Resume Example: Biostatistician

SUMMARY OF EXPERIENCE

- Lead Sr. Biostatistician for Pharmaceutical, Drug, Devices and Clinical Research Organizations
- Provided statistical input and support to study design, case report forms, analysis and reporting for NDA/IND regulatory filing activities, in SDTM and ADAM formats.
- Contributed to protocol development by choosing an appropriate study design and statistical methodology, defining endpoints, calculating necessary sample size, and writing statistical sections of the protocol
- Developed statistical analysis plans and specifications for analysis datasets (SDTM and ADAM), tables, figures and listings (TFLs) for statistical programming
- Collaborated with data management and clinical operations over the course of clinical studies to provide statistical input to study conducts and database development as well as data collection and cleaning activities
- Collaborated with statistical programming to ensure that appropriate programs and documentations were being developed for datasets development and outputs generation, and ensured the statistical analyses specified in scientific protocols and/or analysis plans were conducted appropriately
- Reviewed and approved analyses produced by statistical programming, ensuring the accuracy and validity of results
- Developed statistical programs as necessary to perform analyses
- Provided input and directly contributed to global health authority documents, regulatory interaction and response to healthy authority submissions
- Reviewed clinical and regulatory documents to ensure that the interpretation of data was accurate and statistically sound
- Conducted and participated in validation and quality control of project deliverables
- Provided statistical support for clinical publications, assisted in data interpretation to ensure consistency and accuracy in data presentation
- Established and negotiated accurate timelines

EDUCATION

Accredited University City, State
Master Science, Biostatistics

PROFESSIONAL EXPERIENCE

Clinical Research Organization Company City, State Timeframe
Principal Biostatistician

- Interact with clients as key contact regarding statistical and contractual issues
- Perform QC of derived data sets, tables, figures and data listings
- Lead production and QC of randomizations, analysis plans, statistical reports, statistical sections of integrated clinical reports and other process supporting documents

Pharmaceutical Company City, State Timeframe
Consulting Biostatistician

- Protocol development
- Preparation of Standard Operating Procedures (SOPs) for Statistical Analysis and SAP templates
- Preparation of table shells for Clinical Data Review

Research Company City, State Timeframe
Senior Biostatistician

- Protocol review
- Preparation of Statistical Analysis Plan and shells for Oncology Study
- Preparation of Study Team Review plan

Lab. City, State Timeframe
Senior Statistician

- Provided in-depth statistical expertise in the areas of experiment, protocol, case report form design, database structure, and analysis plans
- Reviewed study protocols, authored statistical sections of protocols, and developed statistical and statistical analysis plans using SAS
- Contributed to development and review of clinical study reports

Biotechnology Company City, State Timeframe
Senior Statistician

- Partner with Senior Scientists, contributed to clinical development projects, including study design and implementation topics, data analyses and CSR preparation
- Review study protocols, authored statistical sections of protocols, prepared the study randomization, and developed the statistical and data analysis plans in SAS
- Reviewed case report forms to ensure protocol objectives are met and project standards are maintained. Develop statistical programs necessary to perform analyses, reviewed and approved

Clinical Company City, State Timeframe
Senior Statistician

- Responsible for the statistical input provided by the group to all major documents, including clinical development plans, protocols, statistical analysis plans, clinical study reports, and summaries of clinical safety and efficacy
- Served as an advisor for technical issues associated with the design, performance, and analysis of clinical trials
- Worked closely with management to ensure a coordinated approach to statistical work

Research Company City, State Timeframe
Associate Director Biostatistics

- Provision of expert statistical input to protocols, analysis plans and statistical/clinical reports
- Programming of statistical analyses in SAS and other commercially available statistical packages
- Review of statistical deliverables
- Provided expert statistical input and consultancy to clinical trials and clinical development projects including design of clinical trials, specification and production of analysis and reporting deliverables (including integrated summaries) on behalf of and/or in conjunction with clients
- Provision of expert statistical input to protocols, analysis plans and statistical/clinical reports