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

www.AllianceFoundationTrials.org

Job Description

Job Title:	**Manager, Clinical Research Site Engagement**	**Job Category:**	Exempt ☒ Non-Exempt ☐
Department/Group:	Alliance Foundation Trials, LLC (AFT)	**Reports to:**	Director, Clinical Trial Operations/COO
Location:	Boston Office	**Travel Required:**	Occasional
Level/Salary Range:	$	**Position Type:**	Full-Time ☒ Part-Time ☐ Contract ☐ Temporary ☐
HR Contact:	Human Resources	**Date posted:**	
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, 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:

The Clinical Research Site Engagement (SE) Manager reports directly to the Director, Clinical Trial Operations with an indirect report to the COO for the first 6-12 months

The SE Manager is responsible for oversight of the AFT Site Engagement program. This program addresses: site recruitment – both overall policy and trial specific; site selection; site initiation; ongoing site management; site monitoring and site close-out activities. The manager works collaboratively with leadership and team members of the Quality Management and Compliance (QMC), Clinical Trial Operations (CTO), Contracts Administration and Business Systems and Analytics (BSA).

The manager provides guidance, training materials and site management tools to the CTO Project Management staff that ensures consistent practices across AFT studies. The manager may provide CTO guidance and feedback on selection of sites based on internal AFT site review and Alliance membership standing. The manager may develop consistent site communication templates and refine checklists or processes related to site activation. The manager may provide CTO study staff with guidance on troubleshooting site issues related to poor performance, lack of response in communication, and non-compliance. The manager works closely with CTO teams during site closure activities to ensure consistent practice and centralized documentation.

Working closely with the Associate Director, Quality Management and Compliance and with the QMC team, the manager supports assurance of compliance with Good Clinical Practice (GCP), SOPs, policies and regulatory requirements from site/study start-up through to study closure/data-base lock.

ROLE AND RESPONSIBILITIES

- Manages the AFT Site Engagement program to ensure efficiency in all site management activities.

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- In conjunction with the Director of CTO and the COO, Director of BSA, Director of QMC, and Associate Director of QMC, the SE manager ensures optimal development and functionality of site management systems and tools that maintain and ensure consistent practices across all projects.
- Manages collaborative support and trains the appropriate Project Management staff on site management policy, procedures and tools.
- Oversees/maintains the data located in the Clinical Trial Management System (CTMS) to include AFT member roster, site management, site profiles, Alliance membership data and member accrual status with regular audits of CTMS and standard reports to the Director, CTO.
- Monitors Site Engagement tracking and documentation in the CTMS related to study/site feasibility tracking, patient transfer, site name change, change of principal investigator, and other SE managed processes.
- Manages Site/Investigator review and selection against Alliance membership and policy for participation. Supports site level recruitment strategy and contingency plans in partnership with other functional areas to achieve clinical research targets.
- Manages the site feasibility assessment process; assesses site experience, facility, and information system capabilities to perform study activities.
- Oversees 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.
- Responsible for meeting study milestones and timelines related to site activations, including site activation rates, site inquiry handling, vendor monitoring metrics, compliance with site closure plans, etc.
- Working with the Project Managers is accountable for the quality and consistency of site management activities and compliance with SOPs.
- In consultation with QMC, develops and implements effective corrective and preventive action plans for all quality issues identified at sites or within AFT.
- Ensures compliance with regulations, guidelines and policies for studies implemented at sites.
- Supports budget and contract negotiation with sites and helps to ensure payment for services, as applicable.
- Collaborates with project teams to identify and resolve site, quality or study execution issues.
- Builds and maintains positive relationships with lead network contacts, as well as site principal investigators and site personnel.
- Actively participates with study team to stay current with study needs, communicating as needed with sites within defined timelines.
- Develops and presents training on site management processes and requirements.
- Develops standardized key metrics to be used by AFT to monitor individual study activity (site set-up, accrual activity, etc.) to determine status and progression.
- Develops and monitors network/site quality and performance (metrics); provide performance analyses to AFT leadership and develops solutions to optimize performance.
- Ensures all safety issues are communicated and managed by Principal Investigator and study team in timelines appropriate to the regulatory and protocol requirements.
- Primary liaison to Alliance membership manager for exchange of site level performance information.
- Manages reporting and submission of accrual (patient enrollment) to Alliance membership manager.

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- Serves as a liaison to the Alliance Clinical Research Professional (CRP) committee and manages AFT CRP subcommittee.
- Works with the Directors of QMC, BSA and CTO to develop training and information presentations at Alliance group meeting and as needed for site clinical research associate and investigators; may also be required to present and hold training sessions for AFT staff and at Alliance Group Meetings.
- Manages AFT system wide communication to network members and AFT study sites in conjunction with other departments.

QUALIFICATIONS AND EDUCATION REQUIREMENTS

- A minimum of a BA/BS degree, required.
- Degree in a health or science major, preferred.

REQUIRED SKILLS:

- Minimum 3 years clinical research site experience required, particularly in site management area.
- Understanding FDA Code of Federal Regulations, drug development process, Good Clinical Practice (GCP).
- Solid computer skills to include MS Office Applications (Word, Excel), database use and management, CTMS exposure.
- Exposure to eTMF, experience with creation and management of site regulatory files is required.
- Understanding of general clinical research operations at institutions/sites.
- Excellent organizational, leadership and problem-solving skills.
- Excellent written and verbal communication skills.
- Ability to successfully work both within a team and independently.
- Ability to travel several times a year.

ADDITIONAL NOTES

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

Approved By:	Carter DuFrane	Date:	11/12/2020
Last Updated By:	Candice French	Date:	8/13/2021

Employee Name: Date:

Employee Signature: _____