ReCor Medical
Ultrasound Denervation Therapies

Clinical Research Associate
Department: Clinical - EU
Reporting to: Clinical Affairs Manager
Location: DE

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 Research Associate (CRA) will ensure trial patients' safety and high data quality by ensuring sites are conducting the ReCor studies ethically, within regulatory compliance, reporting data accurately, and adhering to Data Protection (e.g. GDPR, HIPAA), Good Clinical Practice (ICH GCP and ISO 14155), and relevant local laws and regulations, company SOPs, study protocols, and manuals.

Responsibilities and Duties
•Draft and/or review study documents as required, for compliance with local and national clinical study requirements.
• Support or lead the preparation of submissions to Ethics Committee/Independent Regulatory Board (IEC/IRB), and to regulatory authorities, as applicable.
• 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
- Review and maintain continuously the Investigator Site Files for completeness as well as collect documents for Sponsor Files.
- Identify and escalate issues as need to investigators, coordinators, and Sponsor. Work with investigative site personnel and Sponsor to address identified issues and propose solutions to prevent recurrence.
- Confirm investigational device accountability by reviewing documentation of the history of investigational devices from Sponsor to the sites and through final disposition.
- Deliver training to investigators and site staff on GCPs, study protocols, database, compliance, device accountability, adverse event reporting, and regulatory documentation requirements.
- Complete monitoring reports and follow-up letters, which includes summaries of the significant findings, deviations, deficiencies, and recommended actions to secure compliance.
- Conduct all activities in compliance with Monitoring Plan and Sponsor SOPs.
- Support the preparation of activities related to sites audits and/or regulatory inspections.
- Support proactively the sites during the entire course of studies.
- Provide ongoing feedback on how to continuously improve working processes and tools.