Head of Clinical Operations

COMPANY OVERVIEW

AIRNA is a biotechnology company with a mission to transform lives, one RNA edit at a time.

AIRNA is pioneering the discovery and development of RNA editing therapeutics to realize the therapeutic potential of base editing for patients with rare and common diseases. RNA editing modality is poised to lead the next generation of RNA therapeutics by bringing the precision of gene editing technology with a potent and safe medicine that can be conveniently re-dosed and manufactured. Our RESTORE+™ platform is based on groundbreaking research by academic co-founders Thorsten Stafforst (University of Tübingen) and Jin Billy Li (Stanford University), who were the first to elucidate a therapeutic approach for precise editing of RNA.

AIRNA has received $90 million in Series A financing from world class venture capital firms, including Forbion and Arch Venture Partners, and is headquartered in Cambridge, MA with research operations in Tübingen, Germany.

JOB DESCRIPTION:

The Head of Clinical Operations will be responsible for the overall management and performance of clinical operations, including outsourcing, vendor management, process development and improvement. The candidate will be responsible for timelines, budgets, resources, selection of clinical trial sites, CRO evaluations and selection, as well as close oversight to ensure clinical strategies are implemented and for high quality clinical project deliverables. The main responsibility of the role is to ensure projects are delivered on time, within budget and are of high quality. This individual represents clinical operations and can clearly and concisely provide updates to senior management and guidance to clinical leads responsible for various assets under development. The individual must be able to work independently as an effective and engaged team member in a fast-paced environment. Strong initiative, flexibility, problem solving, positive attitude and follow-through are essential for this role.
The role reports into the CMO and partner closely with cross-functional team leaders to ensure seamless collaboration and communication to ensure timely delivery of clinical trials.

This position is based in Cambridge MA.

RESPONSIBILITIES

- Leadership responsibility for Clinical Operations strategy, initiation, and execution of clinical trials across all phases, including (but not limited to) CRO/vendor selection, site engagement, contracts & budgets, CRO oversight, and proactive risk management to ensure the quality conduct of trials with a high level of data integrity.

Head of Clinical Operations

- Scoping geographic region- and site-specific approaches with substantial experience in global clinical trial execution for successful incubation of trials during diligence and launch post transaction is highly critical
- Direct all aspects of timeline/fiscal management, analyses, compliance, and conduct global and domestic clinical trials to ensure delivery of company goals on time, within budget and in compliance with SOPs, FDA and ICH/GCP guidelines.
- Partner collaboratively with key internal functions such as Medical, Regulatory, CMC, and Program Management to implement the Company's clinical strategies and drive organizational success.
- Optimize and implement SOPs, processes, communication, & infrastructure within the Clinical Operations Department to support company goals including Regulatory filings.
- Responsible for oversight of adverse event reporting from clinical studies, monitoring, adherence to protocols through study completion.
- Ensures clinical data is "clean" and investigators and sites are trained to deliver uniformity. Identification of data trends especially as they relate to protocol deviations.
- Responsible for the development and management of budgets, develop mechanisms to drive accountability of actions and broadly contribute to strategic thinking and provide data driven executive recommendations.
- Participates in the preparation of regulatory documents in support of regulatory submissions, including clinical section of IND's and CTA's, IND safety reports and annual reports for assigned trials, responses to regulatory authorities and Ethics Committees/IRBs, and other documents as appropriate.
- Provides scientific and clinical input to study-related documents and analysis plans including Informed consent forms, clinical research forms, statistical analysis plans, and clinical study reports. Represent clinical operations plans and status to partners and senior audiences, both internally and externally.
- Participates in investigator meetings and other meetings/conferences, as necessary.
- Develop and maintain good working relationships with KOLs, Investigators and study staff.
- Performs other duties as assigned related to clinical and preclinical programs.

Head of Clinical Operations

Qualifications:

- 15+ years of clinical operations experience, with at least 5 years in a leadership role.
- Proven track record of managing clinical trials across multiple phases.
- Prior experience leading clinical programs in a small, start-up biotech strongly preferred.
- Bachelor's degree, ideally science related, with advanced (clinical) degree preferred.
- Significant experience conducting and managing large-scale, multi-site, multi-country, clinical trials at all Phases of development.
- Track record of establishing successful collaborations with study sites including PIs and their study teams
- Excellent team interaction skills along with demonstrated ability to lead and influence others.
- Demonstrated evidence of strong project management capabilities.
- Excellent oral and written communication skills
- Well-developed critical reasoning skills and in risk management assessments.
- Detail oriented and able to operate in a fast-paced, fast-growth environment with limited resources.
- Ability to work collaboratively in a fast-paced, team-based matrix environment and to function independently as appropriate.
- Candidates with experience in global clinical research and interacting with regulatory authorities preferred.
- Willingness and ability to travel domestically and internationally as required