

Biostatistician Services: Overview

- Study design
- Sample size/power calculations
- Statistical analysis plans
- Statistical analyses
- Final products

Study Design

- Type of study:
 - Prospective
 - Retrospective
 - Observational or Experimental
 - Longitudinal
 - Chart/Database Review
- Well-defined specific aims and endpoints

Study Design

- Database design (**IMPORTANT**)
 - REDCap
 - Access, Excel, et cetera
- Discussing the details in the planning stage is eye-opening for many investigators
- *You may also want to talk about data management*

Sample Size/Power Calculations

- “How many subjects do I need?”
- Bring to your meeting:
 - Idea of effect size
 - Baseline/control group mean and standard deviation or equivalent
 - Expected mean and standard deviation of experimental group or equivalent (*ideal*)
 - or-
 - Percent change and estimate of variability
- Papers describing similar studies (content or design)
- Preliminary studies or data, if available

Statistical Analysis Plans

- Statistical analysis plans for
 - Proposals
 - IRB applications
 - Protocols
- Usually just 1-2 paragraphs + sample-size justification, but more complex studies may require stand-alone, detailed statistical analysis plans (e.g., RCTs seeking FDA approval)

Statistical Analyses

- Should be pre-specified in proposal
- Descriptive statistics
- T-tests
- ANOVA
- Chi-square tests
- Non-parametric analyses
- Regression modeling
- Graphics

Final Products

- Statistical analysis sections for manuscripts
- Graphics for manuscripts/presentations
- Tables for manuscripts*
- Comprehensive manuscript review for content*

*Not every biostatistician will provide these services while others may, time permitting.

Initial Meeting

- To your first meeting, bring
(you may not have all of these)
 - Draft proposal
 - Supporting papers
 - Supporting pilot data
 - Estimate of effect size
 - Questions
 - Your (estimated) deadlines

What to Expect: Initial Meeting

- If you have already collected data without seeking biostatistical advice, expect
 - A lot of questions from the biostatistician!
 - Requests for considerable data clean-up on your behalf.
 - The possibility that the data you have collected may not answer the question(s) intended.
- Data must be de-identified.
- Discuss time frame & deadlines.

What to Expect:

Subsequent Meetings

- Some biostatisticians expect
 - You to sit with them while they do the analysis
 - To do analysis on their own after consulting with you
 - A combination of the two

Plan Ahead

- *Do not collect data until you have IRB approval.* If possible, include the CTSC biostatistician as an investigator.
- New NIH guidelines require IRB approval *before* submitting grant proposals
- Statistical analysis takes time, and can take much longer than you might expect.
- Biostatisticians are usually working on 10-15 concurrent studies. Everyone wants results ASAP.
- Biostatisticians are faculty members who have other duties:
 - Teaching
 - Work at the VA
 - Only partial FTE in CTSC
 - Their own research

Plan Ahead

- Provide sufficient lead time.
- General time guidelines:
 - Grant submission with basic statistical support: **1 month**
 - Grant submission with major statistical collaboration: **3 months**
 - Grant submission with multiple projects: **4 months**
 - Letter of support for grant: **1 week**
 - Statistical analysis: **varies widely**

When to Schedule a Meeting

- Initially, during the design phase of your study
- When you have your database designed to discuss structure
- When you have finished data collection
- As requested by the biostatistician