

CTSC Services Catalog

Biostatistics

Biostat Consultation - General	Conduct a preliminary discussion to determine the scope and needs of a specific project.
Study Design/Protocol Development	<p>A proper study design is critical for ensuring that the data collected in a study will support a defensible evaluation of a study's aims. Through this service, a biostatistician will work with an investigator to design a study, including, as appropriate,</p> <ul style="list-style-type: none"> • determining the structure of the study (e.g., two-arm study, case-control study, cross-over, etc.), • defining the control population, • clarifying inclusion and exclusion criteria, • establishing randomization procedures, • developing matching criteria and/or strata, and • specifying interim analysis procedures. <p>The statistician will write relevant sections of the grant or protocol. Please allow at least 6 weeks prior to the submission date for assistance with study design/protocol development.</p>
Sample Size/Power Calculations	<p>Research studies and clinical trials need to have a sufficient, but not excessive, number of subjects to be able to detect a meaningful change in the primary outcome of interest. Through this service, a statistician will determine the number of subjects needed to assess a study's primary aim at an appropriate level of statistical power. It is advisable to engage a biostatistician in developing the study design, defining outcome measures, and other aspects of the proposal, and not just with a sample-size calculation.</p>
Grant Proposal Preparation	<p>Grant proposals typically require several sections specifically involving statistics, such as the sample size justification and a statistical analysis plan detailing the methods that will be used to evaluate the primary and secondary aims of the study. A biostatistician can assist in preparing these sections of a grant proposal by working with the investigator on all aspects of grant proposal development, including</p> <ul style="list-style-type: none"> • refining the study's specific aims, • developing the study design, • determining sample size requirements, and • preparing a statistical analysis plan. <p>The biostatistician will prepare the relevant sections of the grant proposal. Please consult with the CTSC Biostatistics Core at least 6 weeks prior to the submission deadline for a grant proposal.</p>
Statistical Analysis Plans	<p>Statistical analysis plans describe the statistical methods that will be used to evaluate the hypotheses of a study. Typically, these plans are prepared as part of a grant proposal or clinical trial protocol. Through this service, a CTSC biostatistician will develop a plan for statistically analyzing an investigator's study questions and communicate this plan to the investigator either verbally or through a written plan.</p>

Data Collection and Data Management Guidance	Identifying what data to collect and how to store and manage the data are important to define prior to initiating a research study or clinical trial. Under this service, a biostatistician will work with an investigator and biomedical informatics staff to identify what data to collect in a study, develop a data dictionary, and define the database structure. These tasks are important for ensuring that the data necessary for assessing a study's aims are collected and are stored in a manner conducive to conducting the proposed statistical analyses.
Data Safety and Monitoring Board (DSMB) Participation	A biostatistician will serve on the DSMB for your clinical trial and conduct statistical assessments defined in the study protocol for the DSMB.
Statistical Analysis and Interpretation of Data	A biostatistician will work with an investigator to analyze study data and interpret the results. The statistician will <ul style="list-style-type: none"> • develop a statistical analysis plan that addresses the study aims, • conduct the analyses, • prepare graphs and tables to illustrate the findings, and • provide a written report of the analytical methods and results to the investigator.
Manuscript Preparation and Review	A biostatistician will prepare a description of the statistical analyses conducted, describe the results of the study and provide figures and tables as necessary to illustrate the results. This service is typically limited to projects for which the biostatistician has conducted the data analysis for the project.
Response to Reviewer Comments	Biostatisticians can assist investigators in responding to reviewer comments involving statistics. Under this service, the biostatistician will review the submitted manuscript and reviewer comments, and provide input to the investigator on how to respond to the comment.
Statistical Advice	For investigators conducting their own analyses, biostatisticians are available to provide advice. This service is appropriate for investigators with a focused, one-time question. Investigators may also select this service if they need help defining what statistical services they need.