Position:

Senior Clinical Data Manager

About the Company:

Dren Bio (the "Company") is a privately held, pre-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 programs. The first program surrounds DR-01, the Company's 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 is a proprietary antibody-based technology platform, its Targeted Myeloid Engager, which utilizes a novel mechanism of action to selectively engage myeloid cells for the targeted depletion of diseased cells and disease-inducing agents, as well as to induce immunostimulation.

Function:

Data Management

Level:

Senior Clinical Data Manager

Location:

Foster City, CA (partially remote)

Reporting Manager:

VP, Clinical Operations

About the Opportunity:

The Senior Clinical Data Manager provides oversight for the execution of data management activities at the program level (for an indication or for multiple studies within an indication) from start up through to regulatory submission. Serves as the lead study data manager on the study team(s) and in collaboration with external vendors. Designs, implements, and maintains electronic case report forms, clinical trial database and electronic data checks for ongoing and new clinical research studies. Develops, implements, and executes data review plans to ensure quality of collected clinical data, including oversight of multi-functional data review teams. Manages electronic data received from clinical sites, data transfers and reconciliations, and the development of technical study documents and reports such as data transfer plans, annotated case report forms and database/data quality metrics.

Role and Responsibilities:

- Responsible for overseeing and supporting data management activities for assigned projects in accordance with ICH/GCP, GCDMP and other relevant procedures and guidelines.
- Provide a high level of expertise in data management to support clinical studies.
- Ensure the quality of clinical data meets standards for regulatory submission, publications, and other high-profile business activities.
- As the main point of contact to the Study Team, work collaboratively with Clinical Operations, vendors, statistical programmers, Clinical Development, Safety/PVG, Regulatory and Project Management functions to meet data management deliverables and clinical trial timelines.

- Manages data extractions and/or provides simple data listings for safety review meetings and other meetings as needed.
- Monitor data management processes and CRO performance to ensure study deliverables and timelines are met.
- Responsible for eCRF design, development, validation, and maintenance of clinical study database(s) for clinical trials in collaboration with vendor(s).
- Generate and implement the Data Review Plan (DRP) defining and documenting the data quality review strategy and procedures for data quality review and data acceptance prior to data analyses and/or database lock for each clinical trial in collaboration with cross-functional team.
- Oversee/perform data review and cleaning activities, assuring quality interim and final reporting of clinical data.
- Lead the set-up and validation of vendor data transfer, data cleaning activities, generation and approval of data management documents, generation and distribution of data management metrics, data listings and status reports.
- Manage data transfers with CROs and third-party data sources, SAE/AE reconciliation and MedDRA/WHO-DD coding.
- Provide clear verbal or written information and hands-on support to project team members and to CROs related to eCRF and database design, data quality, and reporting of database/data quality status.
- Identify and mitigate risks to data management deliverables.
- Collaborate cross-functionally to resolve or escalate data management issues and ensure effective communication throughout all clinical trial phases.
- Oversee the transfer, locking, and archiving of study databases.
- Manage scheduling and time constrains across multiple projects.
- Prepare recommendations for new or improved processes for data management and data flow.
- Contribute to the ongoing development, review, and revisions of data management SOPs and standard DM templates, as needed.

Education, Experience and Qualification Requirements:

- BS/BA degree and a minimum of 9 years of related experience; or MS/MA degree and 7 years of related experienced or equivalent.
- A minimum of 5 years of clinical data management experience in the pharmaceutical industry or clinical trials.
- Oncology experience required; experience with lymphomas a bonus.
- A minimum of 4 years in a project leadership role.

Core Competencies, Knowledge and Skill Requirements:

- Experience working in an outsourced data management model.
- Experience with Electronic Data Capture (EDC) is required, preferably with Viedoc.
- Experience with IRT systems preferred.
- Highly collaborative and demonstrated ability to work well in teams in a cross functional manner.
- Knowledge of ICH/GCP, GCDMP and other relevant procedures and guidelines.
- General knowledge of FDA regulations that govern the execution of clinical trials and EDC systems.
- Identifies and implements methods and procedures to achieve results.
- Leads or manages the work of others by providing guidance to subordinates or teams based on company goals, with responsibility for results.
- Performs and is able to prioritize a variety of complicated tasks with a large degree of creativity and latitude.
- Has complete understanding and wide application of technical principles, theories, concepts, and techniques.
- Has a good knowledge of other related disciplines.
- Ability to communicate and work independently with scientific/technical personnel.
- Ability to think critically and demonstrated troubleshooting and problem-solving skills.
- Self-motivated and willing to accept temporary responsibilities outside of initial job description.
- Comfortable in a fast-paced company environment with minimal direction and able to adjust workload based upon changing priorities.

- Excellent verbal and written communication skills, including presentation and interpersonal skills.

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. Exact cash and equity compensation shall be commensurate with candidate's experience and qualifications.

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