ASSOCIATE DIRECTOR / DIRECTOR, BIOSTATISTICS

POSITION DESCRIPTION

Job Title:	Associate Director/ Director of Biostatistics
Reports to:	Vice President Biostatistics
Classification:	Full-time, Exempt, Salaried

Company Summary: Aeglea BioTherapeutics, Inc. is an Austin, TX based biotechnology company committed to developing engineered human enzymes for the treatment of genetic rare diseases and cancers associated with abnormal amino acid metabolism. The company's engineered human enzymes are designed to degrade specific amino acids in the blood to reduce toxic levels of amino acids in genetic rare diseases or to starve tumors dependent on extracellular amino acids. Aeglea's clinical program for its lead product candidate, AEB1102, includes three recently initiated Phase 1 clinical trials, studying AEB1102 for the treatment of patients with Arginase I deficiency as well as patients with solid tumors or hematological malignancies. The company is building a pipeline of additional product candidates targeting key amino acids, including AEB4104, which degrades homocystine, a target for metabolism genetic rare disease, as well as two potential treatments for cancer, AEB3103, which degrades cysteine/cystine, and AEB2109, which degrades methionine.

Position Summary: Aeglea is actively recruiting for an Associate Director or Director of Biostatistics (title to depend on experience level). The position is responsible for biostatistical study design, management of study data, analysis of study data, and formal communication of study results in order to meet the needs of patients, regulators, and company stakeholders. This role implements data analytic and communication strategy, and serves as a central point of contact and oversight for Contract Research Organizations who provide statistical and/or data management services for Aeglea. This position is hands-on, requiring the knowledge to implement and oversee the statistical and data management aspects of advanced clinical trials, and create and execute data plans for regulatory submission.

Essential Duties and Responsibilities: To perform this job successfully, an individual must be able to perform the following:

- Participate in, and lead the statistical aspects of, cross-functional project teams, ensuring biostatistically sound and regulatory compliant planning, design, conduct, data capture and management, analysis, and reporting of clinical trials
- Manage trial-level budgets for statistical vendors
- Provide statistical/data management support for Steering Committees, Advisory Committees, Data Monitoring Committees, Adjudication Committees, and Publication Committees
- Provide statistical insight into study design, serving as the subject matter expert in statistics
- Participate with clinical development team in investigator meetings, advisory boards, and other clinical/scientific interactions

- Provide input into selection of any statistical or data management vendors
- Liaise with other internal functional areas, including Regulatory, Clinical Operations, Project Management, Drug Safety, and Medical to ensure effective execution of study
- Collaborate in the preparation of regulatory submissions and regulatory meetings such as Advisory Committee meetings
- Able to represent the company at academic, medical, industry and regulatory meetings
- Direct the data management / statistics vendors in creation of datasets and associated documentation in compliance with CDISC standards
- All other duties as assigned and required in order to ensure successful delivery of product

Qualifications: To perform this job successfully, an individual must be able to perform each essential duty. The requirements listed below are representative of the knowledge, skill, and/or ability required.

Education/Experience: The ideal candidate will offer:

- For the title of Associate Director:
    - A PhD in statistics, biostatistics, or related field with 6+ years of clinical drug/biologic development experience in regulated industry and 2+ years of management experience or project management experience with statistical deliverables
      --OR--
      A MS in statistics, biostatistics, or related field with 10+ years of clinical drug/biologic development experience in regulated industry and 2+ years of management experience or project management experience with statistical deliverables
- For the title of Director:
    - A PhD in statistics, biostatistics, or related field with 10+ years of clinical drug/biologic development experience in regulated industry and 2+ years of management experience
- Demonstrated understanding of the drug development process with clinical trial design, study implementation, statistical methodology, and regulatory requirements pertaining to statistics and data standards for human clinical studies.
- Familiarity with the implementation of FDA, GCP, ICH, and PhRMA guidelines as they relate to statistics
- Familiarity with relevant FDA regulations and demonstrated experience in responding to written FDA questions
- Experience with preparations of NDA and/or BLAs

Desirable Knowledge, Skills and Abilities:

- Experience with drug development in oncology and/or inborn errors of metabolism
- Knowledge of EU, Canada, and/or Japan regulations and experience with written submissions/responses to regulatory agencies in addition to FDA.
- Experience with preparation for, and speaking for, a pharma/biotech company at advisory committee meetings, labeling negotiations, and other regulatory interactions
- Strong communication (oral and written), presentation, and analytical skills
- Ability to work independently, prioritize tasks efficiently, and meet expected timelines
- Ability to interact collaboratively with colleagues, investigators, key opinion leaders, and regulators.
- Experience building strong teams
- Experience with statistical analysis software such as SAS, experience with electronic data capture platforms such as Medidata Rave, experience with MedDRA and WHODRUG dictionaries

Work Environment:
This is a high growth, fast paced small organization. The ability to be productive and successful in an intense work environment is critical. Willingness and ability to travel domestically and internationally on occasion is required, it is anticipated that this will be less than 30% of work time.

Physical Demands: The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

The above job description is not intended to be an all-inclusive list of duties and standards of the position. Incumbents will follow any other instructions, and perform any other related duties, as assigned by their supervisor.