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

2019 KoNECT-MOHW-MFDS International Conference 안내문

국가임상시험재단(KoNECT)은 올해로 5회째를 맞이하는 2019 KoNECT International Conference 를 **9월 18일(수) ~ 19일(목), [Pre-Workshop 17일(화)]** 보건복지부와 식품의약품안전처와의 공동주최로 여의도 콘래드 호텔에서 개최합니다. 특히, 올해는 **"Accelerating Clinical Development, Bringing Hope to Patients"**의 주제로 임상시험 최신 동향을 공유하고, 임상시험과 신약개발의 새로운 도전과 비전 그리고 협력을 논의하는 자리로 만들고자 합니다.

아시아의 대표적인 임상시험 국제행사이자 전세계 20개국 1,000여명의 전문가들이 한자리에 모이는 협력의 장인 KoNECT International Conference 에 함께하여 자리를 빛내 주시기 바랍니다.

*WHY KIC? The reasons to attend

1. **임상시험 규제 정보 및 동향 (Regulatory Updates)**

   빠르게 변화하는 임상시험 규제환경을 다루는 Regulatory Updates 등의 Workshop과 Session 을 통해, 한국, 일본, 중국을 포함한 여러 국가의 규제현황, IND, 임상시험 전략에 대한 정보를 얻을 수 있습니다. 특히, 올해는 다수의 식품의약품안전처(MFDS) 발표가 예정되어 있습니다.

   *토픽 별 Target Audience 첨부문서 참조

   - Workshop 1. Biologics CMC for IND [9월 17일]
   - Workshop 3. How to Manage Safety in Clinical Development; Lessons Learned [9월 17일]
   - Session 1. Impact of NMPA Reform in China [9월 18일]
   - Session 1. Regulatory Updates on Japan [9월 18일]
   - Session 1. Regulatory Updates on Korea [9월 18일]
   - Session 1. Regulatory Updates on US FDA or EMA [9월 18일]
   - Session 3. Use of Real World Evidence to Support Regulatory Decision Making [9월 18일]
   - Session 4. Challenges in Drug/Device Combination Products Trials (by MFDS) [9월 18일]
   - 이 외 다수세션

2. **임상개발 및 임상시험 Operation에 바로 적용 가능한 실무적인 논의의 장**

   실무에 바로 적용 가능한 실용적인 이슈 및 임상시험의 최신 지견을 숙지하여 임상개발 및 임상시험 Operation에 직접적인 도움을 줄 수 있습니다.

   - Workshop 2. Risk Based Quality Management [9월 17일]
   - Workshop 3. How to Manage Safety in Clinical Development; Lessons Learned [9월 17일]
   - Session 9. Advancing Patient Protection in Clinical Trials [9월 19일]
   - Session 13. Quality Planning and Management in Protocol Execution [9월 19일]
   - Session 14. Success to NDA through Optimal Study Design [9월 19일]
   - 이 외 다수세션

3. **제약사, 바이오텍을 위한 임상개발의 최신 정보 및 실제**
   신약개발의 각 단계별 접근뿐 아니라 전주기 임상시험의 글로벌 최신 정보를 접할 수 있습니다.
   - Session 7. Interpretation of Non- Clinical Finding for Better Clinical Trials [9월 18일]
   - Session 2. Successful Outsourcing Strategy in Clinical Development [9월 18일]
   - Workshop 4. Maximizing Success in Immuno-Oncology Drug Development [9월 17일]
   - Session 11. Creating Value through Clinical Development [9월 19일]
   - Session 10. Pioneering the fundamental, Gene & Cell Therapy [9월 19일]
   - Session 12. Early Engagement of Biomarker in Drug Development [9월 19일]
   - Session 14. Success to NDA through Optimal Study Design [9월 19일]
   - 이 외 다수세션

4. **성공적인 임상시험을 위한 비임상시험의 실제**
   - Session 7. Using Pre-Clinical Data to Inform Clinical Trials [9월 18일]
   - Session 7. Non-Clinical Development of Various Cases [9월 18일]

5. **국내외 주요제약사, CRO, 바이오텍 및 유관기업을 한 자리에서** 만나 볼 수 있으며, 특히, 국내 임상CRO Fair 를 통해 한국 주요 임상CRO들을 한자리에서 만나 각사의 서비스와 역량을 들을 수 있는 장이 마련되어 있습니다.

6. 미국 FDA, 일본 PMDA를 비롯한 해외 정부기관 및 글로벌 유관기관, 대학 등에서 참여하는 연자들을 통해 최신지견 습득 및 **글로벌 네트워크를 구축**할 수 있습니다.

7. 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. (웹사이트-Partnering 카테고리 참조)

8. 이 컨퍼런스는 식품의약품안전처에서 지정한 **임상시험등 종사자 직능공통 심화, 보수교육**으로 인정되는 교육과정입니다.

2019 KoNECT-MOHW-MFDS International Conference 참가문의
등록/전시 문의사항: info-kic@konect.or.kr
공식웹사이트: www.konectintconference.org

*별첨. 세부프로그램 현황 참조

*별첨. 세부프로그램 현황

Intensive Workshop

September 17th

Time	Program	Speaker	Affiliation	Target Audience
09:00~09:30	**Registration**			
Workshop 1: Biologics CMC for IND				
09:30~11:00	**Biologics CMC for IND**	**Chair : Hyi-Jeong Ji, HyangWon Min**		임상개발전문가, RA, Clin Op, Biologics 개발사 등
09:30~10:00	Special Lecture – Continuous Manufacturing for Bioproducts	Jungwon Yoon	Celltrion	
10:00~10:30	CMC Data Requirement of IMPD for Early 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	Jin A Kim	MFDS	
11:00~11:30	Coffee Break			
11:30~13:00	**Experience sharing with key CMC issues from Korea-IND**	**Chair : Yeo Wook Koh, Esther Bang**		
11:30~12:00	Major CMC Issues in Biosimilar Development	Sooyoung Lee	Celltrion	
12:00~12:30	Manufacturer's Experience with Early Phase Studies	Yu Jin Jung	Lilly	
12:30~13:00	CRO's Experience with MNC Global Development Studies	Kyunghwa Son	Mediheplline	
Workshop 2: Risk Based Quality Management				**Target Audience**
09:30~11:00	**Risk Management Planning**	**Chair : Carlo Maccarrone, Hye Jong Yoo**		임상개발전문가, 의학부, RA, Clinical Safety, Clin Op 및 CRC 등
09:30~10:00	Introduction of Risk Based Monitoring	Yoon-Duk Han	Pfizer	
10:00~10:30	RBM Methodology - identifying, assessing and mitigating Risk	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, Hye Won Song**		
11:30~11:50	on-site monitoring in the RBM model	Eahwa Pae	BMS	
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	
12:30~13:00	wrap up -			
Workshop 3 : How to Manage Safety in Clinical Development; Lessons Learned				**Target Audience**
14:00-16:00	**Regulatory updates in clinical development**	**Chair : Stewart Geary, Seong Choon Choe**		

14:00~15:00	Global regulatory framework for clinical safety	Ann Strauss	MSD	임상개발전문가, 의학부,RA, 신약개발사, MFDS reviewer, Clin Op 및 CRC 등
15:00~16:00	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 Streefland Sung-ho Beck**		
16:30-17:30	Challenges on implementation of global standards and our future; 1) From global perspectives	Mariette Boerstoel-Streefland	Alexion	
	2) From local perspectives	Sungmin Yoon	Celltrion	
Workshop 4 : Maximizing Success in Immuno-Oncology Drug Development				**Target Audience**
14:00~15:30	**Successful in Immuno-Oncology Drug Development**	**Chair: Jin Hyoung Kang, Myung Ju Ahn**		임상개발전문가, 항암제개발사, 의학부, 연구자, Clin Op 및 CRC 등
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	BMS	
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	

PROGRAM DETAILS

September 18th

Time	Program	Speaker	Affiliation	Target Audience
8:30	**Registration**			
			Room ABC	
09:00~09:10	**Opening Remarks**	Deborah Chee	KoNECT	

09:10~09:20	**Welcome Remarks 1**	T.B.D.	MOHW	
09:20~09:30	**Welcome Remarks 2**	Eui Kyung Lee	MFDS	
09:30~09:50	**Plenary Lecture 1.**	Chair : Yil-Seob Lee		
		T.B.D.	MOHW	
09:50~10:10	**Plenary Lecture 2.**	Chair : Yung-Jue Bang		
		Young-ok Kim	MFDS	
10:10~10:30	Coffee Break			
				Room AB
10:30~12:00	**S1: Regulatory Updates**	**Chair : Kyung Won Seo, Jessica Liu**		**Target Audience**
10:30~10:50	Impact of NMPA Reform in China	Xiaoyuan Chen	Tsinghua University	임상개발전문가, 제품개발전문가, 신약개발사, 연구자,RA, Clin Op 및 CRC 등
10:50~11:10	Regulatory Updates on Japan	Junko Sato	PMDA	
11:10~11:30	Regulatory Updates on Korea	Myung-Ah Chung	MFDS	
11:30~12:00	Regulatory Updates on US FDA	Jiao Song	J&J	
12:00~13:30	Lunch			
				Room A
13:30~15:00	**S2: Successful Outsourcing Strategy in Clinical Development**	**Chair : Sora Lee, KyoungHee Seo**		**Target Audience**
13:30~14:00	Key Considerations To Develop Optimum Outsourcing Strategies to Fit Your Unique Needs	KyoungHee Seo	Hanmi	임상개발전문가, 신약개발사, 연구자, Clin Op 등
14:00~14:30	How to select a right CRO for your company	Bokjin Hyun	Handok	
14:30~15:00	Building healthy partnership between sponsor and CRO to achieve joint goals	Graham Birrell	Syneos Health	
				Room B
13:30~15:00	**S3: Improving Evidence Generation Using RWD**	**Chair : Hyo Min Lee, Min Soo Park**		**Target Audience**
13:30~13:55	Use of RWE for Clinical Development Support	Leo Anthony Celi	Harvard Medical School	임상개발전문가, 의학부, 연구자, IRB 위원, Clin Op및 CRC등
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
13:30~15:00	**S4: Expanding the Horizon of Clinical Trial to Medical Devices**	**Chair : Hea-Young Cho, Soo Kyung Shin**		**Target Audience**

13:30~14:00	Global Medtech Market Trend and Hot Issues; Clinical & Regulatory perspectives	Tan Wilson	IQVIA	임상개발전문가, RA, Clin Op 등
14:00~14:30	Clinical/Regulatory Considerations on Combination Products	Jeong-Ja Oh	Synex	
14:30~15:00	Challenges in Drug/Device Combination Products Trials	Jusun Nam	MFDS	
				Room A
15:30~17:00	**S5: Smart Technology in Clinical Trials**	**Chair: Howard Lee, Byung-In Yoon**		**Target Audience**
15:30~16:00	Utility of New Technology in Clinical Trial (AI, Block Chain)	Ruthanna Davi	Medidata	연구자, IRB 위원, Clin Op및 CRC등,
16:00~16:30	Utility of Smart Technology in Clinical Studies	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
15:30~17:00	**S6: IIT: Now is the time to pivot**	**Chair : Young-suk Lim, Sin Gon Kim**		**Target Audience**
15:30~16:00	Contribution of IIT to Clinical Practice Change	Tae-Won Kim	Asan Medical Center	임상개발전문가, 신약개발사, IRB 위원, 연구자, Clin Op 등
16:00~16:30	Infrastructure of IIT in Japan including Government Support	Akira Myoui	Osaka University	
16:30~17:00	New Government Initiative on IIT in Korea	Jin Hyoung Kang	Korean Cancer Study Group	
				Room C
15:30~17:00	**S7: Interpretation of Non-Clinical Findings for Better Clinical Trials**	**Chair : Se-Woong Oh, Joonhoon Park**		**Target Audience**
15:30~16:00	Non-clinical development of Lasertinib for NSCLC	Se-Woong Oh	Yuhan	임상개발전문가, 신약개발사, 연구자, 의학부 등
16:00~16:30	Non-clinical development of universal CAR-T	Enrico Pesenti	Accelera	
16:30~17:00	Oncolytic Virus Immunotherapy: Pexa-Vec and Its Place in the Immuno-Oncology Combination Regimens	Hyukchan Kwon	SillaJen	

September 19th

Time	Program	Speaker	Affiliation	Target Audience
8:30	**Registration**			
				Room ABC
09:00~09:30	**Plenary Lecture 3.**	**Chair : Deborah Chee**		
		Andy Lee	**MSD**	
09:00~09:30	Coffee Break			
09:30~10:00	**Patient Voice**	**Chair: Jin Hyung Kang, (Youngtae Park)**		

				Room AB
10:30~12:00	**S8: Improving Patient Experience and Quality by Patient Facing Technologies in Clinical Trials**	**Chair : Andy Lee, Yoon-Duk Han**		**Target Audience**
10:30~11:00	Digitizing a Patient-Focused Clinical Trial Experience	Denise Reyes	TransCelerate	의학부,연구자, IRB 위원, RA, Clin Op 및 CRC 등
11:00~11:30	The Future of Informed Consent	Ji-Won Yun	Roche Korea	
11:30~12:00	Current Landscape and Tools for eLabel	Hyun Joo Lee	Sanofi	
12:00~13:30	Lunch			
				Room A
13:30~15:00	**S9: Advancing Patient Protection in Clinical Trials**	**Chair: Seung Min Kim, Jong Woo Jung**		**Target Audience**
13:30~13:55	A System to Secure the Safety of the Patients	Woo Seong Huh	Samsung Medical Center	연구자, IRB 위원, 의학부, Clin Op 및 CRC 등
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 Summer	AAHRPP	
14:45~15:00	Recognition Survey on Clinical Trials in Korea	Ryungwoo Kang	KoNECT	
				Room B
13:30~15:00	**S10: Pioneering the fundamental, Gene & Cell Therapy**	**Chair : Hun Che Cho, Sora Park**		**Target Audience**
13:30~14:00	Cell Gene Therapy Industry and Clinical Development Trend	Sora Park	Inha University	임상개발전문가, 신약개발사, 의학부, 연구자 등
14:00~14:30	Advanced Cellular Therapeutics Landscape & Key Considerations for Human Trials	David Kim	Cure Therapeutics	
14:30~15:00	Commercial Trends and Clinical Challenges of Gene Therapies	Bryan Choi	Inha University	
15:00~15:30	Coffee Break			
				Room C
13:30~15:00	**S11: Creating Value through Clinical Development**	**Chair : Hyo-Young Rhim, Sung Chun Kim**		**Target Audience**
13:30~14:00	Deal Makers(Investors)' perspectives: What makes your product(asset) value increased	Sung Chun Kim	KDDF	임상개발전문가, 신약개발사, 의학부, BD, 연구자 등
14:00~14:30	Key Questions to Ask Yourselves Throughout Clinical Development Process for Product Success	Toral Shah	Syneos Health	
14:30~15:00	Case Study : Challenges and Success – big local pharma, small bio-tech	Seokkuee Kim	CJ Healthcare	
				Room A
15:30~17:00	**S12: Early Engagement of Biomarker in Drug Development**	**Chair: In Jin Jang, Hyun Cheol Chung**		**Target Audience**
15:30~16:00	Pharmacodynamic Biomarkers in Early POC Studies	Hyeong-Seok Lim	Asan Medical Center	임상개발전문가, 신약개발사, 의학부, BD, 연구자 등
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				
15:30~17:00	**S13: Quality Planning and Management in Protocol Execution**	**Chair: SungJa Cho, Jun Li**		**Target Audience**
15:30~16:00	Risk Management Planning	Hyongyong Ji	Lilly	임상개발전문가, Clin Op 및 CRC, 연구자 등
16:00~16:30	Quality Management at site	Jungmi Baik	Seoul National University Hospital	
16:30~17:00	Central monitoring – how do we detect the risk and deal with it?	Yumi Sugiura	BMS	
Room C				
15:30~17:00	**S14: Success to NDA through Optimal Study Design**	**Chair : Hanlim Moon, Yong H Rho**		**Target Audience**
15:30~16:30	Acceleration of drug development from First-Time-in-Human	Roessner Martin	PAREXEL	임상개발전문가, 신약개발사, 연구자, 의학부, RA, Clin Op 및 CRC 등
16:00~16:30	New initiatives to accelerate drug development using master protocol	William HH Reece	Covance	
16:30~17:00	Statistical strategy accelerating drug development	Tomomi Kaneko	Novartis	

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