



PMDA-ATC PV Webinar 2023

As of 2022.11.17

1. Preliminary session (Webex Meeting)

Time (JST)	Session	Title			Duration
Monday Jan. 30	Preliminary	14:00-15:00 General Guidance	-Participants self-introduction -Connectivity check	-General information -Breakout session trial	60 min

2. Live Sessions (Webex Meeting)

Time (JST)	Day 1 Monday, Feb. 6	Day 2 Tuesday, Feb. 7	Day 3 Wednesday, Feb. 8	Day 4 Thursday, Feb. 9
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	14:00-16:10 Group Work 1 Risk Management Plan (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 Causality Assessment of ICSR and Planning Risk Minimization Activity - Brief Introduction (10min) - Group Discussion (60min) - Group Presentation (30min) - Q&A / Wrap up (30min)	14:00-14:40 Session 4 (Lecture 30m.+Q&A 10m.) 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			14:40-16:10 Session 5 (Case study) Pharmacovigilance Methods - Brief Introduction (10min) - Group Discussion (50min) - Q&A / Wrap up (30min) - Introduction of MID-NET activities
	15:00-15:50 Session 2 (Lecture 30m.+Q&A 20m.) End-to-End Labeling process: Safety labeling system & electronic and patient centric labeling			16:10-16:20 Break
	15:50-16:00 Break			16:20-17:10 Session 6 Utilizing Real-World Data - Real-World Data and Real-World Evidence (Lecture 15m.) - Quality Assurance of Real-World Data for NDA Applications (Lecture 15m.) - Q&A (20m)
	16:00 - 16:50 Session 3 Pharmacovigilance of COVID-19 vaccines -Regulator perspective (Lecture 15m) -Industry perspective (Lecture 15m) - Q&A (20min)			
	Evaluation Form (Day 1) Due			Evaluation Form (Day 2) Due
16:50-17:20 (optional) Free Study Room for Group Work 1	16:10-16:40 (optional) Free Study Room for Group Work 2	16:10-16:40 (optional) Free Study Room for Group Work	Evaluation Form (Day 4) Due	