JOB DESCRIPTION: EXEMPT	DATE: November 2020
Title: Clinical Research Associate (CRA)	**Reports to:** Project Manager, Clinical Affairs

FUNCTION

The CRA is responsible for the monitoring and management of clinical sites for trials conducted by Inquis Medical. This position focuses on all activities required to evaluate, initiate, monitor, and close out clinical sites in compliance with CRF, ICH/GCP guidelines and Inquis Medical's Standard Operating Procedures.

PRINCIPLE RESPONSIBILITIES

- Ensure study compliance to SOPs, ICH-GCP guidelines, regulatory requirements, the study protocol, and overall study objectives.
- Maintain a working knowledge of the study protocol, investigational device, and Clinical Affairs SOPs and Study Plans.
- Assist with identifying and qualifying potential investigators via activities such as performing remote or on-site Qualification Visits.
- Assist the In-House CRA and Project Manager with site start up activities including but not limited to essential document collection, review, and budget/contract negotiations.
- Responsible for setting up the clinical site, which includes ensuring each site has the appropriate study materials and training required to conduct the trial.
- Conduct Site Initiation Visits either remotely or in-person.
- Serve as the main point of contact for the site from activation through close-out.
- Collaborate with the Clinical Site Managers and members of the Clinical Affairs team to ensure alignment and successful execution of the study.
- Monitor the study throughout its duration by visiting the site on a regular basis, as stipulated in the Monitoring Plan.
- Verify that the data entered onto the CRFs are consistent with patient clinical notes and/or source documents.
- Track and report the progress of the study, including patient enrollment/screening, data monitoring, imaging upload, protocol deviations, issue resolution, and follow-up compliance.
- Ensure device accountability is accurate and complete.
- Ensure that the study staff complies with all safety reporting requirements.
- Prepare and submit visit trip reports and Confirmation and Follow up letters within the required timeframe.
- Ensure completeness and accuracy of the site regulatory binder.
- Ensure clinical site training records are current and maintained as required.
- May assist in the preparation and follow up of sponsored quality audits, as well as regulatory authority inspections.
- Work with the site to ensure that study timelines and milestones are met.
- Assist Data Management as requested.
- Identify data discrepancies, trends, and other analytics related to site performance.
- Attend staff meetings and trainings as required.
- Adhere to Clinical Operations or project-specific quality documents (i.e. SOPs, Work Instruction, etc.) as applicable.
- Other duties may be assigned as deemed necessary by the supervisor.
- This position requires approximately 80% travel, may include international travel.
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JOB REQUIREMENTS *(The minimum qualifications required to adequately perform the job.)*

Education and Experience:

- Advanced Degree or relevant industry experience
- Minimum 5 years' experience in Clinical Research
- Preferably 2-4 years' experience in Device Monitoring
- Cardiology and/or Vascular experience a plus
- Previous Study Coordinator experience a plus
- Strong working knowledge of Microsoft Excel and Power Point
- Proficiency with software applications for PC
- Excellent time management and communication skills (written, verbal)
- Able to set priorities and be flexible within a fast-paced environment

ADDITIONAL SKILLS:

- Hands-on team player with the ability to work in a fast paced, dynamic startup environment.
- Ability to think critically and make strategic decisions.
- Experience working with small cross-function product/process development teams.

Special Requirements:

Environmental Situation:

- General office environment
- Laboratory environment
- Domestic and international travel
- Medical device research and manufacturing environment
- Ability to travel to home office when not on-site or as requested by manager.

Physical Functionality:

- Includes varying work schedule
- Prolonged periods of sitting, standing and walking
- Travel by automobile, train and aircraft (up to 20%, depending on the needs of the project or company)
- Occasional travel on weekends