Avenda Health

Director of Clinical Affairs

Santa Monica, CA (Remote Position)

Come help us improve the lives of patients with prostate cancer. With FDA "Breakthrough Device Designation," Avenda Health is primed to be the first new therapy approved by the FDA for localized prostate cancer in over 40 years. Voted the "most promising focal therapy" by Urologists, our AI-based male lumpectomy treats prostate cancer in an office-based setting while preserving quality of life.

Avenda Health is a fast-paced startup company passionate about building and launching impactful products that directly improve patients' lives. We are seeking a Director of Clinical Affairs to implement and execute a marquee pivotal trial, the first of its kind in the focal therapy field. The Director of Clinical Affairs will build and manage a clinical staff as well as external vendors. We are looking for someone willing and able to contribute directly to her/his team's success as well as the success of the trial. The Director of Clinical Affairs will report directly to the COO.

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.