CLINICAL RESEARCH PERSONNEL

1. Principal Investigator

1.1. Responsibilities of the PI

The PI is ultimately responsible for all aspects of conducting the research study, including the supervising of all staff to whom study responsibilities are delegated. While the PI may delegate responsibilities as appropriate, it is the PI who is responsible for ensuring that all research activities are carried out correctly.

The PI must be qualified by education and training in the therapeutic area in which the research is being conducted. The PI must be familiar with the protocol and investigational articles being tested and must also comply with the applicable regulatory requirements Code of Federal Regulations, FDA Good Clinical Practice (GCP) and International Conference on Harmonization (ICH GCP Guidelines), state statues, other applicable federal regulations, and institutional policies and guidelines.

PIs are responsible for the following:

Protecting the safety and welfare of research participants

Training and supervising collaborating faculty and staff

Adherence to regulatory and IRB requirements and guidance

2. Responsibilities of a Clinical Research Coordinator (CRC)

The CRC works with and under the direction of the PI. Although the PI is legally responsible for all aspects of the research study, the CRC often handles the bulk of the daily study activities and plays a key role in the study conduct and management. The CRC is frequently responsible for organizing the documentation and files pertaining to a study and for coordinating the activities of the investigators and the study participants.

The responsibilities of the CRC will vary at each site, but may include the following:

Protecting the rights and welfare of human subjects

Evaluating new protocols for feasibility

Preparing the site for study conduct

Participating in the informed consent process

Managing study conduct

3. Clinical Research Associate (CRA)

Following is outlined what you will require to succeed in a career as a CRA (clinical research associate). You will also find good information about CRA as a career, such as job

duties, job description (JD), a list of prospective employers, salary prospects and much more!

Job Description (JD) Clinical Research Associate

A CRA has an important task within the clinical trial process. He/she has the key responsibility to verify that the safety, rights and well-being of human subjects (patients) are protected and that the reported clinical trial data are accurate, verifiable from source documents and complete. Most importantly, the clinical research associate makes sure that the conduct of the trial is in compliance with the recently approved protocol or amendment(s) protocol, with good clinical practice (GCP), and with applicable regulatory authority requirement. The CRA performs clinical site (hospital) monitoring and manages/ collects clinical research documents, including clinical study protocol, ICFs (Patient Informed Consent Form), CRFs (clinical case report forms), IBs (Investigator Brochure) and clinical trial related documents.

Clinical Research Associate Job Responsibilities

CRA need to ensure safe and right conduct of clinical trials according to ICH-GCP guidelines.

- Maintain current understanding of organization's SOP (standard operating procedures) and also required sponsor SOPs if applicable.
- CRA required in providing clinical study progress reports to Clinical Trial Manager /Designee periodically.
- CRA must plan & conduct pre-study site evaluation visit with Sr. Clinical Research Associate / Clinical Trial Monitor.
- CRA must conduct clinical site feasibility and also help CTMs in study feasibility.
- CRA Prepare and maintain Clinical Study Files including Trial master files (TMF), Investigator Site File (ISF), Investigator File (IF), study essential documents and regulatory documents etc.
- CRA prepare EC (Ethical committee) document for submission and other tools, templates and documents before clinical site initiation.
- CRA also attend and assist with IM (investigator meeting) in presentations, training materials, logistic preparation, and coordination.
- CRA plan & perform SIV (site initiation visit) with Sr. Clinical Research Associate/CTM
- At the time of site initiation visit (SIV) CRA meet clinical investigators (PI) and their team to make sure that all aspects of the study are understood by the principal investigator and

his/her staff, validate the suitability of the EC / IRB & make sure that all records required for the study are complete.

- CRA is also expected to handle clinical central laboratory in regard to issues of site.
- CRA plans, conducts site monitoring visits (SMV) as per study protocol under the supervision of the CTM/Designee.
- CRA keep track of patient recruitment procedure by contacting clinical sites & verify patient screening & enrollment development.
- Assessment of subjects (patients) for study protocol compliance though SDV (source data verification).
- CRA monitor patient Informed Consent progression for clinical study.
- CRA examine on-site CRFs (Case Report Forms) aligned with source documents for data authentication.
- CRA make out the discrepancies in the case report forms against the source documents, resolve them and after that take away the CRFs.
- Periodic follow up with clinical site for resolution of DCFs or any queries.
- Adverse event/serious adverse event AE/SAE reporting and follow up with the concern departments.
- CRA make sure appropriate Investigational Product (IP) answerability at site.
- CRA plan and conduct site close out visit (SCV) and make sure that collection of all clinical study data are complete.
- CRA prepare the applicable site visit reports and follow up letter.
- Subsequent to study completion, make sure that investigational products (IP) of the study are returned to the CRO / sponsor.

Education and Training Required to Become a Clinical Research Associate (CRA)

To get an entry-level job in clinical research, you are required to be an undergraduate degree in life sciences, nursing, biotech or medical sciences and a diploma or certification in clinical research from a reputed institute. It is suggested to have a graduate degree as it can enable one to stand eligible for much more senior level positions, a higher pay grades and achieve benefits over other individuals.

It is sometimes feasible to break into this profession from the administrative side as well without having formal education and learning in the above-mentioned areas; however it demands a significant amount of administrative knowledge in clinical research, and perhaps further qualifications.

Skills Required to Become a Clinical Research Associate (CRA)

In order to turn out to be an efficient clinical research associate, you need to have a certain set of skills. Being efficient in this skill set could allow you to move into more responsibilities and better pay. These skills include:

- Understanding of the clinical research, healthcare system, healthcare regulation and procedures for regulating the growth of healthcare products.
- Should be capable to prepare a clinical development plan.
- Should be capable to make sure clinical trial data is reliable and correct and that the legal rights, sincerity and privacy of trial subjects are safeguarded.
- Require to have a complete knowing of liabilities and responsibilities of performing study with human subjects.
- Should have a knowing of the challenges and restrictions of implementing and retaining databases.

Who Employs Clinical Research Associates (CRA)?

- Clinical research associates (CRA) are generally employed by the following kinds of organizations:
- Contract Research Organization (CRO)
- Biotech companies
- Pharmaceutical companies
- Self-employment (Freelance basis)

Clinical Research Associate (CRA) Salary

The salary ranges of clinical research associates can differ based upon a variety of aspects, which include their level of education and learning, their amount of experience, the place of work, whether they have done any clinical research diploma/ training/ certification or not, the stage of funding for their project, organization HR policy and several others.

The fact is that there is no unique salary data for clinical research associates in many countries such as Canada or the United States, India. We can on the other hand, get an excellent idea of their salary level by looking at the CRA job posting posted by various organization in their website, pay scale grading organization and many reputed job portals.

Becoming Clinical Research Coordinator (CRC)

If you are curious in clinical study, working with other individuals and looking for office based work, then a **career as a clinical research coordinator** (CRC) is probably a good fit for you!

Listed below we have defined what you will need to be successful in a career, as a clinical research coordinator (CRC). We have also provided handy information for a clinical research coordinator profession, such as a job description (JD), remuneration, a list of prospective employers and much more!

Education and Professional Training in Clinical Research required to Become a Clinical Research Coordinator (CRC)-

Even though educational specifications on how to become a clinical research coordinator differs from employer to employer, aspiring clinical research coordinators generally need to have clinical research knowledge and experience, due to the medical nature of the job. Clinical Research Certification/Diploma enables clinical research coordinators to demonstrate that they have met eligibility requirements and at least have a minimal level of job-related knowledge and skills.

Having a professional training in a clinical research field, such as diploma in clinical research, master in clinical research or certificate in clinical research is an excellent way to break ice into the industry and work as a clinical research coordinator. Any life science graduate is also acceptable for entry-level jobs as a clinical research coordinator.

Who Employs Clinical Research Coordinators (CRC)?

Companies who generally hire clinical research coordinators include:

- Contract research organization (CRO)
- Hospitals
- Site Management Organization
- Pharmaceutical companies
- Federal government
- Universities

Job Description (JD) Clinical Research Coordinator (CRC)

Clinical research coordinators are accountable for assisting, coordinating, and facilitating daily clinical trial activities of clinical studies. Clinical research coordinators need to provide assistance on the administration of the trial such as financial, compliance, staff members and other relevant factors.

Average Salary of Clinical Research Coordinator

The pay scale may vary for clinical research coordinators, based on factors such as place of work, their level of education and expertise, and a lot of other aspects. According to the National Center for Biotechnical Information (NCBI), clinical research coordinators generally earn in excess of $46,000 per year in USA and Canada.

Clinical Research Coordinator Job Duties

- Coordinate and assist to Principal Investigator in providing all coordinator functions as specified by the site delegation log for the proper conduct of the clinical study. These characteristics consist but are not limited to:
- Training and explaining to patient and his/her family in regard to the treatment method and any possible side effects connected to study treatments.
- Facilitates Principal Investigator in obtaining informed consent form (ICF) and also document the informed consent process
- Make sure study protocol adherence, which includes completion of protocol specific procedures and the finalization of protocol specific documents.
- Obtain applicable health-related details from patient.
- Manage and maintain site study logs / progress reports to monitor both presently enrolled as well as expected follow-up participants.
- Enter patient data onto case report forms (CRFs) and /or into electronic database as applicable.
- Complete corrections /site queries needed at site audits / monitor visits.
- Make sure data reliability and consistency in electronic database and written records.
- Maintain screening, patient recruitment, deviation, adverse events (AE), concomitant medication and tumor measurement.

Clinical Research Coordinators Work Conditions

The usual work environment for a clinical research coordinator is in a laboratory environment. In this environment, clinical research coordinator interacts with study subjects, the principal investigator and other study staff and laboratory staff.

The work routine of a CRC depends extremely on the clinical research activities being performed. For instance, if the CRC is involved in a study pertaining to eating habits in the day time vs. the evening time, the CRC must be present at the site with the patient at corresponding times.

References:

http://ora.research.ucla.edu/OHRPP/Documents/Researchers/CRC_Study-Related_Tasks.pdf

https://irb.ucsf.edu/responsibilities-pis-and-crcs

https://job-descriptions.careerplanner.com/Clinical-Research-Coordinator.cfm