



Gupta Programming, <http://www.SASSavvy.com>

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**“I took your CDISC 101 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 101: Mapping SDTM and ADaM Variables

COURSE DESCRIPTION

This course teaches SAS programmers 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.

COURSE OUTLINE – CDISC 101: Mapping SDTM/ADaM Variables

- I. Mapping plan and tools from raw datasets to SDTMs
 - a. Compare & Contrast SDTMs and ADaMs
 - b. DM/SUPPDM/ADSL, AE/SUPPAE/ADAE, LB/ADLB, QS, RELREC, EX and Trial Design Model domains (TE/TA/TV)
 - c. Applying control terminology files as metadata
- II. Mapping plan and tools from SDTM to ADaMs
 - a. DTYPE (blank, LOCF), Basetype (Baseline, Open Label) and BASE (value) required variables
 - b. Slice/Dice Vertical structure for meaning - Subset, PARAM, etc.
- III. Understanding the hierarchy of Adverse Events variables
- IV. Processing Paired Lab variables
 - a. Convert between character and numeric lab result values and units
 - b. Assignment of unscheduled visits
 - c. Lab visit window techniques
 - d. Multiple methods to identify the Lab baseline values
 - e. Calculate the study day variable XXDY
- V. Creating and processing ISO8601 dates and durations
 - a. Handling partial dates
 - b. Converting between character and numeric ISO8601 date variables
- VI. Creating the corresponding SUPPXX datasets to store extra domain variables
- VII. Tools and checklists to QC SDTMs and ADaMs

Satisfied students from: Quintiles, Pharmacyclics, Exelixis, Santarus, Biosense Webster, Theorem Clinical Research, InClin, Seattle Genetics and Kaiser Permanente.

(Helpful to prepare for the SAS Clinical Trials Certification exam)

Get your questions answered. Course Length: Three 2-Hour Online Classes. Recording video access will be available. Register for only \$379. Space is limited.