Clinical Data Standards — HL7 FHIR & CDISC (SDTM/ADaM) — Hands-on

Learn how clinical data standards such as HL7 FHIR and CDISC SDTM/ADaM provide common structures for exchanging and analysing genomics and clinical data. This module focuses on concepts, data models and mapping patterns so that bioinformatics and data teams can design outputs that are easier to integrate with clinical systems, trials and downstream analytics.

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Session Index

Session 1

Fee: Rs 8800 Apply Now

Clinical Data Standards Landscape

Why standards matter for clinical genomics data

interoperability across systems | **reuse of data across projects** | **regulatory and quality expectations snapshot**

Main families of standards in this space (high level)

HL7 FHIR for healthcare exchange | **CDISC SDTM and**

ADaM for studies terminologies and code sets snapshot

Where genomics pipelines meet standards thinking

sample and subject identifiers mindset results and interpretation structures audit trails and metadata concepts

Session 2

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HL7 FHIR Concepts for Genomics

FHIR basics and healthcare data exchange ideas

resources and profiles concepts patients, encounters, observations snapshot APIs and modular design mindset

Genomics related FHIR ideas (high level)

representing variants and tests conceptually linking patients, samples and results using codes and value sets snapshot

Design mindset for FHIR compatible outputs

stable identifiers and references capturing key attributes for mapping later simple examples of structured result rows

Session 3

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CDISC SDTM/ADaM Concepts for Studies

Why CDISC standards are used in clinical studies

regulatory submissions mindset (high level) consistent analysis ready datasets traceability from raw to analysis data idea

SDTM and ADaM at a glance

subject level and domain concepts | time points and visits snapshot | analysis dataset ideas

Thinking about genomics data in a CDISC aware way

subject and sample keys alignment | linking variant calls to study events | basic mapping tables mindset

Session 4

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Mini Capstone: Mapping Outputs to Standards

Start from a simple genomics and clinical output table

Theory + Practical

Draft a mapping sketch towards FHIR and SDTM/ADaM views

which fields map to which concepts | identifier and code alignment | metadata and provenance notes

Summarise design decisions and open questions

assumptions log | gaps and future improvements | handover notes for implementation teams