Biostatistics Director

Hiring organization
Alector

Job Location
United States

Base Salary
$ 77500 - $ 117500

Date posted
June 1, 2024

Apply Now

Description

Our mission is to develop therapies that empower the immune system to combat neurodegeneration and our team is focused on developing treatments for some of the most challenging diseases facing our society. We are supported in this mission by experienced and accomplished scientists and clinicians, a novel portfolio of programs, leading healthcare investors, and pharma company partners, who share in our commitment to bettering the lives of patients and realizing a world where we make brain disorders history As the Biostatistics Director, you will provide statistical leadership and expertise in support of the clinical development activities for multiple therapeutic areas. You will be responsible to provide statistic contribute strategically to project decisions with a focus on pre-study planning, protocol development, sample size/power calculations, Statistical Analysis Plan preparation/review, data quality reviews, development of tables/listings/figures, preparation/mapping of clinical study data for regulatory submission, and integrated safety and efficacy reporting. You are expected to apply innovative statistical approaches to the work; support and defend analyses and their interpretations in meetings and teleconferences with regulatory agencies and prepare written responses to agency questions. The Director will possess the ability to influence key decision-makers within the project team and within senior management to ensure a high degree of rigor to the statistical and scientific decision-making process and outcomes.Do you want to apply your existing technical skills, join a high-performing team and learn and implement new capabilities? Can you see yourself playing a key role in clinical development and trial design for our antibody therapeutics? If so, we want to hear from you. nDuring your first year, your goals will include:Define how you will contribute to Alector’s overall 3-5 year vision to continually improve our clinical development strategyCollaborate with internal and external partners in the optimized clinical study design, end point selection and sample size calculations, analysis, interpretation, and publication of clinical trial dataExecute protocols, statistical analysis plans, study reports, ensure statistical integrity of presentations and publications of clinical studiesSupport project team and clinical study team including but not limited to derivation of go/no-go criteria, generation of data visualizations and summary reports, and interpretation of results to support internal decision-makingParticipate in regulatory interactions and responsible for biostatistics input into study protocols and clinical study reportsReview study randomization specifications, oversee outsourced development of analysis data and results; and reviewing case report forms while managing workflow to ensure quality, prioritization, and timeliness across multiple programsProvide statistical oversight in the development of key study documentsManage external vendors and serve as a key Biostats liaison with external organizationsParticipate in establishing and maintaining policies, standards, and guidance for Biostatistical operationsEnsure up to date knowledge of industry and academic developments in the Neuroscience and Orphan disease fields and apply to clinical study design and analysis We’d love to hear for you if you have:PhD with 8-10 years, or MS with 10-12 years of proven experience in academia or industry. Pharmaceutical/biotech industry experience preferredSolid understanding of theoretical and applied statisticsExperience with multiple imputation, multivariate statistics and statistical methods to quantify uncertainty in multi-dimensional data; experience running simulations and mixed modelsHands-on ability to drive and lead statistical strategies for clinical development of drug candidates from first-in-human testing to all later phases of clinical investigation, including pivotal Phase 2/3 studies and NDA/BLA submissionsExperience with rare disease and real world dataDemonstrated success in leading the statistical strategy, analysis, and design of a clinical development programKnowledge of applicable regulatory rules and guidelines, e.g.,

ICH, GCP, HIPAAAdvanced programming skills in in SAS and/or R and other relevant statistical software solutions.Ability to code programs to analyze and report complex clinical trial data, as well as for electronic review, exchange, transformation, and submission of data in CDISC, SDTM and ADaM formatsStrong application of innovative study designs and developing landmark criteria (e.g. Go/No Go criteria).Detailed knowledge of adaptive designs, Bayesian methodology, trial simulation, and data modeling strongly preferredn$250,000 – $265,000 a yearBase salary ranges will be determined by the candidateâ??s level, qualifications, skill set, and experiencen#LI-BL1#LI-RemoteAt Alector, our vision is bold, people are our priority, and our values are at the core of everything we do. Our dynamic and flexible environment encourages our teams to experiment, take ownership of decisions, and question convention to solve complex problems. We value shared wins, perseverance, and a growth mindset, which drives us forward, together. Among the things you'll discover at Alector from your very first day are our committed and driven colleagues, a bold company vision, and new, modern offices designed to inspire innovation and collaboration in South San Francisco, right at the heart of Biotech Bay. Our benefits are thoughtfully designed around Alectorians and their loved ones and include flexible hybrid work options, competitive compensation, and comprehensive and unique benefits that enhance your health and well-being. Come join us! We believe that hard-working teams include people from a wide variety of backgrounds and experiences who can challenge each otherâ??s assumptions with fresh perspectives and bring creative ideas to the table. We are committed to building an open, diverse, and inclusive environment for all employees. We do not discriminate on the basis of race, religion, color, national origin, sex, gender, sexual orientation, age, marital status, veteran status, or disability status, or any other characteristics protected under applicable federal, state, or local laws. We will ensure that individuals with disabilities are provided reasonable accommodation to participate in the job application or interview process, perform essential job functions, and receive other benefits and privileges of employment. Please contact us to request accommodation. Review our Privacy PolicyPlease mention the word **PREMIER** and tag RMjE2LjI0NS4yMjEuOTE= when applying to show you read the job post completely (#RMjE2LjI0NS4yMjEuOTE=). This is a beta feature to avoid spam applicants. Companies can search these words to find applicants that read this and see they're human.

Contacts

Job listing via RemoteOK.com