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:	**Clinical Study Manager**	**Job Category:**	Exempt ☒ Non-Exempt ☐
Department/Group:	Alliance for Clinical Trials in Oncology Foundation	**Reports to:**	Chief Administrative Officer
Location:	Chicago	**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.		
Internal posting URL:	Click here to enter text.		

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. The Alliance conducts trials as part of the National Cancer Institute (NCI) Clinical Trials Network (NCTN). 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.

Purpose/Scope:

The Clinical Study Manager is responsible for managing the development and implementation of Alliance for Clinical Trials in Oncology studies.

ROLE AND RESPONSIBILITIES

- Develops detailed project plans, schedules, project estimates, resource plans and status reports, as appropriate.
- Manages efforts of the project team for assigned clinical trials. Represents pharmaceutical collaborations on the cross-functional project team, and liaises with medical, regulatory, quality, protocol, legal and financial personnel.
- Assists with the design, planning, implementation, conduct and management of clinical studies from initiation through to completion.
- Reviews and develops study related materials including, but not limited to monitoring reports, clinical trial agreements, etc where needed.
- Review budgets and milestones, and develop related scope of work.
- Works closely with the study teams to implement specific study plans and to ensure appropriate resources are assigned.
- Identifies, assesses and recommends selection of vendors where applicable.
- Regulatory filing as needed.
- Identify information/data needed and ensure that they are effectively presented for the marketing approval registration of products worldwide.
- Implement processes to ensure and monitor inspection readiness by regulatory authorities.
- Tracks study progress and timelines, including regulatory document collection, IRB approval

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

and enrollment, management of clinical supplies etc. as needed.

- 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 to promote the study, enhance accrual and address study management issues.
- Participates in the reporting of clinical data for regulatory or medical scientific purposes
- Participates in the development and implementation of SOPs and study operations processes and systems
- Willingness and capability to handle multiple projects and responsibilities within time constraints
- Serve as the project manager for pharmaceutical collaborations and vendor management, managing multiple aspects of study development and working closely with the program manager, executive officer and other study team members.

QUALIFICATIONS AND EDUCATION REQUIREMENTS

- A minimum of a BA/BS degree is required.
- Degree in a health or science major preferred.
- 3 or more years Pharmaceutical or Clinical Research research experience required
- Project management experience required.
- Technical/medical writing experience is preferred (protocol, IND, ICF, etc.)
- Regulatory documentation; IND preparation and filing experience
- Demonstrated, project management 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

CLICK HERE TO ENTER TEXT.

ADDITIONAL NOTES

Click here to enter text.

Reviewed By:	Click here to enter text.	Date:	Click here to enter a date.
Approved By:	Click here to enter text.	Date:	Click here to enter text.
Approved By:	Click here to enter text.	Date:	Click here to enter a date.
Last Updated By:	Click here to enter text.	Date/Time:	Click here to enter text.

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

Employee Name: Date:

Employee Signature: _____