Avenda Health

Director of Clinical Affairs

Santa Monica, CA (Remote Position)

Avenda Health was founded in 2017 by a diverse team of passionate entrepreneurs dedicated to simplifying cancer treatment, improving the standard of care. Our flagship product is an image-guided focal treatment for prostate cancer that preserves quality of life. Our technology uses proprietary sensing and artificial intelligence to guide and monitor cancer treatments in real-time in a doctor's office.

We are a clinical-stage startup that is seeking multi-talented individuals who are passionate about building and launching impactful products that can directly improve patients' lives.

We are seeking a Director of Clinical Affairs to implement and execute a marquee pivotal trial in full compliance with GCP and all other applicable regulatory requirements. The Director of Clinical Affairs will manage a small clinical staff as well as external vendors. The Director of Clinical Affairs will report directly to the COO. Director must be willing and able to contribute directly to her/his team's success as well as the success of the trial.

Specific Responsibilities

- Implementation and execution of a multi-site RCT on-time and on budget
- Manage the process of screening, qualifying, selecting, and contracting with investigators, sites and vendors required for the clinical trial
- Selection and development of software and database to execute clinical trial
- Internal team selection, training, and development
- Obtain necessary clinical trial approvals from IRBs and regulatory bodies such as the FDA and Health Canada
- Ensure studies are on track for site initiation, patient recruitment and enrollment, and take corrective actions where necessary to address issues
- Ensure clinical results are interpreted and documented clearly and concisely for regulatory submissions and publications
- Develop SOPs and work instructions to assure internal files and clinical study files (patient; site; country) conform to Good Clinical Practice regulations and standards
- Ensure adherence to protocols and compliance with regulatory (FDA/ISO/GCP) guidelines as well as SOP procedures
- Identify clinical training needs and develop training materials for in-house and clinical site use
- Develop and implement a publication strategy

Skill Requirements

- Strong track record in successfully implementing and executing medical device clinical trials

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- Demonstrated expert knowledge and comprehensive understanding of applicable GCP, ISO, & FDA guidelines and applicable international regulations
- Strong, hands-on manager with experience in managing KOLs, clinical affairs staff, CROs, Core Labs, Data Management, Biostatistics, and Medical Affairs Safety Reporting
- Knowledge of electronic data capture systems and web-based clinical trial management tools
- Excellent interpersonal, written / verbal communication & organizational skills with attention to detail
- Collaborative team player
- Ability to work within a fast-paced and sometime resourced constrained startup environment
- Willing & able to travel for trial implementation, as required (up to 30%)

Desired Skills

- Familiarity with the urology and prostate space
- Experience with trials in Canada
- Experience working on trials to support a PMA submission
- Familiarity and experience working with CMS and private insurers

Avenda Health is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, religion, color, national origin, gender, age, status as a protected veteran, among other things, or status a qualified individual with a disability.

If you are qualified and interested in the above position, please email your resume with cover letter to careers@avendahealth.com with "Director of Clinical Affairs" in the subject line.