



## Biostatistics.

Premier Research's biostatisticians, biostatistical programmers, and pharmacokineticists understand that well designed studies with appropriately planned and communicated data analyses are the key to obtaining clinical trial results that support development of your compound or device.

### Services

- Regulatory Statistical Consulting and Representation
- Integrated Clinical/Statistical Development Planning
- PK/PD Model Development and Analysis
- Design and Analysis of Clinical Trials
  - Study Design and Analysis Planning
  - Statistical Analysis Plans
  - Sample Size Calculations and Simulations
  - Statistical Methods for Protocol
  - Protocol and CRF Consultation and Review
  - Randomization Schedules
  - Interim Analysis and DMC Support
  - Statistical Programming and Modeling
  - Table, Listing and Figure Generation
  - Statistical Reports (CSR, Manuscripts, IB)
- Design and Analysis of Observational, Registry, and Rx-to-OTC Switch Studies
- Health Outcome, Pharmacoeconomic, and Quality of Life Analyses
- Large-Scale Data Warehousing and Integration
- ISS/ISE Planning, Analyses, and e-Submissions
- DMC Support and Participation
- CDISC Compliant Dataset Development
- Manuscript Preparation and Meeting Presentations
- Marketing Support

### Benefits

- Strong technical expertise and experience gives you confidence that your data will be rigorously analyzed and effectively communicated for greatest impact
- Significant therapeutic experience ensures greater understanding of the nuances of clinical data in specific indications
- Availability of full-service and stand alone support models tailored to provide an optimal fit to enhance your development team dynamics
- Our record of successful performance in large, complex projects provides assurance of our ability to meet the challenges of your development program
- Broad-ranging expertise and experience in applied statistical methods provides many options for the effective and cost-efficient analysis of clinical data
- Using our Parallel Processing Approach™, biostatistical activities are directly integrated with staged progress of database set-up, data entry, shell report development and generation of tables, listings and figures

### Case Study: Providing High Quality Data Analysis

A client contracted the Premier Research biostatistics team to deliver high quality data analysis and communications of study results for a comprehensive drug development program of 17 studies that were submitted for regulatory approval.

Our team of five biostatisticians and nine biostatistical programmers delivered seven locked databases over a seven week period of time, with top line study results delivered to the sponsor within one week and comprehensive tables, listings, and graphs delivered within two weeks of database lock to support this drug development program. The work included a comprehensive safety analysis, efficacy analyses of patient reported outcomes, pharmacokinetic and pharmacodynamic data analyses, and completion of a Through QT Prolongation (TQT) study.

The biostatistics team collaborated with colleagues in data operations, medical writing, and the sponsor to deliver the complete biometrics package for this client resulting in a successful approval.

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Our biostatisticians work with you to determine the optimal cost effective methods for collecting, analyzing, and presenting data while maintaining compliance with regulatory guidelines. Our programmers create customized tables, optimized for unique study designs.

## Expertise: The People

- Biostatistics professionals with an average of 10 years in the industry
- All biostatisticians have advanced degrees
- Technical expertise in biostatistical programming and a broad range of applied statistical methods
- Technical expertise in the design, conduct, and analysis of PK/PD, toxicokinetics, and exposure-response study analyses
- Strong study design and analysis, consulting and communications, and submission experience

## Designs

- Frequentist
- Group Sequential and Adaptive
- Equivalence
- Noninferiority
- Superiority
- Case-control Epidemiology Designs

## Methods

- Descriptive Statistics and Univariate Analyses
- Linear and Nonlinear Models
- Generalized Linear Models/Mixed Linear Models
- Categorical Data Analysis
- Event Time Distribution Models
- Nonparametric Models
- Imputation Strategies/Sensitivity Analyses
- Non-compartmental and Compartmental PK/PD Models
- Nonlinear Mixed Effects Models (Pop PK)
- Risk Assessment Models
- Integrated Summaries and Pooling Analysis Methods
- CDISC Compliant Analysis Data Modules (ADaM)

## Case Study: Providing Integrated Summary of Safety for an NDA

The Premier Research biostatistics team was contracted to provide an Integrated Summary of Safety (ISS) for an NDA submission. The timeline for the submission was four months from contract initiation. Our biostatisticians, collaborating with regulatory affairs, data operations, medical writing, and biometrics project management, integrated studies from external vendors with the studies completed by Premier Research to complete the ISS and write the clinical modules for the eCTD NDA for submission.

This work included meeting with the FDA in a pre-NDA meeting, weekly meetings with the sponsor, as well as external vendor management. Our team of three biostatisticians and six biostatistical programmers completed the ISS Statistical Analysis Plan with comprehensive pooling strategies, development of the CDISC compliant Analysis Data Modules (ADaM), table, listing and figure development, programming and validation, as well as supported the medical writing team to complete the eCTD clinical modules. The NDA was submitted on-time to the FDA.



## Premier Research

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