n-lorem FOUNDATION

Position Title: **Preclinical Scientist (Study Monitor / Toxicology)**
Reporting to: Vice President, ASO Discovery and Development
Hours: Full-Time
Location: Remote or Hybrid in San Diego, CA
Compensation: $90K - $120K /annual+ benefits

n-Lorem Foundation

Though n-Lorem is pioneering a novel non-profit model, to provide personalized experimental ASO treatments for free, for life to patients with the rarest of mutations (nano-rare), we are functionally a biotechnology company. We have a large and growing portfolio of ASO medicine discovery programs, ASO medicines in development and multiple clinical programs.

With a seasoned leadership team and strategic partnerships, the n-Lorem Foundation provides the framework, funds and access for nano-rare patients who are amenable to our technology to receive personalized ASO medicines for free, for life. We hope that you will consider joining us as we strive to change the world, one nano-rare patient at a time.

If you are a preclinical professional with strong biotechnology/toxicology experience and would like to join a cohesive, experienced team committed to the belief that we can change the world one patient, one family at a time, we may have a position for you.

Job Overview:

n-Lorem is seeking an experienced, highly organized, and action-oriented Preclinical Scientist to support discovery and development programs, with a primary focus on nonclinical study oversight and toxicology. This role will serve as a key scientific and operational interface between n-Lorem Preclinical Development, external contract research organizations (CROs), and internal cross-functional teams.

The individual in this role will assume primary responsibility for the planning, execution, and monitoring of preclinical studies, ensuring scientific rigor, data quality, and alignment with program timelines and regulatory expectations. This position requires strong scientific judgment, effective communication, and the ability to independently manage multiple studies in a fast-paced, mission-driven environment. The role will also contribute to the preparation of nonclinical components of regulatory submissions and related documentation.

Key Responsibilities:

- Serve as scientific lead and primary study monitor for assigned nonclinical programs, with accountability for study conduct, data quality, and scientific interpretation.
- Review and approve study protocols, amendments, deviations, and reports ensuring alignment with program objectives and regulatory expectations.
- Critically evaluate toxicology data to support go/no-go decisions and program progression.
- Identify risks early and proactively propose mitigation strategies, including study redesign, sequencing changes, or additional exploratory work.
- Author or co-author nonclinical sections of INDs, amendments, briefing documents, and responses to regulatory questions, in collaboration with the cross functional team, as needed.
- Oversee CRO performance, including scientific quality, timelines, and budget adherence; escalate issues as needed and drive resolution.
- Participate in CRO selection and scope definition, including review of proposals and scientific alignment.
- Ensure studies are conducted in compliance with applicable GLP or non-GLP standards, internal SOPs, and sponsor expectations.
- Maintain accurate study tracking and documentation, including timelines, budgets, study status, and deliverables.
- Ensure data integrity, archiving, and traceability of study materials and reports.
- Contribute to continuous improvement of internal processes, templates, and best practices for preclinical development.

Requirements:

- MS or Ph.D. in Biology, Biotechnology, Toxicology, Veterinary Medicine or closely related field, with 3 + years of experience working in a pharmaceutical, biotech or CRO
- Demonstrated experience acting as a study monitor for in vivo nonclinical studies, including toxicology and/or safety studies; Experience with antisense oligonucleotides (ASOs) preferred.
- Comfortable working with incomplete datasets and making scientifically sound recommendations under time pressure.
- Working knowledge of FDA nonclinical expectations for rare disease or individualized therapeutics preferred.
- Experience supporting IND-enabling programs is a strong plus.
- Strong documentation discipline, with attention to traceability and version control
- High degree of personal accountability and ownership for assigned programs.
- Ability to independently manage multiple studies and priorities with minimal oversight.
- Comfort interfacing with senior internal stakeholders and external partners, including CRO scientific leadership.
- Ability to respectfully challenge assumptions and data quality, including with external vendors.
- Adaptability and resilience in a fast-moving, mission-driven environment.
- Strong sense of urgency balanced with scientific rigor.
- Collaborative mindset with the ability to work across functions and disciplines.

n-Lorem offers a competitive benefits package including medical, dental, vision, 403(b), four weeks paid vacation, paid sick time, life insurance, employee assistance program. n-Lorem is a small foundation with an extraordinary mission, to provide hope and potentially help to nano-rare patients. Every employee in our organization is a significant contributor to this mission. We know that our work could have a profound impact on the life of a patient today.

n-Lorem is an equal opportunity employer. All applicants will be considered for employment without attention to race, color, religion, sex, sexual orientation, gender identity, national origin, veteran or disability status. n-Lorem is committed to providing reasonable accommodations for candidates with disabilities in our recruiting process. If you need any assistance or accommodations due to a disability, please let us know.

For more information on n-Lorem, please visit our website www.nlorem.org