# 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)

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| 10:00 | Opening |
| 10:15<br>(5min) | Message from PMDA |
| 10:20<br>(25min) | Key Note Speech<br>Strategies and challenges for drug development<br>- Future movements and backgrounds of development strategies - |
| 10:45 | Break |
| 11:00<br>(45min) | History of drug evaluation using overseas data in Japan |
| 11:45<br>(45min) | Scientific insights about ethnic factors |
| 12:30 | Lunch |
| 14:00<br>(120min) | <Session 1><br>Introduction of review systems and regulations by participants |
| 16:00 | Break |
| 16:15<br>(105min) | <Session 2><br>International cooperation and alignment<br>● Global Platform for Medical Innovation as an Academic Research Organization (ARO)<br>● Challenge for global cooperation of regulatory agencies |
| 18:00 | End of day 1 |
| 18:15 | Friendly get together |

DAY 2 (January 16, 2018)

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| 9:00<br>(90min) | <Session 3><br>Points to consider when planning and designing MRCT<br>● Points of attention for consultation about MRCT from PMDA's experience<br>● Case study -Planning and designing MRCT- |
| 10:30 | Break |
| 10:45<br>(120min) | <Session 3> Case study (Group discussion) |
| 12:45 | Lunch |
| 14:15<br>(90min) | <Session 4><br>Points to consider when evaluating results<br>● Statistical considerations for MRCT based on the ICH E17 guideline<br>● PMDA's experiences to review MRCT results |
| 15:45 | Break |
| 16:00<br>(120min) | <Session 4> Case study (Group discussion) |
| 18:00 | End of day 2 |

DAY 3 (January 17, 2018)

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| 9:00<br>(90min) | <Session 5><br>Considerations for MRCT operations<br>● Practical issues and solutions on MRCT operations (Investigator's viewpoint)<br>● Practical issues and solutions on MRCT operations (Industry's viewpoint) |
| 10:30 | Break |
| 10:45<br>(90min) | <Session 5> Case study (Group discussion) |
| 12:15 | Lunch |
| 13:00<br>(270min) | Clinical site tour<br>National Center for Global Health and Medicine (NCGM) |
| 17:20 | End of day 3 |

DAY 4 (January 18, 2018)

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| 9:00<br>(90min) | <Session 6><br>GCP inspection of global study<br>● Addendum to ICH-E6 & oversea GCP inspection by PMDA<br>-How to Perform GCP Inspection for MRCT-<br>● Point to consider of GCP inspection for MRCT from sponsor perspective<br>● Experiences of GCP inspection at academic trial site<br>-How we prepare for investigator-initiated study- |
| 10:30 | Break |
| 10:45<br>(120min) | <Session 6> Case study (Group discussion) |
| 12:45 | Lunch |
| 14:00<br>(90min) | <Session 7><br>Post-market safety evaluation of approved drugs based on MRCT<br>● Pharmacovigilance in Japan<br>● Global and local risk management planning in pharmaceutical companies based on the multi regional clinical development<br>● Company perspective on managing urgent safety issues internationally |
| 15:30 | Break |
| 15:45<br>(90min) | <Session 7> Case study (Group discussion) |
| 17:15 | Wrap-up,<br>Closing ceremony |
| 17:45 | End of day 4 |