ReCor Medical
Ultrasound Denervation Therapies

Sr. Clinical Research Associate
Department: Clinical Affairs
Reporting to: Clinical Affairs Manager
Location: Remote

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 approximately US$13 billion in the fiscal year ending December 2021 and has a market capitalization of approximately US$19 billion.
http://www.omd.otsuka.com/en/ http://www.otsuka.com/en/

Position Summary
The Senior Clinical Research Associate (CRA) will ensure trial patients' safety and high data quality by ensuring investigative sites are conducting trials ethically, in compliance with all local and national regulations, reporting data accurately, and adhering to the study protocol.

Responsibilities and Duties
- Lead regular regional monitoring team meetings to establish best practices, process improvements, and consistency across monitoring team.
- Collaborate with global counterpart(s) to ensure the sharing of best practices for global studies.
- Review monitoring visit reports.
- May review protocols, eCRFs, ICFs and other study related documents, as requested by the Clinical Project Manager and/or Lead CRA.
- May prepare submissions to Ethics Committee/Independent Regulatory Board (IEC/IRB), and to regulatory authorities.
- Conduct site qualification, initiation, interim, and close-out visits as required.
- Review, plan, and prepare for site visits to ensure source data verification is completed in accordance with study timelines.

- Ensure that the rights and well-being of subjects are protected, monitor data collection for clinical trials at assigned investigative sites. Assess source documentation against study database for accuracy and completeness.
- Assess and ensure regulatory and clinical protocol compliance is maintained at assigned sites, including but not limited to:
  - maintaining appropriate regulatory documents
  - ensuring adverse events and protocol deviations are reported in a timely manner
  - ensuring device complaints and malfunctions are reported in a timely manner
- Establish and develop processes to ensure compliance to monitoring plan and monitoring procedures such as Visit Report Tracking and Projection, Action Item Tracking, and Monitoring Visit Report Completion Guidelines.
- Identify and escalate issues as need to investigators, coordinators, and Clinical Project Manager. Work with investigative site personnel and Sponsor to address identified issues and propose solutions to prevent recurrence.
- Confirm investigational device accountability by review documentation of the history of investigational devices from Sponsor to the sites and through final disposition.
- Develop and deliver training on GCPs, study protocols, database, compliance, device accountability, adverse event reporting, and regulatory documentation requirements.
- Completion of monitoring reports and follow-up letters, which includes summaries of the significant findings, deviations, deficiencies, and recommended actions to secure compliance.
- Conduct activities in accordance with Monitoring Plan and Sponsor SOPs.
- Mentor and train junior team members by conducting co-monitoring visits as needed for training and continuous performance assessment.

Requirements

- Bachelor's Degree in scientific or health-related discipline.
- Clinical Research Associate certification preferred.
- 5-9 years of related experience monitoring interventional cardiology, cardiovascular, or other medical device trials.
- Strong attention to detail.
- Excellent presentation, verbal, and written communication skills.
- Understanding of regulatory submissions, reporting, and audits.
- Position requires primarily regional, domestic travel up 70% of the time.

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. **COVID-19 vaccines will be 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 >=14 days post-completion of the primary series of an FDA-authorized COVID-19 vaccine. **This is a full-time office position** (hybrid remote may be possible; minimum of three days in the office, as permitted by law and company policy).

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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.

E-mail resume to HR: Careers@recormedical.com