

Biostatistician

Applied Genetic Technologies Corporation (AGTC) is a clinical stage biotechnology company dedicated to developing novel gene therapies for ophthalmic diseases. AGTC is aggressively expanding and seeks a full-time Biostatistician.

Reporting Relationship:

- The Biostatistician will report directly to the VP, Clinical Research and Development

Responsibilities:

Job responsibilities will include, but are not limited to, the following.

- Perform/oversee production and quality control of randomization schedules, statistical analysis plans, statistical reports, statistical sections of integrated clinical reports and other process supporting documents.
- Perform/coordinate the production of statistical outputs for various analysis and reporting purposes, and provide statistical review and program validation for each project, to ensure the integrity, adequacy and accuracy of the outputs.
- Design statistical analysis plans and table shells in accordance with study protocols or for integrated efficacy and safety summaries for New Drug Application (NDA) submissions.
- Develop, test, maintain and archive SAS program code to perform statistical analysis and generate analysis datasets and statistical reports of clinical data.
- Design analysis file specifications in accordance with the statistical analysis plan and table shells, and CDISC ADaM standards if applicable.
- Perform statistical QC review of source code and output developed by other CRO biostatisticians for statistical reports.
- Provide statistical input for Data Safety Monitoring Committee (DSMC) activities, including development of DSMC charters, analysis plans, and reports.
- Manage CROs in regards to statistical work; including identifying suitable partners, defining CRO responsibilities, and maintaining interactive management.
- Perform statistical review of clinical data and communicate data issues to data management and clinical trial and research managers.

Requirements:

The successful candidate will meet the following requirements.

- M.S. in biostatistics, mathematics or statistics and at least 5 years' experience in statistical analysis of clinical trials data, general linear models, mixed models, survival analysis, categorical data analysis and non-parametric methods.
- Experience in ophthalmology and/or rare disease clinical trial design and data analysis preferred

AGTC offers competitive compensation commensurate with education and experience. AGTC is an EOE and maintains a drug-free workplace. Please send CV or resume to:

Tavara K. Andrews, Senior Director, Human Resources
Applied Genetic Technologies Corporation,
14193 NW 119th Terrace, Suite #10, Alachua, FL 32615
tandrews@agtc.com