

ReCor Medical

Ultrasound Denervation Therapies

Manager, Clinical Affairs

Department: Clinical Affairs

Reporting to: Director, Clinical Affairs

Location: US

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 Affairs Manager is responsible for the management and development of the clinical operations team, including initiation and execution of the operational aspects of clinical projects.

Responsibilities and Duties

- Manages the performance and development of the clinical operations team, which may include Clinical Trial Specialists, Contract and Payment Specialists, and Clinical Research Associates.
- Determines resources and manages tasks for assigned clinical projects and supports team with prioritization of duties.
- Collaborates with cross-functional partners and represents the operations team.
- Ensures team members are trained and projects are conducted according to SOPs and Work Instructions.
- Communicates project progress and escalates risks and mitigations to Project Manager as needed.
- Assists with developing project specific materials and documents.
- Participates in process improvement initiatives and updates internal processes and tools as needed.
- Ensures completion of study start-up activities including the collection of site regulatory documentation, contract and budget development, and supply maintenance.
- Oversees Trial Master File (TMF) compliance and maintenance to ensure audit readiness.
- Oversees site closure activities including eTMF and financial reconciliation, device accountability, and data review.
- Ensures site monitoring activities are conducted and monitoring reports are completed, reviewed, and approved, in accordance with the monitoring plan, SOPs and WIs.
- Evaluates and provides feedback on current clinical systems and contributes to development and implementation of new clinical systems.
- Leads regular meetings to review team compliance, share best practices, identify process improvements, and create consistency across operations team.

ReCor Medical

Ultrasound Denervation Therapies

- Collaborates with global partners to ensure consistency across geographies.
- Maintains current knowledge of FDA regulations, and GCP (ISO and ICH) Guidelines for clinical research, and Data Protection (GDPR, HIPAA).
- Complies with Data Protection (GDPR, HIPAA), Good Clinical Practice (ISO14155), relevant local laws and regulations, SOPs, WIs, clinical protocols, and Manual of Operations.
- Reviews and approves expense reports and PTO requests.
- Supports operations team development and conducts annual performance evaluations.
- Other duties as assigned.

Requirements

- Bachelor's degree or international equivalent required, advanced degree preferred in medical or scientific field.
- Minimum of 5 years related clinical operations experience.
- Knowledge of global clinical trial and regulatory process including understanding of FDA; ICH and ISO 14155 regulations.
- Ability to lead an interdisciplinary team, including field-based personnel preferred.
- Knowledge of clinical research processes from study initiation through regulatory submission.
- Strong problem solving and critical thinking skills.
- Excellent communication, organizational, and interpersonal skills.
- Expertise in Microsoft Office Suite, including Teams, Word, Excel, and PowerPoint.
- Travel up to 20%, as needed.

Range: \$125K - \$155K (commensurate with experience, skills, education and training)

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 ≥ 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.