Clinical Data Manager

Who are we?

We Are Cancer Insight. We are a growing CRO that specializes in developing cutting-edge immuno-oncology (IO) drugs. We specialize in designing and executing early-phase IO trials, yet we also run large, multi-site, adaptive, later-stage trials. We are specialists in the most exciting field in medicine—immuno-oncology. Our success is driving growth. We are committed to saving lives and are constantly striving to be the best at what we do. Our impact is real and we see it every single day.

Job Overview:

As a Clinical Data Manager for Cancer Insight, the person in this role will be responsible all data management activities from start-up through closeout of study. The CDM will work with the Clinical Project Manager (CPM) and Biostatistician to ensure the accuracy, timeliness and complete collection of clinical study data. They will be responsible for representing data management in meetings and providing status updates and metrics as needed. Excellent communication skills and a desire to be an active team player are a must.

Reports To:

Director of Biometrics.

Responsibilities:

- Critically review protocols and provide feedback as it pertains to data collection and data management activities.
- Contribute to the design of study databases, case report forms (CRFs) and edit checks.
- Perform User Acceptance Training (UAT).
- Develop and maintain proper study documentation throughout the lifecycle of a study, to include, but not limited to Data Management Plans, (DMP), eCRF Completion Guidelines, Database Specifications, Edit Check Specifications, and UAT Test Plans.
- Create and validate standard, study specific, and ad hoc study reports.
- Develop training material and provide electronic data capture (EDC) system training for internal users and site personnel.
- Perform quality control review checks.
- Perform serious adverse event (SAE) reconciliation between EDC and safety database.
- Perform coding and review auto-coded terms within EDC using MedDRA and WHODrug dictionaries.

- Ensure that all data management activities leading to database lock are completed; work with the clinical team as needed to ensure timely database lock.
- Perform data transfers from EDC to sponsors.
- Interact with third-party vendors, such as central laboratories, to carry out data management tasks
- Communicate project statuses and key issues to CPM and study team as needed.
- Participate in cross functional team meetings as requested.

Skills and Requirements:

- Minimum 5 years of clinical trial data management experience in the biopharmaceutical industry or at a contract research organization.
- Knowledge of industry standards, such as ICH guidelines, CDASH, 21 CFR Part 11, and FDA guidelines.
- Experience with clinical databases such as Medrio, OpenClinica, Oracle.
- Strong understanding of clinical trial processes and EDC platforms.
- Proficient in Microsoft Excel, Word, PowerPoint and GSuite Applications.
- Excellent verbal and written communication and organizational skills.
- A high degree of flexibility and willingness to take on non-traditional CDM tasks.

Application process:

Contact Ashlee Richie at (arichie@cancerinsight.com).

The above description is intended to describe the general nature of the job and may include other duties as assumed or assigned; it is not intended to be all inclusive or limit the duties of the position. Cancer Insight is an EEO/AA employer and is committed to providing opportunities to minorities, women, veterans and individuals with disabilities.