Job Description

Position Title:	**Senior Clinical Research Associate**
Report To:	**Senior Clinical Affairs Manager**
Department:	**Clinical**
Location:	**Remote**
FLSA:	**Exempt**
Date:	**August 2024**

APPLY

We are changing the standard of care for millions of untreated sufferers of ENT conditions. We improve patient access to life-changing relief through safe, practical, and effective innovation that changes how and where patients are served. Aerin differentiates itself with our commitment to providing straightforward and clinically proven products so that ENTs and their patients can make treatment decisions together without limits.

At Aerin Medical our values show up as: Aerin Mindset, Integrity, Respect, Innovation and Excellence.

As a Senior Clinial Research Associate at Aerin Medical, you will be an essential part of our mission-driven team, dedicated to transforming the lives of those with untreated ENT conditions. Your role will involve contributing directly to our commitment to innovation and improved patient care.

PURPOSE OF JOB:
The Senior Clinical Research Associate will play a pivotal role in managing and monitoring clinical trials at Aerin Medical. The Sr. CRA will be responsible for Pre-study, Site Initiation, Routine Monitoring and Close-out Visits to ensure it adheres to regulatory requirements, company standards, and Good Clinical Practice (GCP) guidelines. The Sr. CRA will collaborate closely with cross-functional teams, including regulatory, quality assurance, and clinical operations, to ensure the successful execution of clinical studies.

MAJOR DUTIES AND RESPONSIBILITIES:

- **Study Compliance Monitoring:** Ensure that research site personnel, including investigators, adhere to the clinical protocol, Good Clinical Practices (GCP), and regulatory requirements.
- **Site Initiation and Training:** Conduct site initiation visits to ensure that research sites are properly prepared and trained to conduct the study according to protocol. Provide ongoing training and support to site staff as needed.
- **Monitoring Visits:** Independently conduct monitoring visits, with minimal guidance and support from the Clinical Project Manager and/or Manager of Clinical Affairs.

- **Data Verification:** Confirm that data in Case Report Forms (CRFs/eCRFs) aligns with source documents through rigorous source data verification.
- **Adverse Event Reporting:** Identify and report adverse events in collaboration with the research site staff, ensuring compliance with reporting guidelines under the direction of the Clinical Project Manager.
- **Site Documentation Review/Archiving:** Assess the accuracy and completeness of site records, including the study site file, query resolutions, and other data collection tools. Ensure proper archiving of all study-related documentation in compliance with regulatory requirements and company SOPs.
- **Investigational Product Accountability:** Ensure proper accountability of investigational products at the site level.
- **Compliance Assessment:** Maintain regular contact with sites to assess and ensure study compliance. Ensure that all studies are conducted in accordance with ethical principles, including obtaining informed consent from participants and maintaining confidentiality of participant data.
- **Enrollment Tracking:** Monitor screening and enrollment activities, reporting any issues to the Clinical Project Manager.
- **Audit Readiness:** Support the Clinical Project Manager in ensuring that sponsor and investigative site files are audit-ready.
- **Regulatory Documentation:** Collect and manage regulatory documents, including confidentiality disclosures, IRB approvals, investigator agreements, contracts, and annual study reports.
- **Regulatory Submission Support:** Assist in the preparation and submission of regulatory documents to ethics committees, Institutional Review Boards (IRBs), and other regulatory authorities. Ensure all necessary approvals are obtained before the initiation of the study.
- **Forms and Templates Development:** Contribute to the development of clinical research forms, questionnaires, trackers, and templates.
- **Data Management Collaboration:** Work closely with data management teams to ensure accurate and timely data entry, query resolution, and data cleaning. Assist in the review of statistical analysis plans and contribute to the interpretation of study data.
- **Budget and Contract Oversight:** Assist in the negotiation and management of site contracts and investigator agreements.
- **Investigator Meetings Support:** Assist with the logistical and administrative aspects of Investigator Meetings.
- **Project Deliverables:** Complete assigned clinical project deliverables according to the established schedule.
- **Quality Control:** Participate in internal and external audits to ensure that all clinical research activities meet quality standards. Implement corrective and preventive actions (CAPA) as required.
- **Customer Interaction:** Build and maintain strong relationships with investigational sites to promote site engagement and retention throughout the study. Exercise sound judgment when interacting with external stakeholders.
- **Continuous Improvement:** Identify opportunities for process improvement within clinical operations and contribute to the development of best practices for future studies.
- **Mentorship:** Provide mentorship and training to junior CRAs and other clinical staff as needed, fostering their professional development.

EDUCATION REQUIREMENTS:

- Bachelor's degree or diploma in Science, Engineering, Quality or similar discipline is preferred.

EXPERIENCE REQUIREMENTS:

- Minimum of 3 years' experience in clinical research

OTHER QUALIFICATIONS:

- Good oral and written communication skills, with the ability to communicate effectively with medical personnel
- Proven flexibility and adaptability
- Ability to work collaboratively in a team or independently as required
- Skilled with Microsoft Office with the ability to learn appropriate software and internet-based programs
- Ability to travel up to 60%
- Authorization to work in the US for any employer

BENEFITS AND PERKS:

Our culture is rooted in our core values every day, in everything we do.

Our benefits focus on the 5 dimensions of wellbeing: physical, financial, emotional, career and community. Physical benefits include Medical – PPO & HSA with co-contribution, Dental, Vision, Accident Insurance, Critical Illness, Hospital Indemnity, and onsite Tonal & Peloton. Financial benefits include HSA/FSA, 401k with company match, Lifestyle Spending Account, Long Term Disability, Life Insurance, a monthly stipend to cover phone and tech costs, employee discounts, and weekly office lunches. Emotional benefits include Employee Assistance Program, 5 free counseling sessions per issue per year, 80 hours sick leave, 13 holidays, and flexible vacation (exempt employees). Career and Learning & Development opportunities with Aerin led leadership trainings. Community initiatives which include Aerin "give back" week, family days as well as Aerin holiday giving.