Hart Clinical Consultants
P.O. Box 510482
Melbourne Beach, FL 32951

Position/Title: **Sr. Clinical Research Associate**

Job Description:

Acts as project resource to the clinical site, sponsor, and HCC personnel regarding the product under test and the clinical trial conduct. Takes an active role in the development and maintenance of company and departmental processes and procedures. May function as the Lead Monitor on assigned clinical trials to ensure adherence to Federal regulations, clinical protocol, company policies, and any other applicable procedures.

Site Management / Compliance:

- Ensures compliance with protocol and all regulatory policies, procedures and/or guidelines during clinical studies by training/guidance of investigators/research coordinators, conducting periodic on-site evaluations and follow-up of corrective actions.
- Ensures validity of trial information by monitoring and tracking clinical trial data (CRFs, source documents, diagnostic reports, inventory logs, etc.) to identify/resolve discrepancies and obtain missing data.
- Maintains expertise in clinical trial regulations for applicable geographies and types of studies. Serves as a resource related to clinical trial regulations.
- Serves as a mentor for new employees and less experienced staff.
- Ensures timely collection of trial documentation by obtaining, maintaining and controlling all necessary records and documentation according to procedures and regulations.
- Ensures proper product supply, accountability and storage during assigned clinical studies.
- Drives trial enrollment and identifies and communications potential and actual obstacles to enrollment.
- Identifies, evaluates, reports and ensures follow-up of adverse experiences by timely and accurate documentation and appropriate communication of all Adverse Event reports per internal procedures and regulatory requirements.
- Attends investigational cases as needed. Develops and maintains strong knowledge of specific trial therapeutic area and competitive landscape.

Clinical Operations:

- Assist with site start-up activities, including collection of site personnel documents and review and approval of clinical site-specific informed consents.
- Trains contract research organizations (CROs) and other ancillary organizations.
- Ensures adherence to applicable ethical, regulatory, and clinical standards by participating in the creation, review, and approval of departmental operating procedures, code of ethics, and mission statement.
- Contributes to the development of clinical protocols, plans, charters, case report forms, and other trial aids.
- Represents HCC and/or sponsor Clinical Affairs Department on cross-functional meetings and projects.
- Identifies and evaluates qualified investigators, investigational sites, and CROs.
- Understands business environment and relates extensive knowledge of internal and external activities to trends. Interfaces with a variety of management levels on significant matters, often requiring the coordination of activity across organizational units.
- Assists with vendor management activities (e.g. core imaging labs, central labs, CROs).

Project Management:

- Drives assigned projects to completion, soliciting input from cross-functional teams as needed.

Skills/Experience:

Minimum Qualifications:

5+ years of related work experience with a strong knowledge of specified functional area, or an equivalent combination of education and work experience.

Preferred Qualifications:

8+ years of related work experience with expert understanding of specified functional area, or an equivalent combination of education and work experience.

Education/Certification:

Minimum Qualifications:

RN, RT, or associate's degree.

Preferred Qualifications:

RN, RT, and bachelor's or advanced degree preferred in scientific or technical field. Clinical Research Certification (ACRP, SoCRA).

Physical Demands/Work Environment:

50-75% primarily regional travel, however may be required to travel nationally, outside of specified region.