



Position: Senior Biostatistician

Job Description

The Senior Biostatistician oversees all Biostatistics, SAS Programming, and related activities for all clinical trials involving drugs, biologics and devices; oversees the activities of external consultants; and works with project teams and sponsors to ensure all Biostatistics tasks are completed accurately, in a timely manner.

Responsibilities include:

- Develops statistical section in clinical trial protocols
- Consults study design, analysis strategies for interim, final report and ISS/ISE
- Performs sample size and statistical power calculations
- Generates randomization schedule according to the protocol
- Develops Statistical Analysis Plan with input from project team and sponsor per SOPs
- Reviews Statistical Analysis Plans created by Biostatisticians at GMCS or its consultants and provide guidance
- Supports DSMB and CEC committee regarding to statistics analysis
- Consults on other statistical tasks, such as support for CRFs development and study report writing
- Performs SAS programming to generate tables, listings, figures, and statistical analyses
- Supervises, coaches, and develops staff
- Ensures validation and quality assurance aspects of all Biostatistics and SAS programming activities
- Ensures the adherence to timelines for the Biostatistical and SAS programming aspects
- Reviews and revises SOPs and WPDs pertaining to Biostatistics and SAS Programming, consistent with FDA/SFDA and ICH regulations and guidelines

Education and Experience:

- MS degree in medical statistics or above, Ph.D preferred.
- Minimum of 5 years of statistics and/or statistical programming applied to drug or medical device development
- Demonstrated skills in planning, managing and coordinating biostatistics and SAS programming activities in clinical trials
- Demonstrated ability to deal with sensitive inquiries or complaints from clients or potential clients and to protect confidentiality
- Demonstrated team-building skills and the ability to work successfully in a team environment requiring matrix management skills
- Demonstrated ability to make effective presentations in public settings
- Good command of English language and communication skills.
- Demonstrated computer skills including MS Office and Internet usage.