# LEARN SAS AT HOME

## LEARN CLINICAL SAS(SDTM,ADaM,TLF)

Contact: 9878714767
Website: www.clinexpertz.com

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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 and SU
2. **Events**
   a. AE, DS, MH, DV and CE
3. **Findings**
   a. LB, EG, VS, PE, IE and QS 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