Advanced Biostatistics for Translational Research Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

This course addresses the critical need for advanced quantitative expertise in the rapidly evolving landscape of Translational Science. The journey from bench to bedside converting fundamental discoveries into practical clinical applications is fundamentally reliant on rigorous Biostatistical Modeling and data analysis. In the era of Big Data and Precision Medicine, researchers must move beyond foundational statistics to master methodologies that can handle high-dimensional data, complex study designs, and the inherent challenges of real-world evidence (RWE). Advanced Biostatistics for Translational Research Training Course is specifically designed to bridge the gap between theoretical knowledge and practical, high-impact application, equipping a new generation of scientists and data professionals to design, execute, and interpret studies that truly accelerate therapeutic development and patient care.

Our comprehensive curriculum dives deep into state-of-the-art statistical learning techniques and sophisticated Causal Inference methods essential for modern translational research. Participants will gain proficiency in analyzing challenging datasets from Genomics, Biomarker Discovery, and Adaptive Clinical Trials, focusing on creating robust, reproducible research protocols. We emphasize hands-on application using industry-standard software, focusing on the practical skills required to effectively navigate statistical challenges, select the most appropriate methodology for complex research questions, and communicate actionable insights to multidisciplinary teams. Successful completion of this course will directly enhance the rigor and impact of participant-led research, contributing to the organization's goal of transforming scientific data into meaningful clinical outcomes.

Programme Curriculum

Advanced Biostatistics for Translational Research Training Course

Introduction

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Course Duration

10 days

Course Objectives

1. Master the application of Generalized Linear Mixed Models for complex longitudinal data analysis.
2. Design and evaluate Adaptive Clinical Trials and Platform Trials for accelerated drug development.
3. Implement robust Causal Inference methods, including Propensity Score Matching and Instrumental Variables, for Observational Studies.
4. Develop and validate predictive models for Biomarker Discovery and Diagnostic/Prognostic Testing.
5. Analyze High-Dimensional Data from Omics using modern statistical techniques.
6. Apply advanced Survival Analysis models, including Competing Risks and Time-Dependent Covariates.
7. Utilize Machine Learning algorithms for complex data prediction and feature selection in a translational context.
8. Formulate and implement a Bayesian Inference approach for flexible study design and meta-analysis.
9. Ensure Rigor and Reproducibility in statistical analysis through transparent reporting and analytical pipelines.
10. Critically evaluate the statistical methodology and findings of peer-reviewed Translational Research literature.
11. Perform necessary Multiple Testing Corrections and control the False Discovery Rate (FDR) for large-scale hypothesis testing.
12. Translate complex statistical results into clear, actionable, and visually compelling insights for multidisciplinary teams and regulatory submissions.
13. Design statistically sound studies that address Diversity, Equity, and Inclusion (DEI) in patient populations and data collection.

Organizational Benefit

- Accelerated Translation Pipeline.
- Enhanced Research Rigor and Reproducibility
- Optimal Resource Utilization.
- Competitive Advantage in Precision Medicine
- Data-Driven Decision-Making

Target Audience

1. Clinical Research Scientists/Investigators
2. Biostatisticians and Computational Biologists
3. Data Scientists in Pharma/Biotech
4. Epidemiologists
5. Translational Medicine Managers
6. Medical Affairs and R&D Professionals
7. Regulatory Affairs Specialists
8. Post-Doctoral Fellows and Advanced Graduate Students in Health Sciences

Course Modules

Module 1: Foundations of Statistical Inference & Modeling

- Review of core statistical concepts
- Deep dive into Generalized Linear Models (GLMs) for categorical/count data.
- Model specification, selection criteria, and residual analysis.
- Introduction to Statistical Software (R/Python) for advanced analysis.
- Case Study: Comparing cancer incidence rates using Poisson regression across different population subgroups.

Module 2: Longitudinal & Clustered Data Analysis

- Understanding the structure of Correlated Data and its implications.
- Implementation of Generalized Estimating Equations (GEE).
- Mastering Linear and Non-Linear Mixed-Effects Models (LMM/NLMM).
- Modeling subject-specific Growth Curves and trajectories over time.
- Case Study: Analyzing patient pain scores over a six-month treatment period in a multi-site clinical trial using a mixed-effects model.

Module 3: Advanced Survival Analysis

- Review of Kaplan-Meier and Cox Proportional Hazards (PH) models.
- Handling Time-Dependent Covariates and non-proportional hazards.
- Modeling Competing Risks in clinical outcomes
- Parametric survival models
- Case Study: Predicting the time-to-event for a specific adverse outcome, accounting for a patient's subsequent transfer to another treatment arm.

Module 4: Causal Inference in Translational Research

- Introduction to the Potential Outcomes Framework and Directed Acyclic Graphs
- Implementation of Propensity Score Matching (PSM) and Weighting (IPW).
- Analysis using Instrumental Variables (IV) for unmeasured confounding.
- Introduction to Difference-in-Differences and regression discontinuity design.

- Case Study: Using PSM to assess the real-world effectiveness of a new therapy using an electronic health record (EHR) dataset.

Module 5: Adaptive & Novel Clinical Trial Designs

- Principles of Adaptive Trial Design
- Statistical methods for Interim Analysis and stopping rules
- Design and analysis of Platform Trials
- Understanding the regulatory and operational challenges of complex designs.
- Case Study: Simulating an adaptive trial design for an oncology drug, incorporating a pre-planned interim analysis for futility.

Module 6: Statistical Genetics & Genomics

- Statistical methods for Genome-Wide Association Studies (GWAS) and Fine-Mapping.
- Handling large-scale genetic data and population structure.
- Mendelian Randomization for exploring causal relationships between genetic variants and disease.
- Introduction to Differential Gene Expression Analysis (RNA-Seq).
- Case Study: Identifying genetic variants associated with drug response using a large, publicly available GWAS dataset.

Module 7: Predictive Modeling & Machine Learning I

- Principles of model building, bias-variance trade-off, and Cross-Validation.
- Advanced classification and regression using Elastic Net and LASSO for feature selection.
- Deep dive into Random Forests and Gradient Boosting Machines (GBM).
- Evaluation metrics beyond simple accuracy.
- Case Study: Building a predictive model to identify high-risk patients for readmission using a combination of clinical and socioeconomic variables.

Module 8: Machine Learning II

- Techniques for Clustering and patient subtyping.
- Dimension Reduction methods (PCA, t-SNE, UMAP) for data visualization.
- Model Interpretability (XAI).
- Introduction to concepts of deep learning
- Case Study: Using clustering to define new, statistically distinct sub-groups of a disease for targeted treatment.

Module 9: Biostatistics for Biomarker Discovery

- Design considerations for Biomarker studies
- Statistical methods for evaluating Diagnostic Accuracy
- Estimation and interpretation of Sensitivity and Specificity.
- Multivariate approaches for biomarker panel development.
- Case Study: Analyzing proteomic data to validate a new blood-based biomarker for early-stage Alzheimer's disease.

Module 10: Bayesian Biostatistics

- Fundamental concepts: Prior distributions, likelihood, and Posterior Inference.
- Introduction to Markov Chain Monte Carlo (MCMC) algorithms.

- Designing flexible Bayesian Clinical Trials
- Bayesian methods for Meta-Analysis and evidence synthesis.
- Case Study: Using a Bayesian approach to update the efficacy estimate of an existing drug based on new pilot study data.

Module 11: Real-World Evidence (RWE) and Data Fusion

- Statistical challenges and opportunities of using Real-World Data (RWD)
- Methods for handling Missing Data
- Statistical techniques for Data Harmonization and fusion across disparate sources.
- Addressing selection bias and generalizability in RWE studies.
- Case Study: Conducting a comparative effectiveness study using two different national patient registries, requiring data cleaning and bias adjustment.

Module 12: Rigor, Reproducibility, & Data Management

- Creating a robust Statistical Analysis Plan (SAP) for transparency.
- Best practices for Code and Data Management
- Strategies for ensuring Statistical Reproducibility
- Principles of Data Visualization for effective scientific communication.
- Case Study: Developing a fully reproducible analytical pipeline for a key efficacy endpoint, including the annotated code, data, and final report.

Module 13: High-Dimensional Data Techniques

- Adjusting for Multiple Testing and controlling the False Discovery Rate (FDR).
- Network and pathway analysis for interpreting Omics data.
- Introduction to statistical methods for analyzing Neuroimaging data
- Methods for analyzing complex Microbiome data
- Case Study: Applying FDR control to thousands of associations in a high-throughput drug screening experiment.

Module 14: Health Economics and Outcomes Research (HEOR)

- Statistical methods for quality-of-life (QoL) and patient-reported outcome (PRO) measures.
- Introduction to Economic Modeling and cost-effectiveness analysis.
- Statistical approaches for analyzing healthcare utilization data.
- Understanding Propensity Scores in the context of HEOR.
- Case Study: Analyzing patient survey data to determine the statistical significance of QoL differences between two treatment groups.

Module 15: Effective Communication & Regulatory Statistics

- Translating complex statistical findings for non-statisticians and Decision Makers.
- Best practices for presenting results in manuscripts and regulatory reports.
- Understanding the role of the biostatistician in regulatory meetings (FDA/EMA).
- Ethical considerations and statistical governance in translational research.
- Case Study: Drafting the "Statistical Methods" and "Results" sections for a mock New Drug Application (NDA) submission.

Training Methodology

- Interactive Lectures & Discussions.
- Hands-on Software Labs
- Real-World Case Studies
- Collaborative Project Work
- Consultation Simulation

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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