

APACRM Working-Level Meeting Agenda

Date and Time; 12-Oct-2018, 12:00 - 14:00 (JST) (with lunch box)

Duration; 2 hours

Location; PACIFICO Yokohama Conference Center, 4th Floor, 417 room

Participants; Industry group members from China, Korea, Taiwan, India, Japan

Agenda:

- ◆ Introduction
- ◆ Update from APACRM for harmonization
 - ✓ Information sharing from each country
- ◆ Discussion/Information share
 - ✓ Non-clinical studies
 - Necessary/non-necessary studies
 - ✓ Acceptability's of foreign countries' data
 - ✓ How to utilize expedited approval system efficiently
 - Conditional approval system in Japan
 - Sakigake designation