Primary Statistical Service

A typical example of how BioSTAT's statistical services are integrated into a CRO project.

1. **Protocol Development**
   BioSTAT reviews protocol and, if necessary, develops a statistical analysis plan customized for a unique study design, data attributes, or sponsor and regulatory requirements

2. **CRO Conducts the Study and Collects the Data**
   CRO conducts the study and collects data via in-house data management software

3. **In-House Statistical Analysis Software**
   CRO conducts "standard" data analyses via internal resources such as third-party software (eg. Provantis®, Pristima®)

4. **Unique/Complex Data Analyses**
   Data requiring analysis beyond the scope of internal resources are exported to BioSTAT.

   - Single-use analysis programs are developed in SAS®
   - Customized presentation tables, figure and listings are developed
   - Comprehensive statistical summary report is created
   - Independent Quality Control Statistician verifies results of statistical analysis
   - QC'd statistical analysis report is audited by BioSTAT QAU

5. **CRO Study Report**
   Audited BioSTAT statistical analysis report is included in the final study report

6. **Follow-up**
   BioSTAT remains available to address CRO, sponsor or regulatory statistical questions

Additional Services

In addition to providing unique/complex analyses, BioSTAT also offers the following services:

- Statistical Education for Non-Statisticians
- Statistical Analysis Phase Audits
- Statistical Analysis Phase Monitoring