Position Title: Sr. Clinical Trial Manager
Location: Cambridge, MA

Company Description

Cognito is a venture backed (Morningside Ventures) startup company translating scientific findings from MIT into therapeutic approaches for Alzheimer's disease and other neurodegenerative conditions. We are a fast moving, highly motivated team of people with the ambitious goal of helping the millions of Alzheimer's disease patients and caregivers around the world. With our patented gamma stimulation technology, we are committed to developing non-invasive device-based therapies. Developing this unique platform requires expertise across a range of fields. Engineering, Software Engineering, Regulatory, Clinical, Product Design, Data Science, QA, Business Development, Marketing, just to name a few. We are looking to grow our world-class team of scientists and medical device innovators who want to make a difference and improve people's lives on an everyday basis.

Summary of Role

We are seeking an experienced, team oriented, Sr. Clinical Trial Manager (minimum 5 years in direct study management) to join our company who can roll-up their sleeves and help us manage all stages of our ongoing and upcoming clinical trials. You will coordinate and oversee all CRO/clinical site/vendor activities, including being the primary contact between trial sites and Cognito Tx. You will work side-by-side with the Director of Clinical Affairs to assist in clinical trial management tasks as delegated (e.g. trip report review, issue tracking, protocol deviation review, and field support team management), with a focus on providing support during the development and production of timelines, budgets, writing of technical reports and various study plans throughout the duration of each clinical trial.

Deliverables

You will be responsible for:

- Independently planning and implementing all components of clinical trials in accordance with protocols and applicable Standard Operating Procedures (SOP), Good Clinical Practices (GCP), ICHs and applicable local regulations
- Documenting processes through development of Work Instructions and study specific plans, then documenting adherence thereto
- Establishing and maintaining relationships with trial sites, monitoring/co-monitoring, managing, and closing clinical study sites
- Collaborating with colleagues at all levels and in all departments of the company to ensure company success

- Liaising with CROs and other clinical vendors as directed to ensure deliverables are met and methods of communication are developed to facilitate efficient work flow
- Assisting in the management of study progress reporting (from protocol development and planning to study close-out) to assure adherence to intended timelines, internal communication, and achievement of key milestones and overall study goals

Who You Are

You're someone who likes the fast pace and energy of a startup company and wants to influence your own development. You're looking for an early stage company with an exciting technology, where you have the opportunity to make a difference for patients around the world. You will have an entrepreneurial and team spirit, a strong motivation to learn, and the ability to develop creative solutions to complex problems. You are able to work independently while collaborating with the team, demonstrating strong interpersonal, speaking, and writing abilities. Along with being highly organized and detail-oriented, you will have excellent time management and project management skills.

Minimal Qualifications

- B.A./B.S. with 5+ years of managing clinical trials within biotech
- Preference for CNS experience, especially in cognitive impairment
- Comprehensive understanding of clinical development strategies and trial designs
- Understanding of medical and statistical scientific methodology
- In-depth understanding of the legal and regulatory environment of the medical device/ pharmaceutical industry, demonstrated integrity on work-related compliance considerations and solid ethics
- Good communication skills; team oriented

Contact

Interested? Send a short introduction and resume to jobs@cognitotx.com