DIA

Korea Regulatory Science Center

2023 KRSC-DIA Workshop

Regulatory science for the development of innovative healthcare technologies after the COVID-19 pandemic

Dec.5.2023. 09:00-17:15/Auditorium in central post office, Seoul, Korea (서울 중앙 우체국 10 층 대강당)

Overview

Due to the COVID-19 pandemic, we around the world have experienced a period of chaos.
But we overcame the pandemic at a very rapid pace as much it feels like a long time ago.

For the past three years, we made the meaningful and remarkable results of technological development and innovations in the healthcare industry and also we learned how important to make it come quickly into our lives.

Regulatory science is an innovation technology in healthcare sector that contributes to humanity faster and safer works to propose regulatory standards based on scientific data and evidence.

Korea Regulatory Science Center and DIA organized this joint workshop with the title of " Regulatory science for the development of innovative healthcare technologies after the COVID-19 pandemic. We invited experts with extensive experience in domestic and foreign regulatory agencies, academia and industry, including the United States and Japan and other countries, to present the latest trends in regulatory science and healthcare innovations.

Sessions are as follows:

- **Session 1 :** Pathway for implementation of Regulatory Science and future perspective
- **Session 2 :** Regulatory environment of Real world evidence(RWE)/ Real World Data(RWD)
- **Session 3 :** Opportunities and Challenges for Decentralized Clinical Trials (DCTs) through the Lense of Regulatory Science
- **Session 4 :** Regulatory Science in the era of therapeutic transformation with cell & gene therapy.

Capacity of Attendees : 150 people

Program Committee

YilSeob Lee, MD, Ph.D.
Professor, CHA University

Insook Park, Ph.D.
Director General/KRSC

HaeSun Suh, Ph.D.
Professor, KyungHee University

SoHee Kim, Ph.D.
Division Director, MFDS

HeaYoung Cho, Ph.D.
Professor, CHA University

JoonWoo Bahn, MD. Ph.D.
Professor, Director, Asan Medical Center

JeeWon Joung, Ph.D.
Director, MFDS

JooYeon Han
Associate Director, AstraZeneca

HyangWon (Harriet) Min, MSc.
Vice President, Johnson & Johnson

SoJung Lee
VP, Regulatory Affairs, Samsung Biologics

Shogo Nakamori, MBA
SVP & MD, DIA Global

TaekYoung Kim, MBA
Country Manager, Korea

DIA

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DIAglobal.org

2023 KRSC-DIA Workshop:
Regulatory science for the development of innovative healthcare technologies after the COVID-19 pandemic

Agenda

Time	Topics	Chair / Speaker
8:30~9:00	Registration	
9:00~9:10	Opening Remarks	InSook Park, Diector General ,KRSC
9:10~9:20	Congratulation Remark	Shogo Nakamori, SVP & MD, DIA Global YounJoo Park, Director General, NIFDS YunHong Noh, Chairman, KPBMA
Session I	Pathway for implementation of Regulatory Science and future perspective	**Chair** InSook Park, Director General,KRSC SunHee Lee Prof. Ewha Womans University
Time	**Topics**	**Chair / Speaker**
9:20-9:45	Review and selection process of regulatory science research projects for joint work with industries(Draft)	HSA SINGAPORE or PMDA JAPAN (TBC)
9:45~10:10	How PMDA Communicate with Industries and Seeks new Solutions to New Technologies in the Used in Product Development	Mako Kawahara, Technical Officer, PMDA JAPAN
10:10~10:35	MFDS's Strategic Plan for Advancing Regulatory Science and Status	JinHwi Kim, Director, MFDS KOREA
10:35-11:00	Panel discussion	All Speakers & Akiko Ogata, Division Director, PMDA JAPAN
Session II	Regulartory environment of Real world evidence(RWE)/Real World Data(RWD)	**Chair** HaeSun Suh, Prof. Kyung Hee University SoHee Kim, Division Director, MFDS KOREA
Time	**Topics**	**Chair / Speaker**
11:00-11:25	Harmonizing Guidelines on the Use of Real World Data for Post-Approval Observational Safety Studies for Medicines: Background, Status and Future of ICH M14	David Moeny/Acting Deputy Director, USFDA
11:25-11:50	Hybrid Controls Design and Regulatory Landscape in EU, China and Japan	Luan, Jingyu, Senior Director, AstraZeneca
11:50~12:15	Use of Real World Data for regulatory decision-making in Korea	Bonggi Kim,Director, KIDS KOREA
12:15-12:30	Q & A	All
12:30-13:30	Lunch	
Session III	Opportunities and Challenges for Decentralized Clinical Trials (DCTs) through the Lense of Regulatory Science	**Chair** HeaYoung Cho,Prof. CHA University JoonWoo Bahn, Director, Asan Medical Center
Time	**Topic**	**Speaker**
13:30-13:55	Experience of DCTs and regulatory challenges encountered by investigators	KyungSang Yu, Prof. Seoul National University
13:55-14:20	De-centralised Clinical Trials	Greg Jordinson,Associate Director, Mphil, Johnson & Johnson
14:20-14:45	Regulatory Considerations for DCT in Korea	JeongYeon Kim, Director, MFDS KOREA
14:45-15:00	Q & A	All
15:00~15:30	Coffee Break	
Session IV	Regulatory Science in the era of therapeutic transformation with cell & gene therapy	**Chair** JeeWon Joung, Director, MFDS YeoWon Sohn, Prof.Sung Kyun Kwan University
Time	**Topics**	**Chair / Speaker**
15:30-15:55	Regulatory updates for advanced biological products	MiRa Choi, Director, MFDS KOREA
15:55-16:20	Innovation Through Collaboration: Challenges in CGT Development and How the Field Can Partner With Health Authorities to Bring Transformation Products to Patients	Dylan Bechtle,Associate Director, Johnson & Johnson
16:20-16:50	Clinical regulatory considerations and recent FDA perspectives on cell and gene therapy (CGT) development	Steve Winitsky, Vice President, Parexel International
16:50-17:05	Q & A	All
17:05~17:15	Closing	InSook Park, Diector General ,KRSC

REGISTRATION FORM: Register online or forward to DIA Japan, Nihonbashi Life Science Building 6F, 2-3-11 Nihonbashi-honcho, Chuo-ku, Tokyo 103-0023 Japan
tel +81-3-6214-0574

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Event #23380 • December 5, 2023 | Auditorium in central post office , Seoul, Korea (서울 중앙 우체국 10 층 대강당)

REGISTRATION

Register online at the link below or complete this registration from and email to our Japan Office

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MEMBER	Academic	Early Bird (until Nov. 14, 2023)	❑ 130,000
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		After Nov. 15, 2023	❑ 180,000
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		After Nov. 15, 2023	❑ 230,000
	Government	Early Bird (until Nov. 14, 2023)	❑ 180,000
		After Nov. 15, 2023	❑ 230,000
	Industry	Early Bird (until Nov. 14, 2023)	❑ 250,000
		After Nov. 15, 2023	❑ 300,000

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Last Name

First Name

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Address (As required for postal delivery to your location)

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email **Required for confirmation**

Phone Number **Required**

CONTACT INFORMATION

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PAYMENT DETAILS

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Member or Nonmember = 100,000 KRW
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(Member or Nonmember) = 50,000 KRW
Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid.

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