

PMDA-ATC Pharmaceuticals Review Webinar 2020 for NPRA, Malaysia

Date: November 6th, 2020

Agenda

MYT	JST	Sessions
9:00-9:10	10:00-10:10	Opening Ceremony
9:10-10:00	10:10-11:00	1. Regulatory Framework for First-in-Human (FIH) Trial From PMDA (20 min.) From NPRA (20 min.) Q&A: (10 min.)
10:00-10:30	11:00-11:30	2. Review of FIH Studies (PMDA)
10:30-11:00	11:30-12:00	3. Sharing Experiences on FIH Clinical Trials (Academia)
11:00-11:50	12:00-12:50	4. Sharing Experiences on Good Clinical Practice (GCP) Inspections From PMDA (20 min.) From NPRA (20 min.) Q&A (10 min.)
11:50-12:00	12:50-13:00	Closing Ceremony