Part III.

Summary of Round Table Discussion
Summary of Round Table Discussion: Gaps and Challenges for Implementation, and Suggestion for Future Cooperation

A round table discussion at the close of the “Advanced Workshop: Review of Drug Development in Clinical Trials” provided an opportunity for open comments or suggestions from all facilitators and participants to identify gaps and challenges for implementation, and suggestion for future cooperation.

The comments from facilitators and participants are listed below

Gaps and Challenges for Implementation
- Lacks of human resources
- Adopted and implemented the same ICH Good Clinical Practice Guideline, but economies and country have different measures to regulate investigational drugs and their clinical trials.
- The regulatory scientific review/evaluation of investigational drugs and their clinical trials are not yet existed in a few economies and not fully functioned in some economies
- In the world of global drug development, many therapeutic innovative medicines are coming out and ready to be tested in clinical trials. Drug Regulatory Agencies need to perform scientific evaluation in both quality and safety aspects.
- Pharmaceutical Industries become more interested to conduct higher risk trials, e.g. First in Human trial, Adaptive Design, etc, in developing economies.

Suggestion for Future Cooperation
- Basically, do the best with the tools you have
- If the trial has too much risk particularly the higher risk trials, you should seek for help e.g. collaboration, consultation.
- Pharmaceutical and Medical Devices Agency offers support interested participants with practice guidelines, which could be translated from Japanese to English by request
- The training course should continue every year or every other year to update and sustain knowledge, experience sharing, and networking opportunities.
- The training could be a back to back meeting at APEC Life Sciences Innovation Forum. APEC should provide supports, e.g. technical support, experts from competent drug regulatory agencies, and some financial support.
- The keys to reduce the gap are to establish collaboration and information sharing to improve the system.
- Suggested future topics of interests are:
  - Review process for design of clinical trials
  - Pharmacovigilance plan
  - Review of new study design