



Our Mission: Healthy hearing available to all.

Clinical Data Operations Manager

*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' initial focus is on delivery of 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.

Job Summary:

This role manages the end to end clinical data flow and ensures timely project execution, quality data deliverables, and prioritization of all Data Management (DM) milestone delivery. By acting as the primary DM representative to the study management teams, the role partners with key study/program team members to develop and implement project plans for assigned studies, ensuring the functional activities are completed by vendors according to specified quality standards and timelines, and for coordinating ongoing data management activities with vendors. Uses operational knowledge to establish and implement study level operational plans and oversees vendors.

Job Requirements:

- Accountable for development of timelines and project management of all end to end data management deliverables in collaboration with cross functional team members and vendors (including EDC, reading centers, and specialty labs) on assigned studies
- As the primary contact for Data Management, develop strong working relationships and effective communication between Clinical Operations, Data Management, Biostatistics, and other Akouos functional departments
- Lead the development and improvement of data processes, collection, management, and reporting
- Foster collaboration across all projects to improve consistency of systems and processes
- Manage performance and quality issues with vendors and escalate to relevant project leads as needed



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- Run monthly data review meetings with the medical monitoring team to identify changes in clinical outcomes that may be indicative of safety findings
- Provide timely, quality metrics to study teams using a variety of tracking tools (tables, databases, spreadsheets, and files), and program/build additional tools as needed
- Provide training support to investigative sites to ensure accurate and timely completion of eCRFs

Job 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:

- Bachelor's degree in Life Science or related discipline
- A minimum of 2 years of experience in biotech/pharma industry within data management
- A minimum of 2 years of experience in biotech/pharma industry within clinical operations

Knowledge, Skills and Abilities:

- Extensive on-site monitoring experience
- Strong working knowledge of FDA & ICH/GCP regulations/guidelines and thorough knowledge of clinical monitoring procedures
- Working knowledge of at least 1 computer programming language (e.g.: Visual Basic, MATLAB, SQL) for use in statistical analysis and reporting study metrics
- Exceptional attention to detail and excellent organizational skills with a strong initiative
- Excellent oral and written communication skills
- Ability to thrive in a dynamic and fast-paced environment
- Ability to prioritize duties and manage multiple matters from start to finish with minimal supervision with a demonstrated ability to lead change and make independent decisions
- Ability to effectively and positively work with executive-level management
- Ability to handle highly confidential/sensitive materials or information with complete discretion and having good judgment in working with clients, occasionally under ambiguous or challenging circumstances

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.