

# CDISC

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## Syllabus

## Clinical Trials Overview

- Introduction of clinical Research
- Overview of New Drug Development
- Clinical Trial Phases
- Clinical Trial design
- Clinical Trail Protocol
- GCP , Ethics & regulations
- Informed Consent Process
- Essential documents
- Study conduct
- Overview of study documents
- Clinical Research Protocol
- Case Report Form (CRF) Design
- Statistical Analysis Plan (SAP)

## Deep Domain Knowledge

- **DM domain-**
  - What is DM (Demographic?)
  - Clinical trial basics
  - Demographic in Trial
  - Contents in demographic
  - Importance of DM
  - DM concept
  - DM data collection
  - DM dataset
  - DM Analysis/ Report generation
  - AdaM concept
- **AE domain –**
  - Definition of Adverse Event
  - Aspect of AE –
    - What
    - When
    - Intensity
    - Seriousness
    - Causality
    - Classification
  - ADR
  - TEAE
  - AE-Reporting
  - AE CRF
  - AE CRF to AE SAS dataset
  - SAE & reporting SAE

- **EG Domain-**
  - EG concept
  - Introduction to Heart's Electrical System
  - Introduction of Electrocardiogram (ECG)
  - ECG Parameters
  - QT Interval Correction
  - Standards for Dataset
  - Raw / SDTM datasets
  - Analysis Dataset
  - What to look for in SAP
  - What to look in a mock shell

- **Ex Domain –**
  - Definition of Exposure
  - Aspects of Exposure
    - Dose
    - Duration
    - Number of Patients
  - Who talk about EX ?
    - Protocol
    - CRF
    - SAP
    - CTMS
  - Collection of Exposed Treatments
  - Diagrammatic Representations
  - Raw Data Collection
  - Raw Data Table
  - Analysis of Data

- **LB Domain-**
  - LB Concepts
  - LB Data Collection
  - LB Datasets
  - LB Analysis / Reports
  - LB CRF Data Collection
  - LB Reports Analysis

- **VS Domain-**
  - What is Vital sign?
  - Vital Sign parameters
    - Temperature

- Pulse
  - Respiration Rate
  - Blood Pressure
  - Height & Weight
  - Oxygen Saturation
  - Collection of Vital Sign (VS) data
  - VS CRF
  - VS CRF to VS SAS Dataset
  - Standard for Dataset
  - Raw vs. SDTM Dataset
  - Analysis Dataset
- MH Domain-
    - Concept of Medical History
    - When we have to create MH domain
    - Raw data to SAS Data Set Creation

Case Study :

- Clean the data in multiple conditions (I)
- Clean the Data in multiple conditions(II)
- Restructure the Data & handling the missing values
- Dates imputation based on multiple conditions
- How to compare Dataset, observation , variable