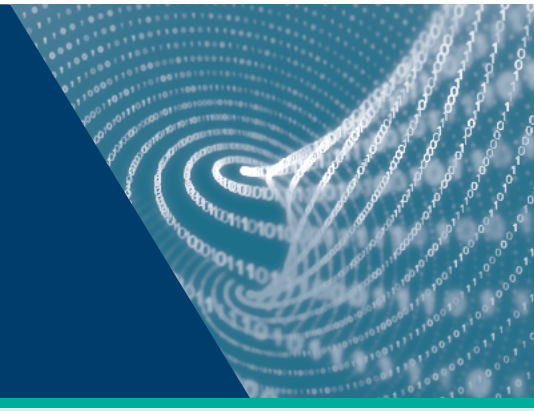
Study Designs and Statistical Analysis Methodology for Clinical Trials



Westat provides clients with innovative, comprehensive study design and statistical analysis services. We provide solutions to meet the needs of a wide variety of products in various stages of the clinical development pipeline and to support regulatory submissions.

SERVICES

- Provide innovative and adaptive study designs and analyses
- Consult and advise on selecting clinical endpoints and estimands
- Provide sample size and power estimates
- Develop statistical analysis plan
- Manage and coordinate data safety and monitoring committees
- Produce data outputs for clinical study reports; assist with interpretation

Our Expertise

Westat's protocol design and statistical staff have expertise in three areas critical to the success of product development—biostatistics, regulatory science, and clinical research. This multidisciplinary approach to study design and statistical analysis means that trials are designed to efficiently meet all scientific and regulatory objectives.

Our experts stay ahead of industry trends, practices, and regulatory precedents, which helps us give our clients the edge in bringing products through development and to the market. We understand the critical need to design trials that are informative to product stakeholders without sacrificing quality and trial integrity.

Our comprehensive services in protocol design and development as well as data analysis include developing the synopsis and full protocol document.

Statistical Best Practices

Propose innovative solutions to expedite and optimize study designs for high probability of success

- Conventional parallel group comparative RCT designs (superiority, equivalence, non-inferiority)
- Cross-over designs
- Master protocols (umbrella, basket, platform designs)
- Observational studies (exploratory, registry, real-world data)
- Meta-analysis
- Adaptive designs

Select appropriate statistical methods, techniques, and tools (frequentist, non-parametric, Bayesian)

- Confirmatory, exploratory, hypothesis-generating, proof-of-concept analysis
- Matching of analysis with type of clinical endpoint or variable (continuous, binary, categorical, ordinal, count, longitudinal, re-peated measures)
- Sample size optimization with required/allowable Type I and II errors
- Simulations planned and run to inform study designs

Justify and validate choice of statistical methodology, tools/ models used to analyze data and interpret results

- Test and demonstrate adequate satisfaction of assumptions of statistical models
- Account for potential biases in study
- Account for missing data
- Account for multiplicity
- Summarize, interpret, and report results of statistical analysis (to support clinical study reports and scientific publications)

CONTACT

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