JOB DESCRIPTION
CLINICAL PROJECT MANAGER

Company Overview

At Prytime Medical Devices, we have a bold vision; to revolutionize the care of severely injured patients by enabling trauma teams to gain control of life-threating bleeding as a bridge to definitive repair. We partner with leading trauma centers to enable endovascular bleeding control through innovative devices and fanatical customer support. Prytime Medical Devices is an innovative medical device company that designs, develops, and commercializes minimally invasive solutions for hemorrhage control. Our flagship product is the ER-REBOA-PLUS™ Catheter, the market leader for endovascular aortic occlusion in trauma. In addition to success with the ER-REBOA-PLUS™ catheter, Prytime was just granted FDA clearance (June 2020) on a next generation product and is poised to create additional strategic opportunities and to lead the introduction of these devices in trauma and adjacent specialties. Prytime is expanding its senior management team as we launch new devices in the trauma and critical care market.

Position Overview

Prytime Medical is seeking a Clinical Project Manager (CPM) to manage an observational study of medical device use in trauma patient care. The CPM will be responsible for performing clinical project management activities in accordance with FDA regulations, company SOPs and study protocols. The CPM will be accountable for achieving high-quality clinical deliverables within established timelines and budget, from study planning through study closeout for a multi-center observational study of REBOA, to include regulatory start-up and study activation, and conduct pertinent trainings. The CPM will be the primary point of contact for communications between clinical sites and Prytime Medical regarding the project. In addition to project management for the observational study, the CPM will be responsible for management of physician feedback data related to the use of the REBOA catheter. The individual who will thrive in this position is a self-motivated professional who is a good communicator, relationship-builder, extremely organized, and who enjoys the fast pace and accountability of a small company and wants to make a contribution as we deliver critical medical devices to the market.

Job Responsibilities

- Develop a realistic detailed study start-up and monitoring plan
- Collaborate with the clinical team and other departments as needed to meet deliverables of the assigned project.
- Regularly communicate with the project team and lead project team meetings to ensure that timelines, resources, interactions, and quality are consistently maintained.
- Effectively communicate with study sites regarding issues such as protocol, patient participation, case report form completion and other study-related issues via mass communication and study newsletters.
- Lead and/or participate in meetings and conference calls with Sponsors, vendors and executive management.
- Prepare clinical study documents such as the patient informed consent form, monitoring Plan, laboratory manual, investigational product manual, and review or contribute to other functional operational plans.
- Prepare study timelines according to project specifications and internal feasibility; monitor compliance to expected timelines throughout the study and escalate potential slippage/delays to appropriate Director.
- Train contract CRAs, CI staff, vendors, and ensure that investigators and study coordinators are trained on study requirements and protocol.
- Review site related materials as needed.
- Assist data management team in the design and development of CRFs, CRF completion guidelines, and UAT as required.
- Review and approve monitoring visit reports.
- Periodically review data to identify potential issues or inconsistencies that could signal problems with data collection or monitoring.
- Manage and maintain database that captures physician feedback on use of REBOA
- Maintain a risk management tool to proactively identify, communicate and mitigate project risks throughout the study.

- Ensure inspection readiness at all times of eTMF and central/site study files.
- Possess an understanding of the assumptions that drive the units in the study budget, and escalate potential overburns to management.
- Understand the project scope of work and identify of out-of-scope activities which may necessitate a change order to the budget and Statement of Work.
- Ensure adherence to FDA regulations, company SOPs and study protocols.
- Provide project status updates to Leadership and escalate issues in a timely manner.
- Maintain records as required by company procedures and regulatory requirements

Qualifications

- Bachelor's degree in Life Sciences, Nursing Licensure or Pharmacy, or other appropriate discipline required.
- Four or more years of clinical operations experience; with increasing levels of responsibility, in the Pharmaceutical, Biotechnology, Medical Device or CRO industry is required.
- Five or more years of clinical project management experience at a sponsor or CRO company is preferred
- Extensive experience with clinical trials, clinical research sciences, and/or regulatory affairs.
- Extensive experience with various aspects of federal and institutional regulatory laws and policy.
- Extensive experience with protocol review.
- Proficiency in the use of software applications, databases, spreadsheets, and word processing required.

Skills and Abilities

- Must have a thorough knowledge of clinical research concepts, practices, and FDA regulations regarding clinical research and data management methods.
- Must have strong attention to detail, be precise, and accurate
- Must possess highly effective analytical, written communication, and presentation skills
- Excellent interpersonal/communication skills; ability to share knowledge in a team setting and effective at all levels of an organization (internal and external)
- Proficient in MS Office Suite and can multi-task and work effectively in a team or independently on assigned tasks,
- Demonstrated problem solving and sound decision-making skills
- Ability to be well organized and flexible
- Must be able to work productively in an extremely fast-paced collaborative environment
- Adaptable to multiple demands, shifting priorities, and be agile to operate at-risk based on available supported information
- Strong technical writing ability
- Experience in trauma trials, critical care, or general surgery clinical research preferred

Travel: Yes, 10-15% to support clinical site set up and periodic in-person site review