

PMDA-ATC & U.S.FDA Pediatric Review Seminar 2023

As of March 23, 2023

JST	Day 1 Monday, July 10	Day 2 Tuesday, July 11	Day 3 Wednesday, July 12	Day 4 Thursday, July 13
10:00-11:00	10:00-10:15 <u>Opening Remarks</u> 10:15-11:00 (Lecture 30m .+ Q&A 15 m.) <u>Session 1</u> (PMDA) PMDA Introduction for Pediatric Drug Development	10:00-11:00 (Lecture 40m. + Q&A 15 m.) <u>Session 5</u> (FDA) Pediatric Pharmacokinetics / Pharmacodynamics	10:00-11:00 (Lecture 45m .+ Q&A 15 m.) <u>Session 8</u> (FDA) Ethical consideration in pediatric clinical trials	10:00-11:00 <u>Session 11</u> (FDA) Case study 3 / Round Table Discussion Modeling/Simulation - Introduction (15 m.) - Interactive Discussion (45 m.)
11:00-12:00	11:00-12:00 (Lecture 45m. + Q&A 15 m.) <u>Session 2</u> (FDA) U.S. FDA Introduction and Pediatric regulation	11:00-12:00 (Lecture 45m. + Q&A 15 m.) <u>Session 6</u> (PMDA) The use of existing knowledge in pediatric drug development	11:00-12:00 (Lecture 45m .+ Q&A 15 m.) <u>Session 9</u> (FDA) Pediatric Extrapolation	11:00-11:45 <u>Session 12</u> Wrap-up (PMDA, FDA) Q&A for all session 11:45-12:00 Closing Remarks
12:00-13:30	Lunch break (90m)	Lunch break (90m)	Lunch break (90m)	12:00-12:10 Evaluation for Day 4 & Overall Lunch break (60m)
13:30	13:30-14:50 (@Presen. 7m .+ Q&A 3m.) <u>Session 3</u> (Participants) Round Table Discussion "Developing Pediatric Program of each country"	13:30-16:20 <u>Session 7</u> (PMDA) Case study 1 / Group work Practical Applications - Introduction (20 m.) - Group Discussion (90 m.)	13:30-16:20 <u>Session 10</u> (FDA) Case study 2 / Group work Ethical Analysis - Introduction (20 m.) - Group Discussion (90 m.)	13:10-14:10 <u>Optional</u> G to G meeting (@30 m.) · country E · country F
15:00	Break (15m) 15:05-16:05 (Lecture 45m. + Q&A 15 m.) <u>Session 4</u> (EMA) EU Paediatric Regulation 16:05-16:15 Evaluation for Day 1	Break (10m) - Group presentation (30m.) - Q&A, Wrap up (20m.) 16:20-16:30 Evaluation for Day 2	Break (10m) - Group presentation (30m.) - Q&A, Wrap up (20m.) 16:20-16:30 Evaluation for Day 3	
16:30	16:15-17:15 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	