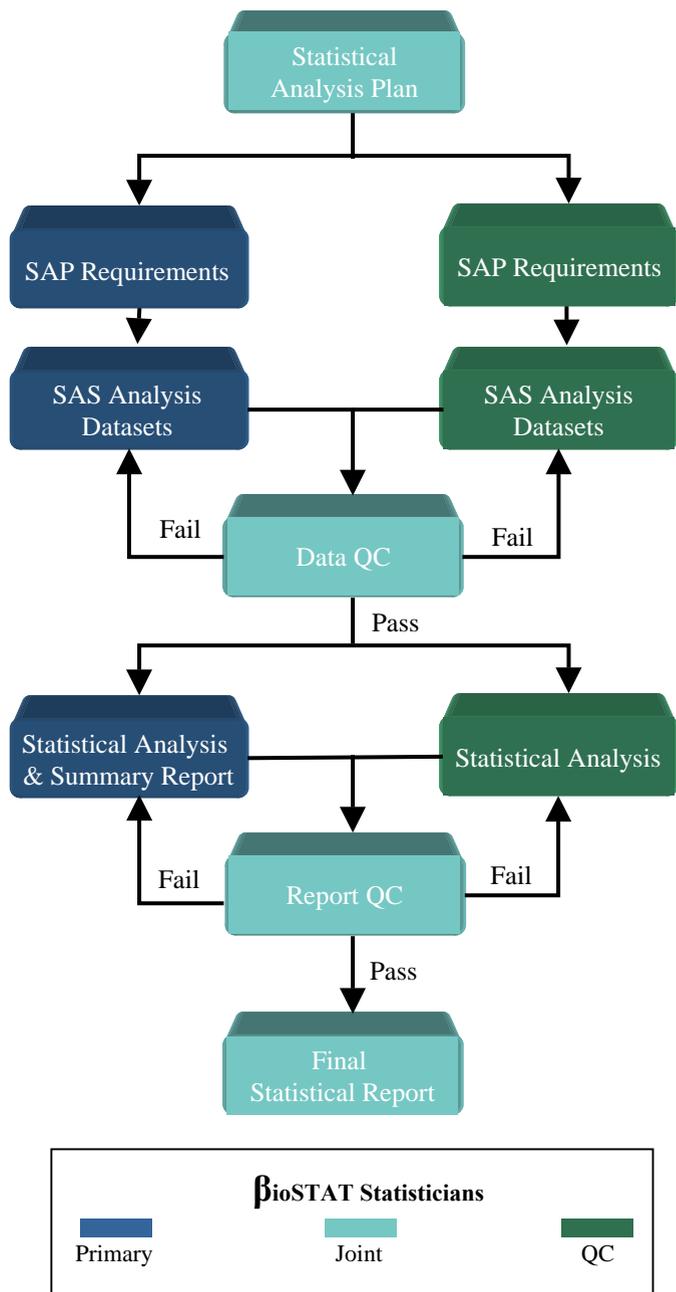


# The **β**ioSTAT Process



Based on blinded duplication of results by a Primary and QC statistician, **The βioSTAT Process** is designed to assure the accuracy and integrity of statistical analyses and reports while providing the client with the necessary components to fulfill GLP requirements.

The **Statistical Analysis Plan (SAP)** outlines analysis specifics, in greater detail than standard protocols, as well as SAS analysis dataset specifications.

**SAP Requirements** establish the requirements necessary to derive the analysis dataset and conduct the SAP.

**SAS Analysis Datasets** are created from client data files and are based on regulatory electronic submission datasets.

**Data QC:** An electronic 100% quality control check assures the independently derived datasets accurately reflect the client data files.

**Statistical Analysis:** Customized SAS programs are written to conduct the SAP and integrate analysis results directly into **Summary Report** tables. There is no manual transcription of analysis results.

The **Report QC** is a quality control check to assure that the report accurately reflects the SAP and protocol methodology.