PMDA-ATC & U.S.FDA

Pediatric Review Webinar 2021

1. Pre-learning（Platon）

Date	Content	Title	Duration
8/17 (Tue) | 9/16 (Thu)	Content 1-1	PMDA Overview (Review Team, Application Dossier, Review Process)	9 min
	Content 1-2	FDA Overview	40 min
	Content 1-3	Introduction for Pediatric Drug Development	15 min
	Content 1-4	Pediatric Extrapolation	24 min
9/7-16	Content 2-1	Case Study 1: Practical Applications - introduction ＜Pre-read*1＞	30 min
	Content 2-2	Case Study 2: Practical Applications - introduction ＜Pre-read*1＞	30 min

*1. Preparatory learnings on materials (ppt, pdf, etc) of Day 2 (Sep 22) and Day 3 (Sep 23).

2. Preliminary session（Webex Meeting）

Date	Session	Title	Duration
9/14 (Tue) 20:00-	preliminary	ice-breaking (internet access testing and self introduction)	60 min

3. Live Sessions (Webex Meeting)

JST (EDT)	Day 1 Tuesday, Sept. 21 Lecture (Live)	Day 2 Wednesday, Sept. 22 Case Study (PMDA)	Day 3 (National holiday:JPN) Thursday, Sept. 23 Case Study (FDA)	Day 4 Friday, Sept. 24 Q&A、Wrap up
20:00- (7:00-)	20:00-20:15 Opening Remarks	20:00-22:30 Session 4 (PMDA) Case study 1 / Group work Practical Applications - introduction - Overview of the text - Group Discussion - Group presentation - Q&A -Wrap up	20:00-22:30 Session 5 (FDA) Case study 2 / Group work Ethical Analysis of a Protocol - Overview of the text - Group Discussion - Group presentation - Q&A -Wrap up	20:00-21:00 (Lecture 25m.+Q&A15 m.) Session 6 (EMA) International collaboration between stakeholders for promoting paediatric drug development
	20:15-20:55 (Lecture 25m.+Q&A15 m.) Session 1 (PMDA) The use of existing knowledge in pediatric drug development			
	20:55-21:35 (Lecture 25m.+Q&A 15 m.) Session 2 (FDA) Pediatric PharmacoKinetics / PharmacoDynamics			21:00-22:00 Wrap-up (PMDA, FDA, EMA) Q&A for all session incl. pre-learning contents
	21:35-22:15 (Lecture 25m.+Q&A 15 m.) Session 3 (FDA) Ethical consideration in pediatric clinical trials			22:00-22:15 Closing Remarks

2021. 9.21.