# **CRCP course Outline**

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| **S.No** | **Module** | **Contact Hours** |
| 1 | Clinical Research Industry Review , Phases of Clinical Trials ,ICH- GCP Guidelines | 4 |
| 2 | Clinical Site Selection, Site Staff Roles & Responsibilities, Establishment of an Ideal Site | 4 |
| 3 | Role of Regulatory Bodies in the  approval of Clinical Trials FDA, EU and Drug Regulatory Authority of Pakistan (DRAP) | 4 |
| 4 | Ethics in Clinical Research (ERC formulation,  documents reviewed by ERC, ERC authorities & decisions, Ethical Dilemma and Issues) | 4 |
| 5 | CRA responsibilities & activities-I(Pre , During & Post study activities,  Computerized systems used in clinical trials-IVRS,eCRF) | 8 |
| 6 | QA Audit/ Inspections and Monitoring | 4 |
| 7 | Study Budget & Documentation | 4 |
| 8 | Pharmacovigillance and Bioequivalence | 4 |
| 9 | Epidemiology | 8 |
| 10 | Protocol writing | 4 |
| 11 | Biostatistics | 12 |