

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

Draft agenda
Date: July 22 - 25 2024

Venue: PMDA office, Tokyo, Japan

As of March 11, 2024

(JST)

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 (FDA)	10:00-11:00 Session 8 (FDA)	10:00-14:20 Session 11 (FDA) Case study 3 / Group Work Modeling/Simulation - Introduction (20min) - Group Discussion (80min)
10:20-11:00 Session 1 (PMDA) Introduction for Pediatric Drug Development	Pediatric PharmacoKinetics / Pharmacodynamics	Pediatric Extrapolation	
11:00-12:20 Session 2 (FDA & PMDA) - U.S. FDA New Drug Regulation and Pediatrics - PMDA Pediatric Regulation in Japan	11:00-12:00 Session 6 (PMDA) The use of existing knowledge in pediatric drug development	11:00-12:00 Session 9 (FDA) Ethical consideration in pediatric clinical trials	
12:20-13:50 Lunch break	12:00-13:30 Lunch break	12:00-13:30 Lunch break	11:40-13:10 Lunch break
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 (20min) - Group Discussion (90min)	13:30-16:20 Session 10 (FDA) Case study 2 / Group work Ethical Analysis - Introduction (20min) - Group Discussion (90min)	(Session 11 cont.) - Group presentation (30min) - Q&A, Wrap up (20min)
Break (10m)	Break (10m)	Break (10m)	14:00-14:40 Session 12 Wrap-up (PMDA, FDA) Q&A for all session
15:30-16:10 Session 4 (EMA) EU Paediatric Regulation	- Group presentation (30min) - Q&A, Wrap up (20min)	- Group presentation (30mn) - Q&A, Wrap up (20min)	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	14:50-15:00 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	16:30-17:30 <u>Optional</u> G to G meeting (@30 m.) • country C • country D	15:00-15:10 Evaluation for Day 4 & Overall
			15:10-16:10 <u>Optional</u> G to G meeting (@30 m.) • country E • country F