CLINICAL PROJECT MANAGER
POSITION DESCRIPTION

Job Title:	Clinical Project Manager
Reports to:	Head of Clinical Operations/Sr. Project Manager or Designee
Classification:	Full-Time/Exempt/Salaried

Company Summary: Aeglea BioTherapeutics, Inc. is an Austin, TX based biotechnology company committed to developing enzyme-based therapeutics in the field of amino acid metabolism to treat rare genetic diseases and cancer. The company's engineered human enzymes are designed to modulate the extremes of amino acid metabolism in the blood to reduce toxic levels of amino acids in inborn errors of metabolism or target tumor metabolism for cancer treatment.

Position Summary:
The CPM (Clinical Project Manager) in close collaboration with their supervisor, is responsible for the management of all aspects of Clinical Trial Team activities for assigned project(s). The CPM, in concert with their supervisor, 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 with the Clinical Trial Team (CTT) including management of trial timeline, budget, resources and vendors.
- Providing efficient updates on trial progress to the Project Team and supervisor(s), with respect to vendor selection, project plans, trial budget and timeline management, quality standards and risk mitigation.
- Lead project 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.
- In conjunction with supervisor/mentor, develop, optimize and implement effective project plans for each project
- 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 supervisor when the probability of occurrence and expected impact suggest a significant risk to timing, cost or quality of the project and where no effective contingency or mitigation strategy has been developed.

- Chair CTT meetings and ensure meeting minutes are completed, distributed to team members and filed in the Trial Master File (TMF) in a timely manner.
- May review and approve site visit reports; ensure tracking, follow up and resolution of site issues have been completed in a timely manner.
- Proactively monitor the quality of project 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 vendor 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.
- 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:

- Minimum of a bachelor degree in Life Sciences or Nursing Licensure
- Prior experience as a clinical project manager, clinical lead or senior CRA is required.
- Prior monitoring experience is preferred
- Relevant therapeutic experience is preferred

Knowledge, Skills and Abilities:

- Demonstrated ability to build a project team environment of open collaboration within a pharmaceutical, biotechnology or CRO organization
- Demonstrated ability to integrate and mobilize individual team members to achieve project goals
- Demonstrated ability to clearly and consistently communicate goals aligned with the project and organizational deliverables
- Demonstrated ability to recognize and minimize issues with the potential to cause significant group conflict within the project team
- Demonstrated ability to identify creative ways of enhancing/exploiting new ideas, practices or approaches
- Demonstrated ability to offer constructive opinions and ideas regarding new initiatives/systems/processes and remain open minded to the views of others
- Demonstrated ability to remain calm under stress during period of change or high demand and remain focused on managing tasks and meeting deadlines
- Demonstrated ability to provide feedback to project team members and recognize the contributions of others
- Demonstrated ability to solicit feedback from others and react positively to constructive criticism
- Demonstrated ability to work effectively across functional boundaries and bring together resources across the matrix to accomplish goals
- Demonstrated ability to offer arguments based on facts and logic to persuade others of the merit of a position

- Demonstrated ability to seek compromises and trade-offs when necessary to gain cooperation and achieve goals
- Demonstrated ability to plan, organize and prioritize own workload and schedule to successfully meet timelines and deliver results
- Demonstrated ability to establish a project plan including setting clearly defined objectives and timelines and the ability to effectively achieve goals and timelines
- Demonstrated ability to assign tasks appropriately and successfully while avoiding duplication and retaining sufficient oversight to ensure quality output in a timely manner
- Demonstrated ability to take ownership and accept accountability for project and actions
- Demonstrated ability to identify and anticipate issues that put the project at risk and alert appropriate individuals (including management) with suggestions for resolution
- Demonstrated ability to apply logic and gather information required to make decisions and resolve challenges in a timely manner with minimal guidance
- Demonstrated ability to critically evaluate suggestions and input from a range of sources to effectively resolve issues and progress solutions
- Demonstrated ability to build trust and credibility with project team members, subordinates, peers and supervisors
- Demonstrated ability to understand the relationship between time, cost and quality and to identify which of these is the key driver for project deliverables while balancing the other two
- Read, write and speak fluent English; excellent verbal and written communication skills
- Familiarity with MS Project preferred
- Must have a thorough knowledge of clinical research concepts, practices, and FDA regulations and ICH Guidelines regarding drug development phases, clinical research and project 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.