221 Longwood Avenue, Room 108
Boston, MA 02115
P: 617-525-3032

www.AllianceFoundationTrials.org

Job Description

Job Title:	**Clinical Research Specialist**	**Job Category:**	Exempt ☒ Non-Exempt ☐
Department/Group:	Alliance Foundation Trials, LLC (AFT)	**Reports to:**	Chief Operations Officer
Location:	Boston	**Travel Required:**	Occasional
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 the Alliance Foundation Trials, LLC (AFT), respectively, a wholly owned subsidiary of the Foundation. AFT 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:

Reports to Chief Operating Officer (COO) to be deployed to support specific Executive Officer (EO) and Project Managers (PM) and Quality Manager (QM). Will also work with Business Systems & Analytics (BSA) Team to learn CTMS (Clinical Trials Management System) and eTMF (Trial Master File)

ROLE AND RESPONSIBILITIES

ASSISTANT TO THE EXECUTIVE OFFICER (50%)

Provides administrative support to the assigned Executive Officer (EO) by proactively working with the EO to coordinate scheduling across all of the EO's calendars.

- The CRS will meet regularly with the EO to identify upcoming meetings and travel plans:
  1) ensure that all work related commitments are coordinated in one calendar,
  2) on a weekly basis provide the EO with a schedule and confirm that all appoints have been noted.
- Responsible for arranging conference calls and scheduling meetings for the EO.
- Responsible for the EO's travel planning (working with the Alliance Meeting Planner)
- Handling information requests, and
- Performing clerical functions such as preparing correspondence, receiving visitors, and other work as requested by the EO.

ASSISTANT TO THE OPERATIONS TEAM (50%)

SITE ENGAGEMENT

- Working with BSA Oversee/maintain the data located in the Site Management tab of the CTMS (Global site management) with routine reviews/audits. Provide support to enable project teams to maintain study-specific site management information.
    - Create trackers of site activity documented in the CTMS and follow up by AFT staff
- Working with PMs, coordinate the site feasibility assessment process: site experience, facility, and information system capabilities to perform study activities.
- Working with PMs coordinate site initiation and start-up, site monitoring, site management and site/study close-out according to GCP, internal SOPs and policies, and within required timelines.
- Working with PMs support budget and contract negotiation with sites and helps to ensure payment for services, as applicable.
- Arrange regular meetings between CRC/site leadership and AFT to address site-identified trial management concerns.

REGULATORY

- Works with the study teams to compile, organize and forward (to Pharmacovigilance Officer) study protocols and supporting documentation (1571, 1572, IND, safety reports) for submission for IND applications and annual reports.
- Work with COO, PMs with contract IRB organizations.
- Monitor central IRB submission deadlines and submission of updated documents to central IRB as applicable, ensure all central IRB documentation and correspondence is maintained in study level TMFs.
- Participate with study teams to draft and review Informed Consent documents (ICF) for Project Managers prior to study initiation.
- Review and respond or triage questions from sites related to Informed Consents
- Working with COO and PMs, liaise with external Review IRB and maintain records of correspondence and document exchange.

QUALIFICATIONS AND EDUCATION REQUIREMENTS

- Bachelor's degree, accreditations preferred
- Minimum of five years direct experience with clinical trials that include site activation and regulatory compliance aspects of clinical studies
- Ability to juggle multiple projects and competing priorities effectively
- Strong communication skills and experience communicating relevant issues
- Understanding of the clinical trial process and all regulatory/business concepts involved in creating and building clinical relationships
- Experience working both independently and within a team.
- Proficiency with Office and document management.

ADDITIONAL NOTES

Last Updated By:	Heather Choukri	Date/Time:	02/04/19