



Head of Clinical Operations

*Akouos is building the leading gene therapy company focused on hearing disorders. Our objectives are to **restore** the inner ear's ability to produce functional proteins required for hearing, **rejuvenate** structures of the hearing circuit critical for high-fidelity signal transduction and inner ear homeostasis, and **reinforce** healthy hearing with local, enduring protein production to protect against drug-, noise-, and age-associated ototoxicity.*

Ensuring delivery to the right cells, in the right amounts, and at the right time is central to our ability to restore and preserve hearing. Recombinant adeno-associated viruses (AAVs) can be harnessed as powerful vectors that are capable of safely and efficiently delivering therapeutic nucleic acids to the nuclei of target cells. Akouos's initial focus is on delivery of adeno-associated viral (AAV) gene therapies to treat hearing loss in genetically-defined patient populations.

Akouos launched in 2017 with backing from 5AM Ventures, New Enterprise Associates, and Partners Innovation Fund.

RESPONSIBILITIES

The Head Clinical Operations will have broad responsibility for the strategic and tactical operational leadership of all clinical programs and ensure the successful delivery and execution of studies. Will create and manage study timelines, budgets, and study management plans while adhering to regulatory and corporate quality standards. Is accountable for clinical sourcing strategy, including the selection and governance of clinical vendors, such as Clinical Research Organizations (CROs), as well as hiring and development of clinical team members. Will play a key role in the selection of clinical investigators and sites globally.

This newly created role will lead the evaluation, selection, and oversight of CROs and other vendors to ensure successful clinical trial implementation and execution on all clinical programs. This includes providing guidance on the framework for contract negotiations and vendor selection, and review and approval of vendor contracts and scope of work. Will perform periodic visits to sites and/or CROs to assess progress of studies/protocol compliance. Will oversee TMF maintenance, monitoring. Will work with internal regulatory and pharmacovigilance groups and external CROs to help oversee safety reporting.

Will effectively engage and utilize internal and external data management, biostatistics, and medical writing resources to achieve clinical operation objectives. Will partner with internal program management, regulatory, and quality functions to ensure compliance and alignment with company objectives, procedures, and policies. Contribute to the writing and review of clinical documents such as protocols, informed consent forms, investigator brochures, monitoring plans, and clinical study reports.

Will provide strategic and tactical guidance in risk management and anticipate/recognize risks and issues on assigned programs and associated studies; manage resolution and/or escalation of study related issues.

REQUIREMENTS

- BA/BS in a scientific field and a minimum of 10 years of experience in Clinical Operations in the Pharmaceutical/Biotech industry
- Outstanding verbal and written communication skills, including experience writing protocols, consents, investigator brochures, CSRs, and other supporting documents
- Demonstrated ability to effectively lead multi-disciplinary teams
- Experience hiring and developing clinical operations teams and leading those teams to excel
- Thorough knowledge of global regulations and guidelines, including good clinical practice to ensure the appropriate conduct of clinical studies
- Experience successfully selecting and managing external vendors
- Excellent project management skills, including timeline and budget management
- Early stage company experience preferred
- Previous experience in rare disease and/or gene therapy clinical trials preferred

Qualified applicants should submit their resume to careers@akouos.com.

Akouos is committed to equal employment opportunity and non-discrimination for all employees and qualified applicants without regard to a person's race, color, sex, gender identity or expression, age, religion, national origin, ancestry, ethnicity, disability, veteran status, genetic information, sexual orientation, marital status, or any characteristic protected under applicable law.