
# Senior Clinical Research Associate/Country Lead Monitor

**Application Period**
24 July 2018 – 10 August 2018

**Reference Code**
PHSCRA072018

**Division**
Pharma

**Company**
Bayer (Pty) Ltd

**Department**
Clinical Research

**Location**
Isando

**Functional Area**
Adminstration

**Position Grade**
VS 1.1

**Employment Type**
Permanent

**Work Time**
Regular

**YOUR TASKS AND RESPONSIBILITIES**

Senior CRA is accountable and responsible for:

- All aspects of site management and monitoring activities for assigned applicable Phase I and all Phase II-IV clinical Investigator sites within the approved Clinical Development Plan (CDP). These global, complex studies are conducted within the standards set by Bayer Global Development, according to Good Clinical Practices (ICH - GCP) and applicable regulatory and legal requirements.
- Managing Investigator site and site activities and monitoring site data, to ensure patient safety and ethical and regulatory compliance necessary to provide quality data required for global regulatory submissions for approval of drugs.
- Managing Investigator sites to ensure the Investigator and Site Staff meet all aspects of study delivery and commitments to make certain the operational study execution is on track from site selection to site close out.
- Rigorous regulatory guidelines exist to ensure overall patient safety related to reporting of serious or unexpected adverse drug reactions. The Sr. CRA is responsible for training the Investigator and site staff on these strict regulations and procedures for timely reporting and as well as monitoring ongoing compliance.
- Due to the highly regulated clinical trial environment, the Sr CRA proactively identifies potential issues and develops site Corrective Actions / Preventive Actions (CAPAs) Plans.
- Required to be a key contributor in the preparation, conduct and follow up of Site Audits and Regulatory Inspections to ensure a successful outcome.

- Conduct co-monitoring visits as defined in the Study Oversight Plan to mitigate risks and ensure the quality and reliability of study data and processes.
- Act as mentor and role model for new or less experienced CRAs on process, study, technical or behavioral competencies.

Country Lead Monitors (CLM) is accountable and responsible for:

- To ensure consistency, quality and efficiency across the Country CRA Study Team, a CLM is assigned for every participating country and is responsible for and oversees the CRAs and study progress at the country level from study feasibility to study archive.
- Managing the cross-functional Country Feasibility team and process, involving the local Monitoring and Site Management and local Medical organizations.
- Leading cross-functional Site Selection Team to identify and determine interest and suitability of investigator's for participation in the assigned study.
- Developing Core Country Study Documents to initiate the study and ensures all study sites are initiated according to planned study timelines.
- Developing the Country Enrollment and Retention Plan
- Managing and tracking the Study Country Level Budget .The CLM manages country budget and payments in appropriate tools.
- Ensuring all country CRAs are trained sufficiently for the trial. .
- Overseeing Country Study Oversight Plan to ensure quality and compliance which may include co-monitoring visits and coordinating Data Verification Initiatives.
- Proactively indentifying potential or actual country related issues. Responsible for Country Level Corrective Action / Preventive Action Plans (CAPAs)
- Creating Country Monthly report and proactively notifying SLM and LHMSM of any potential issues with proposed solutions to ensure country participation remains consistent with country commitments.
- For outsourced studies: the CLM is the primary contact with the country CRO team and will support the CRO with regulatory and ethics submissions. The CLM will keep the Country Medical Director and local MSM teams informed of the status of the study. In addition, the CLM may conduct co-monitoring visits with the CRO as detailed in the Study Oversight Plan

**WHO YOU ARE**

- Bachelor's Degree (or equivalent) with 5 years of relevant healthcare experience including 4 years of monitoring & site management experience required.
- Responsible for site management and monitoring of applicable Phase I and all Phase II-IV complex and global clinical trials. This requires an in-depth knowledge of the drug development process including monitoring and site management, local and international regulations, ICH – GCP, drug safety requirements, data management processes and investigator grant parameters.
- The position also requires awareness and understanding of cultural differences as well as regional operational differences and budget management.
- Effective written and verbal English communication skills, strong oral presentation, interpersonal, decision-making and issue resolution skills are required.
- Effective planning and organization skills, attention to detail and excellent follow through
- Preference will be given to eligible EE/AA candidates

**CONTACT US**

| Address | Telephone | E-mail |
|---|---|---|
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