I. Clinical Research Theory – 15 Hours

- Introduction to Clinical Research
- INDA, NDA, ANDA applications
- Types, Designs and Phases of Clinical Trials
- ICH GCP guidelines (ICH E6)
- Roles and Responsibilities of Investigator and CRA
- Roles and Responsibilities of Sponsor and CRC
- Contract Research Organizations-CRO
- Case Report Form and its Contents with live example
- Contents of protocol
- Explanation of Research protocol with live example
- Informed Consent Form
- Institutional Review boards(IRB)/IEC
- Participant safety and Adverse events reporting
- Safety definitions and reporting requirements
- Monitoring of Study at participating sites
- Source Data Verification
- Investigator's Brochure (IB)
- Standard operating procedures
- Essential documents
- Data Coding using MedDRA and WHODD
- CRF Design Guidelines
- SAE/AE Reconciliation