

Centre for Education and Training in Clinical Research (CETCR)

DOW UNIVERSITY OF HEALTH SCIENCES

OUTLINE OF CLINICAL RESEARCH CERTIFIED PROFESSIONAL COURSE

- 1. Introduction to Clinical Research Certificate Program, Pharma Industry Review.**
- 2. Pre-Clinical Research, Phases of Clinical Trials.**
- 3. International Conference on Harmonization and good Clinical Practices guidelines (ICH-GCP guidelines)**
- 4. Ethics in Clinical Research (ERC formulation, documents reviewed by ERC, ERC authorities & decisions, Ethical Dilemma and Issues)**
- 5. Review and Approval Processes of Investigational New Drug/New Drug Application (FDA, EU and DRAP)**
- 6. Study design & Protocol writing**
- 7. Clinical Site Selection, Site Staff Roles & Responsibilities, establishment of an ideal site (site infrastructure, site staff capabilities, recruitment strategies and related topics)**
- 8. CRA responsibilities & activities-I(Pre , During & Post study activities, Computerized systems used in clinical trials-IVRS,eCRF)**
- 9. Safety Monitoring and QA audit**
- 10. Pharmacovigilance & Bio Equivalence studies**
- 11. Study Budget & Documentation**
- 12. Basics of Epidemiology**
- 13. Basics of Biostatistics**