SAS CDM COURSE CONTENT

- Clinical Trails and Clinical Data Management :
    - Phase trails: preclinical1,2,3 and 4
    - Drug discovery and development
    - ICH GCP
    - Computer system validation
    - 21 CFR 11
    - CRF designing
    - Pharmacokinetics
    - Pharmacovigilance
    - Clinical data management process
    - CDISC introduction
    - CTM systems
    - Data management plan
- 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
    - IRB
    - Informed consent form
    - ICH history
    - GPC guidelines
    - FDA history
    - FDA guidelines
    - IND,NDA reviews

    - Clinical research study document
    - CRF reviews and sample CRF's
    - CRF data submission
    - CRF receiving
    - Introduction to SAS in CDM
- Components of SAS Different Data Types
    - Base/SAS
    - SAS/STAT
    - SAS/Graph
    - SAS/ACCESS
    - SAS procedures
    - SAS Procedures
    - SAS Macros
    - SAS (working with sql)
- Open Clinical
    - Data base design
    - Protocol planning
    - CRF Data entry
    - Data management
    - Study planning
    - Study design
    - Oracle clinical (overview)