

Clinical Trial Informatics & eCRF Design (CDISC SDTM/ADaM) — Hands-on

Build audit-ready clinical data pipelines from protocol to analysis. This hands-on module covers eCRF design and EDC configuration, CDISC SDTM domain mapping, ADaM analysis dataset creation, metadata/traceability (define.xml, aCRF), edit checks and data queries, TLF shells, and governance aligned to 21 CFR Part 11 and GCP.

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Session 1

Fee: Rs 20120 [Apply Now](#)

Protocol → eCRF & EDC Foundations

From endpoints to forms

objective/endpoint mapping **schedule of assessments**
visit structure

EDC & eCRF design

form libraries & coding **edit checks & queries** **roles & audit trails**

Coding & dictionaries (overview)

MedDRA/WHO-DD units/controlled terms concomitant
meds, AEs

Session 2

Fee: Rs 24320 Apply Now

CDISC SDTM Domains & Mapping

SDTM essentials

IG/CT/ODM (high-level) DM, AE, EX, VS, LB
findings/events/interventions

Mapping from eCRF to SDTM

value-level metadata supplemental qualifiers relrec &
identifiers

QC & conformance checks

validator tools spec tables derivation logs

Session 3

Fee: Rs 28520 Apply Now

ADaM Datasets, Traceability & TLFs

ADaM structures

ADSL, ADAE, ADVS, ADLB BDS/ADTTE param/aval
framework

Traceability & metadata

from SDTM to ADaM analysis flags & derivations
programming specs

TLF shells & outputs

tables/listings/figures safety/efficacy endpoints
reproducible runs

Session 4

Fee: Rs 34120 Apply Now

Validation, define.xml & Compliance

Submission package & metadata

define.xml & aCRF **reviewer guides** **ADM/SDRG/ADRG**
notes

Validation & governance

conformance checks **change control & SOPs** **issue**
management

Regulatory readiness (overview)

21 CFR Part 11 **GCP & audit trails** **privacy & security**