Clinical-Research Associate (CRA)

Reports to: Project Manager or Clinical-Research Site Manager

**Main Duties**

- **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.

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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.

Competencies

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

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

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:

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