

PMDA-ATC Pediatric Review Seminar 2025

Draft agenda
Date: June 9-12 2025
Venue: Tokyo (PMDA office)

(JST)

As of February 4, 2025

Day 1 Monday, June 9	Day 2 Tuesday, June 10	Day 3 Wednesday, June 11	Day 4 Thursday, June 12
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 Pediatric Extrapolation including ICH E11A	10:00-10:45 Session 8 Pediatric Pharmacokinetics/Pharmacodynamics	<Day 4 Advanced Session > 10:00-10:45 Session 11 Practical considerations for using existing knowledge in pediatric review
10:20-11:00 Session 1 Introduction for Pediatric Drug Development		Break (10 m.)	10:45-12:10
11:00-12:20 Session 2 - New Drug Regulation and Pediatrics - Pediatric Regulation	11:00-12:00 Session 6 Case study 1 / Group work Practical Applications - Introduction - Group Discussion	10:55-12:00 Session 9 Ethical consideration in pediatric clinical trials	Session 12 Case study 3 Pediatric Clinical Pharmacology - Lecture Modeling/Simulation - Group Discussion
12:20-13:30 Lunch break (70m.)	12:00-13:20 Lunch break (80m.)	12:00-13:20 Lunch break (80m.)	12:10-13:20 Lunch break (70m.)
13:30-14:50 Session 3 (Participants) Round Table Discussion - Introduction of Pediatric Regulations by participants	13:20-14:10 - Group Discussion (cont.) Break (10m.) 14:20-15:10 - Group presentation - Q&A, Wrap up	13:20-16:10 Session 10 Case study 2 / Group work Ethical Analysis - Introduction - Group Discussion	13:20-14:30 (Session 12 cont.) - Group Discussion - Group presentation - Q&A, Wrap up
Break (10m.)	Break (10m.)	Break (10m.)	Break (10m.)
15:00-16:00 Session 4 ICH E11 and the use of existing knowledge in pediatric drug	15:20-16:00 Session 7 EU Paediatric Regulation	- Group presentation - Q&A, Wrap up	14:40-14:55 Closing Ceremony
16:00-16:15 Feedback on Day 1	16:00-16:10 Feedback on Day 2	16:10-16:20 Feedback on Day 3	14:55-15:10 Feedback on Day 4 and Overall
16:45-18:00 Get together	16:30-17:30 Optional G to G meeting (@30 m.) ▪ country A ▪ country B	16:30-17:30 Optional G to G meeting (@30 m.) ▪ country C ▪ country D	