

Biostatistical Services

Excellence in biostatistics is the foundation for accurate clinical research results. With more than 25 years of experience, NERI employs one of the largest and most seasoned statistical groups in the Northeast. These talented biostatisticians offer an unmatched breadth and depth of experience in all aspects of clinical research study design, data analysis, and results interpretation. All of NERI's biostatisticians have advanced degrees and average 11 years of experience and 6 years of tenure. These dedicated professionals provide meticulous expertise in areas such as:

- Clinical trial design, including adaptive and cluster unit trials
- Design and analysis of complex surveys
- Instrument design, development, and pre-testing
- Data quality control
- Longitudinal analysis
- Categorical data analysis
- Methods for handling missing data
- Mixed model analytic methods
- Patient selection/randomization
- Propensity score methodology
- Reliability and validity assessment
- Sequential monitoring of trials
- Survival analysis

“At NERI, biostatistics is a true passion. Those of us who work in this challenging field view it as very creative, interesting, and solutions-oriented. Our approach is to find and implement the simplest and most direct methods for addressing a sponsor's clinical research question.”

Anne M. Stoddard, ScD

Director, Statistical Analysis
and Research

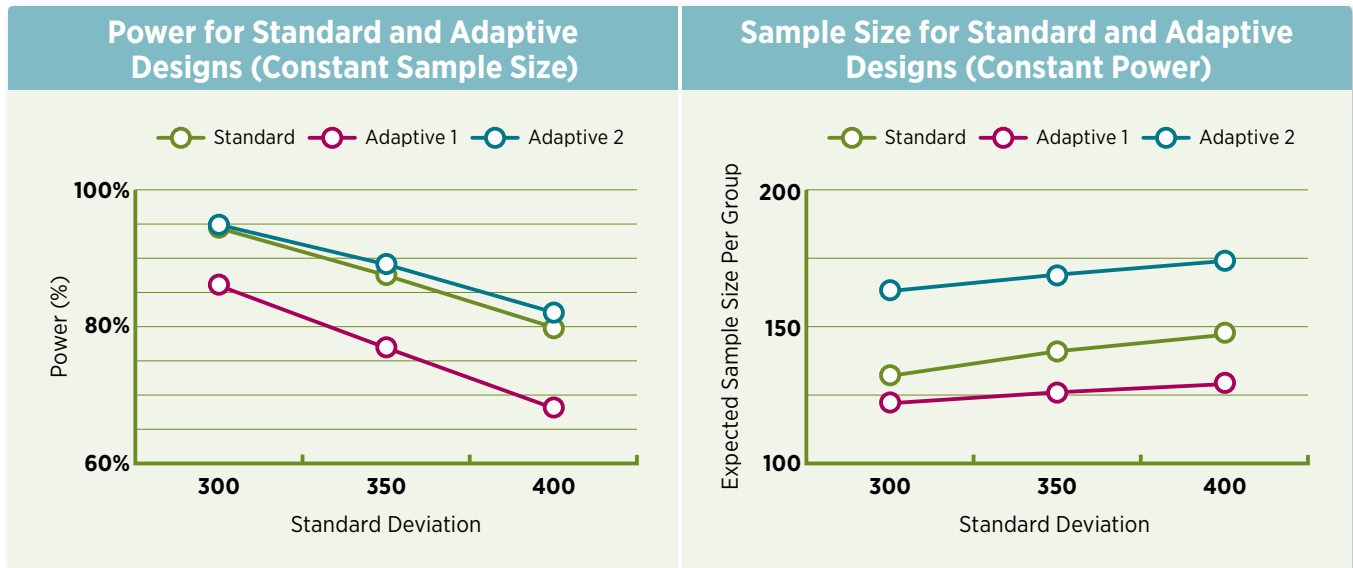
CASE STUDY: Standard versus Adaptive Design Simulation

Clinical trial simulation is one tool that NERI biostatisticians use to increase clinical success rates while reducing overall development time and cost. In one particular case, NERI helped a sponsor choose between a Standard and an Adaptive Trial Design for a Phase III study. The answer was not immediately evident for two key reasons:

1. Little prior information to estimate the standard deviation in each treatment arm
2. No information to help determine which design would provide the best ratio between statistical power and expected sample size

NERI used Clinical Trial Simulation to run multiple Adaptive Design scenarios to determine that:

- Adaptive Design #1 provided an attractively lower sample size than Standard, but the power was unacceptably low
- Adaptive Design #2 provided a slightly better power than Standard, but a larger and more expensive sample size
- **Standard Design was the optimal choice for the study**



Global Services

- Phase II – IV, Registries
- Study Feasibility
- Protocol Design
- Project Management
- Regulatory Affairs
- Site Selection, Recruitment, and Management
- Clinical Monitoring and Training
- Data Management
- Biostatistics
- Quality Assurance

Specialized Capabilities

- Drug, Biologics, Biomaterials, and Medical Device Studies
- Pediatric, Elderly, and Orphan Indication Studies
- Biomarker Studies
- Complex Instrument Design, Development, and Pre-Testing
- Biologic Specimen Collection and Tracking
- Biologic Specimen Repository Set-Up and Management
- Complex Data Extraction and Cleaning
- Proprietary CTMS/EDC
- Proprietary IVRS/IWRS

To learn more about NERI's Biostatistical Services, please contact our Business Development Department:

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