



## Gupta Programming

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# Standards for CDISC Compliance and Clinical Data Quality Checks Using SAS

*For Better Data Quality and FDA Submissions!*

## **COURSE DESCRIPTION**

This class includes topics such as unit domain checks, domain specific checks and integrated domain checks. This represents the main features of what SAS users need to know about CDISC compliance. Essential data management and validation tasks such as Variable Definition, Join Tables and Subset Dataset will be included.

The class expands on my article on ‘Standards for Clinical Data Quality and Compliance Checks’ in the Society for Clinical Data Management Data Basics magazine in winter 2008. Recently, I was informed that my CDISC data quality article will be referenced in a chapter of the Society for Clinical Data Management's Good Clinical Data Management (GCDMP) document.

(<http://sassavvy.com/resources/SAS%20Downloads/Standards%20for%20Clinical%20Data%20Quality%20and%20Compliance%20Checks.pdf>)

You will have access to online SAS as well as an annual premium membership, valued at \$149, to SASSavvy.com. See examples of popular SAS tip blogs - <https://blogs.sas.com/content/sgf/2012/06/20/adding-group-descriptive-statistics/>

## **OUTLINE**

### **I. Dataset Checks**

- a. Core Checks
- b. Dataset Transfer Checks
- c. Group Descriptive Statistics Check
- d. Zero Dataset Records Check
- e. Disposition Population Trees (SAFFL, ITTFL)

### **II. Data Values Check**

- a. Duplicate Records Check
- b. Any Missing Values in Required Variables Check
- c. Codelist and Value-Level Checks and Lookup Table
- d. Variable Unique Counts Check
- e. ISO 8601 Datetime and Time Check
- f. Duration Check
- g. Codelist and Value-Level Uppercase Check
- h. Data Range Check
- i. Negative Values Check
- j. Numeric Outliers Check
- k. Compare Related Variables Check
  - 1) Sequence of Two Date Variables Check

- 2) No Data beyond Data Cuts Check
- 3) Date and Label Check
- 4) Multivariate Non-Missing Check
- 5) Multivariate Check
- I. Calculations and Derived Variable Check
  - 1) Numeric Calculations Check
  - 2) Study Day Check
  - 3) Append AEACTION code into one Variable Check
  - 4) Complex summary calculations
  - 5) Transpose Response Times
- m. Lab Data Checks
  - 1) Lab Unit Conversions Check
  - 2) Lab Differentials Check
  - 3) Special Characters in Lab Data Check
  - 4) Character Variables Left Alignment Check
  - 5) Lab Data Normal Range Flag Check
- n. Mapped Raw, SDTM and ADaM Variable Checks

### **III. Protocol Compliance Checks**

- a. USUBJID Missing in DM/ADSL Check
- b. Missing Exposure record in EX for DM USUBJID Check
- c. Missing Required Daily Dose Check
- d. Missing Scheduled Visits Check
- e. Interval between Weekly Visits Check
- f. Difference between Calculated Mean and Recorded Mean Check
- g. All Randomized USUBJID in each BDS Domains Check
- h. Lab Data Baseline Checks
  - 1) Incorrect ADBLFL Baseline Flag Record Check
  - 2) No Baseline Result for VS, LB, EG, DA Check
  - 3) Multiple ABLFL when BASTYPE is Missing Check
- i. No Dose Change but Dose Change Reason Exists Check
- j. Site Differences in Visit Windows or Protocol Violations Check
- k. Disposition Tree Check

### **IV. CDISC Compliance Checks**

- 1. SDTM Checks
  - a. Consistency between AENUM and CENUM Check
  - b. Consistency between XX.XXSEQ and SUPPXX.IDVARVAL Check
  - c. Orphan Records in SUPPXX Check
  - d. Consistency between RELREC and SDTMs Check
  - e. Consistency within USUBJID Across Time Check
  - f. Consistency in DOMAIN Value and Name Check
  - g. Required SDTM Domains (TA, DM, EX and DS) do not Exist Check
- 2. ADaM Checks
  - a. Valid DTYPE Checks
    - Consistency between PK detail and summary Domains Check
  - b. Consistency between Analysis Visit Windows and Protocol Check
  - c. Consistency between ADSL.TRTRXPN and ADXX.APERIOD Check

- d. Consistency between BDS TRTAGyN and TRTAGy Check
- e. Traceability Variable Codelist and Integrity (SRCDOM, SRCVAR, SRCSEQ) Check
- f. Consistency between Method of Assessment and Lesions Check
- g. One PROC Away Check

## **V. CDISC Specifications Checks**

- a. Consistency between DM Specifications and Attributes (Type, Name, Length, Label) Check
  - b. Required SDTM and ADaMs Variables Exist Check
    - 1) BASE Variable Exists but ADBLFL Variable Does Not Exist Check
  - c. Non-missing Dataset Label Check
  - d. No Permanent Format in DM Check
  - e. DM Correct Order of Variables Check
  - f. Valid DM Record Order Check
  - g. All ADaMs contain all Core Variables Check
  - h. Variable Length is Max of Values or 200 Check
  - i. Consistency between Non-missing, Missing and Exists across Studies Check
  - j. Consistency between Domain in Define-XML and Domain is Missing Check
  - k. Consistency between Variable in Define-XML and Variable is Missing Check
2. Consistency between Common Variable Values by USUBJID

**Course Length:** One Day Hands-On Course