**Clinical Trial Manager - Opthalmology,** Waltham, Massachusetts

**Responsibilities:**

The Clinical Trial Manager is accountable for the management of one or more clinical trials including trial start-up, conduct, and close-out activities. Will lead one or more Study Management Teams.

- Ensure trial adherence to ICH/GCP/local regulations.
- Develop study plan(s) including key milestones and timelines.
- Ensure country and site selection meet study requirements.
- Develop and manage clinical trial budgets.
- Ensure accuracy and timeliness of vendor and site payments.
- Vendor identification and management (e.g., CROs, IVRS, Reading Centers, etc); including participating in negotiation of vendor scope of work, budgets, performance management, issue resolution, and quality assessments.
- Ensure availability of clinical/non-clinical supplies.
- Provide input for clinical regulatory documents (IB, CSR, IND updates).
- Participate in development and testing of clinical systems (laboratory, data entry, IVRS, etc).
- Ensure internal and external systems are updated in a timely manner (CTMS, clinicaltrials.gov).
- Maintain and oversee the Trial Master File.
- Author/co-author protocols in collaboration with Medical Monitor and other stakeholders.
- Identify, address, and communicate quality and compliance concerns.
- Ensure inspection readiness internally and externally.
- Provides regular study status updates and as requested.
- Communicate effectively with internal and external study personnel (investigative staff, vendors, etc).
- Provide study-specific direction, mentoring, and management to other staff as appropriate.
- Manage direct reports as assigned.
- Other duties and responsibilities as required.

**Qualifications:**

- Bachelor's Degree required.
- Experience in ophthalmology required.
- 2+ years' experience managing clinical trials within biotech, pharmaceutical or medical device environment.

**Skills, Knowledge & Abilities:**

- Excellent verbal and written communication skills.
- Experience in a start-up environment preferred.
- Must be pro-active team player, flexible, and open to change.
- Knowledge of GCP and ICH.
- Experience developing study plans and budgets including risk mitigation strategies.
- Experience in multiple phases of research preferred.

**Other:**

Applicants must be authorized to work in the U.S.

**Apellis is…**

A clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade. We believe that this approach can result in broad inhibition of the principal pathways of the complement system and has the potential to effectively control a broad array of complement-dependent autoimmune and inflammatory diseases.

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