StatsVia

TRAINING & WORKSHOPS

COURSE 01 · HANDS-ON WORKSHOP

CDISC SDTM & ADaM for Statistical Programmers

Take a study from raw clinical data to submission-ready SDTM and ADaM datasets, taught by programmers who build CDISC packages for sponsors every day.

Raw data → SDTM → ADaM → define.xml & submission

WORKSHOP AT A GLANCE

8 modules with hands-on labs
From CDISC foundations to a full capstone mock study.

Current CDISC standards
SDTMIG v3.4, ADaMIG v1.3 and define.xml v2.1.

Submission-ready skills
aCRF, mapping specs, reviewer guides and Pinnacle 21 validation.

Code you keep
SAS programs for every lab and a define.xml template.

WHY LEARN WITH STATSVIA

Taught by practitioners
Trainers who deliver CDISC packages for sponsors across all therapeutic areas.

Aligned with regulators
Built around FDA, PMDA and CDSCO data expectations.

COURSE 01 · HANDS-ON WORKSHOP

StatsVia

CDISC SDTM & ADaM for Statistical Programmers

Take a study from raw clinical data to submission-ready SDTM and ADaM datasets, with the metadata and reviewer guides regulators expect.

WHO SHOULD ATTEND

SAS programmers new to CDISC

Data managers moving into programming

Biostatisticians who specify or review datasets

YOU WILL BE ABLE TO

Map raw data to SDTM domains

Derive analysis-ready ADaM datasets

Write define.xml, cSDRG and ADRG

Resolve Pinnacle 21 findings

BEFORE YOU JOIN

Working Base SAS: DATA step, PROC SQL, macros basics

Familiarity with clinical trial concepts

Bring a laptop with SAS access

Course modules

Each module closes with a lab on a sample study

01 CDISC foundations
Clinical data flow from CDASH to SDTM to ADaM, FDA and PMDA data requirements, controlled terminology.

02 SDTM model & SDTMIG
Observation classes, domain structure, variable roles and core status, ISO 8601 dates and study days.

03 aCRF & mapping specifications
Annotating the CRF, writing mapping specs, supplemental qualifiers (SUPPQUAL) and RELREC.

04 Building SDTM domains
Hands-on DM, AE, CM, EX, LB and VS from raw data, with EPOCH, baseline and visit handling.

05 Trial design domains
TA, TE, TV, TI and TS, subject visits and elements (SV, SE), and running Pinnacle 21 checks on SDTM.

06 ADaM principles & ADSL
Traceability and analysis-readiness, population flags, treatment variables and key dates in ADSL.

07 BDS, OCCDS & ADTTE
PARAMCD, AVAL and CHG, baseline flags, imputation rules, adverse event occurrence data and time-to-event.

08 Metadata & submission
define.xml 2.1, cSDRG and ADRG, validation issue resolution, and an end-to-end capstone study.

STANDARDS & TOOLS

SAS · SDTM v2.0 / SDTMIG v3.4 · ADaMIG v1.3 · define.xml v2.1 · CDISC Controlled Terminology · Pinnacle 21 Community

YOU TAKE AWAY

Course notes, the sample study data, mapping specs, SAS programs for every lab, and a define.xml template.

HOW THE WORKSHOPS RUN

Choose the format that suits your team

Open workshops

Join programmers and statisticians from other organisations in a scheduled batch.

In-house training

A private batch for your team, tailored to your SOPs, standards, data and tools.

Live online

Instructor-led sessions with shared lab environments, wherever your team is based.

EVERY WORKSHOP INCLUDES

- Hands-on labs in every module
- Course notes, datasets and code to keep
- Q&A with senior statisticians and programmers
- Small batches, so each participant gets support

YOUR NEXT STEP

Continue with Course 02, R Programming for Clinical Trials, to analyse and report the ADaM datasets you build in this workshop.

01 · SDTM & ADaM → **02 · R analysis & reporting**

ENQUIRE OR REGISTER

Ask us for upcoming dates, fees and in-house options.

EMAIL
connect@statsvia.com

PHONE
+91-9704623666
+91-9391934799

REGD. OFFICE
Plot No: 118, 1st Floor, Lakshmi Narasimha Puram Colony, Karmanghat, Rangareddy, Hyderabad – 500079