CYCLACEL

Senior Manager/Associate Director, Clinical Data Management.

Location: Based onsite in Berkeley Heights, N.J. (subject to COVID-19 restrictions). Remote location would be considered.

The role: The Senior Manager/Associate Director, Clinical Data Management leads the data management of all studies in the portfolio. They are responsible for the performance of data management tasks from study start-up, inclusive of database design, through database lock for assigned projects within electronic data capture (EDC) systems. They are responsible for the creation of CRFs, programming of edit checks, facilitating User Acceptance Testing (UAT), data cleaning, query generation and management, and development of relevant data management documents. They also lead process improvements initiatives and provide leadership during audits and inspections. The CDM leads and participates closely with other functions to implement new technologies & tools. This role will be expected to lead internal managed clinical studies and/or oversee CRO/FSP vendors for multiple clinical studies. The CDM stays current with industry standards and trends related to Data Management activities and ensures Cyclacel processes are aligned.

In this role: You will specifically,

- Author and maintain data management documents: Data Management Plan (DMP), Edit checks, eCRF completion guidelines, Data Cleaning Plan, External Data Reconciliations, Investigator training slides specific to the database
- Lead and Develop Case Report Form (CRF)
- Develop database (DB) clinical trial data specifications, including eCRF design, user requirements, edit rules/checks, query logic and data validations
- Develop Data Transfer Specification(s) (DTS) between external data vendors and/or core labs
- Reconcile electronic data transfers from vendor to Sponsor
- Develop test scripts and execution logs for User Acceptance Testing (UAT)
- Lead and participate in the standardization of eCRF & validation specifications
- Be responsible for data cleaning activities including data review, query generation and management, and development of study metrics

- Oversee CRO data management functions when applicable
- Participate in SOP development
- Lead study-level audit and inspection readiness activities, as required
- Partner with other functional groups eg project management and safety to ensure data management aspects integrated appropriately into activities.

For this role: You should have,

- BS degree in scientific or mathematical discipline (advanced degree preferred)
- 5+ years of experience in clinical data management in the pharmaceutical/ biotechnology industry
- Oncology experience preferred
- CCDM certification, highly desirable
- EDC experience in Medidata RAV; J review report creation
- Ability to perform basic programming of reports
- Extensive experience managing CROs, for both In-sourced and Outsourced studies
- Experience with CDISC/SDTM, highly desirable
- Demonstrated ability to learn quickly, plan and be proactive within tight deadlines whilst working independently as well as collaboratively
- Ability to understand and work with technical database specifications
- Extensive knowledge of clinical trials data management best practices and working knowledge of clinical data management systems
- Excellent communication skills (oral and written) and demonstrable attention to detail.

To apply for the above position, please send your CV with an accompanying letter via email to recruitment@cyclacel.com or by post to Human Resources, Cyclacel Pharmaceuticals Inc., 200 Connell Drive, Suite 1500, Berkeley Heights, NJ 07922.

Closing date for applications is **Monday, December 7, 2020**.

We look forward to hearing from you.

Cyclacel Pharmaceuticals, Inc. is an Equal Opportunities Employer.

This job description describes the general duties of the position and provides some illustrative examples. Other duties may be assigned by management as business circumstances require.