

1 Overview

The CRA is responsible for monitoring clinical studies to ensure that the rights of the study subjects are being observed and their safety is protected, to ascertain that reported study data are accurate, complete and verifiable from source documents, and to ensure that study conduct is in compliance with the protocol, cGCP, all applicable regulatory requirements and company SOPs.

2 Qualifications

Undergraduate qualifications in Pharmacy, Pharmacology, Biological/Biomedical Sciences, Nursing or a Medical discipline.

- Biotech/Biomedical
- Medical Devices
- CRO (Contract Research Organization)
- Healthcare
- Academia
- PhD in biological sciences, pharmacy, pharmacology

3 Salary Range

Permanent \$45,000 - \$90,000pa

4 Previous Positions

- Clinical Trials Assistant
- Nurse with clinical study experience
- Clinical Research Nurse
- Study Coordinator
- Trial documentation management
- Research Coordinator (Clinical Trials)
- Any role with monitoring
- Recent Medical Graduates
- PhD Graduate

6 Career Progression

- Different therapeutic areas
- Senior CRA
- Project Manager
- Clinical Research Team Leader
- Clinical Research Manager
- Clinical Operations Manager
- Medical Marketing (Phase IV)
- Trainer
- Systems Compliance

5 Industry Background

- Pharmaceutical

7 Typical Responsibilities

- Manage Phase II, III or IV trials
- Perform pre-study site visits to select qualified sites
- Collect and review regulatory documents
- Conduct study initiation visits
- Perform regular interim site visits to review data to ensure accuracy of data collected and close-out visits to terminate the study at a certain investigative site
- Perform source document verification
- Oversee drug accountability at investigative sites
- Retrieve CRF and performs query resolution in a timely manner
- Support the investigators in study logistics
- Ensure SAE reporting according to project specification
- Serve as key contact for the investigator
- Document investigator contacts in form of telephone/visit reports in a timely manner
- Documentation and follow-up of study status/site enrolment status
- Ensure sponsor and investigator obligations are being met and are in compliance with FDA/TGA/IEC regulatory requirements and ICH/GCP