Clinical Trial Associate

Remote

Summary

Reporting to the Director, Clinical Supplies, the Clinical Trial Associate will provide support for the day to day operations of the Clinical Operations department and assist with project-specific tasks in order to ensure the timely delivery of trial objectives.

Responsibilities

- Responsible for each study's Trial Master File including set-up, maintenance, QC of the CRO central files/eTMF and regular review of incoming communication from the TMF email account for appropriate filing.
- Utilize the study client portals of CROs in order to extract data for use in project reporting, as well as review/QC of CRO trackers to ensure accuracy of summary reports and study metrics.
- Support efforts for forecasting and calculating Investigational Medicinal Product (IMP) supply needs and maintain an IMP dispensing tracker to ensure adequate IMP supply at clinical sites.
- Coordinate the shipment and receipt of all IMP to clinical sites, including appropriate import and export documentation required for global clinical trials.
- Tracking of patient visits and investigator payments in order to verify invoices sent from clinical sites and ensure payments to sites are accurate and timely.
- Create the site and patient cost budgets for each study and manage quarterly patient payment accruals.
- Assist with the creation of clinical site budget templates and review site contract revisions from the CROs.
- Assist to ensure all study documents (e.g. clinical site manuals, lab manuals, charters, IMP distribution manual, communication plans, study records/forms/logs/worksheets, etc.) are current and modified as required for study initiation or changes (e.g. personnel, vendors, protocol amendments).
- Assist with the development of patient recruitment materials and create patient facing documents such as the patient diaries, GP letter, ID cards etc.
- Provide support to Project Managers for meetings, calls and web conferences by issuing agendas and minutes and reviewing CRO meeting minutes for accuracy.
- Perform specific aspects of study execution under the direction of Clinical Project Managers or Managers of Clinical Supplies.
- Regularly assist with updates to Clinicaltrials.gov and other similar clinical trial registries with current site status or results.
- Process site confidentiality (CDAs) and clinical trial agreements (CTAs) from CROs to obtain internal electronic approvals and signature
- Other related duties as assigned.

Qualifications and Requirements

- Undergraduate degree in a related discipline with a minimum of 3 years directly related experience in Clinical Operations, or the equivalent combination of education and experience.
- Expert user of MS Word, Excel, PowerPoint, and Visio and other computer programs, systems or applications with the capability of effectively working with large complex documents.
- Superior administrative skills and attention to detail.
- Strong analytical skills to identify and solve problems.
- Working knowledge of Clinical Operations processes.
- Ability to exercise independent judgment in making decisions.
- Demonstrated Project Management experience and skills, with the ability to coordinate multiple projects in a demanding fast-paced environment.
- Excellent oral and written communication skills for effectively interfacing with all levels of management and departments within the company, vendors and contract sites.

How to Apply

To apply for this role, please submit your CV and cover letter in PDF format to hr@sierraoncology.com. Please indicate the position title in the subject line of your email.

We thank you in advance for your interest in Sierra. We will contact you directly should we wish to arrange a meeting to discuss this position further.