STATISTICAL ANALYIS PHASE AUDIT

OBJECTIVE: For BioSTAT Quality Assurance (QA) to conduct a comprehensive audit of the statistical analysis phase of a study

SCOPE

- Compliance with applicable Good Laboratory Practice (GLP) regulations
- Adherence to applicable Standard Operating Procedures (SOPs)
- Review of the Statistical Analysis Report, including verification of protocol requirements
- Execution of BioSTAT's Statistical Quality Control (QC) Process

RECEIVABLES

From *Testing Facility*:

- Signed protocol and amendments
- Audited data file(s)
- Any additional documentation required to conduct the statistical analysis

From *Contributing Scientist (CS)/Principal Investigator (PI)*:

- Relevant SOPs including. but not limited to
    - Data management and security
    - Software validation
    - Data retention and archival
- Statistical Analysis Report

BIOSTAT STATISTICAL QC PROCESS

To confirm correct execution of protocol statistical methodology, a GLP-trained statistician will:

- Construct SAS® analysis dataset(s) from the received data file(s)
- Construct SAS® programs to execute the protocol statistical analysis methodology
- Confirm the statistical analysis details reported by CS/PI including:
    - Descriptive statistics (e.g. mean, standard deviation, n)
    - Derived analysis parameters (e.g. corrected QT Interval)
    - Inferential analysis results accurately reflect the protocol planned statistical methodology (e.g. p-values, least square means, significant "flags")
    - Text describing inferential analysis results accurately reported
- Provide a summary of completed statistical QC to QA

DELIVERABLES

- QA Report identifying findings and/or comments communicated to the CS/PI, as well as Study Director, Study Director Management, and Quality Assurance Lead
- QA Statement for inclusion in the Final Study Report
- Archival of QA records generated as a result of the statistical analysis phase audit