

1. Pre-Live Self-learning

Date	Type	Session	Title		Duration	
Sep. 21 -25	E-learning	Session 1	PMDA	PMDA Overview (from PMDA-ATC e-learning contents)	40 min	
	Pre-recorded Lectures	Session 2	FDA	FDA Overview	30 min	
		Session 3	PMDA	Introduction for Pediatric Drug Development		30 min
		Session 4	FDA	Pediatric PK/PD		30 min
		Session 5	FDA	Pediatric Extrapolation		30 min
		Session 6	PMDA	The use of existing knowledge in pediatric drug development		30 min
		Session 7	FDA	Ethical consideration in pediatric clinical trials		30 min
		Session 8	PMDA	Case Study 1: Practical Applications - introduction		30 min
		Session 9	FDA	Case Study 2: Practical Applications - introduction		30 min
Sep.25	Mini-test/ Evaluation Form/ Questionnaire (Session 3-7) Due (9:00 JST)					

2. Live Sessions (Webex Training Center)

JST (EDT)	Day 1 Monday, Sept. 28	Day 2 Tuesday, Sept. 29	Day 3 Wednesday, Sept. 30	Day 4 Thursday, Oct. 1
20:00 - (07:00 -)	20:00 - 20:20 Opening Remarks (PMDA, FDA) Photo session	Session 8 Case Study (PMDA) 20:00 - 20:20 - Overview of the session 20:20 - 21:20 - Group Discussion 21:20 - 21:40 - Group Presentation 21:40- 22:00 - Q&A and Wrap up	Session 9 Case Study (FDA) 20:00 - 20:20 - Overview of the session 20:20 - 21:20 - Group Discussion 21:20 - 21:40 - Group Presentation 21:40- 22:00 - Q&A and Wrap up	Closing Session 20:00 - 21:00 Overall Q&A and Wrap-up (PMDA, FDA) Closing Remarks (PMDA, FDA)
	20:20 - 20:40 Q&A for Session 3 (PMDA)			
	20:40 - 21:00 Q&A for Session 4 (FDA)			
21:00 - (08:00 -)	21:00 - 21:20 Q&A for Session 5 (FDA)			
	21:20 - 21:40 Q&A for Session 6 (PMDA)			
	21:40 - 22:00 Q&A for Session 7 (FDA)			
22:00 - (09:00 -)	22:00 - 22:20 Ice Breaking Session for Day 2-3 Case Study			