Position: **Senior Clinical Trial Manager - Contractor**

Reports to: **VP, Clinical Operations**

Location: **Brisbane, CA**

Summary

The Contract Senior Clinical Trial Manager will be responsible for the operational management and oversight of clinical trials within a clinical development program. The position will work closely with the cross-functional internal and external representatives including Clinical Science, Data Management, Biostatistics, and Regulatory/QA to ensure successful completion of all clinical activities/project deliverables within the required time frame and budget. The position will also provide oversight of the CRO and other third-party vendors on the assigned study.

Specific Responsibilities:

- Identify, select, and monitor performance of investigational sites for clinical studies; prepare accurate and timely visit reports from all site interaction visits
- Manage study startup activities (i.e., generation of study plans, managing contracting process, ICF development, essential document collection, IRB/EC set up, site tools and binder preparation, etc.)
- Responsible for review or approval of IP release packages
- Manage and lead the day-to-day operations of assigned studies to ensure completion per established project team goals and objectives in compliance with applicable GCP/ICH guidelines and other regulatory requirements
- Oversee performance of CROs and third-party vendors to ensure compliance with study protocol and in accordance with scope of work; identify areas of concern and escalate as needed
- Perform clinical data review of data listings and summary tables, including query generation
- Develop and maintain good working relationships with investigators and study staff
- Ensure studies are carried out according to the study protocol, SOPs, and ICH/GCP regulations and study-specific manuals and procedures
- Track and report on progress of study including site activation, patient enrollment, monitoring visits
- Review key study quality metrics (e.g., eligibility, primary endpoint data, etc.) and determine appropriate action in conjunction with study team (autonomy may vary with experience)
- Investigate queries, monitor discrepancies
- Manage investigational product (IP) supply/resupply, accountability and reconciliation process

- Review of site, CRO and other third-party study vendor invoices to ensure that work is performed in accordance with scope of work
- Write or contribute to preparation of clinical protocols, amendments, informed consent forms, study guides, case report forms, and any other clinical research related documents

Qualifications / Requirements:

- 8 years Clinical operations experience or a combination of education and relevant work experience in the pharmaceutical industry
- Bachelor's degree or equivalent

Preferred Experience, Special Skills, Knowledge:

- Working knowledge of GCP/ICH guidelines and the clinical development process
- Global Phase III experience desirable
- Experience in leading industry sponsored clinical (pharmaceutical) trials
- Cross-functional team leadership experience
- Management of international clinical studies highly preferred
- Experience managing vendors, including performance assessments and total financial management (invoice review, change order management, budget reforecasting)
- Previous experience working with an electronic data capture system
- Previous experience working with eTMF and CTMS systems desired
- Proficient with MS Word, Excel and PowerPoint. Experience with MS Project a plus
- Strong interpersonal, communication (written and verbal), and organizational skills
- Demonstrated ability to work independently as well as part of a multi-functional study team
- Able to motivate a team to work effectively under a changing environment
- Able to solve problems under pressure
- Self-motivated and able to work effectively in a matrix/team environment

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, AR101 for peanut allergy, is in Phase 3 clinical testing in North America and Europe. The company also plans to begin clinical testing of its investigational drugs for egg allergy and walnut allergy. Headquartered in Brisbane, California – the heart of San Francisco's biotechnology hub – 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.