

NIH Principal Statistical Scientist

PPD, Inc.

Wilmington, NC (Headquarters)

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The Principal Statistical Scientist serves as the Lead or Senior Statistician on broad-based projects or complex, multiple protocol programs. Serves as the scientific and therapeutic area thought leader and training resource for study design and statistical analysis issues for commercial and/or NIH-funded projects in drug, device, or biologics development. May provide scientific strategy consultation to clients for development planning. Maintains expertise in state-of-the-art data manipulations, statistical analyses, biological sciences, and/or specific therapeutic indications.

EDUCATION AND EXPERIENCE:

- Master's degree in statistics, biostatistics, or equivalent field with appropriate statistical coursework and at least 5 years of clinical trials or biologics development experience as a statistician
- Or PH.D. in statistics, biostatistics, or equivalent field with appropriate statistical coursework and at least 3 years of clinical trials or biologics development experience as a statistician
- Or equivalent combination of education, training, and experience that provides the individual with the required knowledge, skills, and abilities as demonstrated by consistently superior project-related performance and scientific leadership
- Active participation in at least one professional statistics organizations (Preferred)
- Demonstrated understanding of CRO working relationships and business nature. (Preferred)
- Demonstrated understanding of the NIH grant application process (Desired)
- Strong professional interest in clinical trials or biologics development methodology (Preferred)

KNOWLEDGE, SKILLS AND ABILITIES:

- Demonstrated initiative and motivation
- Excellent verbal and written communication skills
- Positive attitude and the ability to work well with others in a multi-disciplinary setting.
- Strong knowledge of SAS and other advanced statistical analysis software
- Strong knowledge of clinical biostatistics or statistical methods in molecular biology
- Demonstrated knowledge of the entire drug, device, or biologics development process
- Conversant knowledge of FDA and other Regulatory guidance and regulations
- Demonstrated ability to manage change and uncertainty to optimize positive outcomes
- Must be able to multi task and pay close attention to detail

And a combination of two or more of the following:

- Proven performance in leading complex projects
- Good organizational skills with the ability to adapt and adjust to changing priorities.
- Strong theoretical background and applied statistical knowledge
- Ability to mentor statisticians with regard to scientific principles, statistical methodology, and/or knowledge of a specific therapeutic area
- Ability to communicate complex statistical concepts in a multi-disciplinary setting.
- Demonstrated knowledge in one or more therapeutic areas
- Demonstrated knowledge in molecular biology and the development of mechanistic assays

And at least two of the following: (Preferred)

- Strong professional interest in at least one specific clinical science areas of application e.g, antiviral, respiratory medicine, endocrinology, cardiology, immunology, oncology, transplantation, etc
 - Strong professional interest in molecular biology, genomics or proteomics for the advancement of understanding of the mechanistic basis for disease progression
 - Clear evidence of initiative and planning skills to discern the most efficient way to achieve scientific objectives, need clear evidence of the ability to execute that plan effectively
 - Experience in one or more areas of specific statistical methodology, such as clinical trials design

methodology, categorical data analysis, generalized linear model, longitudinal data analysis, survival analysis, adaptive designs, multivariable analysis or response surface modeling