*Principal Statistician – Job Description*

**Job Description**

Work with the Management Team to ensure Plus-Project provides excellent statistical services. Responsible for managing and leading in-house projects potentially across different phases and therapeutic areas and providing statistical input to single or multiple clinical trials. Support Plus-Project's provision of statistical consultancy services as required.

**Tasks and Responsibilities**

- Reporting into the Management Team, Principal Statisticians provide expert leadership to internal and external study teams in the reporting of clinical trials data, regulatory submissions, safety updates and publications.
- Act as lead statistician for multiple projects 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 (i.e. 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, ISS and ISE, including sections related to data handling and statistical methodology, patient accountability, baseline compatibility, and efficacy results.
- Support business development activities by contributing to proposals, budgets, and attending sponsor bid defense meetings.
- Training:
    - Prepare statistical courses and train internal staff as required
    - Supervise, mentor and line manage statisticians

- Support internal objectives
- Any other reasonable requests at the CEO/Operations Director's discretion.

**Minimum qualifications and experience**

- At least 8 years' experience
- Master's Degree or Ph. D in Statistics (or related discipline)
- Significant relevant experience with drug development statistical analysis
- Strong project leadership experience
- Ability to apply knowledge of statistical design, analysis and programming techniques used in clinical trials
- Proficiency in SAS programming
- Excellent oral and written communication skills

**Signatures**

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|---|---|
| Employee: | Line Manager: |
| Date: | Date: |