STATISTICAL PHASE MONITORING

THE ISSUE

Study monitors provide oversight of outsourced non-clinical studies at contract research organizations (CROs). However, most study monitors lack the training to evaluate the technical intricacies of the statistical phase of a study.

Not all CROs include a statistician on the pre-clinical team. Including a statistician from the planning through reporting phases is a cost-effective means to assure the integrity of a study. To save money, most CROs provide statistical analysis services through third party packaged software or project-specific customized programs. Third party software is often inflexible to unique study designs and reliant on the user's knowledge. Often times the user is not adequately trained in statistics and ill-equipped to make correct statistical choices. Customized project-specific software may be deficient in QC and QA which may lead to costly errors due to inaccurate interpretation of study results.

If studies are being conducted across multiple CROs there may be differences in statistics and reporting of analysis results across laboratories. Non-clinical drug development programs using a statistical monitoring service can ensure that all studies are analyzed in a consistent, standardized manner.

OBJECTIVE

To provide independent monitoring of the statistical phase of a non-clinical study.

SCOPE

Partnering with the study sponsor, a BioSTAT GLP trained statistician will leverage his/her statistical and best practices knowledge to assure the appropriateness, validity, and execution of the statistical phase of a study conducted by a CRO or external source.

- Collaborate with sponsor statisticians, if any, to manage statistical oversight
- Collaborate with study monitor to ensure best statistical practices are being followed
- Evaluate the CROs in-house statistical capabilities including software
- Consult on study design including sample size, randomizations, choice of endpoints
- Assure that protocol statistical analysis plan reflects study objective
- Review accuracy of interpretation of statistical analysis results in the study report
- Ensure statistical analyses are performed consistently across CROs
- If required, conduct an audit of the statistical analysis phase (see below)

STATISTICAL ANALYSIS PHASE AUDIT

In general, quality assurance personnel lack the training to conduct a comprehensive audit of the statistical phase of a non-clinical study. This is particularly true when statistical analysis services are provided via project-specific customized programs such as SAS®. The CROs audit may simply consist of confirming that program output is accurately reported in report tables. But this "audit" does not validate the accuracy of the program code. BioSTAT's comprehensive statistical audit assures that the statistical analysis phase complies with relevant GLP and SOP requirements and that the protocol methodology is accurately executed.