

## Course Structure

### **Certificate Course in Pharmacovigilance[6 Months]**

**Course-Paper-I:** Principles of Pharmacovigilance

**Course-Paper -II:** Methodologies in Pharmacovigilance and Signal Detection

**Course-Paper -III:** Pharmacovigilance Compliance and Management

**Course-Paper -IV:** Pharmacovigilance Regulations and Guidelines

### **Comprehensive Program in Clinical Trials Data Management and Pharmacovigilance [12 Months]**

**Course-Paper-I:** Introduction to Clinical Trials

**Course-Paper-II:** Introduction to Clinical Trials Data Management

**Course-Paper-III:** Principles of Pharmacovigilance

**Course-Paper-IV:** Biostatistics, SAS and Data Management

**Course-Paper-V:** Computerized Systems for E- Case Report Form and Data Acquisition and Validation

**Course-Paper-VI:** Methodologies in Pharmacovigilance and Signal Detection

**Course-Paper-VII:** GCP, ICH, Ethics, IRB, Regulations for Clinical Trials

**Course-Paper-VIII:** Pharmacovigilance Compliance and Management

**Course-Paper-IX:** Case Study Report