875 Mahler Road, Ste. 168
Burlingame, CA, 94010
+1 415-890-3961
www.calahealth.com

Job Description: Clinical Program Manager

Cala Health, Inc.

About Cala Health

Cala Health is a bioelectronic medicine company transforming the standard of care for chronic disease. The company's wearable neuromodulation therapies merge innovations in neuroscience and technology to deliver individualized peripheral nerve stimulation. Cala Health's lead product, Cala Trio™, is the only non-invasive prescription therapy for essential tremor and is now available through a unique digital business model of direct-to-patient solutions. New therapies are under development in neurology, cardiology, and psychiatry. The company is headquartered in the San Francisco Bay Area and backed by leading investors in both healthcare and technology. For more information, visit CalaHealth.com.

The Opportunity

The Clinical Program Manager provides clinical study management and cross functional leadership for product development in support of Cala clinical development and commercial strategies. Key accountabilities include assuring successful conduct of clinical studies consistent with applicable regulations, guidelines and procedures, as well as managing clinical project timelines, budgets, deliverables, and overall communications.

Specific Responsibilities also include

- Overall operational oversight of assigned clinical studies including but not limited to preparation of study related documentation (protocols, case report forms, consent documents, letters of agreement, confidentiality agreements) and investigator selection, analysis and establishment of enrollment strategies.
- Work with senior management to develop project timelines, study budgets and project management plans; report to all stakeholders at regular schedule on project status.
- Participate on product development program teams as the clinical representative for assigned projects; leads clinical study execution teams and serves as point person for communications with program teams.
- Works with senior management to identify and select consultants, vendors, etc.; responsible for overall management of vendors and study monitoring.
- Creates and implements departmental procedures (including project management processes and SOPs) in compliance with industry standards and regulatory requirements. Responsible for the oversight of the ongoing maintenance of the Trial Master File.
- Works with the digital team to develop App and modules for e-consenting, patient screening and study data collection.

- Monitors compliance with all company standard operating procedures (SOPs), GCP, FDA and applicable local regulations concerning clinical activities.
- Organizes the writing and review of clinical sections of regulatory submissions and product labeling and ensures compliance with applicable regulations
- Management of multiple clinical studies (including App based studies) in parallel, through direct reports and/or other support staff, as appropriate

Desired Skills and Experience

- Bachelor's degree or equivalent in the life sciences or related field required; advanced degree (Master's or above) preferred.
- 4+ years' functional experience with managing clinical trials, preferably in a medical device environment
- Ability to identify critical information needs and identify roles / individuals to involve for decision making within clinical studies
- Thorough knowledge of GCP, ICH guidelines and other US and international clinical regulatory requirements.
- Working knowledge about e-consenting and data collection through Apps.
- Excellent verbal and written communication skills. Excellent organizational, record retention, time management, decision making, customer service, and interpersonal skills
- Data management experience and knowledge of statistical principles as applied to clinical trials highly desirable.
- Demonstrated ability to work independently with new, complex technologies and produce professional work products.
- Strong work ethic and demonstrated ability to deliver assignments on time
- Ability to travel as required (up to 15%)

If you or someone you know might be interested in this position, please submit a resume & an introductory email to **careers@calahealth.com.**