ReCor Medical
Ultrasound Denervation Therapies

Clinical Trial Specialist
Department: Clinical Affairs
Reporting to: Clinical Affairs Manager

About ReCor Medical

ReCor Medical, headquartered in Palo Alto, CA, is an innovative medical technology company focused on transforming the management of hypertension, the leading cardiovascular risk factor in the world. ReCor has pioneered the innovative, minimally invasive use of ultrasound in renal denervation to lower blood pressure in patients with hypertension. The company is focused on investing in high quality product development efforts, as well as rigorous clinical studies to create a strong foundation for future clinical adoption.

ReCor Medical is a wholly-owned subsidiary of Otsuka Medical Devices Co., Ltd. Otsuka Medical Devices focuses on the global development and commercialization of endovascular therapies that provide new therapeutic options in areas where patient needs cannot be met through pharmaceutical treatment. Otsuka Medical Devices Co., Ltd. is a subsidiary of Otsuka Holdings Co., Ltd., a leading global healthcare group listed on the Tokyo Stock Exchange (JP 4578). With operations in pharmaceuticals, nutraceuticals, medical devices and other health-related businesses, the group generated worldwide sales of app. US$13 billion in the fiscal year ended December 2019 and has a market capitalization of app. US$25 billion.
http://www.omd.otsuka.com/en/ http://www.otsuka.com/en/

Position Summary
The Clinical Trial Specialist is responsible for clinical study document maintenance and will coordinate closely with Clinical Site Managers, Clinical Research Associates, other study team members, and sites to ensure appropriate documentation of compliance with Data Protection (e.g. GDPR, HIPAA), Good Clinical Practice (GCP), and relevant local laws and regulations, company SOPs, study protocols, and manuals.

Responsibilities and Duties
- Set-up and maintain study specific Trial Master File (TMF); electronically (eTMF) and/or in paper, including reconciliation and archival.
- Ensure timely filing in Trial Master File to support readiness for audits and inspections.
- Review and track incoming and outgoing essential study site documents (site/study status, enrollment, IRB/EC status, regulatory documents, etc.) to ensure completeness, accuracy, and compliance with GDPR, GCP, company SOPs and study protocols.
- Collect and organize investigator and site information and prepares/follows-up on site activation documents.

- Process invoices per the contractual agreement as needed and support study payments, if applicable.
- Create site regulatory/subject binder(s) as well as other study related documents.
- Maintain records of investigational devices for all assigned regulated studies.
- Manage the inventory of study supplies.
- Support and track shipment of study supplies between research sites and sponsor.
- Track and/or ship device system components, if applicable.
- Assist team with site activation and closure activities.
- Provide ongoing feedback on how to continuously improve working processes and tools.
- Support the Field Operations Team in accessing and correctly using quality system and study documents during all phases of the study.
- Track shipments to/from core labs and maintains records of sample status, if applicable.
- Work collaboratively with local and global team members to provide input on process improvement ideas.

Requirements:

- Associates Degree required; Bachelor's degree preferred
- Basic knowledge of clinical research process from study initiation through regulatory submission
- Excellent and demonstrated organizational and interpersonal skills
- Positive attitude and ability to interact with all levels of staff to coordinate study activities
- Ability to reason independently to assess gaps and brainstorm solutions
- Demonstrated problem-solving skills
- Working knowledge of current FDA IDE regulations and ICH GCP guidelines
- Strong written and verbal communication and conflict resolution skills
- Self-organized person able to make decisions about daily tasks and priorities
- Strong attention to detail and accuracy in performing tasks
- Team-oriented, collaborative, and supportive
- Ability to work independently, prioritize responsibilities, and work within a fast-paced team environment
- Working knowledge of Word, Excel, and PowerPoint required
- Experience with Clinical Trial Management Systems (CTMS) and eTMF preferred

Equal Employment Opportunity

At ReCor Medical, we value bringing together individuals from diverse backgrounds to develop new and innovative solutions for patients. As an equal opportunity employer we do not discriminate on the basis of race, color, religion, national origin, age, sex (including pregnancy), physical or mental disability, medical condition, genetic information gender identity or expression, sexual orientation, marital status, protected veteran status, or any other legally protected characteristic.

Join our growing team! Email resume to careers@recormedical.com