

PMDA-ATC Multi-Regional Clinical Trial (MRCT) Seminar 2017

Date: January 23-26, 2017.

Venue: Meeting Rooms 21-23 (14th floor) at PMDA Office in Tokyo

Program overview and time schedule (draft as of November 18, 2016)

Day 1

9:00	Opening remarks
9:20	Key Note Speech Regulation renovation based on regulatory science
9:50	Message from CEO Expectation for regulatory authorities in globalization era
10:00	Key Note Speech Strategies and challenges for drug development : Future movements and backgrounds of development strategies
10:30	Break
11:00	History of Drug Evaluation using overseas data : (Mononational trials in Japan→Bridging study →Global study)
11:30	Scientific insights about ethnic factors
12:00	Lunch
13:30	Session 1: Points to consider when planning and designing MRCT (when consulting about clinical trials)
15:00	Break
15:30	Session 1: Case study
17:30	Friendly get together
19:00	Closing

Day 2

9:00	Session 2: Challenges to conducting MRCT
10:30	Break
11:00	Session 2: Case study
12:30	Lunch
14:00	Session 3: Points to consider when evaluating results (Evaluation of all groups in efficacy and safety and consistency evaluation)
15:30	Break
16:00	Session 3: Case study
18:00	Closing

Day 3

9:00	Session 4: International cooperation and alignment
10:15	Break
10:30	Session 4: Panel discussion
11:30	Lunch
13:00	Session 5: GCP Inspection of global study
14:30	Break
15:00	Session 5: Case study
17:00	PMDA tour
17:30	Closing

Day 4

9:00	Session 6: Post-market safety evaluation of approved drugs based on MRCT
10:20	Break
10:45	Session 6: Case study
12:15	Overall discussion, Closing ceremony
13:00	Closing