# Senior Clinical Research Associate Job Description

- Develop detailed project plans and budgets for clinical trial protocols; oversee and track progress to timelines
- Lead training initiatives and onboarding of research staff at trial sites; provide ongoing support and education
- Create master drug supply forecasts and manage distribution logistics to trial locations
- Conduct on-site and remote monitoring visits of trial locations to review regulatory documentation, drug storage procedures, equipment calibrations, etc. Identify any deficiencies or training issues
- Monitor patient recruitment and enrollment numbers; recommend and assist with recruitment strategies to meet targets
- Review complex datasets and information from trial sites related to safety and efficacy; ensure accuracy and completeness
- Write visits reports, summaries, and other central documents to capture key trial information for lead scientists and regulatory submissions
- Serve as main point of contact for questions, issues, or feedback from site personnel; provide guidance and leadership
- Track site performance benchmarks and metrics related to enrollment, data quality, protocol adherence
- Develop solutions for operational challenges that arise; adjust plans to minimize impact on trial execution
- Ensure ethical guidelines, safety regulations, and GCP principles are strictly followed across all trial locations
- Represent trials and sponsor companies at investigator meetings, conferences, trainings, etc.
- Lead or assist sponsor companies with final analysis, evaluation, and conclusions of trial data
- Prepare sites and systems for regulatory inspections; may participate or present in inspections

- Maintain expert level knowledge on regulations, guidelines, systems in area of medical trials
- Communicate status updates, risks, final reports to leadership and key trial stakeholders
- Develop data validation plans and quality control processes for trial data and systems
- Author SOPs, process documents, and training materials for trial sites and CRA teams
- Perform quality assurance audits on CRA monitoring activities and site performance
- Create agendas, content, and presentations for investigator meetings
- Compile data and generate reports for Data Safety Monitoring Board reviews
- Assist medical writing teams with clinical study report development
- Respond to inquiries from regulatory authorities regarding trial documentation and processes
- Liaise between sponsor companies and central lab facilities coordinating sample analysis
- Develop contingency plans for trial delays, enrollment issues, site staffing problems etc.
- Create newsletters, status communications to inform trial leadership and stakeholders
- Conduct benchmarking studies on site metrics from past trials to set performance targets
- Review CRA monitoring plans and travel itineraries to provide oversight and optimization
- Analyze site contracts, agreements, and budgets during trial planning and initiation
- Assist with design and evaluation of case report forms, data capture tools, and eCRF components
- Develop transition plans for handoff of trials monitoring activities from remote to on-site visits.