Clinical Research Coordinator

National Occupational Standard Summary

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Igniting the bio-economy's brainpower

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BioTalent Canada supports the people behind life-changing science. Trusted as the go-to source for labour market intelligence, BioTalent Canada guides bio-economy stakeholders with evidence-based data and industry-driven standards. BioTalent Canada is focused on igniting the industry's brainpower bridging the gap between job-ready talent and employers and ensuring the long-term agility, resiliency, and sustainability of one of Canada's most vital sectors.

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Definition of occupation| **Clinical Research Coordinator**

The Clinical Research Coordinator (CRC) works at a clinical trial site as a member of a multi-disciplinary team that conducts clinical trials (studies). They execute the day-to-day activities in accordance with the study protocol developed by the trial sponsor and any applicable regulatory and ethical requirements, in order to ensure that all required data is collected and stored in a safe and secure manner, and that all required documentation and records are complete, accurate, and properly stored to ensure confidentiality.

CRCs recruit and enroll subjects for clinical trials. This involves ensuring that the subjects meet the eligibility requirements for the trial, as well as ensuring that that informed consent requirements are met. Informed consent involves a document (informed consent form) and a process for ensuring that the subject is fully informed as to the research nature of the study, its purpose and goals, how it will be conducted, any potential risks and/or side effects to the participant, what their rights and obligations are in relation to the trial, the process for withdrawing from the trial, the number of other subjects who are to be enrolled, and any other information required for the individual to make an educated decision to participate. This will also involve answering questions posed by the potential subject to ensure they fully understand before agreeing to participate. Once the trial is underway, the CRC is the main point of contact and liaison between research subjects and the trial site and ensures that the subjects adhere to the protocol throughout the trial.

During the trial, the CRC collaborates closely with both medical and administrative/scientific staff at the trial site, including the Principal Investigator, site manager(s), and other coordinators, as well as medical, pharmacy, and diagnostic departments and associated staff, in order to ensure that all stages of the trial, from initiation to completion and close-out, run smoothly and in accordance with the trial protocol as well as all legal, ethical, and regulatory requirements. They participate in pre-trial feasibility surveys and serve as a point of contact with/between PI/CRO/Sponsor, as well as monitoring visits by CROs/Sponsors (during the trial), ensuring that all required documentation is complete and available to meet the requirements of the monitoring team.

They also are involved in coordinating site activities with respect to regulatory inspections and audits during the trial.
In the case of academic institutions and investigator-initiated trials, CRCs may also be involved in assisting in/providing input to the preparation of grant applications related to clinical trials, and in the planning and budgeting of trials that may be conducted at their site.

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 of Arts/Bachelor of Science, BSN (Life Science preferred), licensed nurse/LPN, or a diploma in Clinical Research and/or a designation in clinical research from a professional body (SOCRA, ACRP, etc.)
- Minimum two to three years of relevant experience in a clinical research environment
- ICH GCP and Health Canada Division 5 training (certification desirable)
- International Air Transport Association (IATA) training for transportation of dangerous goods (TDG) may be desirable at certain sites or types of trials
- Proficiency in office/management functions (administration, finance, document control) in a health care administration setting is desirable
- Phlebotomy, ECG, and basic biological sample handling training may be desirable for certain sites or types of trial
- Fluency in English (bilingual in Quebec)
- Fluency in other languages 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 COORDINATOR COMPETENCY SUMMARY

Competencies	Complexity Level Required			
	1 Foundational	2 Operational	3 Specialist/ Manager	4 Expert/ Executive
Core				
Patient Recruiting and Enrollment		■		
Data Collection and Recording		■		
Document Management and Control		■		
Technical				
Clinical Trial Inventory Management		■		
Clinical Trial Monitoring Support		■		
Supervision		■		
Contracts, Budgets and Payments		■		
Industry Regulatory Competencies				
Regulatory Compliance		■		
Ethical Compliance		■		

Competencies	Complexity Level Required			
	1 Foundational	2 Operational	3 Specialist/ Manager	4 Expert/ Executive
Personal and Professional				
Equity, Diversity and Inclusion				
Written Communication				
Verbal Communication				
Attention to Detail				
Problem Solving				
Teamwork/Collaboration				

Core competencies

Patient Recruiting and Enrollment

Applies relevant national and international principles of human subject protections and privacy in order to recruit, enrol, and conduct informed consent for subjects for clinical trials. Understands and fully articulates the ethical issues involved when dealing with vulnerable populations to assure human subject protection.

Data Collection and Recording

Applies recognized ALCOA+ (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available) data principles and concepts to collect, capture, enter, access, maintain, and manage the required data in order to guarantee the flow of information during the clinical trial and ensure integrated and sufficient clinical trial procedures. Acts as Functional Lead for Data Management, including acting as the primary contact for anything related to data management activities.

Document Management and Control

Applies knowledge of documentation requirements and clinical trial procedures to ensure all study-related documentation is properly collected, filled out, filed, and maintained, in order to meet the study protocol, applicable regulatory requirements, local SOPs and local REBs, and ICH GCP guidelines.

Technical competencies

Clinical Trial Inventory Management

Applies knowledge of study protocols, clinical trial procedures, IATA TDG regulations, and local SOPs in order to receive, inventory, store, dispense, and return/destroy investigational products (if applicable), patient samples, and other study-related materials required for the study.

Clinical Trial Monitoring Support

Applies knowledge of clinical trial procedures and documentation requirements to assist inspectors/monitors during monitoring visits in order to ensure that all required documentation is provided.

Supervision

Applies effective leadership and people management skills to direct and motivate the trial team and to ensure that the trial is conducted efficiently, effectively, and in accordance with all applicable guidelines, regulations, SOPs, and ethical requirements.

Contracts, Budgets and Payments

Applies knowledge of contracts, budgets, and general financial processes to collaborate with finance/budgeting personnel in order to develop, control, update, and close-out project budgets, as well as submit required expense documentation for invoicing and claims under the contract.

Industry regulatory competencies

Regulatory Compliance

Assists the clinical teams in the preparation, handling, distribution, filing, and archiving of clinical data and processes/procedures to ensure an accurate clinical trial that is aligned with national and international regulations, ICH GCP, and relevant SOPs.

Ethical Compliance

Applies standards and knowledge of ethical requirements to ensure their work is compliant with established standards, protocols, laws, and regulations and adheres to the principles of beneficence and nonmaleficence. Conducts their assigned tasks in accordance with all site standards, SOPs, and applicable regulatory requirements.

Personal and professional competencies

Equity, Diversity and Inclusion

Applies knowledge of cultural, ethnic, and other equity populations to ensure their interactions reflect and generate a climate of awareness, respect, and inclusiveness.

Written Communication

Applies effective writing skills to present complex technical subject matter in a clear and accurate manner that ensures understanding and facilitates project success.

Verbal Communication

Applies effective verbal communication processes to present complex information in a clear and compelling manner that ensures understanding.

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.

Problem Solving

Applies knowledge of requirements and uses effective problem-solving techniques to identify and quantify issues, understand root cause(s), develop and analyze possible solutions, and select the most appropriate solution in order to resolve problems efficiently and effectively.

Teamwork/Collaboration

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

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

Funded by the Government of Canada's Sectoral Initiatives Program. Canada

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