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:

Director of 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
- Lead in-house study management in the United States (no CRO contracted for US study management)
- Contribute to the identification and selection of appropriate ex-US CROs and third-party study vendors
- Oversee performance of ex-US CROs and vendors to ensure study execution
- Develop study training slides and materials and train study team members and vendors on study protocol, associated documents, and key decisions and communications
- Ensure study team members and vendors are trained on protocol, relevant study documents, and key decisions at study start-up and throughout the duration of the study
- 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
- Oversee CTA management of site start-up activity
- Work with central laboratory vendor on lab specifications, manual, and kit design and database build
- Work with central imaging vendor on specifications, charter, manual, supplies, and vendor portal database build
- Work with IRT vendor on specifications, build, testing, and manual for drug supply management system
- Review and contribute to CRF design 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)
- Lead Clinical Operations team in planning and execution of data cleaning for data deliverables.
- Cohort screening and enrollment management in coordination with Medical Monitor
- Collaboration with Medical Monitor and Safety to prepare data and communications for dose escalation Safety Review Committee and DSMB meetings
- 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 and communicate key study quality metrics (e.g., eligibility, primary endpoint data, etc.) and determine appropriate action in conjunction with study team
- Collaborate with cross-functional teams (e.g., regulatory, translational research, quality, CMC, statistics, etc) in study start-up planning as well as to coordinate efforts for study deliverables (e.g., regulatory submissions, sample reconciliation, PK and exploratory biomarker analyses, SOP development, drug supply projections, pharmacy manual and IP management, developing data cleaning timelines for stats/programming TLF deliverables, etc)

Education, Experience and Qualification Requirements:

- BS/BA in the life sciences or in a related field; an advanced degree (e.g., MS, PharmD, or PhD) is preferred
- 5-7 years of experience in clinical operations for biotechnology or pharmaceutical employer; experience in autoimmune disease(s) highly desirable. Experience with internal model (in-house, non-CRO study management) highly desirable.
- 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, and 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. At Dren Bio, pay ranges are determined by role, level(s), and location. The range displayed in this job posting reflects the minimum and maximum new hire pay for candidates located across all United States job markets. Within the range, individual pay will be determined by work location and additional factors, including job-related skills, experience, and relevant education or training. During the hiring process, Dren Bio's Human Resources department can share more about the specific pay range based on the market location of the candidate.

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