Position:

Manager/Sr. Manager, Clinical Data Management

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 specially engineered antibodies. Dren Bio's pipeline encompasses a multitude of programs from its two distinct, wholly-owned technologies. The Company's lead development candidate, DR-01, induces antibody-mediated killing of a specific cell type known to play a key role in various hematologic malignancies and autoimmune disorders. In addition to DR-01, the Company has launched multiple programs from its proprietary Targeted Myeloid Engager and Phagocytosis Platform, a bispecific antibody-based technology that offers a novel mechanism of action focused on selectively engaging myeloid cells (antigen presenting cells) for the targeted depletion of pathologic cells and other disease-causing agents.

Function:

Clinical Operations

Level:

Manager/Sr. Manager

Location:

Foster City, CA (remote candidates may be considered

Reporting Manager:

Director, Clinical Data Management

About the Opportunity:

We are seeking an experienced and talented individual to play a key role in delivering accurate, high quality clinical trial data for one or more clinical trials. The position requires a motivated, self-starter who works well in partnership with internal colleagues and external partners to ensure delivery of high quality clinical studies in a timely manner. Overall responsibilities will include oversight of clinical data management activities from study start-up through study closure in support of trial objectives and corporate goals. Local candidates are preferred, but will consider remote candidates with some travel required.

Role and Responsibilities:

- Provides oversight of clinical data management activities across one or more studies
- Leads the development or co-development with CRO and maintenance of clinical data management documents, including but not limited to: Data Management Plans, Case Report Forms (CRF), CRF Completion guidelines, edit check specifications, data transfer specifications, and report specifications.
- Oversight of DM CRO data management activities.
- Partner with the CRO and EDC vendor(s) to ensure the timely design and development of clinical study databases per study requirements, including system integrations.
- Performs and organizes cross-functional User Acceptance Testing (UAT) of clinical databases and integrations.
- Reviews clinical study documents including but not limited to: Clinical Protocols, Data Transfer Specifications/Agreements, Study Plans, Project Timelines
- Leads discussions with clinical data management partners/vendors to ensure that data management tasks and deliverables remain on target per project timelines.
- Manages ongoing data review and data reconciliation throughout the conduct of the study to ensure timely and appropriate identification of errors, trends, and discrepancies, in collaboration with internal and external stakeholders.
- Responsible for the correction of errors and discrepancies through the query process, for documenting permanent data issues, routinely communicating issues with team members.
- Works on complex issues where analysis of situations or data requires an in-depth evaluation of variable factors, and the ability to work through ambiguity.
- Help to ensure DM documentation is uploaded into the TMF and ensure inspection readiness.
- Ensure compliance with SOPs, Good Clinical Practice (ICH-GCP), and applicable regulatory requirements.
- Contribute to writing SOPS, Working Practices, and Guidelines.
- Attend and present at Investigator Meetings and other industry meetings as needed.
- Responsible for implementing analytics tools for one or more clinical trials.
- Other duties as needed.

Education, Experience and Qualification Requirements:

- Bachelor's degree in clinical, biological, mathematical sciences or related field is required; an advanced degree is a plus
- Minimum of 5 years of clinical data management experience in the biopharmaceutical industry on the Sponsor side; advanced knowledge of Data Management processes and systems
- Solid understanding of clinical drug development processes
- Minimum of 5 years of AutoImmune and/or Hematology-Oncology and/or Oncology Experience
- Minimum 5 years of Electronic Data Capture (EDC) experience (preference for Medidata Rave X experience); IXRS integration experience required
- Knowledge of FDA and/or EMEA Regulations, ICH Guidelines, and GCPs governing the conduct of clinical trials.
- Detail-oriented, strong multi-tasking, and time management skills are required due to deadlines.
- Microsoft office suite (excel, powerpoint, word, outlook)
- Smartsheet
- Willingness to travel up to 20%
- Permitted to work in the United States

Core Competencies, Knowledge and Skill Requirements:

- A highly motivated self-starter
- A mature and self-assured team player who will work well with all other functional areas and can effectively interact with individuals at all levels of the organization and develop a cohesive relationship among the team

- Demonstrable/transformational leadership and interpersonal skills
- Ability to work under pressure and timeline constraints
- Ability to manage multiple competing priorities, being able to rapidly gather, assimilate and disseminate information on critical project components and milestones, and to translate to internal or external staff assigned to projects
- Detail focus with ability to manage technical/scientific aspects

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 $125,000 and $165,000 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