



Position: Senior Clinical Research Associate, Sr CRA (Clinical Operations) - Contractor

Reports to: Associate Director Clinical Operations

Location: Kings Cross, London

Scope: Interim resource until staff currently working on ARC010 are available to move on to ARC005 i.e. when ARC010 nears completion

Summary

The Senior Clinical Research Associate (CRA) is responsible for all aspects of clinical trial site management and monitoring to assure adherence to protocol, GCP, FDA regulators and overall clinical objectives.

Specific Responsibilities:

- Independent management of more complex aspects of clinical studies and fully understands the clinical research process, demonstrating ability to explain process and objectives of the clinical trial
- Understands broader impact of work on the entire clinical trial and demonstrates strategic thinking regarding management of the trial
- Applies problem-solving skills to components of the clinical trial process or study issues
- Independent vendor management responsibility including responsibility for RFP (Request for Proposal), scoping trial, vendor selection and vendor / investigator payments
- Independent oversight of the clinical study monitoring to assure adherence to Aimune SOPs, protocol, ICH-GCP, FDA and other regulations and overall clinical objectives
- Reviews green light package for site activation
- Trains CRAs on study protocols, study procedures and monitoring SOPs
- Reviews and participates in the quality assurance of data
- Authors or participates in the review of project-specific plans (i.e. Clinical Monitoring Plan, Data Management Plan, TMF etc)
- Participates in the development and review of protocols, IBs, scientific review of clinical data, reporting and publishing
- Responsible for first-line approval of vendor expenses
- Review of CRA monitoring visit reports
- Presents during an Investigator Meeting
- Attends study CRA meetings and cross-functional Study Execution Team Meetings
- Follows ICH-GCP and FDA regulations and contributes to GCP inspection readiness activities

Qualifications / Requirements:

- BS/ BA degree, life sciences degree highly preferred
- 5+ years relevant industry experience

Preferred Experience, Special Skills, Knowledge:

- Excellent attention to detail
- Excellent verbal and written communication skills
- Excellent organizational, record retention, customer service and interpersonal skills
- Good command of written and spoken English language
- Ability to travel as required (approximately 10-15%)

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.