125 S. Wacker Drive, Suite 1600 • Chicago, IL 60606
P: 773-702-9171 • F: 312-345-0117
AllianceforClinicalTrialsinOncology.org

Job Description			
Job Title:	**Project Manager**	**Job Category:**	Exempt ☒ Non-Exempt ☐
Department/Group:	Alliance Foundation Trials, LLC (AFT)	**Reports to:**	Director of Project Management
Location:	Boston	**Travel Required:**	< 10% Travel anticipated
Level/Salary Range:	$	**Position Type:**	Full-Time ☒ Part-Time ☐ Contract ☐ Temporary ☐
HR Contact:	Heather Choukri	**Date posted:**	Click here to enter a date.
External posting URL:	Click here to enter text.		
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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

Purpose/Scope:

The Project Manager is responsible for managing the development and implementation of AFT studies.

ROLE AND RESPONSIBILITIES

- Develops detailed project plans, schedules, project estimates, resource plans and status reports, as appropriate.
- Represents clinical operations on the cross-functional project team, and liaises with medical, statistical, regulatory, quality and financial personnel
- Works closely with study teams to implement specific study plans and to ensure appropriate resources are assigned.
- Assists with the design, planning, implementation, conduct and management of clinical studies from initiation through to completion
- Assists in design, configuration, and development of study level systems such as EDC and IRT
- Organizes, schedules, and leads study teleconferences and in person meetings.
- Serves as central escalation point for all study issues originating with component groups such as data management, site management, etc., and tracks escalated issues through to resolution.
- Develops study-related documents together with scientific team and protocol development team including, but not limited to study protocols, informed consent forms, study plans, etc.
- Reviews study related materials including, but not limited to monitoring reports, clinical trial agreements, etc where needed.
- Regulatory filing as needed. Where applicable, the individual may share knowledge and expertise with others in support of team activities. The individual may identify data

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needed; obtain these data and ensure that they are effectively presented for the registration of products worldwide.
- Protocol Writing: ability to initiate and maintain protocol and associated amendment tracking
- Tracks study progress and manage clinical timelines, including regulatory document collection, IRB approval and enrollment, management of clinical supplies etc.
- Participates in and conducts visits / meetings with investigative sites, physicians, vendors and consultants as needed
- Helps build and maintain relationships with sites, site study staff.
- Participates in the reporting of clinical data for regulatory or medical scientific purposes
- Participates in the development and implementation of SOPs and Clinical Operations processes and systems
- Willingness and capability to handle multiple projects and responsibilities within time constraints

QUALIFICATIONS AND EDUCATION REQUIREMENTS

- A minimum of a BA/BS degree is required.
- Degree in a health or science major preferred.
- 4-6 six years Pharmaceutical, Academic Research Organization or Clinical Research Organization research and project management experience required.
- Technical/medical writing experience is preferred (protocol, IND, ICF, etc.)
- Regulatory documentation; IND preparation and filing experience
- Demonstrated PM skills; meeting project timelines and budgets.
- Assisted in trial design, planning and implementation – initiation through completion start
- Solid understanding of the drug development process including GCP and FDA Code of Federal Regulations.
- Excellent organizational, leadership and problem-solving skills
- Excellent written and verbal communication skills
- Ability to successfully work both within a team and independently
- Solid computer skills.
- Ability to travel several times a year.
- Must be authorized to work in the U.S.

PREFERRED SKILLS

Proficient in MS Project Software

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 associated with it.

Last Updated By:	Heather Choukri	Date:	23 August 2018