

## **CLINICAL SITE MANAGER**

---

---

### **PURPOSE OF JOB:**

- Conduct clinical research trials by effectively coordinating the activities of study coordinators and investigators and by ensuring compliance with study protocols, FDA regulations, IRB requirements and overall clinical objectives.

### **MAJOR DUTIES AND RESPONSIBILITIES:**

- Manage all aspects of conducting clinical research studies at investigational sites.
- Establish and foster excellent working relationships with Investigators and site research staff.
- Act as a company representative at clinical cases by traveling to field sites, observing cases, providing support for device questions/issues, soliciting user feedback, preparing written reports on procedures, and ensuring proper collection of data.
- Oversee patient screening and enrollment at assigned clinical study sites.
- Monitor Investigators' compliance to study protocols.
- Ensure adherence to FDA and IRB requirements.
- Work with investigators to quickly and effectively resolve discrepancies.
- Review source documentation, case report forms, and data reports for accuracy and ensure the timely submission of such documentation.
- Develop and direct site training and in-service during site initiation phase.
- Develop materials for clinical training sessions.
- Coordinate meetings with site coordinators and investigators.
- Identify and prepare written reports for serious or unexpected adverse events.
- Prepare accurate and timely reports to management.
- Regularly and promptly recognize problems and recommend and implement methods to improve conduct of clinical study.
- Support company goals and objectives, policies and procedures, Good Clinical Practices, and FDA regulations.
- Perform other duties as assigned.

**EXPERIENCE REQUIREMENTS:**

- 3 - 5 years related experience in coordinating clinical trials. Cardiac background is preferred.

**EDUCATION REQUIREMENTS:**

- BS preferred in Life Sciences, Medicine, or other technical discipline
- RN is a plus

**OTHER QUALIFICATIONS:**

- Excellent written & verbal communication skills.
- Working knowledge of FDA regulatory requirements.
- Ability to work effectively based in a home office
- Requires travel up to 50-75% of time
- Working knowledge of desktop computer & software programs
- Values consistent with Ardian's Core Principles