AcuFocus is looking for a Clinical Research Associate II to join our team!

The Clinical Research Associate II reports to the Director of Clinical Operations and is responsible for the following:

Clinical Study Execution

- Support the clinical department by carrying out assigned tasks and projects leading to the achievement of department goals and objectives.
- Manage clinical studies by Interacting, both verbally and via written communication, with clinical/investigational sites.
- Manage study timelines and budget and communicate potential issues to management.
- Monitor and track study implementation, progress, and execution.
- Manage or assist with managing monitoring activities of a clinical study.
- Clearly and efficiently track, document, and file essential documents in the trial master file.
- Assist in preparation and planning for, and participates in study-specific meetings (e.g., site training), investigator meetings, video conferences and teleconferences.
- Responsible for or assist with management of outside vendors, including Contract Research Organizations (CRO), Data Management (DM) vendor, reading centers, CRF printers, etc.
- Assist with the development of study protocols, investigator brochures, site-specific instruction manuals,case report form designs, patient information documents, monitoring plans, informed consents, site training documents, and source document templates.
- Manage the DCC process for clinical documents.
- Manage or assist with translation services for clinical materials and validating all materials prior to release/production to guarantee accuracy.
- Participate in FDA or other regulatory authority inspections, as needed.
- Participate in preparation of regulatory submissions necessary to initiate and maintain clinical studies and marketing approvals, including clinical study reports, safety reports, and annual reports.
- Assist in review and filing of regulatory documentation including FDA forms and correspondence, financial disclosure forms (FDF), Adverse Events/Serious Adverse Events (AEs/SAEs), Protocols and Amendments, regulatory binders and Protocol Deviation (PD) forms.
- **May personally conduct or assist in oversight of study monitoring activities detailed below, as necessary.**
- Assist in other duties and projects as assigned.

Clinical Monitoring

- May travel to clinical study sites to conduct comprehensive site qualification, initiation, interim monitoring, and close-out visits.
- Ensure monitoring activities are documented in accordance with the Clinical Monitoring Plan (CPM).
- Personally conduct or oversee comprehensive project training and ensure all site study staff are appropriately trained to the protocol(s), study specific requirements and applicable study documents, Sponsor and IRB/EC reporting requirements, and ICH/GCP.
- Ensure site study staff have required access to electronic systems.
- Verify informed consent procedures are properly followed.

- Assure investigator/site compliance with the study protocol(s) and applicable regulations.
- Verify study sites are collecting all required source data per protocol, accurately transcribing onto Case Report Forms, and resolving all data queries.
- Collect and submit CRFs and data queries to Data Management.
- Review the regulatory binder and essential documents at the study site and verify all documents are filed appropriately.
- Verify essential documents are both filed in the site Investigator Site File (ISF) and the Trial Master File (TMF), as required.
- Conduct investigational product accountability during the study and at study closure at study site(s) by verifying investigational product is properly stored, dispensed, and returned, and that accountability of the product and masking requirements, where applicable, are maintained throughout the study.
- Conduct and perform onsite and/or remote monitoring visits according to the CPM and project needs.
- Ensure clear, efficient, and timely communication with study site(s) and project team members.
- Maintain frequent contact with investigators and site study staff to monitor progress, answer questions and provide guidance during a study.
- Assist study site(s) with preparation of IRB/EC submissions/approvals. Verify all essential documents are properly executed and prepared prior to shipment of investigational product.
- Prepare and verify proper execution of all required investigator agreements, including Non-Disclosure Agreement, Investigator Agreement, and Compensation Agreement.
- Work with the Clinical Project Manager to assure site payments are distributed as appropriate and according to the compensation agreement.
- Support the Clinical Project Manager to develop, implement and execute project plans (e.g., to increase enrollment, motivational ideas, etc.), identify problems that interfere with study progress, and implement strategies to resolve issues.
- Prepare emails, newsletters, and other forms of communication to deliver project specific information to/from site(s) and assist with enrollment and study compliance at study sites.

Competence Requirements

- **Communication Skills**: Excellent written and verbal communication. Effective listening skills. Confident, articulate, and professional speaking abilities.
- **Customer Service Skills:** Attentive, courteous, empathetic and responsive.
- **Computer Skills:** To perform this job successfully, proficiency with Microsoft Office applications including Word, Excel, Outlook, PowerPoint, and Adobe Acrobat is necessary.
- **Organizational Skills:** High level of initiative, motivation and ability to organize and prioritize work to meet deadlines.
- **Analytical Skills:** Must have a proactive approach to problem solving and the ability to exercise judgement to appropriately resolve a varying degree of complex problems.
- **Teambuilding Skills:** Strongly team-oriented with a high degree of integrity and work ethic and experience working in a team environment.
- **Detail-Oriented:** High level of attention to detail.
- **US Regulations:** Knowledge and understanding of ICH E6: Good Clinical Practice and all applicable US regulations governing clinical research.
- **FDA Code of Federal Regulations:** Knowledge and understanding of FDAs Code of Federal Regulations applicable to conducting clinical research studies.
- **International Regulations:** Knowledge of International regulations applicable to conducting clinical research studies preferred.

Education Requirements

- Bachelor’s degree in biological science, nursing, or other related discipline.

Experience Requirements

- Minimum 5 years direct clinical research experience; 3 years monitoring experience preferred.
- Experience working with Electronic Data Capture systems.
- Experience working with, reviewing, and filing clinical study essential documents.
- Experience tracking & receipt of clinical study elements, including investigational product distribution, site visits and visit reports, enrollment, CRFs and DCFs, and collection or management of essential documents.
- Experience managing or ordering investigational product shipments.
- Experience preparing CRF binders and study supplies.
- Experience preparing and submitting IRB/EC application documents.

Physical Demands

The physical demands described below are representative of those that must be met by an employee to successfully perform the essential functions of this job. In accordance with the Americans with Disabilities Act, as amended, the California Fair Employment & Housing Act, and all other applicable laws, AcuFocus provides reasonable accommodations for qualified persons with disabilities. A qualified individual is a person who meets skill, experience, education, or other requirements of the position, and who can perform the essential functions of the position with or without reasonable accommodation.

- Considerable time is spent at a desk using a computer.
    - Ability to operate a keyboard at efficient speed and typical business office equipment, including computer hardware.

Work Environment

- Typical indoor office environment with windows.
- May work remotely (based on experience).

Travel Requirements

- Domestic travel (up to 30%) may be required

COVID-19 Vaccination Mandate

AcuFocus is committed to protecting the health of our employees and their families; contractors and visitors; and the community from the risks associated with COVID-19. As such, all employees are required to submit proof of vaccination for COVID-19 or have a valid religious or medical exemption from being vaccinated.

AcuFocus offers the following benefits:

- Medical with 80%+ Employer's Contribution (High deductible plans, PPOs and HMOs with Blue Shield of CA, Aetna, and Kaiser)
- Dental paid 90% by Employer (Delta Dental, Aetna, Guardian Dental and MetLife)
- Vision paid 100% by Employer (Aetna and VSP)
- PTO (3 weeks)
- Eleven Paid Holidays
- Basic Life Insurance & AD&D coverage valued at $50,000
- Group Long-Term Disability Insurance that may replace up to 60% of your salary, up to a max benefit of $12,500 per month for qualifying disabilities
- Participation in the AcuFocus Management Carve-out Plan
- 401K Savings Retirement Plan
- Health Advocate / Employee Assistance Program

Compensation commensurate with experience.

AcuFocus provides equal employment opportunities to all employees and applicants for employment and prohibits discrimination and harassment of any type without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state, or local laws. This policy applies to all terms and conditions of employment, including recruiting, hiring, placement, promotion, termination, layoff, recall, transfer, leaves of absence, compensation, and training.

**Please send resume/CV to tphillips@acufocus.com*