Position:

Clinical Trial Manager/ Senior Clinical Trial Manager

About the Company:

Dren Bio (the "Company") is a privately held, clinical stage biopharmaceutical company focused on developing therapeutic antibodies for the treatment of cancer, autoimmune and other serious diseases. The Company's management team and scientific advisors have profound expertise covering the discovery and development of engineered antibodies designed to selectively target and deplete pathological cells. Dren Bio's pipeline is currently comprised of two distinct drug discovery programs. The Company's first program surrounds DR-01, its lead product candidate, which induces antibody-mediated killing of a cell type that is responsible for a multitude of hematologic malignancies and plays a key role in various autoimmune diseases. The Company's second program surrounds its Targeted Myeloid Engager and Phagocytosis Platform, a proprietary bispecific antibody-based technology that provides a novel mechanism of action to selectively engage myeloid cells for (1) targeted depletion of pathologic cells and other disease-inducing agents and (2) inducing localized immunostimulation. The engagement of antigen presenting cells has the potential to elicit a sustained, durable response.

Function: Clinical

Level: Manager/ Senior Manager

Location: Foster City, CA (Remote candidates may be considered)

Reporting Manager: Head Clinical Operations

About the Opportunity:

We are seeking an exceptionally talented and driven individual for the Clinical Trial Manager/(Senior) Clinical Trial Manager position. This role will be responsible for providing operational execution, leadership and support for studies conducted by the Dren Bio team, and work in partnership with internal colleagues, external partners, and investigators and clinical site staff to ensure delivery of high quality clinical studies in a timely manner..

Role and Responsibilities:

- Responsible for clinical study execution and oversight of all operational aspects
- Contribute to the identification and selection of appropriate CROs and third-party study vendors
- Oversee performance of CROs and vendors to ensure study execution
- Ensure study team members vendor training on study documents
- Manage the development of clinical protocols, amendments, informed consent forms, study plans and any other clinical research related documents, in collaboration with cross-functional team members or CRO-partners
- Organize and run study team meetings on a regular basis to ensure clear and current communication, escalation of potential issues to the appropriate functional leads and team based problem solving and risk mitigation of any arising roadblocks
- Establish and maintain excellent working relationships with investigators and study staff
- Ensure studies are carried out according to the study protocol, SOPs, and ICH/GCP guidelines and study specific manuals and procedures
- Participate in feasibility process for finding and selecting new study sites
- Review and comment on CRFs and database build to ensure integration of all critical aspects of the clinical study being reflected in the clinical database

- Collaborate with Data Management to oversee data quality issues (query and data quality management and resolution)
- Guide, in conjunction with the CRA lead, the monitoring activity of CRAs and timely execution of data clean efforts to ensure timely data entry and continuous data quality improvements
- Review key study quality metrics (e.g. eligibility primary endpoint data etc.) and determine appropriate action in conjunction with study team

Education, Experience and Qualification Requirements:

- BS/BA in the life sciences or in a related field; an advanced degree (eg, MS, PharmD, or PhD) is preferred

  5-7 years of experience in clinical operations in the biotechnology or pharmaceutical; experience in oncology highly desirable. Experience with internal model (non-CRO) a bonus.

- Experience with clinical systems including various EDC, IRT, TMF, CTMS, etc.
- Strong organizational, written and verbal communication skills
- Willingness to travel up to 30% of the time
- Permitted to work in the United States

Core Competencies, Knowledge and Skill Requirements:

- A self-starter who can take on building the operational backbone for early phase clinical studies
- Experienced in leading international Phase I-III clinical trials
- Participation in large multi-center and/or global trials, investigational site and CRO management, data collection study protocol compliance.
- Solid understanding of US and global regulations and guidelines (FDA, EMA, ICH)
- Experience in working in a highly matrix environment and ability to execute in the context of internal and external (vendor) cross-functional teams
- Desire to learn and grow in terms of scientific knowledge, managerial capabilities and personal development
- Willingness to take a hands-on approach
- Ability to work under pressure and aggressive timelines
- Ability to manage multiple competing priorities, being able to rapidly gather, assimilate and disseminate information on critical project components and milestones
- Detail oriented with ability to manage technical/scientific aspects as well as operational components of logistics, timing and quality

Salaries, Benefits and Other Employee Perks:

Dren Bio strongly believes in investing in, and rewarding, its employees. This philosophy is embodied in the Company's total rewards program, which includes competitive cash compensation, equity incentive awards, and employer sponsored benefit offerings. The base pay range for this position at commencement of employment is expected to be between $135,000 and $175,000 per year. However exact base pay offered will be determined based on multiple individualized factors, including job-related knowledge, skills and experience and market location.

Employment Practices:

Dren Bio is an equal opportunity employer. Employment decisions are based on merit and business needs. Dren Bio will not discriminate against any job applicant because of race, color, national origin, ancestry, gender, sexual orientation, age, religion, creed, physical or mental disability, gender identity, medical condition, pregnancy, marital status, veteran status, or any other characteristic protected by federal, state or local law.

Interested Applicants:

Please send resume and cover letter to careers@drenbio.com