



Position: Clinical Trial Assistant - Contractor

Reports to: Director, Clinical Operations

Location: Brisbane, CA

Summary

Provides Clinical Operations Team members with administrative and project-specific support related to the conduct of clinical trials. This includes assisting with study team activities and perform administrative clerical duties. Responsible for obtaining study materials and tracking of invoice and clinical study trackers. Adheres to Clinical Standard Operating Procedures and Good Clinical Practice ICH Guidelines.

Specific Responsibilities:

1. Responsible for the following activities
 - Assist in contacting investigator sites to provide study specific information
 - Ensures receipt, completeness and accuracy of clinical and administrative documents
 - Coordinates distribution and shipment of study-related materials
 - Coordinate investigator site/payment as needed
 - Coordinate vendor payments as needed (tracking of invoice and payments)
 - Maintains telephone contact with sites, contract research organization personnel, vendors and CRAs as needed
 - Facilitates flow and maintenance of correspondence with sites
 - Attends clinical project team meetings and takes minutes
 - Contract, invoice and budget management and tracking
 - Assists in coordination of study initiation documentation materials
2. Responsible for compiling/QC checking/generating copies of clinical documents that are intended for submissions and include the following
 - Investigators 1572's (original and updated)
 - Informed Consent Form
 - Protocol
 - Investigator's Brochure
3. Provides administrative support to Clinical Operations team members
 - Performs administrative and clerical duties
 - Coordinates distribution of study team materials and meeting minutes
 - Drafts and prepares documents for mass mailings (e.g., protocol amendments)

- Assists with preparation of presentation materials
 - Maintains central registry of contact information for clinical sites, contract research organizations, vendors and CRA's.
 - Sets up teleconference calls with sites and team and records minutes
 - Create and maintains Central Clinical files
 - Maintains central monitoring calendar for all site visits
4. Assist with system identification, implementation and on-going management of an electronic Trial Master File
 5. Perform other tasks as assigned by the Manager

Qualifications / Requirements:

- 4-year degree in a scientific or health care discipline preferred
- Minimum of 4 years of relevant work experience in Clinical Operations or related areas in a fast-paced biotechnology environment
- Excellent verbal and written communication skills. Attention to detail
- Knowledge of medical terminology preferred
- Demonstrated ability to work independently and exhibit initiative
- Computer literacy required (MS word, MS Excel, MS PowerPoint and MS Project) and familiar with conferencing technologies

About Aimmune Therapeutics, Inc.

Aimmune Therapeutics is a clinical-stage biopharmaceutical company founded to address the unmet medical need in food allergy, which currently has no approved treatments. Our mission is to improve the lives of people with food allergies, based on our proprietary desensitization treatments in development. Aimmune's lead investigational drug for peanut allergy, AR101, is in Phase 3 clinical testing in North America and Europe. Headquartered in the heart of San Francisco's biotechnology hub, Brisbane, California, Aimmune has additional offices in the Kings Cross area of London, and in Raleigh, North Carolina.

Qualified candidates should forward a resume and cover letter, including a statement of interest, availability, and experience to Human Resources (careers@aimmune.com) with the job title in the subject line.

Aimmune Therapeutics is an Equal Opportunity Employer.

Principals only; no recruiters please.