Clinical Trials Unit (CTU)
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**