Position: Clinical Project Manager (CPM), EU

Reports to: Head Clinical Operations, EU

Summary

The Clinical Project Manager (CPM) is responsible for all aspects of clinical trial execution and delivery (timelines, budget, quality data and day to day operations), overseeing the clinical study to assure adherence to protocol, GCP, FDA regulators and overall clinical objectives.

Specific Responsibilities include:

- Project manage EU or global clinical study (ies) to ensure studies are completed on time, within budget, and in compliance with SOPs, FDA regulations and ICH/GCP guidelines.
- Contribute to the development of protocols, Investigator Brochures, scientific review of clinical data, and study data analysis, reporting and publishing
- Authors project-specific plans (i.e., Clinical Monitoring Plan, Vendor Oversight Plan, Monitoring Plan etc.)
- Involvement in the development of specifications and user acceptance testing of key trial tools e.g. laboratory, eCRF, IXRS
- Responsible for selection, oversight and preparation of recommendations for the selection and management of project vendors, central labs, and other clinical study vendors (i.e. RFP preparation, bid requests, proposal reviews, bid defence meetings, budget negotiations and contract development)
- Identification, feasibility and selection of EU study sites
- Develops, contracts, budgets and financial forecasting for review and tracks and reports progress against plan
- Reviews and confirms green light package is complete for site activation
- Matrix management of field based EU CRAs working on the programme
- Reviews CRA monitoring visit reports and attends co-monitoring visits, as required
- Trains the cross-functional study team on protocols, study procedures and SOPs, as appropriate
- Working closely with US colleagues to ensure information sharing and best practices are adopted
- Reconciles invoice content vs activities completed and responsible for regional study budget
- May chair the cross-functional Study Execution Team meetings
- Effectively interfacing locally and globally with other functional departments (regulatory, medical affairs, CMC, biometrics, QA, PV) to facilitate timely execution of all study-related activities
- Other duties and assignments as required for the overall success of studies. Duties may change based on the current status of clinical programs and company needs.

Qualifications / Requirements:

BSc/BA, RN, or equivalent

- 7+ years working Pharmaceutical/Biotech/CRO experience of which 5+ years as a **CRA**.
- Experience as a lead EU CPM with experience of study start-up
- Ideally experience as a global CPM
- Hands on and used to a start-up/ small company environment
- Knowledge of ICH-GCP
- Proficiency in the implementation, monitoring and management of clinical trials
- Able to work collegially within a team and carry out duties/responsibilities with general instruction
- Demonstrated track record in the oversight of all trial operational aspects including: budgets, timelines, resources, vendor selection and oversight of clinical team staff during study start-up, interim monitoring and closeout activities.

Preferred Experience, Special Skills, Knowledge:

- Experience as a CPM leading large clinical studies
- Experience as a CRA monitoring studies within UK / Europe
- Excellent verbal and written communication skills.
- Excellent organizational, record retention, time management, decision making, customer service, and interpersonal skills.
- Good command of written and spoken English language
- Ability to travel as required (up to 20%)
- Proficiency with MS Word, Excel, Outlook, PowerPoint and Microsoft Project

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 / CV 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.