

## PMDA-ATC & U.S. FDA Pediatric Review Seminar 2019

Date: July 8-11, 2019      Venue: Meeting room 2-5 @ PMDA 6F

	DAY 1 July 8 (Mon)	DAY 2 July 9 (Tues)	DAY 3 July 10 (Wed)	DAY 4 July 11 (Thu)
<b>AM-1</b>	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 5_Physiology and clinical pharmacology in pediatric population	9:40-10:45 8_U.S.FDA - Pediatric extrapolation	9:40-10:45 12_Discussion of ICH E11 Guidelines
<b>Break</b>	10:30-10:45	10:45-11:00	10:45-11:00	10:45-11:00
<b>AM-2</b>	10:45-11:45 1_PMDA Introduction and Updates in Pediatrics	11:00-12:00 6_PMDA - The use of existing knowledge in pediatric drug development	11:00-12:00 9_U.S.FDA - Ethical consideration in pediatric clinical trials	11:00-12:00 13_Final Remarks/ Survey/ Q&A
<b>Lunch</b>	11:45-13:00	12:00-13:00	12:00-13:00	12:00-13:00
<b>PM-1</b>	13:00-14:00 2_U.S.FDA Introduction and U.S. Pediatric Regulation	13:00-15:00 7_PMDA Case-Study Practical Applications with the discussion of Case Studies, roundtable discussions (breakout groups)	13:00-15:00 10_U.S.FDA Case-Study Practical Applications with the discussion of Case Studies, roundtable discussions (breakout groups)	<u>Optional</u> 13:00-15:00 (Slot 1-4) 14_Individual Agency Meetings with PMDA and U.S.FDA (30 minutes each)
	14:00-15:00 3_Roundtable of each country to present current or developing pediatric programs (10 min presentation, 5 min Q&A -Total 15 mins each)			
<b>Break</b>	15:00-15:15	15:00-15:15	15:00-15:15	15:00-15:15
<b>PM-2</b>	15:15-18:00 4_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 7_PMDA Case-Study Practical Applications with the discussion of Case Studies, roundtable discussions (cont)	15:15-17:00 11_U.S.FDA Case-Study Practical Applications with the discussion of Case Studies, roundtable discussions (cont)	<u>Optional</u> 15:15-17:00 (Slot 5-8) 14_Individual Agency Meetings with PMDA and U.S.FDA (cont)
	18:00-18:15 Wrap up	17:00-17:15 Wrap up	17:00-17:15 Wrap up	
	18:15 Get together			