PRACTISE® IIS

A comprehensive training programme on investigator-initiated clinical studies

Course 1: Study Design & Sample Size Calculations
Course 2: Data Management & Practice of Electronic Data Capture
Course 3: Ethics, Regulatory & Legal Compliance
Course 4: Good Clinical Practice (R2)

Organized by LKS Faculty of Medicine, The University of Hong Kong with the support by:

- Clinical Trials Centre;
- Biostatistics and Clinical Research Methodology Unit;
- Department of Pharmacology & Pharmacy.
## Programme

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Participation in individual courses or modules is welcome.
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Participation in individual courses or modules is welcome.
Background

Clinical research is vital for the advancement of human healthcare, and is an essential component for a robust, sustainable healthcare system. Whilst most of the novel drugs, medical devices and other medical products are marketed by the pharmaceutical and medical technology industries after completion of industry-sponsored clinical trials, non-commercial, investigator-initiated clinical studies (IISs) play an important role in translating medical discoveries and hypotheses into clinical practice and help bridge research gaps in areas where high healthcare value is not supported by sufficient commercial incentives. In fact, the Institutional Review Board of The University of Hong Kong / Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB) approves around 800 clinical studies every year, and about 90% of which are IISs.

The value of clinical research is supported by three pillars, including volunteer protection, scientific validity and data integrity. Research personnel engaged in performing or coordinating clinical research need to master the principles and practice of the three pillars in order to ensure that study results are scientifically sounded and trustworthy, and research volunteers’ rights, safety and well-being are well-protected.

Programme Introduction

PRACTISE® IIS comprises four courses, including:

- Course 1: Study Design & Sample Size Calculations;
- Course 2: Data Management & Practice of Electronic Data Capture;
- Course 3: Ethics, Regulatory & Legal Compliance; and
- Course 4: Good Clinical Practice (R2).

The programme covers the core elements of the three pillars, and provides practical tips for tackling the common challenges in designing, planning, managing and performing high quality IISs.

Learning Objectives

Through PRACTISE® IIS, participants should be able to:

- design IISs that appropriately address to research questions based on relevant scientific and statistical principles;
- understand the principles and good practice of clinical study data management;
- master the skills of electronic data capture (EDC), including setting up electronic databases and electronic case report forms (eCRFs) on REDCap, collecting data over REDCap and exporting data for analysis; and
- understand and comply with good clinical practice (GCP) and applicable ethics, regulatory and legal requirements.

Who Should Attend

PRACTISE® IIS is specifically designed for clinical investigators, study coordinators, research nurses, research assistants, research administrators, IRB members and other personnel involved or interested in performing or coordinating IISs.

Registration

Registration is free. Clinical research personnel employed by The University of Hong Kong (HKU) or the Hospital Authority Hong Kong West Cluster (HA HKWC) and with honorary appointment under HKUMed are eligible and welcome to attend. Course announcements will be made on HKU-CTC’s website at www.hkuctc.com or via HKU emails. Participation in individual courses or modules is also welcome.

Certificates of Attendance

A Certificate of Attendance will be issued to each participant upon his/her completion of each course.