Position Title: **Clinical Scientist**

Reporting to: Executive Director of Clinical Development

Hours: Full-Time

Location: On-site in Sorrento Valley, CA

Compensation: $70K - $110K /annual + benefits

**n-Lorem Foundation**

n-Lorem is a non-profit organization founded in 2020 committed to discovering, developing and providing experimental treatments to patients who have genetic diseases caused by nano-rare mutations that affect 1- 30 patients worldwide - for free for life. We leverage decades of experience in antisense oligonucleotide (ASO) technology and a roadmap described in 4 FDA guidance documents from 2021. Since establishment 5 years ago, n-Lorem has grown to meet the needs of the nano-rare patient community and have successfully filed >20 INDs for n-Lorem ASOs and are currently treating >20 patients in the clinic. We continue to be in an exciting time of significant growth while we scale our infrastructure and know that this endeavor is only possible with a strong and mission-driven team.

**Job Overview:**

n-Lorem is seeking a passionate, organized, detail- and action-oriented individual to join our team as a Clinical Scientist. In this role, you will partner closely with the clinical development, regulatory and clinical operations/project management teams. You will help set up, manage and track n-Lorem’s clinical trials, including assisting in protocol and informed consent development, data monitoring, and the preparation of clinical data for internal and external presentations.  You will also support the development of Investigational New Drug (IND) applications, and various regulatory activities. You will be expected to wear many hats and will have the opportunity to expand the scope of your work and responsibilities over time.

You will work across many functional teams which will require clear and timely communication, and the ability to quickly adjust to changing priorities. No two days will be the same, therefore flexibility and self-motivation will be key aspects for a candidate to be successful in our fast-paced biotech environment.

**Job Duties:**

* Assist in the development of clinical materials, including protocols, informed consent documents, IND sections, and site initiation materials
* Assist in the development and implementation of natural history studies
* Ensure timely data entry and assist with facilitating data resolution queries from the sites.
* Track outcomes assessments used across all clinical trials
* Track upcoming clinical milestones
* Provide literature updates on areas relevant to clinical development such as collection of phenotypic data in clinical trials, clinical updates from ASO trials, new outcomes measures
* Assist in compiling important information on rare diseases, such as incidence rates, disease characteristics
* Work with clinical development team on preparing data reports from all n-Lorem programs for presentation to internal and external teams
* Develop, maintain, and improve templates for various documents including clinical protocols, informed consents, clinical trackers
* Proactively identify inefficiencies and propose possible solutions to enhance clinical development operations
* Provide general support for n-Lorem scientific and clinical publications
* Other duties as assigned to support our quickly growing multi-disciplinary team

**Requirements**

* US work authorization
* BSc, MS or PhD degree in a scientific discipline required, preferably rare disease
* Minimum of 3 years of experience working in the pharmaceutical/biotechnology industry / clinical site
* Familiarity with clinical trials and ICH guidelines related to clinical trials
* Understanding of working with rare disease populations
* Exemplify discipline in meeting deadlines and deliverable on a daily basis
* Demonstrated ability to rapidly acquire and apply new skills and concepts
* Excellent interpersonal and communication skills and effective cross-functional collaborations
* Excellent ability to work in a goal and team-oriented setting and handle competing priorities.
* Flexibility within a rapidly changing environment and high attention to details.
* Well-developed organizational skills and the ability to thrive under pressure
* Proficient software skills (e.g., MS Office including Word, Excel, PowerPoint), with experience in Prism, PowerBI, and Electronic Data Capture systems preferred.

**References**

* Initial FDA guidance for ASO for patients with diseases caused by ultra-ultra-rare mutations: [Jan. 4, 2021](https://www.fda.gov/news-events/press-announcements/fda-takes-steps-provide-clarity-developing-new-drug-products-age-individualized-medicine)
* Pre-clinical requirements: Detailed guidance April 2021
* CMC guidance [Dec 2021](https://www.fda.gov/media/154664/download)
* Clinical guidance [Dec 2021](https://www.fda.gov/media/154663/download)

n-Lorem offers a competitive benefits package including medical, dental, vision, 403(b) and 4 weeks paid vacation. n-Lorem is a small foundation with an extraordinary mission, to provide hope and potentially help to nano-rare patients today. 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.

For more information on n-Lorem, please visit our website [www.nlorem.org](http://www.nlorem.org/)

**COVID-19 update:**

We are pleased that 100% of n-Lorem employees/temps who have reported their vaccination status are vaccinated against the COVID-19 virus.

**Additional COVID-19 precautions**

All employees, and contractors/consultants regularly working on-site are strongly encouraged to be fully vaccinated against the COVID-19 virus.