Clinical Trial Associate

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:

The Clinical Trial Associate (CTA) role provides administrative and organizational support to the internal clinical team as well as assigned clinical research sites. The CTA is highly motivated to have lasting impact on the field of oncology by performing key job functions in accordance with ICH/Good Clinical Practice (GCP) guidelines, federal regulations and internal SOPs and work practices. This position is an essential part of the clinical operations project team.

Reports to:

Director, Clinical Operations.

Responsibilities:

- Serve as internal support for all members of assigned project teams.
- Assist investigative sites with completion and submission of all required clinical trial documents prior to site initiation.
- Complete Site Initiation Visits (SIV) and/or Investigational Product (IP) Shipment Authorization review checklists.
- Maintain timely and accurate tracking of all clinical trial activity in Clinical Trial Management System (CTMS).
- Perform reconciliation between CTMS and other systems as requested.
- Assist CPM with compilation of monthly Sponsor status reports
- Support establishment and maintenance of Trial Master Files (TMF) for assigned clinical trials, including management of document expiry timelines.
- Perform Quality Control (QC) of Study and Site Level TMF via quarterly file reviews.
- Ensure audit/inspection readiness of essential documents for each site and internally throughout the duration of clinical trials.

- Coordinate Institutional Review Board/ Ethics Committee (IRB/EC) approvals, annual reviews and closure notifications as appropriate.
- Support overall progress of clinical trials by regularly attending clinical trial team meetings, preparing clinical team meeting agendas and minutes, reviewing team communications and sharing pertinent information with clinical trial team members and investigative sites as requested.
- Manage the procurement of all equipment/supplies provided to investigative sites, and ensure appropriate tracking and reporting.
- Maintain positive interactions with internal and external personnel including investigative site staff and vendors as appropriate.
- Assist with review of Investigator payments based on knowledge of site activities obtained from EDC, IxRS and CTMS tracking.
- Support the successful execution of assigned studies in conformance with ICH/GCP standards, CFR requirements and internal policies and procedures.
- Assist with other duties as assigned.

Skills and Requirements:

- BA/BS degree, life science preferred.
- Minimum 9-12 months experience as CTA at a CRO or Biotech.
- Ability to problem-solve, multi-task and prioritize across tasks.
- Fluent in English (written and verbal).
- Strong communication (written and verbal) and interpersonal skills.
- Expert in Microsoft 365.
- Knowledge of ICH GCPs and CFR requirements.
- Ability to work from a remote environment with minimal supervision.
- Willingness to adapt to the use of new technologies

Contact:

Contact Karen Arrington at (karrington@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.