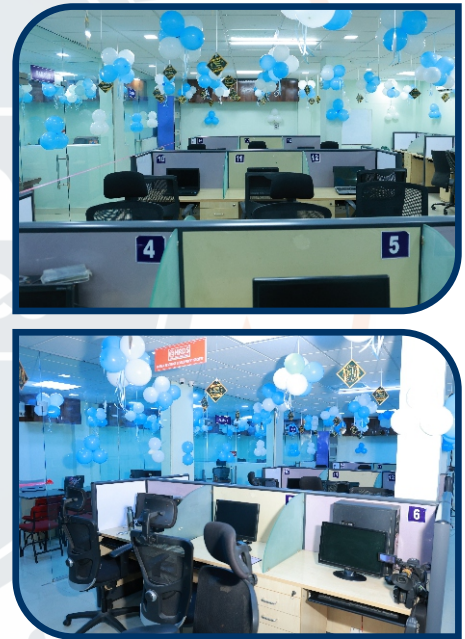




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Course

Clinical SAS-CDISC

Duration : 45 Days

Head Office cum Training Division:

#7-35 1st Floor, Road No 1, Madhurapuri Colony, Dilsukhnagar, Hyderabad - 500060

Call Us : Landline: 040-4007 7129 || Mobile No. +91-99 6606 1444 / 99 1226 1444.

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TRAINING

STAFFING

DEVELOPMENT

1

CDISC SDTM ADaM TLFs Content

Part 1: INTRODUCTION

- a. Introduction about the course
- b. Introduction about the each departments (clinical operations, CDM, Bio-statistics and Medical writing)
- c. Detailed information about the Bio-Statistics (statistician, statistical programmers and SAS programmers)
- d. Introduction about the Client, Regulatory bodies, Submission of the study
- e. Introduction to specifications

Part 2: CDISC - SDTM

- f. Introduction of CDISC
- g. Why CDISC and DATA standards
- h. What are the versions of CDISC
- i. Impact of CDISC Standards on Clinical Activities
- j. CDISC Models
- k. Study Data Tabulation Model (SDTM)
- l. Analysis Dataset Models (ADaM)
- m. Operational Data Model (ODM)

Fundamentals of SDTM

- a. What is SDTM?
- b. Observations and Variables in SDTM
- c. Special Purpose Datasets
- d. General Observation Classes in SDTM
- e. SDTM Standard Domain Models
- f. Creating New Domain

Submitting Data in Standard Format

- g. Assumptions for Domain Models
- h. General Assumptions for all Domains



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Models for Special Purpose Domains

- i. DM, CO, SE and SV

Domain Models Based on the General Observation Classes

1. Interventions

- a. CM, EX, EC and SU

2. Events

- a. AE, DS, MH, DV and CE

3. Findings

- a. LB, EG, VS, PE, IE, DD and DA etc..

4. Trial Design Domains

- a. TA, TE, TS, TI and TV

Supplemental Qualifies

SDTM Mapping Programming Using SAs

SDTM Annotation on CRF

SDTM Mapping Specifications

Real time Project on SDTM

- a. SDTM Mapping programming using SAS
- b. SDTM Mapping Specifications

Part 3: CDISC -ADaM:

- a. Introduction to ADaM
- b. Why ADaM
- c. Key Concepts
- d. ADaM naming conventions
- e. ADaM Implementation
- f. Fundamentals of the ADaM Standards
- g. Variables in General
- h. ADSL variables
- i. BDS Variables
- j. Real time Project on ADaM
- k. ADSL, ADAE, ADEX, ADMH, ADLB, ADVS etc..



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Part 4: TLFs

- a. Introduction to Clinical Trail
- b. Summary Reports (Tables Listings and Figg)
- c. Introduction about the ICH E6,E9 and E3
- d. Protocol
- e. CRF/eCRF
- f. SAP
- g. Mock shells
- h. Introduction about the statistical reports
- i. Introduction about the clinical study report
- j. SAS programs development, and validation (QC)
- k. MeDRA Guidelines
- l. Generating Summary Reports
- m. Generating Listings
- n. Generating Graphs
- o. Real time Project on Phase II Clinical Trial Studies (Diabetics therapeutic area)

Part 5: Define.xml

Introduction to define.xml

Introduction to open cdisc

Part 6: Pinnacle 21

How to Use P21 Tool

How to Check and Resolve P21 Issue

Part 7: Submission documents

SDRG

ADRG



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