PMDA-ATC MRCT Seminar 2020

Date: 20-23 January, 2020　　Venue: Meeting room 21-24@ PMDA 14F

26 September, 2019

	DAY 1 20 Januray (Mon)	**DAY 2** 21 January (Tues)	**DAY 3** 22 January (Wed)	**DAY 4** 23 January (Thu)
AM-1	09:30-10:00 Registration 10:00-10:20 Opening ceremony 10:20-11:05 1_Histry of drug evaluation using overseas data in Japan (incl. Q&A 15 min)	08:55-09:00 Opening/ Agenda for the Day 09:00-10:30 **<Session 3>** **Points to consider when planning & designing MRCT** 6_Points of attention for consultation about MRCT from PMDA's experience 7_Case study -Planning and designing MRCT (Q&A 15 min)	08:55-09:00 Opening/ Agenda for the Day 09:00-10:30 **<Session 5>** **Consideration for MRCT operation** 12_Practical issues and solutions on MRCT operations (investigator's view point) 13_Practical issues and solutions on MRCT operations (industry's viewpoint) (Q&A 15 min)	08:55-09:00 Opening/ Agenda for the Day 09:00-10:30 **<Session 6>** **Regulatory review based on results of GCP inspection** 16_How to perform GCP inspection -Role of GCP inspection in review process 17_How to consider GCP inspection results from reviewer's perspective 18_Applicant's experiences to undergo GCP inspection (incl. Q&A 10 min. each)
Break	11:05-11:20	10:30-10:45	10:30-10:45	10:30-10:45
AM-2	11:20-12:05 2_Scientific insights about ethnic factors (incl. Q&A 15 min.)	10:45-12:45 8_Case study (Group Discussion) (Wrap up 10 min)	10:45-12:15 14_Case study (Group Discussion) (Wrap up 10 min)	10:45-12:00 19_Case study (Group Discussion)
Lunch	12:05-13:30	12:45-14:15	12:15-13:00	12:00-13:30
PM-1	13:30-16:00 **<Session 1>** 3_Introduciton of review systems and regulations by participants	14:15-15:45 **<Session 4>** **Points to consider when evaluating results** 9_Statistical consideration for MRCT based on the ICH E17 G/L 10_PMDA's experiences to review MRCT results (Q&A 15min)	13:15-14:00 move to site 14:00-17:30 15_**Clinical site tour**	13:30-14:20 19_Case study (Group Discussion) -continued- (Wrap up 10 min)
Break	16:00-16:15	15:45-16:00		14:20-14:35
PM-2	16:15-17:25 **<Session 2> International cooperation and alignment** 4_Global Platform for Medical Innovation as an Academic Research Organization 5_Challenges for global cooperation of regulatory agencies (Q&A 15min)	16:00-18:00 11_ Case study (Group Discussion) (Wrap up 10 min)		14:35-16:05 **<Session 7>** **Post market safety evaluation of approved drugs based on MRCT** 20_Global standard for Pharmacovigilance 21_Risk management plan based on MRCT -industry perspective 22_Risk management based on MRCT -Regulatory Agency Perspective (Q&A 15min)
	17:25 end of the day	18:00 end of the day	17:30 end of the day	16:20-16:50 Closing ceremony
	17:40 Get together			