

Director, Biostatistics

Location: Cambridge, Massachusetts

Position type: Full time

Description

The Director of Biostatistics provides leadership to the biostatistical activities for one or more clinical development programs. The position reports to the Vice President of Biostatistics and Outcomes Research. Specifically, this individual will oversee the design, development and evaluation process of all clinical trials within the clinical development program. This includes development of the necessary technical/statistical infrastructure as needed to provide for regulatory submissions. Other duties include providing expert technical guidance to Biostatisticians and to promote interdisciplinary understanding within the groups of other departments and project teams, wherever possible. A summary of job responsibilities follows:

- * Provide leadership to the development of biostatistical internal infrastructure, including development of SOPs.
- * Identify and provide solutions to statistical issues related to overall clinical development projects, individual studies, biomarker studies and PK/PD data.
- * Play a leading role in managing statistical activities, including timelines, resource planning and statistical deliverables related to clinical development projects.
- * Interact and provide statistical leadership to manage activities outsourced to contract research organizations.
- * Oversee the evaluation of new technologies and the development of innovative biostatistical methodologies to ensure high quality data and analyses in accordance with FDA regulations, ICH Guidelines and corporate timelines.
- * Retain, mentor and recruit qualified biostatistical staff as needed setting objectives, directing work and appraising performance.
- * Discuss complex statistical issues with R&D staff, Senior Management, regulatory authorities and various Key Opinion Leaders (KOLs) in order to convey and facilitate the understanding of germane statistical concepts.
- * Oversee database integration tasks involving all aspects of design and analysis of ISS/ISE databases.
- * Provide an environment of process enhancement allowing for the development and refinement of tools needed to compile regulatory submissions.
- * Prepare/review study protocols, statistical analysis plans, study reports, regulatory submission materials, and manuscripts.
- * Provide statistical training to the Biostatistics department and other Research and Development staff.
- * Participate in meetings with regulatory agencies to support regulatory filings.
- * Follows all relevant SOPs and working practices. Leads in and contributes to the establishment and maintenance of common formats and templates for key Biometrics documentation (e.g., statistical section of protocol, standard CRF pages, Statistical Analysis Plans, Tables, Figures and Listings). Leads in the design of standards for SAPs.
- * Contributes to the publication plan. Reviews abstracts, posters, and manuscripts to support Medical Affairs.
- * Provide statistical leadership in supporting early clinical development programs (Phases 1 and 2).

Requirements

- * Ph.D./equivalent and 9 years of relevant experience, or M.S./equivalent and 12 years of relevant experience.
 - * Wide-ranging and deep knowledge of clinical biostatistics in the pharmaceutical industry. The required experience should span all areas of development (Phase I-IV) and should include previously held positions that were key in driving regulatory meetings, filings, and defenses of submitted packages to regulatory authorities .
 - * Working knowledge of SAS software and an excellent understanding of statistical procedures in SAS.
 - * Extensive understanding of the regulatory process in the US and abroad, including guidelines.
 - * Excellent interpersonal skills and verbal/written communication skills.
 - * Experience in the analysis of pharmacokinetic endpoints.
 - * Experience in PK/PD modeling is preferred.
 - * Proficient in the use of innovative statistical techniques that include models and designs for studying human subjects for establishing proof of mechanism and proof of concept of new drugs.
 - * Clinical development experience in Oncology is highly desirable.
 - * Ability to develop and improve internal infrastructure, including development of SOPs.
-