Principal Statistical Specialist

Job Description

Primarily providing statistical services to clients, the Principal Statistical Specialist provides technical leadership, expertise, mentoring and support to the Plus-Project team. Responsible for the provision of Plus-Project's statistical services, both in-house and statistical consultancy, and inputs to the continuous improvement of statistical practices and processes.

Tasks and Responsibilities

- Primary responsibility is provision of expert statistical services to clients.
- Provide statistical expertise, mentoring and support to all members of Plus-Project.
- Prepare statistical courses and train internal staff as required.
- Provide expert leadership to internal and external study teams in the reporting of clinical trials data, regulatory submissions, safety updates and publications.
- May serve as lead statistician for one or more studies with any level of complexity.
- Collaborate in the process of protocol development by choosing an appropriate study design, including statistical methodologies, calculating necessary sample size to achieve a pre-specified power, and writing the statistical section of the protocol.
- Act as the primary contact with the sponsor for all statistics related activities on assigned projects.
- Perform statistical review of relevant study documentation (e.g. case report form, randomisation specification) and clinical study reports.
- Author and review Statistical Analysis Plans (SAPs) based on the protocol, including development of output shells for tables, figures and listings.
- Statistical review of dataset specifications.
- Programming and validation of efficacy analysis datasets and associated tables, figures and listings.
- Participate in Data Safety Monitoring Board and/or Data Monitoring Committee activities, including charter development.
- Prepare key portions of the integrated clinical/statistical report, including sections related to data handling and statistical methodology, patient accountability, baseline compatibility, and efficacy results.
- Provide input to regulatory submission strategy including input to key documents such as ISS and ISE. Provide statistical advice and analysis to support regulatory defence activities.
- Support business development activities by contributing to proposals, budgets, and attending sponsor bid defence meetings. Expertise in clinical trials and statistical methodology for a therapeutic area and/or statistical methodology for specialised applications.
- Keeps abreast of new developments in statistics, drug development, and regulatory guidance through literature review, conference attendance, etc.

- Support internal objectives
- Any other reasonable requests as requested by the Plus-Project Leadership team.

Minimum qualifications and experience

- At least 12 years' experience
- Master's Degree or Ph. D in Statistics (or related discipline)
- Ability to apply expert knowledge of statistical design, analysis and programming techniques used in clinical trials
- Significant relevant experience with drug development statistical analysis
- Strong project leadership experience
- Proficiency in SAS/R programming
- Excellent oral and written communication skills

Signatures

Employee:

Date:

Line manager:

Date: