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CDISC SDTM ADaM TLFs Content

Part 1: INTRODUCTION

a. Introduction about the course
b. Introduction about the each deportments(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

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..

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