PMDA-ATC Multi-Regional Clinical Trial (MRCT) Seminar 2019

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

DATE: January 21-24, 2019. VENUE: PMDA Meeting Room #21-25 on 14th floor

DAY 1 (January 21, 2019)

10:00 (20min)	Opening ceremony Photo session
10:20 (25min)	Key Note Speech Strategies and challenges for drug development - Future movements and backgrounds of development strategies –
10:45 (45min)	History of drug evaluation using overseas data in Japan Q&A (11:15 - 11:30)
11:30	Break
11:45 (45min)	Scientific insights about ethnic factors Q&A (12:15 - 12:30)
12:30	Lunch
14:00 (150min)	<Session 1> Introduction of review systems and regulations by participants
16:30	Break
16:45 (60min)	<Session 2> International cooperation and alignment ● Global Platform for Medical Innovation as an Academic Research Organization (ARO) ● Challenge for global cooperation of regulatory agencies Q&A (17:45 - 18:00)
18:00	End of day 1
18:15	Friendly get together

DAY 2 (January 22, 2019)

9:00 (90min)	<Session 3> Points to consider when planning and designing MRCT ● Points of attention for consultation about MRCT from PMDA's experience ● Case study -Planning and designing MRCT- Q&A (10:15 - 10:30)
10:30	Break
10:45 (120min)	<Session 3> Case study (Group discussion) Wrap up (12:35 - 12:45)
12:45	Lunch
14:15 (90min)	<Session 4> Points to consider when evaluating results ● Statistical considerations for MRCT based on the ICH E17 guideline ● PMDA's experiences to review MRCT results Q&A (15:30 – 15:45)

15:45	Break
16:00 (120min)	<Session 4> Case study (Group discussion) Wrap up (17:50 - 18:00)
18:00	End of day 2

DAY 3 (January 23, 2019)

9:00 (90min)	<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) Q&A (10:15 - 10:30)
10:30	Break
10:45 (90min)	<Session 5> Case study (Group discussion) Wrap up (12:05 - 12:15)
12:15	Lunch
13:00 (300min)	Clinical site tour
17:30	End of day 3

DAY 4 (January 24, 2019)

9:00 (90min)	<Session 6> Regulatory review based on results of GCP inspection ● How to Perform GCP Inspection in Japan -Role of GCP inspection in review process- ● How to take GCP inspection results into consideration for review from reviewer's perspective ● Applicant's experiences to undergo GCP inspection ● Trial site's experiences to undergo GCP inspection Q&A (10:15 - 10:30)
10:30	Break
10:45 (120min)	<Session 6> Case study (Group discussion) Wrap up (12:35 - 12:45)
12:45	Lunch
14:00 (90min)	<Session 7> Post-market safety evaluation of approved drugs based on MRCT ● Global Standards for Pharmacovigilance ● Risk management plan based on the multi-regional clinical development -From perspectives of pharmaceutical companies- ● Risk management based on the multi-regional clinical development - From perspectives of regulatory agencies - Q&A (15:15 – 15:30)

15:30	Break
15:45 (90min)	<Session 7> Case study (Group discussion) Wrap up (17:05 - 17:15)
17:15	Closing ceremony
17:45	End of day 4