3F)
15:30~17:00	**S13: Role of Clinical Trial Centers in Global Collaboration (KSCTC session)**	**Chair : In Jin Jang, Yoon-Duk Han**	
15:30~16:00	Quility Improvement of a CTC by Certification Program	Min-Gul Kim	Chonbuk National University Hospital
16:00~16:30	Clinical Trial Center in Japan	Daisaku Nakatani	Medical Center for Translational and Clinical Research
16:30~17:00	Role of Korea Clinical Trial Centers	Min Soo Park	Yonsei University College of Medicine
			Park Ballroom (5F)
15:30~17:00	**S14: A Step Forward in IIT**	**Chair : Young-suk Lim**	
15:30~16:00	Opportunities and Challenges in Conducting IIT in Korea	Il Ju Choi	National Cancer Center
16:00~16:30	National Institute of Health Research (NIHR) Research and Infrastructure in the UK		
16:30~17:00	ARO Infrastructure for IIT in Japan	Masanori Fukushima	Translational Research Informatics Center, Japan

PROGRAM DETAILS

November 2(FRI)

Time	Program	Speaker	Affiliation
08:30	**Registration**		
			Grand Ballroom A (3F)
09:00~10:30	**S15: How Smart Will Clinical Trials Centers Be? (KCGI session)**	**Chair : Min Soo Park**	
09:00~09:30	Smart Clinical Trials Management System	Dong-Wan Kim	Seoul National University Hospital
09:30~10:00	Smart Clinical Development Support System	Min-Gul Kim	Chonbuk National University Hospital
10:00~10:30	AI-based Clinical Trial Resources Information System (ACTRIS)	Howard Lee	Seoul National University Hospital and College of Medicine
			Grand Ballroom B (3F)
09:00~10:30	**S16: Securing Quality and Compliance in Clinical Trials**	**Chair : Sora Lee, Helen Wong**	
09:00~09:30	ICH GCP (R2): Quality Management System & Risk Management	Helen Wong	MSD
09:30~10:00	How to Embed QMS (Quality Management System) into the Daily Work?	Hannah Chen	J&J
10:00~10:30	The Role of Quality Assurance in Multi-Center Trials	Choy Kiew Cheong	IQVIA
			Park Ballroom (5F)
09:00~10:30	**S17: Trends in Gene & Cell Therapy**	**Chair : Hun Che Cho, Dae Cheol Kim**	
09:00~09:25	Gene and Cell Therapy: How It Started, Where We Are, and What Is Next?	Young Jik Kwon	University of California
09:25~09:50	Global Trend & Case Study in Cell Therapeutics	Meehyun Jung	MEDIPOST
09:50~10:15	Global Trend & Case Study in Gene Therapeutics	Jae-Gyun Jeong	ViroMed Co., Ltd.
10:15~10:40	Understanding of Gene & Cell Therapy Regulations at a Practical Level	Kyungtak Nam	MFDS
10:40~11:00	Coffee Break		
			Grand Ballroom A (3F)
11:00~12:30	**S18: Adaptive Design of Clinical Trials in Oncology Drug Development**	**Chair : Jin Hyoung Kang, Eric Groves**	
11:00~11:30	Why Adaptive Clinical Trials in Oncology Drug Development?	Hanlim Moon	CUREnCARE Research
11:30~12:00	Benchmark and Ongoing Adaptive Trials in Oncology	Jee Hyun Kim	Seoul National University Bundang Hospital
12:00~12:30	Statistical Considerations in Adaptive Trials	Eric Groves	IQVIA
			Grand Ballroom B (3F)
11:00~12:30	**S19: Answering Clinical Questions Using Medical Big Data (MIT collaboration session)**	**Chair : Kenneth Paik, Hyung Jin Yoon**	
11:00~11:30	Application of Deep Learing in Solving Medical Challenges	T.B.D.	Massachusetts Institute of Technology
11:30~12:00	Usage of Medical Data for Care Improvement	Hyung Jin Yoon	Seoul National University
12:00~12:30	Scalable and Accurate Deep Learning with Electronic Health Records	T.B.D.	Massachusetts Institute of Technology
			Park Ballroom (5F)
11:00~12:30	**S20: Clinical Trials in Rare Diseases**	**Chair : Sin Gon Kim, Seong-Choon Choe**	
11:00~11:25	Partners' Platform to Activate Clinical Trials for Rare Diseases Using Nation-Wide Big Data	Kyong Hwa Park	Korea University College of Medicine
11:25~12:50	Rare Disease Research: Opportunities and Challenges	Tagle Danilo	NIH
12:50~12:15	The Rare Diseases and Pediatric Clinical Research Networks in Europe	Jacques Demotes	ECRIN
12:15~12:40	T.B.D.	Chang-Won Park	MFDS