

PMDA-ATC & U.S.FDA Pediatric Review Seminar 2024

Draft agenda

(JST) **Date: July 22 - 25 2024** **Venue: PMDA office, Tokyo, Japan** As of June 18, 2024

Day 1 Monday, July 22	Day 2 Tuesday, July 23	Day 3 Wednesday, July 24	Day 4 Thursday, July 25
9:30-10:00 Registration	9:30-10:00 Registration	9:30-10:00 Registration	9:30-10:00 Registration
10:00-10:20 Opening Ceremony	10:00-11:00 Session 5 (PMDA) The use of existing knowledge in pediatric drug development	10:00-11:00 Session 8 (PMDA) Practical considerations for using existing knowledge in pediatric review: From PMDA experience	10:00-14:00 Session 11 (FDA) Case study 3 Pediatric Clinical Pharmacology - Lecture Pediatric Pharmacokinetics/Pharmacodynamics - Group Work Modeling/Simulation
10:20-11:00 Session 1 (PMDA) Introduction for Pediatric Drug Development	11:00-12:00 Session 6 (FDA) Pediatric Extrapolation	11:00-12:00 Session 9 (FDA) Ethical consideration in pediatric clinical trials	
11:00-12:20 Session 2 (FDA & PMDA) - U.S. FDA New Drug Regulation and Pediatrics - PMDA Pediatric Regulation in Japan			
12:20-13:50 Lunch break (90m)	12:00-13:30 Lunch break (90m)	12:00-13:30 Lunch break (90m)	11:40-13:00 Lunch break (80m)
13:50-15:20 Session 3 (Participants) Round Table Discussion - Introduction of Pediatric Regulations by participants	13:30-16:20 Session 7 (PMDA) Case study 1 / Group work Practical Applications - Introduction - Group Discussion	13:30-16:20 Session 10 (FDA) Case study 2 / Group work Ethical Analysis - Introduction (20 m.) - Group Discussion (90 m.)	(Session 11 cont.) - Group presentation - Q&A, Wrap up
Break (10m)	Break (10m)	Break (10m)	13:50-14:20
15:30-16:10 Session 4 (EMA) EU Paediatric Regulation	- Group presentation - Q&A, Wrap up	- Group presentation - Q&A, Wrap up	Session 12 Wrap-up (PMDA, FDA) Q&A for all session Break (10m)
16:10-16:20 Evaluation for Day 1	16:20-16:30 Evaluation for Day 2	16:20-16:30 Evaluation for Day 3	14:30-14:40 Closing Ceremony
16:40-18:00 Get together		16:30-17:30 <u>Optional</u> G to G meeting (@30 m.) • country A • country B	14:40-14:50 Evaluation for Day 4 & Overall 15:00-16:00 <u>Optional</u> G to G meeting (@30 m.) • country C • country D