Clinical-Research Associate (CRA)

Reports to: Project Manager or Clinical-Research Site Manager

Pharmabio Développement
Comité sectoriel de main-d'œuvre des industries des produits pharmaceutiques et biotechnologiques

Main Duties

may vary from one company to another

- **Assesses site qualification potential:** reviews study requirements; conducts pre-study visits and drafts pre-study evaluation reports.
- **Participates in the implementation of clinical studies:** communicates with investigators and their staff; ensures compliance with terms and conditions; properly trains site personnel and writes initiation visit reports.
- **Supervises the conduct of clinical studies:** acts as liaison between site personnel and the sponsor; performs monitoring in the field; ensures compliance with protocols, regulatory requirements, and good clinical practices; writes follow-up visit reports.
- **Ensures the quality of the project:** verifies materials and data integrity; assists site personnel with internal audits or regulatory inspections; and perform ongoing follow-up with the in-house project team.
- **Closes clinical studies:** verifies the integrity of investigator files; ensures availability of clinical and non-clinical materials; jointly reviews with investigators the obligations inherent at the end of the study and writes closure visit reports.

Evolution of the Profession

- While company mergers may have an impact on organization, procedures and methods, the role of the Research Associate remains the same.
- The development of specialized software lightens the burden related to managing regulatory documents. Online data capture (increasingly used) accelerates data collection, processing, and validation.
- Companies are implementing new procedures pursuant to an observation (audit, inspection, etc.), as well as verification measures in order to protect themselves from legal proceedings, bias, or irregularities.

Best Practices

- Keep knowledge up to date to remain proficient.
- Attend symposiums, conferences, and continuing-education training.

Main responsibilities

Coordinate Clinical Trials

- Visits trial sites regularly.
- Acts as liaison between project managers and research-site personnel.
- Maintains the quality of the work and relationships.
- Monitors the conduct of clinical trials and compliance with established timelines.
- Ensures harmonization of in-house monitoring practices.

Ensure Quality Assurance of Projects

- Adheres to protocol regulatory requirements, good clinical practice regulations, and standard operating procedures.
- Assesses the trial site and applicable personnel on an ongoing basis.
- Ensures compliance with the patient-consent process.
- Verifies the receipt, handling, accounting, storage conditions, and availability of clinical products under investigation.
- Verifies compliance and quality of collected data.
- Ensures compliance with the procedures to apply in the event of serious adverse events.
- Drafts an appropriate intervention plan for the avoidance of redundant errors and deviations.
- Verifies investigator records and checks for consistency with the contents of sponsor files.

Qualifications

- College nursing diploma or
- Bachelor of health sciences, nursing, biomedical sciences, pharmacy, pharmacology, or a related discipline.
- Master's degree in one of the aforementioned disciplines or another postgraduate degree[1] (an asset).
- Communication skills and good interpersonal relationships.

- Ability to work independently, coupled with management and organizational skills.
- Meticulous and detail oriented.
- Bilingual.
- Proficiency in the use of the Microsoft Office Suite and specialized software for electronic databases such as CRF[2], INFORM[3], e-Clinical, TrialStat, OC-RDC, etc.
- Knowledge of the product under investigation for its mechanism of action, pharmacokinetics, and pharmacodynamics.
- Understanding of the regulatory context, good clinical practices and standard operating procedures.
- Availability to travel frequently.

Career-Path Options

Depending on experience in the fields of health-care and clinical research as well as areas of interest, CRAs can aspire to, among other positions, the following:

- Lead CRA.
- Head of Clinical Research.
- Project Manager.
- Director of Clinical Operations.

The work of a Clinical-Research Associate opens career opportunities in the pharmaceutical research-and-development sector for positions in pharmacovigilance, regulatory affairs, and marketing.

Competencies	Behavioural Indicators
Interpersonal Relationships Ability to build trust with site personnel and communicate with concerned personnel.	• Adapts behaviour to situations and individuals in personal interactions. • Is empathetic, receptive, and attentive. • Acts as liaison between the sponsor and site personnel. • Detects and decodes non-verbal cues/behaviours. • Communicates clearly and effectively (written and spoken).
Teamwork Ability to work cooperatively as part of a team.	• Actively contributes to the team. • Promotes cooperation with others. • Coordinates activities with those of other team members. • Exchanges relevant information with colleagues.
Information Analysis Ability to establish links between various elements necessary to the proper conduct of the clinical study.	• Verifies the protocol and assesses training needs of site personnel. • Reviews the process used to obtain a fully informed consent of the patient. • Ensures the investigator is aware of all his obligations. • Verifies application of regulatory requirements relative to site activities.
Problem Solving Ability to solve problems related to clinical trials.	• Identifies potential problems during the conduct of the trial. • Assists in developing an action plan specific to or in response to observations identified in inspection and audit reports. • Makes realistic and appropriate decisions. • Follows up on compliance issues until final resolution.
Responsible Management Ability to monitor clinical trials.	• Manages the various monitoring activities. • Performs verifications required for the proper conduct of the trial. • Maintains close contact with site personnel and ethics committee. • Effectively manages priorities. • Accurate assessment of unforeseen situations.
Compliance Control Ability to ensure that site personnel comply with the research protocol, regulatory requirements, good clinical-practice regulations, and standard operating procedures.	• Is very proficient with the contents of the research protocol, regulatory requirements, and good clinical-practice regulations. • Takes into consideration the standard operating procedures of the company, research site, and ethics committee. • Enforces compliance with regulations. • Judiciously detects non-compliant situations. • Proposes relevant and realistic solutions. • Maintains consistent follow-up and adherence to established timelines.

[1] For example, the *D.É.S.S. (Diplôme d'Études Supérieures Spécialisées)* in drug development, a postgraduate diploma, is a specialization and training development program that qualifies graduates to work in the biopharmaceutical, governmental, and other sectors.
[2] An acronym for electronic case report form, which serves as the patient case-record form.
[3] Depending on the therapeutic area, the product can be a drug or medical device.

Please refer to the *Clinical-Research Associate's (CRA) Analyse de profession** and *Profil de compétences** for all additional information.

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* This document has not been translated yet.

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