Gupta Programming, http://www.SASSavvy.com
Register by phone (805) 577-8877 or by e-mail Sunil@GuptaProgramming.com

"I took your CDISC class in the PharmSUG one-day event in San Diego. I think your course will be very helpful to my work!",
Wendy Huang, SAS Programmer, Inclin

CDISC Mapping and Strategies – On-line Class

Satisfied students from selected clients: Quintiles, Pharmacyclics, Exelixis, Santarus, Biosense Webster, Theorem Clinical Research, InClin, Seattle Genetics, Edwards Life Sciences, Clinical Outcomes Solutions, DOCS and Kaiser Permanente.

COURSE DESCRIPTION

This course teaches SAS programmers and Biostatisticians essential concepts about creating and validating SDTM (v 3.1.2 IG) and ADaM (v 1.0 IG) variables in key CDISC datasets (DM, AE, LB, ADSL, ADAE, and ADLB). Attendees learn how to create and process ISO8601 dates, hierarchy of adverse events variables, paired lab variables, as well as lab visit window techniques. Examples of both SDTM and ADaM dataset structures will be reviewed and compared. In addition, a mapping plan from raw datasets to SDTM to ADaM datasets will also be outlined. To help assure higher quality clinical data, a qc checklist and some key edit check macros will also be introduced. Students get a copy of all SAS macros reviewed in class. Also included is a one month free trial membership to www.SASSavvy.com for making smarter SAS searches.

E-mail us for registration and information.

Self-study program includes the following: Class slides, SAS macros, a total of three up to thirty-minute one-on-one web sessions, a unique 40 page e-guide, access to five video recordings of CDISC classes and nine CDISC portals to access industry expert presentations. Students study 1) mapping to SDTM and ADaM steps, 2) compare and contrast SDTMs and ADaMs, and 3) main SDTM and ADaM components/summary.

Three-Day COURSE OUTLINE – CDISC Mapping and Strategies

1: Overview, Specifications and FDA Requirements

a. Understanding CDISC Terms
b. SDTM Map – The Big Picture

c. MindMaps - SDTM and ADaM Domains, SDTM Variable Types and Roles
d. CDASH, Study Data Standardization Plan and Submission Data Standards
e. SDTMs and ADaMs Specifications
f. Metadata Files and Control Terminology
g. CDISC Reference and Guides
h. DEFINE.XML and DEFINE.PDF – Differences and Examples

i. CRF Annotations
j. Templates – SDTM and ADaM Specifications, Defaults, Master SDTM to ADaM Map

2: Compare and Contrast SDTM and ADaM Steps

a. Compare SDTM and ADaM – Key Differences
b. When are Key SDTM/ADaM Variables Created
c. Mapping Raw Data to SDTMs by SDTMs
d. Nine Step SDTM Mapping Plan
    i. Confirm Date Variables
    ii. SDTM Mapping of Study Day, ex AESTDY
    iii. Three types of Raw Data Collected
    iv. Three types of Dataset Joins
    v. Match DM Variables: Three Types of Raw Variable Mapping to SDTMs
    vi. Mapping macros

3: SDTMs 80% / 20% Mapping Rule

A. SDTM 80% General Domains/Variables
    i. Mapping to SDTM Variables: Four Types
    ii. Apply one of seven mapping methods
    iii. Eight Variable Types Based on Values
    iv. Control Terminology – Format Metadata from CODELISTS tab
    v. SDTM Metadata Excel File
    vi. AE MedDRA Hierarchy Structure
    vii. Purpose of Trial Designs: Trial Elements (TE), Trial Arms (TA) and Trial Visits (TV)
    viii. DM, AE, EX, SE and SV
    ix. Oncology Domains: TU, TR and RS
B. SDTM 20% Special Domains/Variables
    i. SUPPDM and SUPPAE
    ii. Questionnaire Data (QS) – Patient Reported Outcomes (PRO) Online Reference
    iii. Findings About (FA) – Collection of different CRFs
    iv. Handling Comments Domain (CO)
    v. Relationship Domain (RELREC)
    vi. Pharmacokinetics Domains (PC, PP)
    vii. Custom Domains (X-, Y-, Z-)

4: LAB to LB to ADLB

a. Processing Paired Lab variables
b. Convert between character and numeric lab result values and units
c. Assign unscheduled visits using visit windows
d. Apply Lab visit window techniques
e. Calculate the study day variable XXDY

f. Using Proc SQL to identify baseline flags
g. Understand and apply Proc SQL Subqueries
h. Apply programing techniques to add group descriptive statistics

5: Overview of Medical Devices Domains

a. SDTMs: DI, DU, DX, DE, DT, DR and DO
b. ADaMs: ADTTE (Time to Event)
c. Control Terminology
d. Related Medical Device and Pharma Domains: DX/EX, DE/AE, DR/RELREC
e. CDISC Implementation Guide and FDA
f. Procedure and the CEC Adjudication

6: ADaM Models – ADSL, BDS and ADAE

a. Seven Step ADaM Mapping Plan
   i. ADaM Model Concepts
   ii. ADaM Six Levels of Flag Variables
   iii. ADaM BDS Variable Types
   iv. Three ADaM Models
   v. Traceability
   vi. ADaM Mapping Plan – Analysis Visit Windows
   vii. ADLB – DTYPE='XXX' New Records
b. ISO8601 Dates
c. Partial Dates
d. Durations and Periods
e. ADaM Variables
   i. Analysis Variables
   ii. Imputation Methods
   iii. Baseline Identification
   iv. Visit Windows and Unscheduled Visits
   v. ADSL, ADAE, ADEFF and ADTTE
   vi. ADaM - DTYPE, Other ex. ADVSLT

7: XML, ODM, DEFINE and DATASET XML Files

a. Learning about XML files
b. SDTM and ADaM Dataset Models and Process Flows
c. Comparing and Contrasting XML files: Define.xml and Dataset.xml
d. Creating and QCing Define.xml & Dataset.xml
e. Metadata Submission Guidelines
f. Case Report Tabulation Data Define Specification (Define.xml)
g. ODM-XML File Structure and Content
   i. Global Element Order
   ii. Understanding Tagsets
   iii. Components – Metadata, Clinical Data, Administrative, Reference and Audit

8: QC, QA and Best Practices to establish Controls and Quality, FDA's Review Process and Issues

a. Study Validation Checklists
b. SDTM and ADaM QC Forms
c. OpenCDISC and SAS Clinical Standard Toolkit
d. Templates – SDTM and ADaM Specifications, Defaults, Master SDTM to ADaM Map
e. ISS/ISE - Master Control Terminology

9: Understanding the FDA Review process and preventing delays - FDA's High Expectations

a. Understanding how to avoid FDA Review issues - Challenges
b. Sponsor's Best Practices for better FDA Submissions - Lessons Learned

10: CDASH

a. Standards
b. Best Practices
c. Comparisons with SDTMs
d. Formedix Tools

11: Group Presentations