PMDA-ATC & U.S.FDA
Pediatric Review Webinar 2022

as of September 6, 2022

1. Pre-learning（PMDA-ATC portal site）

Date (TBD)	Content	Title		Duration
8/10 (Wed) | 9/12 (Mon)	Content 1	PMDA Overview (Review Team, Application Dossier, Review Process)	ATC E-learning	9 min
	Content 2	FDA Overview	FDA	13 min
	Content 3	Introduction for Pediatric Drug Development	PMDA	12 min
	Content 4	Regulations in the U.S.	FDA	27 min
	Session 1	The use of existing knowledge in pediatric drug development	PMDA	19 min
	Session 2	Pediatric PharmacoKinetics / PharmacoDynamics	FDA	32 min
	Session 3	Pediatric Extrapolation	FDA	24 min
	Session 5	Ethical consideration in pediatric clinical trials	FDA	20 min
—	Session 4	Case Study 1 (PMDA) : Practical Applications - introduction ＜Pre-read*＞	PMDA	19 min
	Session 6	Case Study 2 (FDA) : Modeling/Simulation and Ethical Analysis ＜Pre-read*＞	FDA	30 min

* Preparatory learnings on materials (ppt, pdf, etc) of Day 2 and Day 3

2. Preliminary session（Webex Meeting）

Date	Session	Title	Duration
Sep.5 (Mon) 18:30-	preliminary	ice-breaking (internet access checking and team building)	60 min

3. Live Sessions (Webex Meeting)

JST (EDT)	Day 1 Monday, Sep. 12	Day 2 Tuesday, Sep. 13	Day 3 (National holiday:JPN) Wednesday Sep. 14	Day 4 Thursday, Sep. 15
Day 1 & 2 18:30- (5:30-)	18:30-18:45 Opening Remarks (Video letter from FDA)	18:30-21:10 (160 m.) Session 4 (PMDA) Case study 1 / Group work Practical Applications - Introduction (20 m.) - Group Discussion (80 m.) - Group presentation (30m.) - Q&A, Wrap up (30m.)		
Day 3 & 4 19:30- (6:30-)	18:45-19:15 (Lecture 10 m.+ Q&A 20 m.) Session 1 (PMDA) The use of existing knowledge in pediatric drug development		19:30- 20:20 (50 m.) Session 6 (FDA) Case study 2-1 Modeling/Simulation Modeling/Simulation - Introduction (10 m.) - Interactive Discussion (40 m.)	19:30-20:10 (Lecture 25 m.+ Q&A 15 m.) Session 7 (EMA) EU Paediatric Regulation
	Break (10 m.)	*Break (10 m.)*	*Break (10 m.)*	*Break (10 m.)*
	19:25-20:05 (Lecture 10 m.+ Q&A 30 m.) Session 2 (FDA) Pediatric PharmacoKinetics / PharmacoDynamics	21:20-22:00 (Lecture 10 m.+ Q&A 30 m.) Session 5 (FDA) Ethical consideration in pediatric clinical trials	20:30-21:20 (110 m.) continued Session 6 (FDA) Case study 2-2 / Group work Ethical analysis - Introduction (10 m.) - Group Discussion (40 m.) 21:20-22:20 - Group presentation (30m.) - Q&A, Wrap up (30m.)	20:20-21:20 (60 m.) Wrap-up (PMDA, FDA, EMA) Q&A for all session
	20:05-20:45 (Lecture 10 m.+ Q&A 30m.) Session 3 (FDA) Pediatric Extrapolation	22:00-22:10 Wrap-up/Q&A and Evaluation for Day 2	22:20-22:30 Wrap-up/Q&A and Evaluation for Day 3	21:20-21:30 Closing Remarks
	20:45-20:55 Wrap-up/Q&A and Evaluation for Day 1			21:30-21:40 Evaluation for Day 4 & Overall