

Job Posting

Principal Biostatistician

Position Overview

The Principal Biostatistician is responsible for leading statistical related activities to coordinate with multiple clinical studies for the clinical project(s). Activities include, but are not limited to, coordinating project team meetings with strategies, writing protocols and statistical analysis plans as needed, involvement in programming and validations of statistical outputs and accountable for high quality and timely statistical deliverables of the clinical projects, arranging resources to support projects, and coaching less-experienced statisticians on the team.

Primary Responsibilities

To perform this job successfully, incumbent must be able to satisfactorily perform the essential functions of the role without or with reasonable accommodations. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Essential Functions:

- Lead and coordinate data related activities with statistics, programming, data management functions to support clinical studies.
- Prepare or review the clinical study protocols, case report forms, statistical analysis plans, and table shells as needed.
- Create SAS programs for data management activities, CDISC compliant analysis datasets, and statistical analysis of the clinical trial data.
- Prepare the statistical section of clinical trial reports and presentations of the results to the team.
- Produce high quality deliverables based on the timeline and the resources within the data services functions.
- Mentor and develop less-experienced statisticians in the project team.
- Through experiential learning, gain proficiency to:
 - Demonstrate solid understanding of regulatory guidance and statistical methodology as applied to clinical studies in pharmaceutical development.
 - Identify, evaluate, and implement innovative statistical methods to provide added value client drug development process.

Note: This list is not intended to be an exhaustive list of duties and responsibilities. There may be other duties as assigned.

Qualifications Including Education, Experience, and Skills

- Master's Degree in Biostatistics, Statistics, Mathematics, or related field or equivalent experience defined as a minimum of 8 years related, combined experience in education,

knowledge, and skills that will enable the incumbent to proficiently perform the duties of the role is required. Ph. D is preferred. Note: Statistical coursework is required if Degree(s) not in Biostatistics or Statistics.

- Minimum 5 years clinical trials experience if Master's Degree; Or, minimum 3 year clinical trials experience if Ph. D.
- Working knowledge of SAS or R programming combined with other statistical software packages is required.
- Leadership experience gained leading projects or teams.
- Current knowledge of statistical models in drug development and healthcare industry.
- Able to lead Statisticians and other functions to support clinical studies.
- Strong communication, presentation, and project management skills.

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