Biostatistics for Clinical Trial Design and Analysis 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

Biostatistics is the cornerstone of rigorous, evidence-based medicine, acting as the indispensable link between raw clinical data and actionable scientific conclusions. In the fast-evolving landscape of pharmaceutical and biotech research, the ability to correctly design, execute, and analyze clinical trials is paramount to regulatory success and patient safety. Biostatistics for Clinical Trial Design and Analysis Training Course will equip professionals with the cutting-edge quantitative skills necessary to navigate the complexities of modern trial methodology, from foundational statistical inference and sample size calculation to advanced techniques like adaptive design and survival analysis. Mastery of these core biostatistical concepts ensures that clinical research meets the highest standards of ICH E9 guidelines, maximizing statistical power and accelerating the path from drug development to market approval

This focused training is essential for fostering a data-driven culture within clinical research organizations, directly translating into optimized trial efficiency and reduced development timelines. As the industry shifts towards precision medicine and complex innovative designs, a deep understanding of biostatistics for clinical trial analysis is no longer optional but a critical competency. Participants will gain hands-on expertise in formulating robust Statistical Analysis Plans (SAP), managing missing data imputation, and interpreting complex results from Randomized Controlled Trials (RCTs). By strengthening internal capabilities in advanced biostatistics, organizations can ensure the scientific validity of their research, leading to high-impact publications, successful global regulatory approval, and ultimately, better patient outcomes.

Programme Curriculum

Biostatistics for Clinical Trial Design and Analysis Training Course

Introduction

Biostatistics is the cornerstone of rigorous, evidence-based medicine, acting as the indispensable link between raw clinical data and actionable scientific conclusions. In the fast-evolving landscape of pharmaceutical and biotech research, the ability to correctly design, execute, and analyze clinical trials is paramount to regulatory success and patient safety. Biostatistics for Clinical Trial Design and Analysis Training Course will equip professionals with the cutting-edge quantitative skills necessary to navigate the complexities of modern trial methodology, from foundational statistical inference and sample size calculation to advanced techniques like adaptive design and survival analysis. Mastery of these core biostatistical concepts ensures that clinical research meets the highest standards of ICH E9 guidelines, maximizing statistical power and accelerating the path from drug development to market approval

This focused training is essential for fostering a data-driven culture within clinical research organizations, directly translating into optimized trial efficiency and reduced development timelines. As the industry shifts towards precision medicine and complex innovative designs, a deep understanding of biostatistics for clinical trial analysis is no longer optional but a critical competency. Participants will gain hands-on expertise in formulating robust Statistical Analysis Plans (SAP), managing missing data imputation, and interpreting complex results from Randomized Controlled Trials (RCTs). By strengthening internal capabilities in advanced biostatistics, organizations can ensure the scientific validity of their research, leading to high-impact publications, successful global regulatory approval, and ultimately, better patient outcomes.

Course Duration

10 days

Course Objectives

1. Master the principles of ICH E9 (Statistical Principles for Clinical Trials) compliance.
2. Design methodologically sound Randomized Controlled Trials (RCTs), including blinding and control selection.
3. Calculate precise Sample Size and Power for superiority, non-inferiority, and equivalence trials.
4. Apply appropriate Statistical Inference techniques for various data types.
5. Develop comprehensive and transparent Statistical Analysis Plans (SAP) prior to database lock.
6. Execute Survival Analysis for time-to-event data.
7. Utilize Regression Modeling for primary and secondary endpoint analysis.
8. Evaluate and implement Adaptive Trial Designs for enhanced efficiency and flexibility.
9. Analyze Longitudinal and Repeated Measures Data using Mixed Models for chronic conditions.
10. Manage and effectively address issues of Missing Data using state-of-the-art imputation methods.
11. Conduct rigorous Interim Analysis and establish appropriate Data Monitoring Committee (DMC) stopping rules.
12. Interpret and communicate complex statistical results in Clinical Study Reports (CSR) and regulatory documents.
13. Integrate Real-World Evidence (RWE) and Bayesian Methods into contemporary trial design.

Target Audience

1. Clinical Research Scientists/Associates
2. Statisticians and Data Analysts in Pharma, Biotech, and CROs
3. Physicians and Medical Monitors involved in clinical trials
4. Regulatory Affairs Professionals focused on Biologics and Drugs
5. Clinical Data Managers seeking to understand analysis implications

6. Academic Researchers and Epidemiologists
7. Biomedical Engineers transitioning into clinical research
8. Independent Ethics Committee (IEC)/IRB Members

Course Modules

Module 1: Foundations of Clinical Trial Biostatistics

- Role of Biostatistics in Drug Development and Regulatory Submissions.
- Types of Data and appropriate Descriptive Statistics and Data Visualization.
- Introduction to Inferential Statistics, Hypothesis Testing, and Statistical Errors
- Understanding the ICH E9 Guideline and its impact on trial conduct.
- Case Study: Evaluating the statistical integrity and data presentation of a published Phase I/II oncology trial.

Module 2: Principles of Randomized Controlled Trials (RCTs)

- Randomization, Blinding/Masking, and Placebo/Active Control selection.
- Parallel, Crossover, Factorial, and Group-Sequential.
- Defining the Primary Endpoint and Analysis Population
- Methods for implementing different Randomization Schemes
- Case Study: Designing a Phase III parallel-group trial protocol, focusing on a robust randomization schedule and blinding strategy.

Module 3: Sample Size and Statistical Power

- Factors influencing Sample Size Calculation
- Formulas for Continuous and Binary outcomes.
- Non-Inferiority (NI) and Equivalence Trials sample size justification.
- Practical use of Statistical Software for power analysis.
- Case Study: Calculating the required sample size for a non-inferiority trial comparing a new drug to a standard of care for a cardiovascular endpoint.

Module 4: Core Inferential Statistical Methods

- Application and interpretation of T-tests and ANOVA for continuous data.
- Application and interpretation of Chi-square and Fisher's Exact Tests for categorical data.
- Understanding P-values and Confidence Intervals (CIs) in the context of clinical significance.
- Handling Multiple Comparisons and using Adjustment Methods
- Case Study: Analyzing primary efficacy endpoints using ANOVA from a trial with three different treatment arms.

Module 5: Simple and Multiple Linear Regression

- Assumptions and application of Simple Linear Regression for continuous outcomes.
- Introduction to Multiple Linear Regression for controlling Confounding Variables.
- Interpreting Regression Coefficients and Model Diagnostics.
- Use in ANCOVA for baseline adjustment and increased statistical power.
- Case Study: Developing a linear regression model to predict patient response based on baseline biomarkers and age.

Module 6: Binary Outcomes and Logistic Regression

- Modeling Binary Outcomes in clinical trials.
- Simple and Multiple Logistic Regression and its interpretation
- Assessing Model Fit and using ROC Curves for diagnostic performance.
- Calculating and reporting Risk Ratios and Number Needed to Treat.
- Case Study: Using logistic regression to determine the impact of a drug on the probability of treatment success

Module 7: Introduction to Survival Analysis

- Handling Time-to-Event Data and the concept of Censoring.
- Kaplan-Meier Curves and the Log-Rank Test.
- Introduction to the Cox Proportional Hazards (PH) Model.
- Checking the Proportional Hazards Assumption.
- Case Study: Analyzing survival data in an oncology trial to compare two chemotherapy regimens and generate a Kaplan-Meier plot.

Module 8: Advanced Survival Modeling

- Advanced concepts in the Cox PH Model
- Parametric Survival Models and their applications.
- Modeling Competing Risks in clinical research.
- Advanced techniques for handling Delayed Effects and Crossover.
- Case Study: Applying a Cox PH model in a heart failure trial, adjusting for pre-specified baseline risk factors.

Module 9: Longitudinal and Repeated Measures Data

- Characteristics of Longitudinal Data
- Modeling correlation and using Generalized Estimating Equations.
- Introduction to Linear Mixed Models for repeated measures analysis.
- Comparing different Covariance Structures in mixed models.
- Case Study: Analyzing patient-reported pain scores collected weekly over a six-month chronic pain trial using a Mixed Model.

Module 10: Missing Data Strategies

- Understanding Missing Data Mechanisms
- Last Observation Carried Forward (LOCF) and Complete Case Analysis.
- Multiple Imputation (MI) and Maximum Likelihood (ML).
- The role of Sensitivity Analysis to missing data assumptions.
- Case Study: Performing Multiple Imputation on a large-scale dataset with dropouts and assessing the impact on the primary outcome.

Module 11: Statistical Analysis Plan (SAP) Development

- Structure and critical components of a comprehensive Statistical Analysis Plan.
- Defining the Statistical Methods for primary, secondary, and exploratory endpoints.
- Pre-specifying rules for Protocol Deviations and Subgroup Analysis.
- Ensuring the SAP aligns with the Clinical Trial Protocol and regulatory requirements.
- Case Study: Developing a complete SAP template for a Phase II infectious disease prevention trial.

Module 12: Data Monitoring and Interim Analysis

- Purpose and function of the Data Monitoring Committee (DMC) or DSMB.
- Principles of Interim Analysis for efficacy, futility, and safety.
- Implementing Stopping Rules and Alpha Spending Functions.
- Statistical considerations for Safety Reporting and Adverse Event (AE) monitoring.
- Case Study: Simulating an interim analysis on trial data and determining if a pre-specified stopping boundary has been crossed.

Module 13: Innovative Clinical Trial Designs

- Introduction to Adaptive Design methodologies
- Understanding Master Protocols
- Overview of Dose-Escalation designs in Phase I trials.
- Statistical challenges and benefits of Bayesian Methods in clinical trials.
- Case Study: Evaluating the trade-offs of using an adaptive design versus a fixed-sample design for a drug with high uncertainty in effect size.

Module 14: Practical Statistical Programming Workshop

- Introduction to Statistical Software for clinical trial analysis.
- Data Import, Manipulation, and Cleaning techniques.
- Running and interpreting key statistical tests and regression models.
- Generating Regulatory-Ready Tables, Listings, and Figures.
- Case Study: Hands-on session performing an end-to-end analysis from a simulated dataset, including data cleaning and final report generation.

Module 15: Interpretation and Reporting

- The CONSORT Statement and its role in transparent trial reporting.
- Structure and content of the Clinical Study Report.
- Effective communication of Statistical Uncertainty and Clinical Significance.
- Guidelines for presenting results to Regulatory Authorities and scientific journals.
- Case Study: Critically reviewing a draft CSR to ensure statistical conclusions are accurately and transparently represented.

Training Methodology

The course employs a Blended Learning approach, integrating:

1. Interactive Lectures and Discussion.
2. Hands-on Software Workshops.
3. In-Depth Case Studies.
4. Group Protocol & SAP Development.
5. Q&A/Troubleshooting Sessions.

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
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

Ready to enroll or request a customized program? Book online or contact us:

Register Online Now

Email: info@fineskilltrainingcenter.com | Website: www.fineskilltrainingcenter.com