

Job Description			
Job Title:	Project Manager	Job Category:	Exempt <input checked="" type="checkbox"/> Non-Exempt <input type="checkbox"/>
Department/Group:	Alliance Foundation Trials, LLC (AFT)	Reports to:	
Location:	Boston	Travel Required:	< 10% Travel anticipated
Level/Salary Range:	\$	Position Type:	Full-Time <input checked="" type="checkbox"/> Part-Time <input type="checkbox"/> Contract <input type="checkbox"/> Temporary <input type="checkbox"/>
HR Contact:	Chelsea Martin	Date posted:	Click here to enter a date.
External posting URL:	Click here to enter text.		
Internal posting URL:	Click here to enter text.		
AFT Mission: <p>Alliance Foundation Trials, LLC (AFT) sponsors and conducts high-quality cancer clinical trials funded exclusively by non-NCI (National Cancer Institute) sources. AFT leverages the internationally recognized scientific experts and thought leaders of the Alliance for Clinical Trials in Oncology with its expansive and established network of hospitals, medical centers, and community clinics across the North America.</p>			
Purpose/Scope: <p>The Project Manager is responsible for managing the development and implementation of AFT studies</p>			
ROLE AND RESPONSIBILITIES <ul style="list-style-type: none"> • 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 the Operations Director and 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 			

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
- May serve as the operational lead, managing all aspects of study development and execution while working closely with the Operations Director and Executive Officer on studies

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.

PREFERRED SKILLS

Proficient in MS Project Software

ADDITIONAL NOTES

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Last Updated By:

Trinidad Ajazi

Date:

22 August 2016