Short Communication
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Clinical research associate/ clinical research or trial monitor- a career path

Keywords: anatomy, physiology, clinical research associate, liaison, accurate

Abbreviations: SOP, standard operating procedures; ICH, international conference on harmonization; GCP, good clinical practice; CTA, clinical trial administrator; TMF, trial master file; EDC, electronic data capture

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Introduction

One of the career paths for Bachelor/ Master Anatomy – Physiology is a Clinical Research Associate / Clinical Research Monitor. A Clinical Research Associate, CRA is a liaison between research sites where different research activities are supported by the sponsor of the research or Clinical Research Organization that takes contracts from different sponsors. The role of CRA is to ensure that clinical research / trials are conducted in accordance with Standard Operating Procedures (SOP) and International Conference on Harmonization (ICH) and Good Clinical Practice (GCP) guidelines. The CRA has the responsibility to verify that the rights and well being of human subjects are protected and that the reported trial data are accurate, complete and verifiable from the source documents and/ or patient charts. The CRA also has to ensure that the trial is in compliance with the most recently approved protocol.

Who can be a CRA?

a. Bachelor/ master anatomy and physiology.

b. Bachelor/ master nursing.

c. Bachelor in basic science/Biology/Biomedical related scientific degree or relevant experienced subjects who have knowledge of Medical terminology and experience in healthcare.

d. Experienced Research Coordinator who has experience in healthcare and GCP- ICH certification.[1]

Where a CRA can work?

a. Medical device industries.

b. Pharmaceutical industries.

c. Contract research organizations.

d. Universities and research institutions.

e. Regulatory affairs industries.

Skills required being CRA

a. Ability to work independently and within a team.

b. Good written and verbal communication skills.

c. Good time management with attention to timelines.

d. Self-motivated and ability to make informed decisions as per supervisor/ manager's instructions and ability to take responsibility for actions.

e. Strong observation and organizational skills with attention to details.

f. Computer skills – word-processing, excel and power point presentations.

g. Electronic Data Capture knowledge.

h. Precise delivery of work.

i. Providence of assistance as per project manager/ clinical research manager's directions.

j. Review of protocol or related documents.

k. Review of informed consent.

l. Review of worksheets.

m. Assistance of sites with IRB/IEC submission.

n. Collection of documents from these sites.

Typical workday of a CRA

The CRA will schedule and plan monitoring visits to the site based on protocol requirements. CRA has to verify source documents with Electronic Data Capture (EDC) system's data entry and ensure research data are accurate, complete and verifiable with source. CRA has to collect documents from the site and make sure that they get submitted to sponsor's Trial Master File (TMF). Usually TMF is managed by Clinical Trial Administrator (CTA). If using EDC system, then he/ she should be trained on particular EDC system that the company uses. If EDC has an issue, then the CRA will work with Data Management to resolve the issue while monitoring at the site or while working on the EDC system. A Communicative, Technical and Administrative skills are required to be a CRA.

Responsibility

a. Review and monitor clinical data for safety and efficacy purpose to protect the right, safety and welfare of the study subjects.

b. Writing reports in timely fashion and follow up with the site as per requirements.

c. Liaising with principle Investigator, Medical Affairs team/ health professionals, project managers and meeting with colleagues.

d. Take care of the site issue in timely contacting the required team member and providing required solution or documents as applicable.

Work condition

a. There are In- house and travelling/ Trial monitor, both types of work scenario available for CRA.

b. In- house CRA work from the office and review and monitor the data for accuracy purpose.

c. Travelling is the main requirement for a clinical research monitor who has to visit the research sites for monitoring activities. Percentage of required travel depends on many factors such as company policy, number of protocols CRA working on, and time line for completion of project. The CRA can also work remotely and travel to the research site for monitoring activities. Opportunity for freelance work is possible.

Types of site visits

a. SQV- Site Qualification Visit, to qualify the research site for the project

b. SIV- Site Initiation Visit is to initiate the research site after selection has been made. It is also to train the site study staff on protocol and electronic systems as per the requirements of particular project.

c. IMV- Interim Monitoring Visit is to monitor the research activities at the site. Frequency of IMV is depends on different factors such as protocol requirements, company policy, project managers requirements and if issue arises then as applicable.

d. COV- Close Out Visit required if site needs to be closed down for any reason such as if the study has been completed or if sponsor has decided to close the site for any reason such as if site is not fulfilling the requirements related with the study or any other issue and sponsor has decided to terminate the site form the study.

The CRAs are more in control of the travel they are willing to do and the pay rates are as per the projects and as per the requirements and demand of the position and the type of company they are willing to work for.

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None.

Conflicts of interest

The authors declare there is no conflict of interest.

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