Alliance for Clinical Trials in Oncology
FOUNDATION

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AllianceforClinicalTrialsinOncology.org

Job Description			
Job Title:	**Clinical Research Associate**	**Job Category:**	Exempt ☒ Non-Exempt ☐
Department/Group:	Alliance Foundation Trials, LLC	**Reports to:**	Director of Clinical Trials Operations
Location:	Boston	**Travel Required:**	<10%
Level/Salary Range:	$	**Position Type:**	Full-Time ☒ Part-Time ☐ Contract ☐ Temporary ☐
HR Contact:	Director of HR, Boston	**Date posted:**	Click here to enter a date.
External posting URL:			
Internal posting URL:			

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY FOUNDATION'S MISSION:

The Alliance for Clinical Trials in Oncology Foundation (Foundation) is a nonprofit, tax-exempt foundation created to enhance and expand the ability of the Alliance for Clinical Trials in Oncology (Alliance) to conduct cancer clinical research and address important treatment questions through large-scale clinical trials. Through efforts of the Foundation in support of the Alliance, clinical trials and laboratory research are conducted to discover new or improved ways to prevent, treat and cure many types of cancer, including leukemia and lymphoma, and cancers of the breast, prostate, lung and GI tract, and help educate the medical community on methods of cancer diagnosis, treatment, and prevention.

In May 2014 and February 2015, the Foundation created the Alliance Foundation Trials, LLC (AFT, LLC) and Mastering Breast Cancer, LLC (MBC, LLC), respectively, which are wholly owned subsidiaries of the Foundation. These entities were also created to conduct cancer clinical research and address medical care and treatment through large-scale clinical trials involving various industry related partners.

PURPOSE/SCOPE:

The in-house CRA is responsible for managing various aspects of AFT site management and project management strategies, including but not limited to administration of the CTMS system, study trial master file set up and maintenance, CRO vendor oversight, site feasibility, and start up activities.

ROLE AND RESPONSIBILITIES

- Assist operations team in supporting the Alliance member sites and escalate site related issues when necessary.
- Send, track, and review study-specific and global feasibility questionnaires.
- Assist with site selection and recruitment by generating site identification reports (e.g., site accrual); collecting, reviewing and tracking site feasibility/credentialing documentation and follow-up on site accruals accordingly.
- Track training information and issue trainings for sites and contacts.
- Collection of essential documents related to study start-up and review IP release packages.
- Prepare for and execute Investigator meetings and other site training programs.
- Assist with creation of start-up plans and templates.
- Ensure proper and timely filing of all relevant study documents into the eTMF on an ongoing basis to ensure compliance with applicable work instructions, SOPs and ICH GCP guidelines and AFT expectations.
- Perform routine review of filing procedures to ensure adherence to current quality guidelines at all times.
- Accurately enter and manage data within the Clinical Trial Management System (CTMS) by: tracking completed training information that could carry over to other studies; maintaining site information and

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rosters; reviewing monitoring reports to identify deficiencies, reviewing adequacy of issue escalation and issue resolution; and provide feedback to appropriate CRO contacts.
- Participate in co-monitoring activities.
- Communicate with CROs, vendors, and/or study sites as necessary to support the study, which includes monitoring email accounts related to studies.
- Conduct regulatory review of ICF changes and coordinate review by Executive Officer and contracts team
- Coordinate study related meetings; take detailed minutes at meetings on decisions and action items and distribute to the team, as assigned.
- Other related duties as assigned to meet departmental and company objectives.

QUALIFICATIONS AND EDUCATION REQUIREMENTS

- A minimum of a BA/BS degree is required.
- Degree in a health or science major preferred.
- 2 – 4 years relevant experience in biotech, pharma, and/or CRO, including 1 year of clinical research industry experience.
- Working knowledge of clinical monitoring responsibilities and procedures.
- Previous experience with eTMF, CTMS, and IRT clinical trial systems is strongly preferred.
- Proficient in Microsoft Office Suite, especially Word and Excel.

PREFERRED SKILLS

- Strong organizational skills and ability to prioritize workload to meet tight deadlines in a fast-paced and dynamic work environment.
- Strong interpersonal, written, and verbal communication skills.
- Flexible and adaptable to a small business workplace environment.

ADDITIONAL NOTES

The above statements are intended to describe the general nature and level of the work being performed by people assigned to this job. They are not an exhaustive list of all duties and responsibilities associate with it.

The Alliance for Clinical Trials in Oncology Foundation is an at-will, equal opportunity employer that provides equal employment opportunities (EEO) to all employees and applicants for employment without regard to race, color, religion, sex, national origin, age, disability, genetics, veteran status, or any other legally protected status under local, state, or federal law.

Last Updated By:	Heather Choukri	Date/Time:	May 30, 2019
Approved By:			

Employee Signature: Date: