Training of Regulators

Training of global regulators, including reviewers and inspectors is a central focus of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center). The goals of this effort are to build local capacity, particularly in emerging economies, and to facilitate review and oversight of multi-regional clinical trials.

Our most recent training efforts are being conducted in strategic partnership with two entities: the Asia-Pacific Economic Cooperation (APEC) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) as described below. Working with APEC and ICH, we aim to position the MRCT Center as a Center of Excellence for Regulatory Training that would draw regulators globally.

APEC Pilot Center of Excellence (CoE)

In February 2017, the APEC Life Sciences Innovation Forum, through its Regulatory Harmonization Steering Committee, endorsed the MRCT Center to become a Pilot Center of Excellence (CoE). Our aim is to become certified as an Asia-Pacific Economic Cooperation (APEC) Training Center of Excellence for Multi-Regional Clinical Trials (MRCTs) and Good Clinical Practice (GCP) inspection for training of regulators from APEC economies. Our first training is scheduled at Harvard University for April 2018.

Vision

Promote regulatory convergence through the development of an MRCT Center of Excellence focused on the regulations and science of MRCTs and of GCP Inspection.

Objectives

- To build skilled capacity in clinical trial regulatory science to facilitate review and oversight of MRCTs and GCP inspections in the APEC economies.
- To collaborate closely with other MRCT/GCP Primary Work Areas (PWAs) to determine the optimal curricula, method(s) and configuration to deliver training in a culturally-appropriate manner.

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

For more information about the MRCT Center and our resources visit:
http://mrctcenter.org/focus-areas/training/

ICH Training Program

The MRCT Center was invited by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Secretariat to conduct a pilot training program on the latest ICH guidelines for Good Clinical Practice (GCP).

This ICH training program was a workshop specifically designed for regulators with responsibility for drug review and approval. The workshop goals were to advance the understanding of the ICH E6 guidelines, with a particular emphasis on the new and revised ICH E6(R2) guidelines for Good Clinical Practice to facilitate their adoption and implementation.

Learning Objectives

- Describe the standards of Good Clinical Practice (GCP) as set out in ICH E6 as well as the changes in the ICH E6(R2) revision, as applied to multinational design, conduct, oversight, reporting and review of regulated trials
- Describe models of implementation of the changes in the ICH E6(R2) addendum
- Demonstrate practical approaches to fulfilling the requirements of ICH E6(R2) consistent with revised standards (e.g., risk-based quality management).
- Describe and demonstrate best practices to assess clinical trial regulatory submissions, including study design, data packages, essential documents, reports, and filings for alignment with ICH GCP
- Define inspection methodologies to assess clinical trial conduct for alignment with ICH GCP including review of corrective actions.

The highly successful MRCT Center ICH GCP Pilot training took place October 17-19, 2017 at the Harvard Faculty Club, with 25 participants from 14 countries.

Both the APEC CoE and ICH GCP workshops use case-based learning, presentations, and open discussion of scientific, statistical, and practical approaches. The faculty includes regulators from the USFDA, EMA, PMDA and others with the assistance of academic and industry leaders.