

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

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

As 25 April, 2019

	DAY 1 8 July(Mon)	DAY 2 9 July (Tues)	DAY 3 10 July (Wed)	DAY 4 11 July (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 4_Physiology and clinical pharmacology in pediatric population	9:40-10:45 7_U.S.FDA - Modeling/Simulation	9:40-10:45 11_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 5_PMDA - The use of existing knowledge in pediatric drug development	11:00-12:00 8_U.S.FDA - Ethical consideration in pediatric clinical trials	11:00-12:00 12_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 6_ <u>PMDA Case-Study</u> Practical Applications with the discussion of Case Studies, roundtable discussions (breakout groups)	13:00-14:00 9_US.FDA - Pediatric extrapolation and Components of iPSP	<u>Optional</u> 13:00-15:00 13_Individual Agency Meetings with PMDA and U.S.FDA (4, 30 minutes each)
	14:00-15:00 3_Roundtable of each country to present current or developing pediatric programs		14:10-15:15 10_ <u>U.S.FDA Case-Study</u> Practical Applications with the discussion of Case Studies, roundtable discussions (breakgorup groups)	
<b>Break</b>	15:00-15:15	15:00-15:15	15:15-15:30	15:00-15:15
<b>PM-2</b>	15:15-18:00 3_Roundtable of each country to present current or developing pediatric programs	15:15-17:00 6_ <u>PMDA Case-Study</u> Practical Applications with the discussion of Case Studies, roundtable discussions (cont)	15:30-17:00 10_ <u>U.S.FDA Case-Study</u> Practical Applications with the discussion of Case Studies, roundtable discussions (cont)	<u>Optional</u> 15:15-16:45 13_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			