Alliance for Clinical Trials in Oncology
FOUNDATION

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

Job Description

Job Title:	**Clinical Research Specialist III - Regulatory**	**Job Category:**	Exempt ☒ Non-Exempt ☐
Department/Group:	Alliance Foundation Trials, LLC (AFT)	**Reports to:**	Regulatory Manager
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 Clinical Research Specialist (CRS) provides clinical research expertise by participating in the design and implementation of research projects as needed. Responsible for specific responsibilities listed below as well as assigned aspects of research infrastructure development, coordination projects and communicates status and improvement areas to leadership.

The CRS III- Regulatory reports directly to the Regulatory Manager and is responsible for initiating and providing support to project teams in all regulatory aspects of AFT clinical trials. This includes coordinating with the study operations, finance, contracts and quality teams, plus other internal and external collaborators and is responsible for ensuring the highest quality regulatory oversight.

ROLE AND RESPONSIBILITIES

- Works with the study team to organize study protocols and all supporting documentation (1571, 1572, IND, safety reports) to internal and external regulatory bodies/organizations, including electronic submissions for submission by the Regulatory Manager including:
    - Initial IND submission development and processing

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  - FDA response management
  - Development of annual reports for FDA and international health authorities
  - Updates on US data for international health authorities
  - Routing IND updates for signature and follow-up to ensure final signatures were obtained and the documents properly submitted.
  - Maintenance of electronic files and folders for each submission and all IND/FDA correspondence.

- Is responsible for Central IRB submission including:
  - Review of protocols, amendments and Informed Consent for regulatory and related issues, prior to submission to CIRB
  - Central IRB Submission and follow up response(initial)
  - Local IRB follow response as required (initial)
  - Central IRB Submission (continuing review study level)
  - Site IRB continuing review document production
  - Central IRB submission of updated documents (protocol/ICF amendments, updated IBs, DSMB/IDMC letters, safety reports)
- Prepares and submits clinical trials (ct.gov) registrations and ensures compliance with applicable regulations for trial registration.
- May represent AFT to external study teams / pharma partners, regulatory agencies and IRB for all regulatory matters, and attends all relevant study meetings and offers guidance / expectations with respect to regulatory requirements.
- Serves as primary liaison to institutions for regulatory inquiries.
- Communicates clearly and effectively with all internal and external stakeholders and ensures acceptance and commitment.
- Continues training and development annually.

QUALIFICATIONS AND EDUCATION REQUIREMENTS

- Bachelor's degree, accreditations preferred
- Minimum of three to five years direct experience managing regulatory aspects of clinical studies
- Ability to juggle multiple projects and competing priorities effectively
- Strong communication skills and experience communicating relevant issues
- Expert understanding of the clinical trial process and all regulatory/business concepts involved in creating and building clinical relationships
- Experience working both independently and within a team.
- Proficiency with Office and document management systems.

Last Updated By:	Heather Choukri	Date/Time:	03/08/19