Clinical Site Manager

Remote

Summary

Reporting to a Senior Clinical Project Manager, the Clinical Site Manager will be responsible for the clinical site management aspects of study trials working with the internal and external cross functional teams liaising with project leadership for ensuring timely deliverables that comply with Sierra Oncology Standard Operating Procedures (SOPs) and Regulatory Guidelines (ICH, GCP).

Responsibilities

- Work directly with CRO Clinical Trial Lead (or equivalent), to ensure site management and clinical oversight is maintained, performing co-monitoring as needed.
- Develop and oversee enrollment projections, ensuring pro-active recruitment strategies and site-specific plans are developed and implemented.
- Analyze site screening data, monitor low enrolling sites, continuously review and update recruitment plans, evaluate outreach opportunities, develop site tools to aid with recruitment and provide regular reports to senior management on status and progress.
- Review all clinical study site documents and ensure they are current and modified as required for phase of the study (e.g. monitoring plan, monitoring tools, site manuals etc.) or changes (e.g. personnel, vendors, protocol amendments).
- Oversee all site start-up activities and amendment implementation including reviewing /negotiating site contract language (in collaboration with our in-house contract group) and site budgets, ensuring CRO is expeditiously moving each site to initiation.
- Input into or drafting of master ICF for the study and review of all country ICF customizations as well as approving site level changes escalated from the CRO.
- Review issues identified by Data Management or Medical Management specific to site management (e.g SDV backlog, site data entry metrics, protocol non-compliance reports etc.) to ensure remediation and resolution.
- Site Investigational Product (IP) release pack review.
- Perform User Acceptance Testing specific to the CRA role for clinical database release.
- Review the CRO’s Monitoring Visit Reports for sponsor oversight and to identify site or study issues.
- Other related duties as assigned.

Qualifications and Requirements

- Undergraduate degree in health sciences or related field with minimum of 5 years’ clinical trial experience including at least 2 years as a CRA and at least 2 years as a Clinical Trial Lead (or equivalent)
- Clinical trial experience in oncology indications
- Expert user of MS Word, Excel, PowerPoint, and other computer programs, systems or applications with the capability of effectively working with large complex documents.
- Superior oral and written communication skills and attention to detail.
- Proven ability to identify and solve problems and decision-making.
- Independent worker, who thrives in a multi-tasking demanding fast-paced environment.

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.