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Position: Clinical Research Coordinator
Industry: Medical Device
Location: Orange, CA

Company Overview

Our client is a clinical-stage medical device company based in Irvine, California. They have developed a novel wearable therapeutic ultrasound approach to non-invasive outpatient treatment of critical limb ischemia (CLI). Treatment of this condition, which affects over 2M patients in the US alone without any adequate solution, represents a new market opportunity of over $1B. The technology is based on decades of pre-clinical and clinical research by the company's co-founder and his colleagues in the field. The first-in-human proof-of-concept data with the device will demonstrate statistically significant increases in blood supply and tissue perfusion.

We are assembling a team of highly motivated and experienced individuals to lead the company to reach its corporate objectives and milestones.

Essential Job Functions

The key objective of this role is to manage a clinical site and assist in the execution clinical research operations to assure that clinical trials are completed according to committed timelines and regulations. The job requires a hands-on person to manage clinical operations at a clinical site in a focused, efficient, and effective manner.

The position is a hybrid with location in Orange, CA.

Principal Duties and Responsibilities

- Interview, recruit, schedule and screen potential candidates based on the clinic's medical records
- Oversee and perform clinical activities at a clinical trial site
- Function with minimal supervision handling various clinical study assignments
- Build good and effective relationship with clinical site's personnel
- Work independently and actively to coordinate activities between Vibrato and investigational site, improving subject enrollment rates, assuring timely completion of case report forms
- Participate in development of detailed clinical site training materials, interface and train clinicians and site staff on as-needed basis
- Maintain sponsor's required documents such as case report forms, informed consents, source documents, and others. Verify trial/study data, including maintaining appropriate regulatory documents both internal and external. Assure timely completion of accurate study status reports
- Lead in the investigation of all discrepancies in study documentation, by applying clinical protocol knowledge and GCP; and develop processes to mitigate reoccurrence throughout study phases. Organize and prepare submissions to IRB if needed

Knowledge, Skills and Abilities

- Minimum of 5 years of Clinical Research Coordinator experience at a well-known clinical site
- Knowledge of ICG GCP guidelines and expertise to review and evaluate medical data
- At least 3 years of Medical Device clinical trial experience, including knowledge of medical device regulations
- Excellent written and verbal communication in English language; proficiency in Spanish language a plus
- Demonstrated problem-solving and critical thinking skills
- Knowledge of Peripheral Vascular diseases and therapies is a plus
- Nursing or other Cinical degree is a bonus