Senior Statistician, Novo Nordisk

Princeton, NJ

The scope of responsibility includes individual or multiple clinical trials.

This is a technical position. Work under moderate supervision, the incumbent is responsible for the delivery of statistical support to NNI’s clinical development, registration, and marketing support programs. Functions include clinical trial design, data analysis, report writing, and general consultations.

RELATIONSHIPS:

Reports to the head of Biostatistics, or under temporary assignment, to senior statistical staff. Through project teams, works closely with clinicians, medical writers, data managers, regulatory managers, and marketing managers.

ESSENTIAL FUNCTIONS:

- Under moderate supervision, participate in clinical study teams. Assure that statistical and scientific methodologies are fully considered and documented.
- Under moderate supervision, participate in the review of study protocols, critic and suggest improvement on scientific methodology, write statistical sections, develop plans and perform statistical analysis and presentation.
- Under Moderate supervision, manage the relations with NNI internal customers, including clinicians, medical writers, regulatory staff, and marketing managers.
- Under moderate supervision, participate in meetings or communications with the regulatory agencies (primarily the FDA).
- Have the ability to direct the statistical activities for individual or multiple clinical trials.
- Moderate supervision is required.
- Keeping abreast and observe general guidance established in the pharmaceutical industry, including FDA guidelines, ICH guidelines, NN SOPs, and generally accepted GCP.
- Keeping abreast with current statistical literature, assure the most current regulatory requirement are followed and sound methodologies are adopted.
- Participate in the development and update of internal SOPs and working procedures.
- Manage the interactions with NNA/S headquarters statistical group through department head.
- Under moderate supervision, prioritize task assignment, timelines, and outsourcing management.
- Participate in the development and maintenance of statistical routine libraries.
- Perform hands-on programming or direct statistical programming staff in order to assure that data listing, tables, and graphs are produced with highest efficiency and quality.

KEY SUCCESS FACTORS: EDUCATION, EXPERIENCE, KNOWLEDGE AND SKILLS

- A Ph.D. degree in biostatistics, statistics, or relevant areas required.
- At least two (2) years of experience in pharmaceutical industry engaged in statistical support of clinical development with progressively increasing scope of responsibility.
- Good communication and interpersonal skills.
- Good statistical computer programming skills.
- Knowledge of statistical concepts and techniques and of clinical trial principles.

https://www.statsjobs.com/jobs/senior-statistician-novo-nordisk/