ReCor Medical
Ultrasound Denervation Therapies

Title: Sr Clinical Data Manager
Department: Clinical Affairs
Location: Palo Alto

About ReCor Medical

ReCor Medical is a medical device company that designs and manufactures the Paradise System, a proprietary ultrasound ablation system for renal denervation (RDN). RDN is a new potential therapeutic approach for the treatment of hypertension, one of the most prevalent medical conditions. The Paradise System is approved for sale in the EU and bears a CE mark, but is not approved for sale in the United States. The System's intravascular catheters denervate renal nerves by combining the protection of water-based cooling of the renal artery with high intensity ultrasound energy for circumferential renal nerve ablation. The Paradise System has been studied in clinical trials of approximately 300 patients to date. Following the positive outcomes of the RADIANCE-HTN SOLO trial, ReCor will continue its evaluations of Paradise in RADIANCE-HTN TRIO (a feasibility study of patients with resistant hypertension), REQUIRE (a pivotal study of patients with resistant hypertension in Japan and Korea), and most recently with the launch the RADIANCE II pivotal study (a study of patients with moderate hypertension) in the United States and Europe.

Position Summary

The Senior Clinical Data Manager (Sr. CDM) is responsible for the coordination, application, and delivery of Data Management services, project plan timelines, processes, and standards on assigned projects.

Responsibilities

- Serves as data management lead and primary point of contact for assigned projects.
- Accountable for assigned project data management services and responsible for oversight and delivery of processes.
- Develops and maintains data management study documentation (e.g., Data Management Plan, CRF completion guidelines, Data Transfer Agreement) that deliver accurate, timely, and consistent clinical data, including maintenance with trial master file uploads.
- Manages the development and maintenance of the clinical database system, data collection tools, and applications from set up to database archival
- Creates specifications for database setup, which can include database specifications, dynamic rules, validation checks, monitoring specifications, etc.,
- Contributes to protocol development and review.

- Compiles, analyzes, cleans, and validates clinical trial data to ensure data integrity.
- Ensures data management deliverables are on time and of high quality
- Develops data management reports and monitors study status to ensure timelines are met.
- Represents the data management function to key internal and external stakeholders and participates and/or leads internal/external meetings
- Designs and programs outputs to be able to identify, analyze and interpret trends and patterns in complex data sets.
- Communicates and collaborates effectively with internal operations team and vendors to ensure accurate and complete data collection.
- Provides training and mentoring for junior level data managers, as applicable
- Considered an advanced individual contributor that is highly skilled and proficient in discipline.
- Conducts complex, important work under minimal supervision and with wide latitude for independent judgement.
- Other duties as assigned

Requirements

- Education Requirements
- 5 years relevant experience in a Contract Research Organization (CRO), Pharmaceutical, or Medical Device Company with Bachelor's degree in Health Sciences, Life Sciences, Mathematics, Computer Sciences, or a related discipline (or international equivalent) preferred
- 3+ years relevant experience in a Contract Research Organization (CRO), Pharmaceutical, or Medical Device Company with Master's degree in Health Sciences, Life Sciences, Mathematics, Computer Sciences, or a related discipline (or international equivalent)
- Experience with data management startup, maintenance, and closeout activities
- Exposure to statistical programming packages (e.g., R, S, SAS, SPSS)
- Understand principals of ICH, GCP, ISO 14155; Project Management; Vendor Management; MedDRA and WHO Drug coding & CDISC standards
- Effective written and verbal communication
- Excellent attention to detail and organizational skills
- Ability to manage multiple projects and prioritize effectively

ReCor Medical
Ultrasound Denervation Therapies

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, a s well as all new US office employees joining our company. Fully vaccinated persons are those who are >=14 days post-completion of the recommended series of an FDA-authorized COVID-19 vaccine.

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.