Senior Biostatistician

Summary:
Senior Biostatistician will provide statistical support for Clinical Affairs or/and other departments. This position is responsible for leveraging the Danaher Business System and tools in the timely and high-quality execution of biostatistics for pre-market and post-market programs.

Duties & Responsibilities:
- Provide statistical support to clinical team, study projects, and data management.
- Consult with project teams and apply statistical expertise to ensure scientific validity and proper design of studies, prepare written summaries for use by regulatory agencies and project teams.
- Provide statistical support to assist with sample size and data analyses for clinical trials.
- Work cooperatively with scientists to design of experiments for identifying critical factors, sources of variation and optimization studies.
- Participate in development of the statistical analysis plan (SAP) for a clinical studies and execute SAP throughout lifecycle of the study.
- Perform data review and statistical analyses. Collaborate writing statistical sections for integrated reports or/statistical reports.
- Develops statistical programs as necessary to perform analyses and prepare data displays.
- Participate in developing the case report form (CRF).
- Participate in development of database clinical trial data specifications, including eCRF design, user requirements, edit rules/checks, query logic, and data validations.
- Comply with data integrity standards and business ethics requirements.
- Keeps abreast of new developments in statistics, industry development, and regulatory guidance through literature review and attendance at workshops and professional meetings.

Requirements:
- The qualified candidate will have a PhD with 0-2 years' experience, or a Master’s degree (Biostatistics or equivalent) with 2+ years’ of experience within a pharmaceutical or medical device environment.
- Strong knowledge of statistical theory, experimental design and clinical trial methodologies, linear and nonlinear modeling, categorical and non-parametric methods, sample size calculations.
- Expertise in SAS is required. Solid knowledge of BASE SAS, SAS/STAT, SAS MACROS, etc.
- Familiarity with diagnostic clinical trial statistics is a plus.
- Familiar with FDA guidelines and other regulatory requirements is a plus.
- Must be highly-motivated, team-oriented, and organized with a strong attention to detail.
- Must have the ability to write documentation and understand, interact and communicate effectively with others.

Danaher is a leading manufacturer of biomedical testing instrument systems and blood tests required for the diagnosis and monitoring of diseases. Spanning the biomedical testing continuum - from pioneering medical research, clinical trials to laboratory diagnostics and point-of-care testing - Danaher installed systems provide essential biomedical information to enhance health care around the world.