中國醫藥大學附設醫院
China Medical University Hospital

PRACTISE Core Training Workshop

【課程目的】Parctical workshop on clinical trials principles and practice for investigators and clinical research personnel.

【訓練對象】已具備臨床試驗經驗之主持人、醫師、護理、醫事和研究人員

【主辦單位】中國醫藥大學附設醫院臨床試驗中心

香港大學臨床試驗中心

【課程地點】中國醫藥大學立夫教學大樓六樓 第一會議室

【課程時間】106 年 5 月 20 日(六) 09：00 - 17：30

【課程費用】押金 1000 元，全程上課完成後於當日全額退還

【備註】

1. 本課程為中英文授課之專業臨床試驗訓練課程，採小組討論方式進行，報名前請確定可全程參與課程討論。
2. 本課程名額有限，將依押金繳交順序作為錄取順序。
3. 押金繳交方式：

   請使用**現金袋將押金 1000 元於 106/5/15 前**寄至

   404-47 台中市北區育德路 2 號 中國附醫第一醫療大樓 B1 臨床試驗中心 藍珮慈小姐 收
4. 線上報名網址：**https://goo.gl/forms/RLfvNQskVSS3c91Y2**
5. 全程參與課程並遵守簽到退者，核發 6 小時 GCP 證明及 TransCelerate 證書。
6. 嚴禁代簽，未於正式表格及規定時間內簽到退者，一律不發與訓練證明。
7. 為維護學員上課權益，當日無故缺席者恕不退還押金 1,000 元。
8. 本課程完成報名後不接受取消報名。
9. 連絡人：藍珮慈/ jessielan.cmuh@gmail.com / (04)22052121 #1473

Professional Research Accreditation for Clinical Trials Investigative Site Executives

PRACTISE® *Core* Program

May 20,2017 (Saturday)

Time	Topics	Key Contents
09:00 – 09:15	• Opening Remarks	• Clinical Trials Centre, The University of Hong Kong • China Medical University Hospital Clinical Trial Center of Excellence
09:15 – 09:35	❖ Clinical Research Compliance	• What is compliance? • Clinical Research Compliance: The 3 Pillars • 6-dimensional Compliance in Clinical Research
09:35 – 10:00	❖ ICH GCP: Overview & Principles	• Background of ICH GCP • ICH GCP: What is it about? • ICH GCP & The 3 Pillars of Clinical Trials
10:00 – 10:30	❖ ICH GCP: Insight for Investigators & Study Personnel	• The Roles of Investigators & Study Site Personnel • Responsibilities: Subject Protection • Responsibilities: Data Integrity • Responsibilities: Science
10:30 – 11:00	➢ Tea Break	
11:00 – 11:45	• **Practical Session**	• **Case Studies on ICH GCP**
11:45 – 12:45	❖ Informed Consent: Principles & Practical Considerations	• Principles of Informed Consent • Contents of Informed Consent • Informed Consent Process • Enrolling Vulnerable Subjects
12:45 – 14:00	➢ Lunch Break	
14:00 – 14:30	❖ Quality Management at Study Sites	• Concepts of QA and QC • Quality Assurance for Clinical Study Sites
14:30 – 14:45	❖ Safety Management & Reporting	• Investigators' Responsibilities in Safety Management • Definitions & Reporting of Safety Events
14:45 – 15:30	• **Practical Session**	• **Case Studies on Informed Consent, Quality Management & Safety Management**
15:30 – 15:45	➢ Tea Break	
15:45 – 16:15	❖ 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
16:15 – 16:45	❖ Study Document Management	• The Concepts of Essential Documents • The Concepts of Source Documents & Source Data • Source Documentation Methods • Completion of Case Report Forms • Retention of Essential Documents
16:45 – 17:30	• **Practical Session**	• **Case Studies on Investigational Product & Study Document Management**

❖ **Participants completed this program will be awarded a certificate recognized by TransCelerate BioPharma.**