Professional Research Accreditation for Clinical Trials Investigative Site Executives

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)

Participation in individual courses or modules is welcome.

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.

HKU Med LKS Faculty of Medicine The University of Hong Kong 香港大學李嘉誠醫學院

- Clinical Trials Centre
- Biostatistics and Clinical Research Methodology Unit
- Department of Pharmacology & Pharmacy

Programme

Module	Description	Duration (Mins)
Course 1: Study Design & Sample Size Calculations		
1.1 Big Data Research	• Principles and Practice of Big Data Research • Case Sharing: Practical Tips & Tricks	30
1.2 Clinical Trial Design	• What is Clinical Trial? • Types of Clinical Trials • Various Clinical Trial Designs	45
1.3 Sample Size Calculations	• Study Endpoints • Hypotheses • Statistical Tests	45
Course 2: Data Management & Practice of Electronic Data Capture		
2.1 GCP in Clinical Data Management	• User Training • Access Control • Version Control • eCRF/Database Testing	30
2.2 Building eCRF in REDCap	• Online Designer • Data Dictionary • Field Types • HTML Customizations	30
2.3 Advanced Features in REDCap	• Longitudinal Data Collection • Repeatable Forms and Events • Data Quality Check • Data Import/Export • Randomization	30
2.4 eCRF/Database Standardization	• Traceability and Reusability • Standard Collection Domains • Standard Codelists and Data Formats • Data Integration and Data Sharing	30
Course 3: Ethics, Regulatory & Legal Compliance		
3.1 Types of IISs and Investigators' Roles	• Classification of IISs • Roles of Investigators • Contractual Relationships	15
3.2 Compliance with IRB Requirements	• Initial Application & Approval • SAE Reporting • Regular & Final Reporting	30
3.3 Compliance with Local Regulatory Requirements	• Application for Clinical Trial Certificates • Application for Drug Import Licences	30
3.4 Compliance with China Regulatory Requirements	• Approval by IRBs • Application to Human Genetic Resource Administration of China (HGRAC)	15
3.5 Registration on Public Clinical Trials Registries	• Registration on www.ClinicalTrials.gov • Registration on www.hkuctr.com	30

Participation in individual courses or modules is welcome.

Programme

Module	Description	Duration (Mins)
Course 4: Good Clinical Practice (R2)		
4.1 Clinical Research Compliance	• What is compliance? • Clinical Research Compliance: The 3 Pillars • 6-dimensional Compliance in Clinical Research	15
4.2 ICH GCP: Overview & Principles	• Background of ICH GCP • ICH GCP: What is it about? • ICH GCP & The 3 Pillars of Clinical Trials	15
4.3 ICH GCP: Insight for Investigators & Study Site Personnel	• The Roles of Investigators & Study Site Personnel • Responsibilities: Volunteer Protection • Responsibilities: Data Integrity • Responsibilities: Scientific Validity	15
4.4 Informed Consent: Principles & Practical Considerations	• Principles of Informed Consent • Contents of Informed Consent • Informed Consent Process • Enrolling Vulnerable Subjects	15
4.5 Study Document Management	• The Concepts of Essential Documents • The Concepts of Source Data & Source Documents • Source Documentation Methods • Completion of Case Report Forms • Retention of Essential Documents	15
4.6 Investigational Product Management	• Principles of Investigational Product Management • Receipt of Products • Storage of Products & Inventory Control • Handling & Dispensing of Products • Return of Products • Disposal of Products	15
4.7 Safety Management & Reporting	• Investigators' Responsibilities in Safety Management • Definitions & Reporting of Safety Events	15
4.8 Quality Management at Study Sites	• Concepts of QA and QC • Quality Assurance for Clinical Study Sites	15

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.