CLINICAL PROJECT MANAGER

POSITION DESCRIPTION

Job Title: Clinical Project Manager
Reports to: Clinical Program Director
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 in order to reduce toxic levels of amino acids in genetic rare diseases or to starve tumors dependent on amino acids by reducing blood levels below the normal range. 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: The Clinical Project Manager (CPM) is responsible for the management of all aspects of Clinical Trial Team activities for assigned project(s). The CPM, in concert with the Clinical Program Director, is accountable for achieving successful delivery of Aeglea clinical team activities at the project level by meeting company and regulatory requirements according to time, quality/scope and budget constraints.

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

- Proactively manage project level operational aspects of Clinical Trial Team (CTT) including management of trial timeline, budget, resources and vendors.
- Provide efficient updates on trial progress to the Clinical Program Director (CPD) and/or Senior Director of Clinical Operations (DCO), with respect to vendor selection, project plans, trial budget and timeline management, quality standards and risk mitigation.
- Lead sponsor study startup process, including but not limited to conduct of the Trial Kick-off meeting, the set-up of trial master file (TMF), site selection and finalization of site and vendor Clinical Trial Agreements and budgets.
- Ensure effective project plans are in place and operational for each trial and work proactively with the Clinical Trial Team (CTT) to set priorities in accordance with applicable project plans, company standard operational procedures (SOPs), ICH/GCP guidelines and regulatory requirements.
- Ensure potential study risks are escalated to the attention of the CDP when appropriate.
- Chair CTT working group and vendor status update meetings and ensure meeting minutes are completed, distributed to team members and filed in the Trial Master File (TMF) in a timely manner.
• Review and approve site visit reports; ensure tracking, follow up and resolution of site issues have been completed in a timely manner.
• Monitor the quality of vendor deliverables, address quality issues with the appropriate team member and identify opportunities to improve training, execution and quality control across the clinical team.
• Review and approve vendor invoices in collaboration with the Accounting team to ensure investigator payments occur in a timely manner.
• Review and approve vendor responses to quality assurance audits for appropriateness, timeliness and accordance with company SOPs and regulatory requirements.
• Ensure all project level study documentation is filed in the TMF in accordance with company SOPs/all regulatory requirements and provide oversight to the clinical team regarding TMF filing, maintenance and archival procedures.
• Effectively provide support to Clinical Site Manager(s) in the conduct of the trials.
• Other duties as assigned.

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:
• Bachelors degree in Life Sciences, Nursing Licensure or Pharmacy, at minimum.
• Four or more years of clinical operations experience for CPM; with increasing levels of responsibility, in the Pharmaceutical, Biotechnology, Medical Device or CRO industry is required.
• Five or more years of clinical project management experience at a sponsor or CRO company is preferred for CPM.
• Therapeutic experience in oncology and/or rare disease (preferred).
• Experience in early phase trials (Phase I-II) and First-In-Man trials (preferred).

Knowledge, Skills and Abilities:
• Read, write and speak fluent English; excellent verbal and written communication skills.
• Must have a thorough knowledge of clinical research concepts, practices, and FDA regulations and ICH Guidelines regarding drug development phases, clinical research and data management methods.

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 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.