Associate Director Clinical Development

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:

The Associate Director is responsible for developing and preparing the Clinical Development Plan (CDP), ensuring its effective and efficient execution across the assigned molecule(s) and/or indication(s). This role involves drafting clinical documentation, representing clinical development across sub-teams and other relevant forums, supporting the training of study site personnel, and acting as the primary point of contact for inquiries related to clinical development studies and programs. The Associate Director will also conduct ongoing medical and safety data reviews and provide clinical development input into study reporting.

Responsibilities:

- Develops and/or prepares the Clinical Development Plan (CDP) under the guidance of Senior Medical Director, with a particular focus on clinical study design.
- Collaborates with Clinical Operations to ensure consistent language and criteria for key clinical documents, including the Informed Consent Form (ICF), protocol eligibility, dose modifications, safety protocols, Case Report Forms (CRFs), and CRF instructions.
- Reviews and/or writes additional clinical development documentation, and provides input on documents managed by other teams, such as protocol summaries, safety monitoring plans, investigator brochures, etc.
- Works closely with Clinical Operations to prepare materials for investigator meetings and other relevant study or program-related meetings.
- As needed, attends study site visits and investigator or other meetings with Clinical Operations staff.
- Collaborates with Clinical Operations, Data Management/Biostatistics, and other groups to conduct clinical reviews of study data, identifying and evaluating trends, outliers, protocol violations, and other key findings.
- Participates in safety meetings, tracking and analyzing potential safety events, and ensuring accurate reporting.

- Prepares for internal and external meetings and presentations, including investigator meetings, advisory boards, data safety monitoring committee meetings, and regulatory agency meetings.
- Writes and/or reviews abstracts, posters, and content for scientific meetings, conferences, and other events, coordinating review processes with internal partners and stakeholders.
- Coordinates submissions to scientific meetings and other relevant venues or groups.
- Maintains scientific and clinical expertise in the relevant therapeutic and disease areas.
- Collaborates with a variety of internal and external stakeholders, including clinical investigators, clinicians, scientists, KOLs, and multidisciplinary internal groups (e.g., clinical operations, research, business development, commercial operations, legal, etc.).

Qualifications:

- Advanced Clinical Degree required (e.g., MD, OD, MD/PhD or OD/PhD).
- Minimum of 4 years of clinical trial experience in the pharma/biotech industry or 6 years of academic experience with clinical trials. Experience as clinical scientist in the pharma/biotech industry preferred.
- Data listing review experience preferred.
- Familiarity with electronic data capture (EDC) systems (e.g., Medidata RAVE) is preferred.
- Experience in authoring experimental protocols and/or study results and conclusions preferred.
- Relevant ophthalmology experience is preferred.
- In-depth understanding of drug development processes preferred.
- Experience with data analysis techniques, interpretation, and clinical relevance preferred.
- Comprehensive understanding of product and safety profiles is a plus.
- Strong knowledge of medical aspects of GCP (Good Clinical Practice), ICH (International Conference on Harmonisation), FDA, EMEA, NICE, and other relevant guidelines and regulations.
- Proficiency with Microsoft Office Suite (Word, PowerPoint, Excel) required; familiarity with graphing software (e.g., GraphPad Prism) and statistical software (e.g., R) is preferred.

Required Skills:

- Exceptional attention to detail.
- Strong understanding of basic statistics and ability to identify trends and outliers in data analysis.
- Strong business acumen with a working knowledge of the multidisciplinary functions involved in drug development (e.g., clinical operations, biostatistics, regulatory, commercial operations).
- Excellent project management skills, including the ability to prioritize multiple tasks and ensure timely, on-target, and budget-conscious completion.
- Strong interpersonal, verbal communication, and influencing skills, with the ability to influence without authority.
- Excellent written communication skills.
- Strong business presentation skills; comfortable and effective in presenting to internal and external audiences.
- Strong negotiation skills, with the ability to effectively collaborate to meet deliverables.
- Sound judgment and decision-making skills, balancing ethics and efficacy when making trade-offs.
- Effective team player with a collaborative approach to working with internal and external partners.
- Ability to travel as needed (<20%).

Role Location

Onsite/Hybrid, Durham, NC