Statistician
Medical Information
US - Princeton, NJ

PURPOSE:
This is an entry level technical position. Work under supervision, the incumbent is responsible for the delivery of statistical support to NNI’s clinical development, registration, and marketing support programs. Functions include experiment design, data analysis, report writing, and quality assurance. The scope of responsibility includes individual clinical trials.

RELATIONSHIPS:
Reports to the head of Biostatistics, or under temporary assignment, to senior statistical staff. Works closely with project team members including clinicians, medical writers, data managers, regulatory managers. Close supervision required. Able to perform the statistical analysis and reporting for clinical trials, understand the requirements of GCP, and statistical programming.

ESSENTIAL FUNCTIONS:

- CLINICAL TRIAL DESIGN AND ANALYSIS: Under supervision, participate in clinical study teams. Assure that statistical and scientific methodologies are fully considered and documented.

- CLINICAL TRIAL DESIGN AND ANALYSIS: Under supervision, participate in the review of study protocols, critique and suggest improvement on scientific methodology, write statistical sections, develop plans and perform statistical analysis and presentation.

- CUSTOMER MANAGEMENT: Under Moderate supervision, manage the relations with NNI internal customers, including clinicians, medical writers, regulatory staff, and marketing managers.

- QUALITY AND PROCEDURE IMPROVEMENT: Keeping abreast and observe general guidance established in the pharmaceutical industry, including FDA guidelines, ICH guidelines, NN SOPs, and generally accepted GCP.

- RESOURCE MANAGEMENT: Under moderate supervision, prioritize task assignment, timeline management.

- STATISTICAL PROGRAMMING AND PRESENTATION: Participate in the development and maintenance of statistical routine libraries. Assure efficient use of resources.

- STATISTICAL PROGRAMMING AND PRESENTATION: Develop or review Statistical Analysis Plans. Perform quality assurance and validation of statistical programs. Perform hands-on programming or direct statistical programming using appropriate software for analyses and presentation.

KEY SUCCESS FACTORS: EDUCATION, EXPERIENCE, KNOWLEDGE AND SKILLS

- A MS degree in biostatistics, statistics, or relevant areas required.
- Good communication and interpersonal skills.
- Knowledge of graduate level statistical concepts and techniques.
- Proficient statistical programming skills including analyses and presentations.

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