ALLIANCE
FOUNDATION TRIALS, LLC

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

Job Description			
Job Title:	**Medical Oversight Associate**	**Job Category:**	Exempt ☒ Non-Exempt ☐
Department/Group:	Quality Management	**Reports to:**	Director of Quality Management
Location:	Boston	**Travel Required:**	<20%
Level/Salary Range:	$	**Position Type:**	Full-Time ☒ Part-Time ☐ Contract ☐ Temporary ☐
HR Contact:	Human Resource Director	**Date posted:**	Click here to enter a date.
External posting URL:	Click here to enter text.		
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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.

In May 2014, the Foundation created Alliance Foundation Trials, LLC (AFT), which is a wholly owned subsidiary of the Foundation. It 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 Medical Oversight Associate (MOA) is an essential member of the Quality Management and Compliance team at AFT and provides clinical expertise and oversight for clinical trials conducted by AFT, from initial study design through final study close-out. The MOA works closely with the Study Chair (SC) and the Executive Officer (EO) who are clinicians responsible for medical oversight of AFT clinical trials. The SC is responsible for day-to-day medical oversight of a clinical trial, including consideration of eligibility, treatment and disease outcomes questions. The EO serves as the overall medical officer for trials and is responsible for overall medical oversight/monitoring. Other medical monitors may be assigned for specified activities on a clinical trial.

The MOA is responsible for conducting centralized clinical monitoring and safety/pharmacovigilance activities. This includes centralized review of adverse event, protocol deviations and related data affecting the safety of clinical trial participants. The MOA helps to ensure clinical trial integrity and provide safety accountability for the duration of a study, while serving as a clinical point of reference for investigative sites and project team members, escalating safety and clinical issues to SC and/or EO as needed. As appropriate, the MOA triages clinical issues to the study specific medical monitor and provides documentation of the review outcome and steps taken, as well as ensuring any required reporting is completed and documented.

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The MOA utilizes medical expertise to perform functions according to AFT Standard Operating Procedures (SOPs), the trial protocol and applicable study plans (e.g., safety management, medical oversight and clinical monitoring) as well as applicable laws and regulations (e.g., Code of Federal Regulations/CFR), ICH Good Clinical Practice (GCP) guidelines and other guidance from regulatory authorities.

ROLE AND RESPONSIBILITIES

The MOA will work with assigned personnel to triage the following and escalate when necessary to SC or EO:

- Review of expedited adverse event reports, including SAEs/AESIs upon processing and evaluation by the Safety/Pharmacovigilance units, per applicable safety management plan.
- Review AE/safety listings generated by PV unit and/or data management, prior to submission to regulatory authorities (e.g., DSUR, IND Safety Updates). Review safety listings for potential trends affecting overall trial safety signals for escalation to the medical oversight lead.
- Working with EO and/SC provide guidance to site personnel and study team if/when a subject may need to be unblinded, according to protocol unblinding plan and applicable SOPs.
- Serve as the point of contact for sites, pharmacovigilance personnel, clinical monitors and project teams to address safety issues – review, resolve and document safety issues, escalating to SC or EO as appropriate.
- Provide input and expertise to ensure Medical Dictionary for Regulatory Activities (MedDRA) consistency.
- Review clinical monitoring reports submitted by 3rd party vendors and work with project managers and CRAs to ensure timely follow-up as needed and document all actions taken. Escalate clinical monitoring issues to medical monitor, as appropriate.
- Review protocol deviation listings and escalate issues to medical monitors. At least monthly meet with medical monitor to discuss a summary of important protocol deviations. Escalate critical PDs to medical monitor and oversee process for related corrective and preventive plan (CAPA), in conjunction with quality and project teams.
- Review Key Performance Indicator (KPI) and other centralized monitoring reports to evaluate trends related to protocol non-compliance, ineligibility rates, adverse event rates, treatment adherence, early discontinuation, etc. for potential impact on patient safety and primary endpoint analysis. Discuss findings with medical monitors, study chair, executive officer and other study team members to determine course of action, as appropriate.
- Meets regularly with EOs and SCs
- Maintain regular communications as per clinical study plan with medical monitors and escalate issues to EO and/or SC as necessary. Create and maintain timely documentation of all safety and medical monitoring issues on a per study basis, including review and final resolution of major issues by the EO and or SC.Participate in Study/Site Initiation Visits (SIV). Prepare educational materials for SIVs and other training purposes.
- Review and/or develop medical oversight, safety management plans, as applicable. Review clinical monitoring plans and protocol deviation plans, as applicable.
- Overall facilitate medical monitoring activities and as a member of the medical oversight team, prepare reports for the medical and project teams with focus on issues requiring clinical and medical oversight and judgement.

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- Report critical/serious non-compliance issues to the AFT Quality and Regulatory Compliance unit.

QUALIFICATIONS AND EDUCATION REQUIREMENTS

- 3 years or more clinical trial research experience, oncology preferred
- Education: RN/OCN, NP or PA, PharmD or MD
- Knowledge of the clinical trial process and related regulation including FDA and ICH/GCP
- Ability to work effectively in teams as well as independently
- Ability to organize medical and scientific information in order to provide comprehensive support to Medical monitors and study team members
- Ability to manage confidential health information and data
- Ability to manage multiple projects at a time

PREFERRED SKILLS

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ADDITIONAL NOTES

[Type any additional notes if needed.]

Last Updated By:	Heather Choukri	Date/Time:	July 12, 2019

Employee Name: Date:

Employee Signature: _____