Plenary II
Intra-Regional Efforts to Streamline the Conduct of Clinical Trials: The Tripartite Initiative and the ASEAN Pharmaceutical Product Working Group (PPWG)

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Harmonization in Drug Regulation

Process of integrating national standards with international standards to be universally acceptable to participating countries to facilitate efficient global drug development and local registration

- Technical and science requirements
- Format and content of dossiers
- Assessment and review practices
Session Objectives

• This session will focus on the clinical concerns leading to the Tripartite Agreement entered into by the Ministers of Health for Korea, Japan and China and the resulting work plan to resolve some of these concerns

• This session will also provide an update on the ASEAN Pharmaceutical Product Working Group and its efforts to harmonize compliance requirements in the conduct of clinical trials within the ASEAN region
Speakers

• Haruo Akagawa-PMDA, Japan
  – Perspective for Global Clinical Trials
• Sarah (Kyung Won) Seo-KFDA, Korea
  – Current Regulatory Situation of Korea
• Jian-hua Ding-SFDA, China
  – Tri-Party Clinical Initiatives and Its Prospective
• Yuppadee Javroongrit-TFDA, Thailand
  – The ASEAN Pharmaceutical Product Working Group