



Clinical Trials Unit (CTU)

DOW UNIVERSITY OF HEALTH SCIENCES

OUTLINE OF CLINICAL RESEARCH CERTIFIED PROFESSIONAL COURSE

- 01. Clinical Research Certificate Program, Pharma Industry Review.**
- 02. Pre-Clinical Research, Phases of Clinical Trials.**
- 03. International Conference on Harmonization and good Clinical Practices guidelines (ICH-GCP guidelines)**
- 04. Ethics in Clinical Research**
- 05. Review and Approval Processes of Investigational New Drug/New Drug Application**
- 06. Study Design & Essential Documents**
- 07. Clinical Site Selection,**
- 08. CRA responsibilities & activities**
- 09. Safety Monitoring and QA audit**
- 10. Pharmacovigilance**
- 11. Protocol writing**
- 12. Basics of Epidemiology**
- 13. Basics of Biostatistics**