Contact: Terry McCarthy
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Position: Sr. Clinical Research Associate
Industry: Medical Device
Location: Irvine, 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.

Position Summary

The key objective of this role is to assist in the successful execution of clinical studies from study start-up and study close-out and to assure that company sponsored clinical trials are completed according to committed timelines, FDA regulations, corporate policies and procedures. The job requires a hands-on person to support all clinical operational aspects of the assigned clinical trial/site in an organized and efficient manner.

Responsibilities

- Work independently to coordinate activities between the sponsor and investigational sites including qualification, start-up, enrollment and close-out
- Oversee the execution and monitor progress of the assigned studies, improving subject enrollment rates and assuring timely completion of case report forms
- Assist in site contract and budget negotiation
- Help prepare clinical protocols, informed consent forms, and case report forms
- Verify the site has and maintains the appropriate regulatory documentation to conduct the trial/study, assuring timely completion of IRB renewal and progress reports
- Train site personnel on sponsor's and regulatory requirements for study conduct
- Conduct monitoring visits (site initiation, interim, and close-out), prepare reports, and associated documentation
- Participate in auditing and verifying the quality and completeness of study data
- Manage/oversee tracking and accountability of investigational products and trial materials.
- May provide on-site protocol procedural support

Candidate Qualifications

- Bachelor's Degree in one of the life sciences, biomedical engineering, or health care background (RN, etc.)
- Clinical Research Associate with a minimum of 3 years of site management experience required
- At least 2 years of medical device experience
- Knowledge of ICH GCP guidelines/ FDA regulations as it relates to clinical trial operations

- Excellent written and verbal communication in English language; proficiency in Spanish language a plus

- Must be able to establish and maintain good working relationships and work cooperatively with investigators, clinical research personnel, and patients
- Demonstrated problem-solving and critical thinking skills
- Ability to produce accurate work within tight deadlines
- Strong computer skills in Google Docs, MS Office Suite, including Excel, and PowerPoint
- California State driver's license and access to a vehicle for travel to investigational sites (Orange County) is required