Axio
PARTNERS IN RESEARCH

Biostatistics Planning & Management

Our Biostatistics services include:

- Protocol development and/or review
- Sample sizes for trials or assay validations
- Randomization schema, including adaptive and seamless designs
- Epidemiological and observational studies
- Instrument development and validation
- SAS programming
- Data Monitoring Committee (DMC) support
- Ad hoc statistical consulting

Axio provides a full range of **statistical analysis and programming** capabilities for **all stages of clinical development**. Our highly trained **PhD/MS biostatisticians** collaborate with our clients on optimal design, implementation, evaluation, and reporting on all phases of the clinical development program. Our specialists can also provide **statistical guidance** and **representation at FDA meetings**. Our biostatisticians apply deep experience in **multiple disciplines** and are active in the professional and academic community, attending FDA and ASA meetings; participating in courses and webinars; preparing abstracts, manuscripts, and other communication materials; and giving presentations at scientific sessions.

Our biostatisticians bring accomplished and eclectic experience in multiple disciplines including medicine, health economics, toxicology, pharmacokinetics, epidemiology, bioinformatics, and data management system design across all major therapeutic areas, including oncology, cardiovascular disorders, and inflammatory diseases.

The keystones of quality clinical trial results

Statistical Techniques:

The experience we will bring to your specific project is deep and far-reaching. The many techniques in which our biostatisticians excel include:

- Longitudinal models
- Generalized estimating equations
- Mixed-effects models
- Accelerated failure time and time-dependent proportional hazards models
- ANOVA
- ROC curve regression
- Time series, ordinal, and categorical logistic regression
- Multiple imputation techniques
- Poisson regression
- Propensity score matching
- Spatial statistics
- Financial risk models
- Bayesian cost-effectiveness models

We have the flexibility and capacity to respond rapidly to the changing requirements of our clients, whether working with small companies on a project basis or supplementing the in-house staff of larger companies.

Interim Monitoring
Tackling interim-monitoring plans requires highly specific expertise. Our biostatistical specialists will consult with you to resolve the complexities. We can provide you with an array of interim-stopping boundary possibilities that are commensurate with the clinical question and enrollment achievability of your trial objectives. In addition to efficacy boundaries, we can prospectively run through the range of scenarios available to your study for predetermined safety-stopping rules.

Study Designs
Axio biostatisticians have an extensive track record consulting on all types of study designs. We have a close relationship with the University of Washington, where much of the methodology for adaptive trial design was developed, and many of our biostatisticians studied alongside the biostatisticians who developed these methods. Adaptive designs allow consideration of factors such as a changes in event rates with advances in medicine during an ongoing study—but also present some difficulties with interpretation of results. We can help.

Submission Documents
Producing final statistical reports and integrated summaries of efficacy and safety can be an enormous undertaking. Let Axio take the lead. The dedicated team of experts we assemble will thoroughly know your protocol and your data.

Axio respects your deadlines. When we work in concert with other clinical research organizations (CROs) or individuals whose contributions affect your timeline, we will remain committed to helping you keep your study or submission on track.

Preclinical Biostatistics
Axio biostatisticians can advise on and develop a statistical analysis plan that is right for your unique study or compound. Our specialists have experience with parametric and non-parametric statistical analyses in the full range of good laboratory practice (GLP) and non-GLP studies, including General Toxicology, Developmental and Reproductive Toxicology (DART), Immunotoxicology, Carcinogenicity, and Cardiovascular and Respiratory Safety.

Attractive, Concise Data Presentation
Recent industry trends suggest using graphics as a means to reduce lengthy reports by displaying information in a clear and more concise manner. Axio's statistical graphics team focuses on forward-thinking approaches using current software capabilities. This allows for seamless graphics creation, avoiding the need for exporting data between various software packages, with graphics created in the same manner as other tables or listings. Our graphics capabilities include:

- Forest plots for safety and efficacy outcomes
- Scatter plots for continuous data
- Series plots for continues data over time
- Horizontal and vertical bar charts for discrete data
- Spaghetti plots to show population trends over time
- Panel plots to show multiple displays on a single page
- Matrix plots to show associated trends in continuous covariates

Special Services
We understand how your trial's endpoint selection critically impacts sample size, clinical event monitoring, and final analysis of your trial. Axio's team will carefully consider adjudicated endpoints, composite endpoints, and other special approaches early in your development program. For example, we are skilled at utilizing special survival analysis models to account for late-treatment effects.

Axio's biostatisticians have advised sponsors on modeling approaches that have helped to save their studies; for example, accruing a minimum number of events, broadening the endpoint, increasing enrollment, minimizing dropouts and loss to follow up, and initiating enrichment strategies to enroll more people prone to an event.

Randomization Services
If it can be accomplished, we're the experts to turn to: Axio's biostatisticians can create and recommend randomization schemes that accomplish the ends of your trial and avoid imbalances whenever possible. Our team will carefuly consider the statistical ramifications of using blocks, strata, or baseline and response-adaptive techniques in advance of your trial.

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