Associate Director/Director Biostatistics, Data Management and Programming

Atsena Therapeutics is a clinical-stage gene therapy company that is leveraging novel AAV vectors designed to overcome the unique hurdles presented by retinal disease to reverse or prevent blindness. Our lead program, ATSN-201, is a gene therapy for X-linked retinoschisis (XLRS), which is currently being evaluated in a Phase 1/2 clinical trial. We are also advancing ATSN-101, a gene therapy for the treatment of *GUCY2D* Leber congenital amaurosis (LCA1) towards a Phase 3 trial. We have additional preclinical programs to treat other forms of inherited retinal disease as well as novel capsid technology suitable for addressing large indications.

At Atsena, we are bringing patients into focus. We are passionate about finding cures for visually impaired and blind individuals and are driven by cutting edge science to ensure we achieve the safest and most effective results.

Position Summary:

Atsena is seeking an experienced and highly motivated Associate Director/Director of Biometrics to lead our Biostatistics, Data Management, and Clinical/Statistical Programming functions. This individual will be responsible for developing and executing biometrics strategies that support the design, execution, and analysis of clinical trials across all phases of drug development and commercialization. The ideal candidate will have a strong background in biometrics, regulatory compliance, and cross-functional collaboration within a biotech or pharmaceutical environment.

Responsibilities:

- Lead and manage biometrics functions (statistics, data management, clinical/statistical programming) for all clinical development programs, ensuring alignment with the company's corporate goals, scientific objectives, and regulatory requirements
- Develop and implement a strategy for biometrics resourcing
- Ensure overall high quality and effective operations in biometrics functions.
- Accountable for biometrics input in documentation including clinical development plans, clinical protocols, regulatory documents, publications, internal and external meetings, and presentations.
- Provide expertise in statistical methodology, regulatory submission strategies, and innovative data analysis approaches for retinal disease gene therapy.
- Accountable for the development, implementation and execution of statistical analysis plans that support clinical development plans and clinical protocols, and assures statistical integrity, adequacy and accuracy.
- Accountable for the development, implementation, and execution of randomization strategies for applicable clinical trials
- Accountable for the selection, oversight, and documentation of vendors providing biometrics services for clinical protocols.

- Accountable for the set-up, oversight, and documentation of data deliverables from external vendors providing data for clinical trials.
- Collaborate with cross-functional teams to communicate resource needs, budget, timelines, data insights and biometrics strategies to internal stakeholders and external partners.
- Establish best practices, identify the need and drive the creation of functional standard operating procedures for clinical data management, biostatistics, and clinical/statistical programming.
- Participate in meetings with external experts and regulatory authorities to support safety reviews, statistical endpoints, analyses and related issues.
- Collaborate with researchers and thought leaders in the planning of clinical development programs and the publication of study data.
- Provide ad hoc analysis as needed for internal and external stakeholders for strategic decision making

Qualifications:

- Ph.D. in Biostatistics or Statistics
- At least 10 years biotech industry experience, including at least 3 years of leadership experience at a pharma/biotech company
- Experience directly leading/managing all aspects of biometrics (statistics, programming, and data management)
- Experience working on a Phase III clinical program in Ophthalmology or Rare Disease
- Extensive experience in contributing to NDAs/BLAs submissions, including significant interaction with both FDA, EMEA, and PMDA
- Experience applying principles and techniques of data analysis, interpretation, and clinical relevance in clinical drug development
- Experience managing external CROs, vendors, and partners to ensure biometrics-related deliverables are high quality, on time and within budget.
- Experience presenting data to internal management, external experts, and regulators.

Required Skills:

- Ability to travel as needed
- CRO/Vendor management experience
- Fluent in English (written and spoken)
- Strong computer skills: Word, Excel, PowerPoint, Outlook, Smartsheets

- Expertise in statistical methodology, clinical trial design, and regulatory requirements in the context of ocular gene therapy and/or other gene-based therapeutics.
- Expertise in clinical trial design, statistical modeling, and SAS/R programming.
- Expertise with setup and management of Data Management systems, e.g., Medidata Rave.
- Perseverance mindset with the ability to stick with a task during challenging times
- Strong leadership skills and the ability to manage multiple projects independently
- Strong organizational, written and oral communication, tracking, and presentation skills
- The ability to handle multiple priorities within matrix environment
- Strong problem-solving skills
- Proven track record of fostering creativity, productivity, execution with a sense of urgency, teamwork, accountability, and cross-functional collaboration
- Team-builder who leads by example, employs expertise and influence to encourage collaboration across departments, levels, and groups to achieve key objectives
- Excellent collaboration required – needs the energy to work across global & functional boundaries both internally and externally
- Vision – keen awareness of R&D priorities to apply novel solutions to scientific problems

Role Location

Onsite, Durham, NC