

**Agenda**

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

(JST)

as of 25 Mar 2026

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