Job Description

Job Title: Director, Biostatistics	**Reports To (Title):** Senior Director, Biostatistics	**Date Created: Dec 05, 2023**
Department: Biostatistics and Data Management	**Job Type:** ☒ Full-time ☐ Part-time ☐ Contractor	

SUMMARY OF JOB (brief description): Soleno Therapeutics, Inc., based in Redwood City, California, is a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases. We are seeking a highly motivated individual to join Soleno Therapeutics as a Director of Biostatistics. The Director of Biostatistics will work with cross-functional teams on the design, analysis, and reporting of clinical studies; provide statistical expertise and defense of regulatory submissions; and support the company's external publications and corporate objectives.

RESPONSIBILITIES:

- Write statistical sections of protocols. Author SAPs, and efficacy results sections of CSRs.
- Design and implement clinical studies by overseeing the development of statistical sections of study protocols and statistical analysis plans.
- Provide statistical support and analyses for regulatory meetings, submissions, and regulatory defense.
- Be well versed with details of studies and analyses conducted. Prepare responses to information requests from regulators, participate in regulatory defense activities and inspections.
- Provide statistical insight into the interpretation and discussion of results for sections for the clinical study report (CSR), the ISE, ISE, publications, and business decisions.
- Partner with vendor CROs in the timely and quality execution of deliverables including analysis plans and outputs for individual studies and pooled analyses.
- Collaborate with statistical programming to clarify analysis dataset specifications, documentation, and review of derived variables, as well as the quality control plan.
- Provide statistical consultation to cross-functional groups.
- Input into CRF and database design, particularly efficacy data collection and validation. Study design and protocol development, including sample size estimation, formulation of statistical hypotheses and testing strategy, and statistical methods.
- Maintain statistical expertise by learning new methodologies, choosing which methods to use in analysis, and justifying methods selected.
- Oversee statistical contractors/consultants and manage or mentor junior team members.

QUALIFICATIONS:

- PhD in Statistics with 8 years of experience working in clinical development in a pharmaceutical, biotechnology, or CRO industry environment or an MS in Statistics with 10 years of experience.
- Excellent verbal and written communication skills; ability to work in a team environment with medical personnel, clinical monitors, programmers, data managers and medical writers. Attention to detail is required.
- Knowledge of FDA/ICH guidelines. Experience with preparation of NDAs, briefing documents, and responses to questions from regulatory agencies is required. Advisory Committee experience desirable
- Broad knowledge, and superior understanding of advanced statistical concepts and techniques.

Job Description

- Ability to manage multiple priorities and quickly navigate ambiguity.
- Proficiency in the use of statistical software (eg: SAS, R, JMP, etc.) and in sample size estimation.
- Provide input for planning and management of external budgets related to statistical deliverables.

Salary Range: $220K - $280K