







APEC Center of Excellence (CoE) Pilot Training: ICH E17 and ICH E6(R2)

When: April 10-13, 2018

Where: Harvard University, Cambridge, Massachusetts, USA

Host: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

(MRCT Center), APEC Harmonization Center (AHC)

Learning Objectives

- Enhance regulatory cooperation in the APEC region on the evaluation and regulation of MRCTs
- Increase the acceptability of MRCT data by multiple regulatory authorities
- Describe the concepts of MRCTs and MRCT design as presented in ICH E17 guidance
- Demonstrate practical approaches to GCP as presented in ICHE6(R2)
 - Program to include Didactic and Case-based learning, presentations, and open discussion.

Target Audience

- Regulators (Reviewers and inspectors) with priority to those from emerging economies
- Academic and Industry representatives as space allows
- Involved in MRCTs and/or GCP inspection
- 2+ years of regulatory experience and/or working with clinical trials

Registration Information: Registration will be available from January 29 to March 10 at www.MRCTCenter.org or http://survey.constantcontact.com/survey/a07ef0fb1ewjc6gy59y/start

Additional Information: For more detailed information, please e-mail the MRCT Center at mrct@bwh.Harvard.edu

Limited travel support is available from the AHC for 1 representative from each 11 APEC travel-eligible economies. If eligible, please contact AHC Secretariat for more information at ahckorea@kpbma.or.kr