CLINICAL PROGRAM DIRECTOR
POSITION DESCRIPTION

Job Title: Clinical Program Director – Oncology
Reports to: Senior Director of Clinical Operations
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 rare diseases and cancers associated with abnormal amino acid metabolism. The company’s recombinant human enzymes are designed to degrade specific amino acids in the blood in order to reduce toxic levels of amino acids in rare diseases or to starve tumors dependent on amino acids by reducing 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 homocysteine, a target for an inborn error of metabolism, as well as two potential treatments for cancer, AEB3103, which degrades cysteine/cystine, and AEB2109, which degrades methionine.

Position Summary:
The Clinical Program Director (CPD) is responsible for managing Clinical Operations activities and providing functional supervision for Clinical Operations staff within their assigned Clinical Development Plan (CDP) as determined by the Sr. Director of Clinical Operations. The CPD conducts required tasks in collaboration with Clinical Project Management, Clinical Site Management and the Clinical Operations Specialist as well as with other members of the cross-functional CDP Project Teams. Responsible for representing Clinical Operations at the CDP level and for managing Clinical Operations activities as assigned with an entrepreneurial approach that requires the ability to multi-task on a wide spectrum of activities with an overall external focus.

Essential Duties and Responsibilities: To perform this job successfully, an individual must be able to perform the following within the scope of their assigned Clinical Development Plan:

- Oversee clinical project and site management activities including: trial timelines, budgets, resources and vendors.
- Supervise Clinical Project Managers (CPMs) and Clinical Site Managers (CSMs) as assigned in collaboration with the Sr. Director of Clinical Operations (DCO). Assign short to mid-term responsibilities. Identify training needs to foster high level of performance, support career
development through quality development plans. Proactively manage performances issues. Establish key performance indicators in alignment with department and company objectives.

- Ensure effective project plans are in place and operational for each trial and work proactively with the Clinical Trial Teams (CTT) to set priorities in accordance with applicable project plans, company standard operational procedures (SOPs), ICH/GCP guidelines and regulatory requirements.
- Determine Clinical Operations FTEs required to efficiently execute Aeglea clinical trials and provide regular updates and recommendations to DCO regarding resource management.
- Support the DCO in the development of the annual Clinical Operations budget and hiring plan.
- Ensure potential study risks are escalated to the attention of the DCO when appropriate.
- Develop and implement training and supporting operational documentation in collaboration with the DCO (SOPs, WIs, tools, etc.) for CPMs and CSMs.
- Develop clearly defined strategies and lead or contribute to assigned global, cross-functional interdisciplinary, high priority initiatives and process improvements.
- Cooperate across all Aeglea relevant business units and maintain effective working relationships with interfacing groups.
- Provide Clinical Project Management support on trials when appropriate and as determined by the DCO.
- 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:
- Bachelor’s required, Master’s preferred
- A minimum of 10 years of clinical operations experience, with increasing levels of responsibility, in the Pharmaceutical, Biotechnology, Medical Device and/or CRO industry is required.
- Five or more years of clinical program management experience at a sponsor or CRO company
- Prior line management experience is required.
- Prior monitoring and clinical project management experience is required.
- Therapeutic experience in oncology (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.
- Must have prior experience managing a clinical trial portfolio or large scale clinical trial program globally and be able to demonstrate a proven track record of successfully leading cross-functional projects in a global environment.

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.