ReCor Medical
Ultrasound Denervation Therapies

Clinical Trial Specialist
Department: Clinical - EU
Reporting to: Clinical Affairs Manager
Location: BE

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
Working within the ReCor Medical Clinical Project Management team, the Clinical Trial Specialist (CTS) is responsible for the administrative support during the startup, execution and closing of clinical studies, reporting directly to the Clinical Project Manager. The role of the CTS is to ensure that ReCor Medical clinical studies are documented to the highest level of quality and compliance in accordance with the Study Protocol and company Quality System requirements.

Responsibilities and Duties
The CTS will be responsible for:
- Setting up and maintaining Trial Master Files (TMF) by:
  - Having an overview and tracking all essential documents (and any updates) on a day to day basis, in a proactive and autonomous manner
  - Supporting the Field Operations team in accessing and correctly using quality system and study documents during all phases of the study
  - Reviewing and tracking incoming and outgoing study documents to ensure completeness, accuracy, and compliance with GDPR, GCP, company SOPs and study protocols
  - Filing study documents in the TMF appropriately
- Managing the inventory of study supplies

- Preparing and sending study supplies to sites and/or Field Operations team
- Supporting the tracking of investigational products

• Establishing good communication lines with the Field Operations team
• Supporting the Project Management team as may be required
• Performing general clerical duties including photocopying, mailing and filing
• Performing additional office management and general administrative functions as needed
• Quality. The CTS will be expected to effectively highlight and communicate quality related issues in a timely manner.

Qualifications

•Educated to degree level at minimum
•2+ years medical device or pharmaceutical industry experience in a similar position preferred

Skills & Knowledge:

•Knowledge of Good Clinical Practice (GCP)
•Full Understanding of the clinical research processes, from site activation to study closure
•Experience with managing a TMF
•Ability to communicate and collaborate with people across all levels and from diverse backgrounds
•Independent and proactive personality; able to think critically
•Self-motivated with excellent time management skills
•Meticulous, detailed oriented and efficient
•Proficiency with standard corporate software applications (including MS Word, Excel, Outlook and
•PowerPoint
•Fluency in national language(s) and English is required. Other languages an asset

Travel

•Occasional travel required (team meetings attendance)