PMDA-ATC & U.S. FDA Pediatric Review Seminar 2018

Date: June 11-14, 2018　　Venue: Meeting room 2-5 @ PMDA

	DAY 1 June 11 (Mon)	DAY 2 June 12 (Tues)	DAY 3 June 13 (Wed)	DAY 4 June 14 (Thu)
AM-1		Optional 8:45-9:15 Individual Agency Meetings with PMDA and U.S.FDA	Optional 8:45-9:15 Individual Agency Meetings with PMDA and U.S.FDA	Optional 8:45-9:15 Individual Agency Meetings with PMDA and U.S.FDA
	9:30-10:00 Registration	9:30-9:40 Opening/ Agenda for the Day	9:30-9:40 Opening/ Agenda for the Day	9:30-9:40 Opening/ Agenda for the Day
	10:00-10:30 Opening Remarks/ Agenda Review	9:40-10:45 Physiology and clinical pharmacology in pediatric population	9:40-10:45 U.S.FDA - Pediatric extrapolation	9:40-10:45 Discussion of ICH E11 Guidelines
Break	10:30-10:45	10:45-11:00	10:45-11:00	10:45-11:00
AM-2	10:45-11:45 PMDA Introduction and Updates in Pediatrics	11:00-12:00 PMDA - The use of existing knowledge in pediatric drug development	11:00-12:00 U.S.FDA - Ethical consideration in pediatric clinical trials	11:00-12:00 Final Remarks/ Survey/ Q&A
Lunch	11:45-13:00	12:00-13:00	12:00-13:00	12:00-13:00
PM-1	13:00-14:00 U.S.FDA Introduction and U.S. Pediatric Regulation	13:00-15:00 PMDA Case-Study Practical Applications with the discussion of Case Studies, roundtable discussions (breakout groups)	13:00-15:00 U.S.FDA Case-Study Practical Applications with the discussion of Case Studies, roundtable discussions (breakout groups)	Optional 13:00-15:00 Individual Agency Meetings with PMDA and U.S.FDA (4, 30 minutes each)
	14:00-15:00 Roundtable of each country to present current or developing pediatric programs (10 min presentation, 5 min Q&A -Total 15 mins each)			
Break	15:00-15:15	15:00-15:15	15:00-15:15	15:00-15:15
PM-2	15:15-18:00 Roundtable of each country to present current or developing pediatric programs (10 min presentation, 5 min Q&A -Total 15 mins each)	15:15-17:00 PMDA Case-Study Practical Applications with the discussion of Case Studies, roundtable discussions (cont)	15:15-17:00 U.S.FDA Case-Study Practical Applications with the discussion of Case Studies, roundtable discussions (cont)	Optional 15:15-16:45 Individual Agency Meetings with PMDA and U.S.FDA (3, 30 minutes each)
	18:00-18:15 Wrap up	17:00-17:15 Wrap up	17:00-17:15 Wrap up	
	18:15 Get together	Optional 17:30-18:00 Individual Agency Meetings with PMDA and U.S.FDA *(depends on the number of participating international agencies)*	Optional 17:30-18:00 Individual Agency Meetings with PMDA and U.S.FDA	