

# ReCor Medical

Ultrasound Denervation Therapies

## **Clinical Site Manager**

Department: Clinical Affairs

Reporting to: Senior Manager, Clinical Affairs

Location: US

Workplace Location: Hybrid

Expected Travel: 70% of the time

## **About ReCor Medical**

At ReCor Medical, we are pioneering Ultrasound Renal Denervation (uRDN) therapy to treat hypertension, the leading cardiovascular risk factor in the world. With our Paradise™ uRDN System, we're on a mission to provide the millions of people who suffer from hypertension with a non-drug and minimally invasive option to lower their blood pressure safely and effectively. Join us on our journey and make a meaningful impact on the lives of people around the globe.

## **Position Summary**

The Clinical Site Manager (CSM) is responsible for the identification and overall management of clinical sites, and for ensuring collaborative, compliant, and timely clinical project execution.

## **Responsibilities and Duties**

- Build and maintain relationships with physicians and other Health Care Professionals (HCP);
- Identify and evaluate clinical sites for participation in ReCor projects;
- Manage clinical sites to ensure timely site/team member authorization- EU], protocol compliance and data quality;
- Provide procedure support, as appropriate;
- Coordinate and conduct Site Interest Visit, Site Qualification Visit (SQV) and Site Initiation Visit (SIV) with CRA, PM, and Recruitment, as appropriate
- Support study agreement and budget negotiation with sites, as appropriate
- Collaborate with ReCor Regional and Project Teams to ensure site compliance with study protocol, GCP, and applicable local/international regulations;
- Lead regular local team calls/meetings to ensure continuous site oversight, and risk assessment and mitigation for project conduct;
- Collaborate with Clinical Recruitment to support site enrollments by defining and implementing site-specific recruitment campaigns;
- Collaborate with ReCor cross-functional teams to ensure timely data entry, query resolution and imaging upload at sites;
- Support Scientific Affairs and Marketing with Scientific Meetings and Congress related activities;
- Comply with Data Protection (e.g. GDPR, HIPAA), Good Clinical Practice (GCP), relevant local laws and regulations, ReCor SOPs and WIs, Instructions for Use Manuals, and study protocols;
- Provide ongoing feedback on how to continuously improve working processes and tools;
- Maintain up-to-date scientific, technical and clinical knowledge;

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- Gather market feedback on system improvements, competitive landscape, clinical developments, and therapeutic trends and communicate to internal teams;
- Ensure timely reporting of product complaints and device deficiencies per SOPs, as well as timely site reporting of protocol deviations and adverse events per protocols;
- Support Regulatory, Medical Affairs and Scientific Affairs teams to ensure timely and compliant completion of time-critical tasks;
- Other duties as assigned.

### **Responsibilities specific for CSM providing procedure support:**

- Train relevant HCPs on the ReCor products, procedures and protocol requirements;
- Get site approval(s) for using the ReCor product (generators and disposables), if applicable;
- Manage shipment & return of Site Investigational Product;
- Plan, organize and provide procedure support;
- Ensure proper use of the ReCor product, in compliance with study protocol.

### **Requirements**

- Bachelor's degree or international equivalent required, in engineering, nursing or related medical or scientific field.
- Minimum of 5 years prior experience in field clinical role preferred.
- Medical device experience in a Cath lab or operating room cardiology, electrophysiology, and cardiovascular and/or implantable cardiovascular device industry preferred.
- Knowledge of good clinical and documentation practices, clinical trial and regulatory processes including understanding of FDA; ICH and ISO 14155 regulations preferred.
- Strong attention to detail and problem-solving skills.
- Excellent presentation, verbal, and written communication skills.
- Proven expertise in Microsoft Office Suite, including Word, Excel, and PowerPoint.
- Enthusiastic, positive and professional team player.
- Willingness to travel. Position requires primarily regional, domestic travel up 70%.

### **COVID-19 vaccination requirements**

At ReCor Medical, we care, we collaborate, we challenge, and we create. Pursuant to these core values, we are focused on the health and safety of our employees, as well as the teamwork essential for innovation of our pioneering technology.

**COVID19 vaccines are required for all ReCor US office employees effective June 10, 2021, as well as all new US office employees joining our company.** Fully vaccinated persons are those who are  $\geq 14$  days post-completion of the recommended series of an FDA-authorized COVID-19 vaccine.

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## **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.