Alliance for Clinical Trials in Oncology
FOUNDATION

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

# Job Description

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| **Job Title:** | Manager, Regulatory Affairs | **Job Category:** | Exempt ☒ Non-Exempt ☐ |
| **Department/Group:** | Alliance Foundation Trials, LLC | **Reports to:** | Chief Operations Officer |
| **Location:** | Boston | **Travel Required:** | <10% anticipated |
| **Level/Salary Range:** | | **Position Type:** | Full-Time ☒ Part-Time ☐ Contract ☐ Temporary ☐ |
| **HR Contact:** | Heather Choukri | **Date posted:** | |

## 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 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 Regulatory Affairs Manager is responsible for defining, articulating, and implementing a long-term regulatory strategy on behalf of AFT for each study project. This includes coordinating with the study operations, finance, contracts and quality teams, plus other internal and external collaborators, including pharmaceutical partners, institutions and vendors. The Regulatory Affairs Manager is responsible for ensuring the highest quality regulatory oversight.

## ROLE AND RESPONSIBILITIES

- Works with the study team to organize and submit study protocols and all supporting documentation (1571, 1572, IND, safety reports) to internal and external regulatory bodies/organizations, including electronic submissions.
- Reviews and revises protocols as necessary, based on relevant regulations, good clinical practice and feedback from pharma partners, internal study teams, and regulatory agencies.
- Prepares IND annual reports, data safety update reports (DSURs), and other updates as needed
- Prepares and submits clinical trials (ct.gov) registrations and ensures compliance with applicable regulations for trial registration.
- Develops and implements clinical regulatory strategies across AFT.
- Contributes to AFT Policy and SOP reviews and updates, including strategies for management of Regulatory Affairs for clinical studies and recommendations for improvement.
- Works closely with the quality management, contracts and clinical operations staff to provide guidance regarding regulatory requirements and ensures compliance with all US and Outside US (OUS) regulations applicable to each AFT study.
- Represents 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.

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**QUALIFICATIONS AND EDUCATION REQUIREMENTS**

- Bachelor's degree, accreditations preferred
- Minimum of five to seven 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.

**ADDITIONAL NOTES**

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| Approved By: | Sheilah Hurley | Date: | 06/04/2018 |

Employee Name: Date:

Employee Signature: _____