Job Description		
Title **Lead Clinical Research Associate (Field position)**		
Department Department: Clinical Development	***Reports to: Director, Clinical Operations***	
	Supervises: No	
Effective Date: ***June 11, 2016***	*Page: 1 of 4*	***FLSA: Exempt***

Position Overview

The Lead Clinical Research Associate (CRA) reports to and works closely with the Director of Clinical Operations to provide leadership to CRAs in study start-up activities, implementation, monitoring, and close-out activities of multiple clinical trials and process-improvement activities. The Lead CRA works with clinical leadership, vendors, and CRA teams to assure that protocol requirements, bio specimen collection procedures, regulatory guidelines and study timelines are defined and met. This individual has the ability to mentor, and train a team of CRAs and provide close project oversight with demonstrated problem-solving skills. The Lead CRA will also ensure that Director of Clinical Operations is aware of all monitoring metrics and critical issues. The Lead CRA is the key representative for monitoring responsibilities (in alignment with the Director of Clinical Operations) and assists assigned study monitors in maintaining relationships and rapport with clinical investigational site personnel. This position will review monitoring trends, track monitoring deliverables, review trip reports, and recommend potential solutions to identified issues. The Lead CRA will actively participate in monitoring large, complex study (and multiple studies) clinical trial activities from study start-up through closure and is expected to attend team meetings, Investigator Meetings, support business development efforts, and manage site assignments. Major responsibilities include ensuring the safety and well-being of study participants/patients at assigned site(s); ensuring site(s) compliance with study plans and guidelines, Good Clinical Practices (GCPs), and applicable regulations; ensuring data integrity through the source data verification and monitoring process and/or remote monitoring; and ensuring site compliance with all bio specimen collection activities, shipping kit and buffer storage, inventory, and disposition requirements.

Essential Job Functions

- Conducts trip report review for assigned projects.
- Tracks visit and trip report metrics and summarize/report to teams.
- Reviews site data quality trends via trip reports and data review including queries and protocol deviations.
- Participates in CRA project-specific training.
- Supports preparation and may develop materials related to the training and presentations for CRA training, Site Initiation Visits and Investigator Meetings.
- Develops Clinical Monitoring Plans.
- Develops Monitoring tools and Source Document Templates.
- In conjunction with Clinical Development/Operations leadership and vendor, develops and tests EDC, and TMF functionality.
- Facilitates CRA project meetings.
- Provides a key role in problem solving and issue escalation, regarding bio specimen collection and shipping, monitoring issues, with proposed solutions to the Director of Clinical Operations.
- Mentors and co-monitors with CRAs on assigned teams.

Monitoring Responsibilities:

- Conducts all types of clinical monitoring visits, e.g. pre-study qualifications, initiations, on site and remote monitoring, and close-out) which includes all preparatory and follow-up aspects.
- Attends study specific teleconferences.
- Involved in initial review of study documents, e.g. protocol, CRFs, source documents, bio specimen requisitions and instructions for use documents, specimen collection kit accountability, and informed consent (not all inclusive).
- Monitors site performance and compliance and provide management with necessary reports, updates and recommendations.
- Prepares clinical sites for regulatory agency audits.
- Assists sites and data management with data query resolution.
- Responsibility for a geographic area and travel as required by study(s) needs.
    - Conducts site initiation visits; trains site personnel on sponsor and regulatory requirements for study conduct; participates in and/or conducts site meetings and multicenter investigator meetings, and prepares site initiation visit reports and associated documentation.
    - Conducts site monitoring visits and follow-up to identify significant problems and issues and to ensure that all clinical aspects of studies are being carried out in accordance with study plans, GCPs, and applicable regulations; prepares monitoring visit reports and associated documentation.
    - Reviews on-site files and records, Case Report Forms, and source documents for completeness, accuracy, consistency, and compliance; identifies deficiencies and discrepancies; initiates corrective action as required; and ensures training is provided within a reasonable timeframe, is current, and is documented appropriately.
    - Ensures appropriate transmission of clinical data to the data management centers; reviews data queries, and clarifies and/or obtains changes to data as appropriate.
    - Assists in the close-out of clinical studies by identifying items and issues for review and/or follow-up; assembles necessary documents, conducts site close-out visits to include Investigational Product reconciliation and disposition, review of completeness and accuracy of files, and retrieval of relevant codes and documents; prepares site close-out reports and associated documentation.
- Focus on meeting enrollment timelines and developing subject recruitment strategies.
- Miscellaneous duties, as necessary, in support of Clinical Monitoring initiatives and DTH business priorities and objectives.

Education/Experience Requirements

- Requires a minimum of a Bachelor's Degree, preferably in a scientific, healthcare, or related field.
- Requires a minimum of eight (8) years' monitoring and site management at either a CRO or pharmaceutical/biotech (sponsor) company. Sponsor experience preferred.
- Four (4) years of Lead or Senior CRA experience is required.
- Oncology experience required.
- Device experience preferred.
- CRA certification preferred.
- Must have a valid driver's license.
- Willingness and ability to travel 80% of the time with some overnight and weekend travel required.

Knowledge, Skills, and Abilities (KSAs)

- Highly organized and detail-oriented
- Computer literate.
- Strong problem solving abilities.
- Excellent written and verbal communication and time management skills.
- Excellent understanding of the clinical research process, clinical trial-related systems and procedures, regulations and GCPs.
- Scientific/clinical knowledge to be able to understand the nature of the laboratory assays being studied.
- Must have excellent people skills and demonstrate the ability to work successfully in a team environment.
- Ability to prioritize and to manage multiple tasks as necessary.

NOTE: This job description is not intended to be all-inclusive. Employee may perform other related duties as negotiated to meet the ongoing needs of the organization. Pierian is an Equal Opportunity Employer with a strong commitment to the achievement of excellence and diversity.

PHYSICAL REQUIREMENTS CHECK-OFF FORM

Check off only the physical abilities that can be directly related to the essential functions of the job. (***Caution:*** Make sure you are not setting stricter requirements than for similar workers already employed.)

Job Title:				
Physical Activity Required	**Amount of time**			
	None	**Less than 1/3 (Occasionally)**	**1/3 to 2/3 (Frequently)**	**More than 2/3 (Regularly)**
Standing			x	
Walking			x	
Sitting			x	
Fingering or manual dexterity				x
Repetitive finger motion				x
Lifting or exerting force				
Up to 10 pounds			x	
Up to 25 pounds		x		
Up to 50 pounds	x			
Up to 100 pounds	x			
Over 100 pounds	x			
Reaching or stretching			x	
Climbing or balancing		x		
Crouching or stooping			x	
Speaking				x
Hearing				x
Seeing (with correction)				x

Completed by: *Yvette Payne* Date: *11 June 2016*