As of September 15, 2017

PMDA-ATC Multi-Regional Clinical Trials (MRCT) Seminar 2018

Offered by Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

DATE: January 15-18, 2018. VENUE: PMDA Meeting Room #21-25 on 14th floor

DAY 1 (January 15, 2018)

10:00	Opening
10:15	Message from PMDA
10:20	Key Note Speech Strategies and Challenges for Drug Development - Future Movements and Backgrounds of Development Strategies -
10:45	Break
11:00	History of drug evaluation using overseas data (Mononational Trials in Japan → Bridging Study → Global Study)
11:45	Scientific insights about ethnic factors
12:30	Lunch
14:00	<Session 1> Introduction of review systems and regulations by participants
16:00	Break
16:15	<Session 2> International cooperation and alignment ● Road to a Global Platform for Medical Innovation -Opportunity and Challenge as Academic Research Organization- ● Challenge for Global Cooperation of Regulatory Agencies
18:00	End of day 1
18:15	Friendly get together

DAY 2 (January 16, 2018)

9:00	<Session 3> Points to consider when planning and designing MRCT ● Points to Consider When Planning and Designing MRCT (when consulting about clinical trials) (Regulator's view point) ● Introduction -Case Study-
10:30	Break
10:45	<Session 3> Case study (group discussion)
12:45	Lunch
14:15	<Session 4> Points to consider when evaluating results ● Points to Consider in Evaluation of MRCT Results ● PMDA's Experiences to Review MRCT Results
15:45	Break
16:00	<Session 4> Case study (group discussion)
18:00	End of day 2

DAY 3 (January 17, 2018)

9:00	<Session 5> Considerations for MRCT operations ● Practical Issues and Solutions on MRCT Operations (Investigator's viewpoint) ● Practical Issues and Solutions on MRCT Operations (Industry's viewpoint)
10:30	Break
10:45	<Session 5> Case study (group discussion)
12:15	Lunch
13:15	Clinical Site Tour
17:45	End of day 3

DAY 4 (January 18, 2018)

9:00	<Session 6> GCP Inspection of Global Study ● How to Perform GCP Inspection for MRCT ● Point to Consider of GCP Inspection for MRCT (Sponsor's perspectives) ● Experiences of GCP Inspection at Academic Trial Site -How We Prepare for MRCT Studies-
10:30	Break
10:45	<Session 6> Case study (group discussion)
12:45	Lunch
14:00	<Session 7> Post-market safety evaluation of approved drugs based on MRCT ● Pharmacovigilance in Japan ● Global and Local Risk Management Planning in Pharmaceutical Companies Based on the Multi Regional Clinical Development ● Company Perspective on Managing Urgent Safety Issues Internationally
15:30	Break
15:45	<Session 7> Case study (group discussion)
17:15	Wrap-up, Closing ceremony