

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

## Draft agenda

(JST)

Date: July 22 - 25 2024

Venue: PMDA office, Tokyo, Japan

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