magnusmedical

Sr. Clinical Research Associate

Job Description

Magnus Medical's Senior Clinical Research Associate is a remote, contract role reporting to the Clinical Operations Manager that will have the primary responsibility of leading, managing and executing clinical trials at sites participating in clinical trials sponsored by or in collaboration with Magnus Medical. This position requires the ability to travel up to 70%.

Specific responsibilities include (but are not limited to):

- Responsible for standard site management activities for clinical trial sites participating in clinical trial sponsored by or in collaboration with Magnus Medical
  - Obtaining essential documentation from clinical trial sites in preparation for study start up
  - Preparing study sites for trial readiness and communicating with team members to ensure successful study start up in accordance with Magnus procedures
  - Maintaining current site documentation throughout the course of trial participation
  - Providing site support for protocol questions, study supplies and all other site support required
  - On-site and remote monitoring of data captured for assigned sites
    - Query creation and resolution
    - Follow up of action items to ensure rapid resolution
    - Creation and submission for review of monitoring visit reports according to the monitoring plan for each study
    - Regulatory binder review
  - Maintaining audit readiness of all site documentation at all times

- Support clinical affairs team as it relates to study operations such as:
  - case report form development and Electronic Data Capture (EDC) user acceptance testing
  - Provide input and support the development and validation of Magnus Clinical Database
  - Collaboration with clinical affairs team members for development of Site initiation visit (SIV) training materials
  - Work with Site Managers to coordinate SIV training
  - Collaborate with in house CRAs/Site Managers to manage all studies
  - Trial Master File maintenance

    - Clinical Trial Site invoice review and processing
    - Device accountability and collaboration with cross functional team members as it relates to providing devices to and maintaining adequate functioning of devices at clinical trial sites.
    - Assist with maintenance of the Clinical Trial Management System (CTMS)
- Cross functional collaboration with Marketing/Commercial/Software and Hardware team members as required
- Goal oriented attitude to achieve study milestones as set by Magnus executive team
- Ensures trial adherence to governing regulations (FDA/GCP/ISO/IRB/EC)
- Identifies gaps in recruitment and enrollment communicates with sites and clinical team to facilitate improvement
- Remains current on industry standards and guidance documents
- Elevates identified non-compliance issues to Director and/or VP; develops and implements plan to return to compliance

Experience

The ideal candidate for this role has a minimum of 5 years direct Clinical Research Associate experience responsible for site management, preferably in a medical device start-up environment.

Requirements

- Bachelor's Degree in a life science
- Thorough understanding and experience with standard medical device company's quality systems, SOPs and how they relate to clinical affairs and the everyday conduct of clinical trials
- Thorough understanding of 21 CFR 812, 50, 56 and 11
- Experience with multiple EDC systems
- Ability to communicate with physicians, psychiatrists and clinical research coordinators and vendors with expertise
- Self-starter who works with a sense of urgency and acts as a team player with other disciplines
- Adaptability, flexibility, independence, and resourcefulness to "roll up sleeves" and multi-task in order to thrive in a small-company environment.
- Ability to travel up to 70% during the traditional times of high travel for clinical trials (SIV, data deadlines, study close out). Ongoing travel requirement expected to be approximately 25%.

Salary Range: $70 - $100 per Hour (Contract Position)

Company Statement

Magnus is a venture-funded medical devices startup based in the San Francisco Bay Area, led by industry veterans, and committed to development of novel neuromodulation technology for personalized treatment of psychiatric and neurological disorders.

We are deeply committed to integrity, kindness, and communication, and these principles govern how we will build our team and operate the company.

We value diversity and are committed to creating a positive, inclusive environment for all employees, contractors, and consultants.