Biostatistician

Who are we?

We Are Cancer Insight. We are a growing CRO that specializes in developing cutting-edge immuno-oncology (IO) drugs. We specialize in designing and executing early-phase IO trials, yet we also run large, multi-site, adaptive, later-stage trials. We are specialists in the most exciting field in medicine—immuno-oncology. Our success is driving growth. We are committed to saving lives and are constantly striving to be the best at what we do. Our impact is real and we see it every single day.

Job Overview:

As the experienced Biostatistician for Cancer Insight, the person in this role will lead study design and biostatistical strategies, provide input into protocols, develop and review statistical analysis plans and author/co-author reports, abstracts and manuscripts. As the lead statistical support for all of Cancer Insight's clinical trials this role interacts and consults with clinical and project teams to ascertain their needs and develop an appropriate design and statistical solutions. Critiques and improves study designs developed across the organization. Has primary ownership for statistical support of all major projects and actively mentors less experienced colleagues as needed. Excellent communication skills and a desire to be an active team player are a must.

Reports to:

Director of Biometrics.

Responsibilities:

- Interacts with development and clinical investigators to design clinical trials with appropriate statistical methods and adequate sample size for statistical justification of clinical outcomes.
- Writes statistical analysis plans as needed to capture design elements and statistical methodology.
- Perform statistical activities in support of development and medical affairs studies, including development of study design and protocol, development of statistical analysis plans, data analysis, algorithm development, preparation of final study reports, abstracts, posters, and manuscripts.
- Represent the statistics function on project teams for clinical development programs, providing strategic input and contributing significantly to the design of clinical studies and the clinical development plan.
- Specifies statistical analyses and reviews statistical reports of results.

- Works closely with statistical programmers in the design of clinical deliverables (i.e. patient profiles) as well as ensuring the validation of programming code for tables, listings and figures (TLFs).
- Reviews statistical analyses conducted by statistical programmers and other biostatisticians to ensure accuracy and quality.
- Conducts randomization and blinding of samples.
- Troubleshoots and improves current statistical designs, including those developed elsewhere in the organization.
- Maintains expertise in state-of-the-art data manipulation and statistical analyses, and mentors less experienced colleagues.
- Manages day-to-day biostatistical aspects of a project.
- Monitors work to ensure quality.
- Develop Biostatistics Standard Operating Procedures (SOPs).
- In collaboration with statistical programmers, develop an internal library of codes/programs for common analysis data sets.

Skills and Requirements:

- Knowledge of FDA guidelines for in vivo therapeutics and diagnostic devices, with a particular focus on the field of oncology, and the required statistical basis for sample size estimation, sensitivity, specificity, agreement rates, and reproducibility testing required for validation and FDA clearance and approval.
- Strong ability to collaborate across departments and interact with various levels in the organization.
- High attention to detail with skill in producing organized reports.
- Ability to write statistical code and documentation.
- Ability to work in a team-focused remote environment.
- Ability to prioritize and plan work activities independently and collaboratively.
- M.S. in Biostatistics.
- At least 5 years of experience with biostatistics associated with oncology clinical trials in a CRO or pharmaceutical setting..
- Knowledge of CDISC Data Standards: SEND, SDTM and ADaM
- SAS programming skills required, and knowledge of R preferred.

Point of contact:

Contact Ashlee Richie at (arichie@cancerinsight.com).

The above description is intended to describe the general nature of the job and may include other duties as assumed or assigned; it is not intended to be all inclusive or limit the duties of the position. Cancer Insight is an EEO/AA employer and is committed to providing opportunities to minorities, women, veterans and individuals with disabilities.