Regulatory Submissions & Evidence Packages (FDA/EMA) — Hands-on

Deliver compliant, defensible submissions for precision medicine programs. This module walks you through regulatory pathways, eCTD dossier structure, CDISC (SDTM/ADaM) alignment, statistical analysis plans and TLF packages, validation and traceability for bioinformatics pipelines, and construction of benefit–risk narratives—ending with end-to-end mock inspections and Q&A strategy.

Regulatory Submissions & Evidence Packages (FDA/EMA)

Help Desk · WhatsApp

Session Index **Category 5 · Clinical & Translational Bioinformatics**

Session 1 — Pathways, Dossiers & eCTD | Session 2 — CDISC, SAP & TLF Packages | Session 3 — Validation, Traceability & RWE | Session 4 — Benefit–Risk & Inspection Readiness

Session 1

Fee: Rs 26120 Apply Now

Pathways, Dossiers & eCTD

Regulatory pathways (overview)

IND/IDE → NDA/BLA/De Novo/510(k) **EMA centralized/accelerated** **companion diagnostics touchpoints**

Dossier organization

CTD/eCTD modules (2–5) | technical vs clinical content | lifecycle/sequence management

Submission tooling

validators, publishing & granularity | hyperlinking/leafs/cover letters | meeting packages & Q-sub (overview)

Session 2

Fee: Rs 30320 Apply Now

CDISC, SAP & TLF Packages

Data standards & specs

SDTM domains & mapping | ADaM datasets & derivations | define.xml & reviewer's guide

SAP & analysis outputs

endpoints & estimands (overview) | TLFs & reproducible code | blind review & sign-off

Integrating omics & biomarkers

bioinformatics outputs → ADaM | traceable metadata & codelists | visualizations for reviewers

Session 3

Fee: Rs 34520 Apply Now

Validation, Traceability & RWE

End-to-end validation

programming/biostats QC | bioinformatics pipeline V&V | traceability & audit trails

RWD/RWE for submissions

data fitness & bias checks | protocols & sensitivity

dossier appendices

Governance & controls

provenance/ALCOA+ role-based access & sign-offs change management

Session 4

Fee: Rs 40120 Apply Now

Benefit–Risk & Inspection Readiness

Benefit–risk & narratives

efficacy/safety synthesis labeling considerations responses to RFIs

Mock inspections & Q&A

storyboards & SME prep evidence rooms & trackers CAPA follow-through

Post-submission lifecycle

supplements/variations PSUR/PBRER (overview) label updates & commitments