125 S. Wacker Drive, Suite 1600 • Chicago, IL 60606
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AllianceforClinicalTrialsinOncology.org

Job Description			
Job Title:	**Manager: Site Engagement/ Site Management Group**	**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.
External posting URL:			
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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 Site Engagement Manager reports directly to the Chief Operations Officer.

This a new position that will be responsible for the development, implementation and oversight of the AFT site management program. The site management program will address: site recruitment – both overall policy and trial specific; patient recruitment and retention planning; site initiation; ongoing site management; and site monitoring and site close-out activities. The Site Engagement Manager works in tandem with the Director of Project Management to establish training materials and site management tools for Project Management staff that insure that teams are consistent across projects and all site management activities are compliant with Good Clinical Practice (GCP), SOPs, policies and regulatory requirements from start-up through data-base lock. The Site Engagement Director is also responsible for continuous review and development of tools and processes to establish and ensure consistency across all projects.

ROLE AND RESPONSIBILITIES

- Develops and manages the AFT site management program to ensure efficiency in all site management areas.

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- Manages assignment and deployment of site management resources including integration within project teams and trains the appropriate Project Management staff on site management tools and requirements.
- In conjunction with individual project managers, develop the scope of work for clinical research organizations for site management and/or monitoring services, and associated study plans, e.g., monitoring plan.
- In conjunction with the Chief Operations Officer, the Director of Project Management (PM) and the Director, Business Systems & Analytics (BSA, ensure optimal development and functionality of site management systems and tools that ensure consistency across all projects.
- 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.
- Manage the site feasibility assessment process; assesses site experience, facility, and information system capabilities to perform study activities.
- Manage Site/Investigator selection process.
- Develops site level recruitment strategy and contingency plan in partnership with other functional areas to achieve clinical research targets
- Manage 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.
- Oversees/maintains the data located in the Site Management tab of the CTMS (Global site management) with routine reviews/audits. Provides support to enable project teams to maintain study-specific site management information.
- 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 the Quality Management Group, develop and implement effective corrective and preventive action plans for all quality issues identified at assigned sites and within site management group,
- Ensure compliance with regulations, guidelines and policies for studies implemented at sites.
- Support budget and contract negotiation with sites and helps to ensure payment for services, as applicable.
- Collaborate with project teams to identify and resolve site, quality or study execution issues.
- Builds positive relationships with principal investigators and site personnel
- Actively participate with study team to stay current with study needs, communicating as needed with sites within defined timelines
- Develops and present training on site management processes and requirements
- Develop standardized key metrics to be used by AFT to monitor vendors/CROs contracted for site management and monitoring.
- Develop standardized key metrics to be used by AFT to monitor individual study activity (site set-up, accrual activity, etc.) to determine status and progression.
- Develop and monitor site quality and performance (metrics); provide performance analyses to AFT leadership and develops solutions to optimize performance

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- Ensure 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.
- Serve as a liaison to the Alliance Clinical Research Coordinators (CRC) committee. Working with the Directors of BSA and PM develop training and information sessions for CRCs and coordinate and present sessions at the semi-annual group meetings. Ensure continuous communication and updates to the CRCs and serve as a trouble shooter for CRCs if needed.

QUALIFICATIONS AND EDUCATION REQUIREMENTS

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

Experience/Qualifications:

- Minimum four - six years pharmaceutical or clinical research organization experience required, particularly in site management area
- Solid understanding of the drug development process, including Good Clinical Practice (GCP) and FDA Code of Federal Regulations.
- Solid computer skills
- 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

PREFERRED SKILLS

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ADDITIONAL NOTES

[Type any additional notes if needed.]

Last Updated By:	Sheilah Hurley	Date/Time:	01/08/19