Clinical Research Associate

National Occupational Standard Summary

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Definition of occupation| **Clinical Research Associate**

The Clinical Research Associate (CRA) (This role is also known as a Clinical Trial Monitor) works at Contract Research Organizations (CROs) or sponsor organizations (e.g., pharmaceutical and biotechnology companies) and holds either permanent, full-time, or contract positions. The CRA frequently visits study sites, which involves a significant amount of travelling. They must be able to consistently deliver accuracy in their work despite time constraints, and they must be able to work well with others while under pressure. They also leverage their scientific background to meet the study sponsor's objectives. The CRA may come from a wide variety of backgrounds. For example, some are medical professionals (e.g., foreign doctors, nurses, study coordinators) while others may have a degree in clinical research, life/health sciences, medical technology, health information management, biology, etc.

The CRA is responsible for ensuring that the rights and wellbeing of participants are protected, the integrity of the study is maintained, all study data and documentation are complete, accurate, and verified, and site staff are conducting the study per study documents, local standard operating procedures (SOPs), local/central Research Ethics Board (REB) requirements, International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines, and applicable regulatory requirements. They have the responsibility of ensuring that the sites are well prepared for audits and inspections.

In the case of deviations, the CRA works with the site to understand the root cause and implement solutions to solve the current issues or problems. They ensure processes are implemented to prevent the errors from being repeated.

During the study's start-up phase, the CRA may conduct the pre-study visits (PSVs), also known as qualification visits (QVs), as well as the site-initiation visits (SIVs). They also may create Investigator Site Files (ISFs) for the sites. Once the site has been activated (i.e., ready and approved to start enrolling participants), the CRA is responsible for conducting monitoring visits, writing visit reports, performing source data verification (SDV), training site staff, and ensuring that the sites' source documentation and essential documents are filed appropriately. The CRA ensures that the document management plan is followed and that all required study-related documentation is reviewed and uploaded to the paper/electronic Trial Master File (eTMF).

Level of education, training or designations requirements

Typical Education Required	Secondary	College	**Bachelor**	Master	PhD
Typical Starting Experience	**0-5 yrs.**	5-10 yrs.	10-15 yrs.	15-20 yrs.	20+ yrs.

- Bachelor's degree or higher in health sciences, biomedical sciences, pharmacology, nursing (may have a diploma or certification in Clinical Research)
- Master's degree or other postgraduate degree in one of the disciplines is an asset
- Proficiency in the use of Microsoft Word, Excel, and PowerPoint and data/health management software tools (e.g., Electronic Data Capture (EDC) systems, electronic patient health records, Clinical Trial Management Systems (CTMS), electronic Trial Master File (eTMF), Interactive Web Based Response System (IWRS used for participant randomization and drug assignment/distribution), electronic participant diaries, etc.)
- Experience in source data verification (SDV) and conducting monitoring site visits
- Working knowledge of ICH GCP
- Knowledge of Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)
- Knowledge of Research Ethics Board (REB) and regulatory agency requirements is an asset
- Ability to travel frequently
- Fluency in English mandatory; fluency in French is an asset

This role works in the following subsectors:

Applicable To	**Bio-Health**	Agri-Bio	Bio-Industrial	Bio-Energy

The level of complexity of the role is:

Span of Complexity Levels	Foundational	Operational	Specialist/ Management	Expert/Executive

CLINICAL RESEARCH ASSOCIATE COMPETENCY SUMMARY

Competencies	Complexity Level Required			
	1 Foundational	2 Operational	3 Specialist/ Manager	4 Expert/ Executive
Core				
Monitoring			■	
Quality Assurance		■		
Technical				
Source Data Verification			■	
Study Document Management			■	
Digital Technologies Proficiency		■		
Industry Regulatory				
Regulatory Compliance Verification			■	
Personal and Professional				
Problem Solving			■	
Teamwork/Collaboration		■		
Communication			■	
Attention to Detail			■	
Organization			■	

Core competencies

Monitoring

Follows the risk-based monitoring plan and applicable study requirements and standards in order to carry out all required monitoring-related responsibilities to protect participants' safety and well-being and maintain the integrity of clinical trial data.

Quality Assurance

Through clinical monitoring, ensures that site teams are using verifiable processes and conducting all study-related activities in compliance with the study requirements, local SOPs, ICH GCP, local/central REB requirements, and applicable regulatory requirements, effectively ensuring the integrity of the clinical trial data. Monitors site teams to ensure they are using verifiable processes and conducting all study-related activities in compliance with the study requirements and applicable regulatory standards in order to guarantee integrity of the clinical trial data and the overall quality of the study.

Technical competencies

Source Data Verification

Critically reviews the original source documentation and compares it to what has been entered into data collection tools in a risk-based manner according to the risk-based monitoring plan in order to ensure that the clinical data is complete, accurate, and verifiable as per the study requirements.

Study Document Management

Monitors that the sites follow document control procedures in order to ensure that the trial processes are verifiable and that the integrity of the trial processes and results are maintained.

Digital Technologies Proficiency

Proficiently uses and trains site staff in the digital technologies and software applications used for clinical trials.

Industry regulatory competencies

Regulatory Compliance Verification

Uses best practices in clinical monitoring in order to verify and ensure that site teams are conducting clinical trials according to all applicable ethics and regulatory requirements.

Personal and professional competencies

Problem Solving

Works effectively with others to foster trust and cooperation in the achievement of research and development (R&D) goals and project objectives.

Teamwork/Collaboration

Applies sound teamwork processes to foster cooperation and collaboration across diverse stakeholder groups, enabling effective and efficient project execution and fostering a shared approach to project success.

Communication

Employs fundamental methods to communicate effectively in writing and verbally within the trial and site teams to ensure understanding and enhance team and personal performance.

Attention to Detail

Applies mental focus to their duties to ensure that work is accurate and error free and consistently pays attention to detail to ensure consistency of work and results in order to improve decision-making and achieve results or accomplish tasks/objectives.

Organization

Applies organizational skills to plan, prioritize, track, and complete required tasks within time restraints.

USE NATIONAL OCCUPATIONAL STANDARDS TO:

- ✓ Build a job description
- ✓ Plan professional development
- ✓ Map career progression and succession planning
- ✓ Benchmark compensation

View the full National Occupational Standards at biotalent.ca/NOS

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