CERTIFIED CLINICAL RESEARCH PROFESSIONAL TRAINING COURSE

CPD CERTIFIED
The CPD Certification Service

Metrics Research
Research.Innovation.Excellence

This program is designed to provide training in ICH-GCP guidelines, clinical trials monitoring, investigative site coordination, understanding local/ international regulations, and risk management in clinical trials.

~~PKR 45,000~~
PKR 40,500

Module: 12 Online/Onsite sessions covering a comprehensive curriculum of clinical research.

Eligibility: M.B.B.S/ B.D.S, registered nurses, medical students, M.Phil./ Ph.D. B.Pharm. / Pharm-D/ M.Pharm. B.Sc. (biological sciences), M.Sc. (biological sciences)

Assessment: Total 10 assessments (40% weightage)
One final exam (60% weightage)

Timing: Every Sunday 10:00 AM to 01:00 PM.

Batch-wise Planned Dates:

Batch 01	Batch 02	Batch 03	Batch 04
18th February 2024	26th May 2024	August 2024	November 2024

REGISTER NOW

VISIT OUR WEBSITE :
www.mrcro.com/ccrp/
+92-21-37224982

Location for Onsite Training:

Plot # B-10, Block-16, W.C.H.S, K.D.A Scheme No.24, Gulshan-e-Iqbal, Karachi, Pakistan

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COURSE OUTLINE

DETAILS	MODULES
Pharmaceutical Industry Overview, Drug Discovery & Research.	• Introduction to Pharmaceutical Industry • Industry Drug Discovery and Development • The Pre-Clinical Studies • Phases Of Clinical Trials
Clinical Studies, Design, & Clinical Trials	• Types of Clinical Research • Essential Elements of Clinical Trials • Clinical Trial Design
IRB & Regulatory Process	• Drug Approval Process • IRB/IEC roles and responsibilities • FDA Review Process • Trial approval process (DRAP)
Historical events leading to Formation of ICH-GCP – E6 R2 Guidelines	• Historical Events leading to the current code of Bio-Ethics in Clinical Research • Evolution of ICH-GCP • ICH-GCP E6 R2 guidelines and updates in E6 R3
Clinical Trial Management	• Pre-study and Study Set-up Activities • Site Selection & Site Initiation Visit Clinical Conduct • Subjects Recruitment Retention • Compliance • Safety Reporting & Source Documents Verification
Essential Documents	• Overview of Clinical Trial Essential documents • Study Protocols • Informed Consent Process & Elements of ICF • CRF and design of CRF • Data Collection and Management in Clinical Trials • EDC Tools
Stakeholder Management in Clinical Research/ Trial	• Sponsors and Stakeholders • Clinical Trial Sites and Stakeholders • CROs and Stakeholders
Risk Management in Clinical Trials	• Identification of risks and issues • Mitigation plans and Review of status for mitigation.
Statistical Considerations in Clinical Trials/Clinical Research	• Study Design • Research Methodology • Statistical Consideration in Clinical trial • Null & Alternative hypothesis • Descriptive V/S Analytical Studies • Prevalence Studies & Case Studies
SPSS Hands-on Training	• Data Handling • Data Management • SPSS – hands-on
Bioethical Considerations in Clinical Research – Case Studies	• Understand the difference between ethical and unethical clinical conduct in various scenarios: • Informed Consent, Authorship, Therapeutic Misconception, Clinical Equipoise, Use of Placebo in Clinical Trials