

1. Pre-Live Self-learning

Jan.11-15	E-learning contents 1	#3.1. Review Team (7min) #3.3. Review Process (5min) #3.4 Achievement (6min) #6.1. The PMDA International Strategic Plan (8min) #6.2. International Activities (10min)	E-learning contents 2	#1. History of Drug Evaluation using Foreign Clinical Data in Japan (9min) #2. Example of Bridging Strategy (4min) #3. Why MRCT? (5min) #4. Overview of ICH E17 (8min)
	Recorded Lectures			
	Session 1	1.1 Global Platform for Medical Innovation as an Academic Research Organization (ARO)		30 min
	Session 2	2.1 Scientific insights about ethnic factors		30 min
	Session 3	3.1 How to conduct GCP Inspection in Japan -Role of GCP inspection in review process		20 min
		3.2 How to consider GCP Inspection results from reviewer's perspective		20 min
		3.3 Applicant's experiences to undergo GCP inspection		20 min
	Session 4	4.1. Points to consider when planning & designing MRCT -Points for consultation from PMDA's experience		20 min
		4.2. Points to consider when planning & designing MRCT -Case study introduction		20 min
	Session 5	5.1. Points to consider when evaluating results -Statistical consideration based on ICH E17 G/L		20 min
5.2. Points to consider when evaluating results -PMDA's Experiences to Review MRCT Results		20 min		
Session 6	6.1. Consideration for MRCT operation - Issues and Solutions on MRCT Operations (Investigator's view point)		30 min	
	6.2. Consideration for MRCT operation - Issues and Solutions on MRCT Operations (Industry's view point)		30 min	
ICH E17	ICH Training materials (pre-read)			
Jan.15	Mini test / Questionnaire Due: 9:00 a.m. JST (UTC+9)			

2. Live Sessions

Time (JST)	Day 1 (Jan 18)	Day 2 (Jan 19)	Day 3 (Jan 20)	Day 4 (Jan 21)
13:00	13:00 - 13:20 Opening Session			
	13:20 - 13:40 Q&A for Session 1			
	13:40 - 14:00 Q&A for Session 2			
14:00	14:00 - 14:20 Q&A for Session 3	Session 4 Case Study 14:00 - 14:20 - Overview of the session 14:20 - 15:20 - Group Discussion 15:20 -15:50 - Group Presentation 15:50- 16:00 - Q&A and Wrap up	Session 5 Case Study 14:00 - 14:10 - Overview of the session 14:10 - 15:10 - Group Discussion 15:10 -15:40 - Group Presentation 15:40- 16:00 - Q&A and Wrap up	Session 6 Case Study 14:00 - 14:15 - Overview of the session 14:15 - 15:15 - Group Discussion 15:15 -15:40 - Group Presentation 15:40- 16:00 - Q&A and Wrap up
	14:20 -14:40 Break			
	14:40 - 15:00 Q&A for Session 4			
15:00	15:00 - 15:20 Q&A for Session 5			
	15:20 - 15:40 Q&A for Session 6			
16:00	16:00 - 16:20 Ice Breaking Session for Day 2-4 Group work	Evaluation Form (Day 2) Due	Evaluation Form (Day 3) Due	16:00-16:15 Closing Remarks
17:00	Evaluation Form (Day 1) Due			Evaluation Form (Day 4 & overall) Due