PMDA-ATC PV Webinar 2022

1. Preliminary session (Webex Meeting)

Time (JST)	Session	Title	Duration
Tuesday Jan. 25	Preliminary	14:00-15:00 General Guidance -Participants self-introduction -General information -Connectivity check -Breakout sessio trial	60 min

2. Live Sessions (Webex Meeting)

Time (JST)	Day 1 Monday, Jan. 31	(Reserve) Tuesday, Feb. 1	Day 2 Wednesday, Feb. 2	Day 3 Thursday, Feb. 3	Day 4 Friday, Feb. 4
11:00			11:00-11:30 (Lecture 20m.+Q&A 10m.) **Special Session** Recent Pharmacovigilance Activities in the US		
14:00	14:00-14:10 **Opening Remarks**	No live session	14:00-16:10 **Group Work 1** ; RMP (Safety Specifications) - How to Create RMP – Identification of Safety Specifications - Brief Introduction (10min) - Group Discussion (60min) - Group Presentation (30min) - Q&A / Wrap up (30min)	14:00-16:10 **Group Work 2** ; RMP (Risk Minimization Activity) - How to Create RMP – Planning Risk Minimization Activity - Brief Introduction (10min) - Group Discussion (60min) - Group Presentation (30min) - Q&A / Wrap up (30min)	14:00-14:50 **Session 4** (Lecture 30m.+Q&A 20m.) Pharmacoepidemiology
	14:10-15:00 **Session 1** (Lecture 30m.+Q&A 20m.) Evaluation of Benefit/Risk Balance throughout Product Lifecycle, Assessment of Effectiveness of Risk Minimization Activities				14:50-16:20 **Session 5** (Case study) Pharmacovigilance Methods - Brief Introduction (10min) - Group Discussion (50min) - Q&A / Wrap up (30min)
	15:00-15:50 **Session 2** (Lecture 30m.+Q&A 20m.) End-to-End Labeling process: CCDS/CCSI Labeling System, Electronic Labeling Initiatives				16:20-16:30 **Closing Remarks**
	15:50 - 16:10 **Session 3** (Lecture 10m.+Q&A 10m.) Group Work Introduction - Hypothetical Drug Case				
	Evaluation Form (Day 1) Due		Evaluation Form (Day 2) Due	Evaluation Form (Day 3) Due	Evaluation Form (Day 4) Due