

## **SAS CDM Course Content:**

### **1. Clinical Trails and Clinical Data Management**

- Drug discovery and development
- Phase trails: preclinical 1,2,3 and 4
- Computer system validation
- CRF designing
- Pharmacokinetics
- Pharmacovigilance
- Clinical data management process
- CDISC introduction
- CTM systems
- Data management plan

### **2. Sub Chapter**

- General abbreviated terms
- Introduction to clinical trails
- Responsibilities of CRA
- Activities of CRA in house
- CRA monitoring
- Clinical trail monitoring
- Responsibilities of PI
- Informed consent form
- ICH history
- GPC guidelines
- FDA history
- FDA guidelines
- IND,NDA reviews
- Clinical research study document
- CRF reviews and sample CRFs
- CRF data submission
- CRF receiving
- Introduction to SAS in CDM

### **3. Components of SAS**

- Different data types
- Base/SAS

- SAS/STAT
- SAS/Graph
- SAS/ACCESS
- SAS procedures
- SAS Procedures
- SAS Macros
- SAS (working with sql)

#### **4. Open clinical**

- Data base design
- Protocol planning
- CRF Data entry
- Data management
- Study planning
- Study design
- Oracle clinical (overview)