Alliance for Clinical Trials in Oncology
FOUNDATION

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AllianceforClinicalTrialsinOncology.org

Job Description			
Job Title:	**Translational Research Program Coordinator**	**Job Category:**	Exempt ☒ Non-Exempt ☐
Department/Group:	Alliance Foundation Trials, LLC	**Reports to:**	Director of Clinical Trial 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.

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, the Foundation created Alliance Foundation Trials, LLC (AFT, LLC) which is a wholly owned subsidiary of the Foundation. This entity was 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: Alliance Foundation Trials, LLC is looking experienced laboratory science professionals transitioning into clinical research. This role will support the **Translational Research Program (TRP)** at AFT, serving as primary interface between AFT operations and lead physicians, scientists and statisticians conducting translational research as part of AFT studies, or on banked samples collected during AFT clinical trials. This role will also work directly with AFT operations project managers to execute study protocols at clinical sites in the United States.

ROLE AND RESPONSIBILITIES

TRP COMMITTEE COORDINATOR

- Serves as primary contact between AFT and Alliance TRP leadership.
- Coordinates timely and accurate completion of Translational Science protocol sections, plans, budgets and other documents by TRP leadership and subject matter experts
- Processes Translational Research proposals, ensures all proposals are complete and ready for review by AFT/TRP leadership.
- Ensures correct flow of data and supporting information related to banked research samples and translational science activity between biorepository, study leadership, Statistics and Data Center and relevant Alliance committees (publications, TRP, disease area)
- Working with the Director of Quality Management and Compliance, initiates laboratory qualification process, including compilation and initial review of necessary laboratory related documentation.
- Reviews risk assessments and audit reports from external laboratory vendors.
- Circulates audit reports to subject matter experts for review and response prior to activating new lab vendors for AFT studies.
- Supports reassessment of contracted laboratories as needed per AFT's quality audit program.

CLINICAL RESEARCH ASSOCIATE

- Liaise with CROs, vendors, and Alliance member site personnel as needed to support study and act as the

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primary contact to resolve site related issues for assigned studies, escalate as necessary

- Ensures compliance with applicable work instructions, SOPs, ICH GCP guidelines, and AFT expectations at all times
- Act as Functional TMF Document Specialist for Clinical Operations, to include submission of documents to and maintenance of the eTMF:
- Reviews eTMF to ensure proper and timely filing of all relevant study documents and compliance with all applicable work instructions, SOPs, ICH GCP guidelines, and internal expectations
- Acts as a primary liaison with the CRO to collect trial documents and coordinate review of the eTMF to ensure inspection-readiness
- Assist with collection and maintenance of site essential documents
- Reviews IP release packages during study start-up process
- Reviews site readiness for activation during study start-up process and ensures site's adherence to current guidelines
- Set up site users in all AFT systems, troubleshoot basic system/user issues as presented by sites and/or internal staff and provide resolutions in a timely manner. Escalate to Technology Solutions team as needed.
- Track training information and issue training for site staff, study staff and vendors; proactively update CTMS to account for completed trainings that could carry over to multiple studies
- Review monitoring reports in CTMS to identify deficiencies, adequacy of issue escalation and issue resolution. Provide feedback of review to appropriate CRO contact and Project Manager as necessary
- Generate a variety of reports including site identification reports and monitoring reports by collecting, reviewing and tracking site feasibility/credentialing documentation
- Assist in maintaining site contacts and distribution lists for study related communications
- Assist Project Manager in updating information on clinicaltrials.gov registry(ies) and other registries as necessary
- Engage site personnel to increase accrual
- Prepare and present at Investigator meetings and other site training programs
- Participates in training of CRO teams, investigators and internal staff as needed
- Supports preparation activities for FDA and other regulatory body meetings and inspections by conducting Quality Review of eTMF system
- Support site in-house/contract CRAs and PCs to provide day-to-day operational oversight as needed
- Liaise with interdepartmental study team to track and prioritize site start-up activities
- 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 biotech/pharma, and/or CRO. Prior lab experience required.
- Working knowledge of clinical monitoring responsibilities and procedures.
- Working knowledge of Clinical Trial Master File requirements.
- Proficient with Microsoft Office Suite
- Advanced computer skills and ability to train others in system usage
- Excellent oral and written communication skills and strong organizational abilities
- Proven ability to think critically, analyze existing processes, and suggest process improvements
- Flexible and adaptable to a small business workplace environment
- Must be authorized to work in the U.S.

Last Updated By:	Carter DuFrane/Majagamy Ramos/Sheilah Hurley	Date/Time:	15 October, 2019
Approved By:	Heather Choukri	Date/Time:	31 October 2019

Employee Signature: Date: