Puzzle Medical
Devices

JD–037

MONTREAL, VP Clinical Operations, full-time or part-time, in-person or virtual

Puzzle Medical is developing a percutaneous heart pump for patients with advanced heart failure. The device's modular design allows for safe percutaneous implantation to support both renal and cardiac function through 4mm-pumps anchored in parallel in the descending aorta. To date, Puzzle Medical has successfully: completed a Seed financing round (2022); completed a Series A financing round (2023); completed its 4 patients first-in-human study with all patients experiencing improvements in cardiac and kidney function (2022); received U.S. Food and Drug Administration (FDA) Breakthrough Device Designation (2021).

POSITION SUMMARY

As the Clinical Operations Manager, you will play a pivotal role in the planning, execution, and management of feasibility and pivotal studies related to our ModulHeart device. You will collaborate closely with cross-functional teams and external partners to ensure the successful implementation of clinical trial protocols, adherence to regulatory requirements, and achievement of study objectives.

ROLE AND RESPONSIBILITIES

- Lead the development and implementation of clinical trial protocols, including study design, site selection, regulatory & ethics submissions, investigator recruitment.
- Coordinate all aspects of study initiation, monitoring, and closeout activities, ensuring compliance with study protocols, Good Clinical Practice (GCP), and applicable regulatory requirements.
- Liaise with clinical sites, investigators, and other stakeholders to facilitate effective communication and trial progress.
- In some cases, manage relationships with clinical research organizations (CROs), contract research associates (CRAs), and other external vendors to support study execution and deliverables.
- Oversee site training, enrollment tracking, and data collection efforts to ensure timely and accurate completion of study milestones.
- Monitor trial data for accuracy and integrity, addressing any discrepancies or issues that arise.
- Collaborate with internal stakeholders, including Clinical Affairs and Regulatory Affairs, to address study-related issues and drive continuous improvement initiatives.
- Prepare and deliver regular progress reports, presentations, and risk assessments to management and project teams.
- Facilitate communication and collaboration among study sites, investigators, and study personnel to foster a supportive and efficient clinical trial environment.
- Manage study budgets, forecasting, and resource allocation to optimize study efficiency and cost-effectiveness.
- Stay current with industry trends, regulatory updates, and emerging technologies in cardiac support devices to inform study design and execution strategies.
- Willingness to travel domestically and internationally, as needed, to oversee study activities and ensure compliance with study protocols and regulatory requirements
- Ensure the timely procurement and management of trial materials and equipment.
- Maintain comprehensive records of trial activities, decisions, and outcomes.

QUALIFICATIONS

- Bachelor's degree in life sciences, nursing, or a related field; advanced degree (e.g., Master's, PhD) preferred.
- Minimum of 5 years of experience in clinical operations management, with specific experience in cardiovascular device trials preferred.
- Strong understanding of clinical trial processes, regulatory requirements (FDA, EU MDR, etc.), and industry standards (ICH-GCP, ISO 14155, etc.).
- Proven track record of successfully managing complex clinical trials, including feasibility studies and pivotal trials, from initiation to closeout.
- Excellent project management skills, with the ability to prioritize tasks, meet deadlines, and adapt to changing priorities in a fast-paced environment.
- Effective communication and interpersonal skills, with the ability to build collaborative relationships and influence cross-functional teams and external stakeholders.
- Demonstrated leadership abilities, with experience leading and mentoring multidisciplinary teams in a matrixed organization.
- Proficiency in Microsoft Office Suite (Word, Excel, PowerPoint) and clinical trial management systems (CTMS) or electronic data capture (EDC) platforms.
- Willingness to travel domestically and internationally to support study activities and site monitoring visits.

ASSETS

- Experience with heart failure clinical studies or related cardiovascular trials.
- Knowledge of medical device regulations and compliance.
- Proficiency in data management and clinical trial software.