

PMDA-ATC Pediatric Review Seminar 2026

Agenda

Dates: 23 - 25 June 2026 Venue: Tokyo (PMDA office)

(JST)

as of 19 Feb 2026

Day 1 Tuesday, 23 June	Day 2 Wednesday, 24 June	Day 3 Thursday, 25 June
9:30-10:00 Registration	9:00-9:30 Registration	9:00-9:30 Registration
10:00-10:20 Opening Ceremony	9:30-10:30 Session 4 ICH E11 and the use of existing knowledge in pediatric drug development	9:30-10:40 Session 8 Pediatric Clinical Pharmacology PK/PD, Modeling/Simulation
10:20-11:00 Session 1 Introduction for Pediatric Drug Development	10:30-11:30 Session 5 Pediatric Extrapolation	Break 10:50-12:50 Session 9 Case study 2 / Group work Ethical Analysis - Introduction - Group Discussion
11:00-12:20 Session 2 - Pediatric Regulations in Japan - New Drug Regulations and Pediatrics in the USA	Break 11:40-12:10 Session 6 Case study / Group work Practical Applications - Introduction	Lunch break 14:00-14:50 Session 9 (cont'd) - Group presentations - Q&A, Wrap up
Lunch break	Lunch break	Break
13:30-15:30 Session 3 Round Table Discussion - Introduction of Pediatric Regulations by participants	13:20-15:40 Session 6 (cont'd) - Group Discussion - Group presentations - Q&A, Wrap up	15:00-15:45 Session 10 Practical considerations for using existing knowledge in pediatric review: PMDA experience
Break	Break	Break
15:40-16:00 Case study guidance	15:50-16:30 Session 7 EU Paediatric Regulations	16:00-16:15 Closing Ceremony
16:00-16:15 Feedback - Day 1	16:30-16:40 Feedback - Day 2	16:15-16:30 Feedback - Day 3, Seminar Overall
16:45-18:00 Friendly get-together		