

Clinical Research Associate

Bio-economy Skills Profile

BioTalent™ Canada

Building skills for Canada's bio-economy

About BioTalent Canada

Helping Canada's Bio-economy thrive globally

Canada is a world leader in biotechnology—the application of living organisms to industrial, agricultural, medical and other processes and products. To maintain and build on this leadership, the sector needs highly trained, job-ready people.

By acting as a national hub and central resource for employers, job-seekers, students, educators and government agencies, BioTalent Canada helps make this happen.

BioTalent™ Canada

Building skills for Canada's bio-economy

Canada This project is funded by the Government of Canada's Foreign Credential Recognition Program

www.biotalent.ca • Telephone: 613-235-1402

Table of Contents

About the BioTalent Canada bio-economy skills profiles

Biotechnology's fusion of science and business creates unique requirements for occupations in the sector. Executives and managers must have technical expertise; technical staff often need entrepreneurial skill sets. Occupational descriptions from other sources don't always fit the bio-economy context. That's why, in partnership with industry stakeholders, BioTalent Canada has developed skills profiles specific to the bio-economy including this description of the role of a clinical research associate.

Occupational Definition

A clinical research associate ensures clinical research trials that test new pharmaceuticals on humans are conducted in compliance with government regulations and ethical standards. The clinical research associate works for the study sponsor and establishes effective working relationships with investigative site staff. They frequently visit study sites, which may involve travelling. They leverage their science background to meet the study sponsor's objectives. Key skills include: multi-tasking; paying attention to detail; working with multiple stakeholders; and demonstrating diplomacy and autonomy.

Clinical research associates work for Canadian biotechnology companies of different sizes (i.e., small, medium, large) and in various biotechnology areas, such as:

- Human and Animal Health
- Life Sciences
- Medical Devices
- Nutraceuticals
- Pharmaceuticals

Components of the skills profile

Every BioTalent Canada skills profile presents the areas of competence, tasks and sub-tasks associated with a specific occupation.

Area of competence (AC): This describes a major function or responsibility associated with the profession, trade or position.

Task: This is a specific, observable unit of work with definite start and end points. Tasks can be broken down into two or more steps and are generally performed in a limited period of time. Tasks and ACs are identified in behavioural terms, beginning with a verb that describes the applied behaviour.

Subtask: This is a distinct, observable activity that comprises the steps involved in a task.

Important Action/Performance Standard: This provides a criterion for assessing competence and may be used as a performance indicator.

Focus on competencies

The BioTalent Canada skills profiles are built around areas of competence because competencies are flexible, inclusive and linked directly to performance: they are the traits or qualities a professional must have to succeed in a given role within a given organization, and can be used for recruiting, professional development, curriculum planning and many other purposes.

How to use the profiles

The complete contents of this or any BioTalent Canada skills profile are unlikely to be used for any one position. Because they are comprehensive, they include every area of competence, task and subtask that could be required for a specific occupation. In reality, the definition of a given job will encompass a narrower subset of the profile. Hiring organizations must choose the elements of the profiles that are relevant to their businesses—and tailor those elements as necessary to more precisely describe their particular job requirements.

The profiles can be put to many uses:

- **Employers** can use them to develop job descriptions, performance evaluations, professional development, succession planning, team building, target skills needed, and recruitment plans.
- **Job seekers** can use them to tailor their resumes, prepare for interviews, see job descriptions and identify additional professional development needs.

- **Educators** can build industry-oriented curricula from the profiles to produce job-ready graduates.

- **Students** can enhance their understanding of employers' expectations and choose the right educational programs to equip themselves with the skills for success.

Scenario

The following illustrates how an employer might use the BioTalent Canada skills profiles to identify professional development priorities for his or her team.

Step 1

The employer would review the ACs for each occupation and identify which apply to the related positions within his or her company, omitting those that are not relevant.

Step 2

Under the selected ACs, the employer then notes which of the associated tasks, subtasks and important actions are relevant to that specific position within his or her business.

Step 3

Now with a complete, tailored profile, the employer can assess employee performance. Needs areas are easily identified and defined—to a significant depth of detail.

Step 4

Based on the needs analysis, the employer can either develop or seek out professional development programs that address employee needs areas.

Situational Analysis

Clinical research associates (CRA) work closely with researchers to develop and conduct clinical trials in support of the development of pharmaceuticals and other biotechnology products for use in or by humans. A CRA is a trained professional who ensures that trial sites conduct clinical research trials in compliance with government regulations, ethical standards and the clinical trial protocol approved for the study. They act as a liaison between the organization responsible for conducting the trial and the site staff who conduct the trial. A CRA may be responsible for a single trial site or multiple trial sites within a single clinical trial, or may be working on several different clinical trials each with their own trial site or sites. CRAs are most often employed by pharmaceutical companies, biotechnology firms, medical device manufacturers, medical research universities, government agencies, and contract research organizations.

CRAs typically hold a Bachelor or Master's degree in life sciences, the health field, or RN degree and often possess experience in medical research, pharmaceutical research, or nursing. They come from a wide variety of backgrounds: some are medical professionals – doctors and registered nurses, while others may have a degree in medical technology, business administration, health information management, statistics, biology, teaching, or other areas. They also need a good understanding and knowledge of how to implement and monitor Good Clinical Practices in a trial project. Voluntary certification enhances employability.

CRAs have well developed interpersonal and communication skills (both written and verbal) enabling them to maintain effective working relationships with investigators, site staff, clinicians, scientists, data management staff and other study stakeholders. When faced with challenging circumstances and unforeseen occurrences CRAs apply problem solving skills to identify solutions/new approaches to overcome potential set-backs. They often use their skills in negotiation and diplomacy to solicit site staff support and co-operation to address time sensitive activities and meet deadlines.

Essential Skills

The most important Essential Skill(s) for this Profile: ✓					
	Reading Text		Thinking Skills – Problem Solving	✓	Working With Others
✓	Document Use		Thinking Skills – Decision Making		Computer Use
	Writing		Thinking Skills – Critical Thinking		Continuous Learning
	Numeracy	✓	Thinking Skills – Job Task Planning & Organizing		
	Oral Communication		Thinking Skills – Significant Use of Memory		
			Thinking Skills – Finding Information		

Clinical research associates must be able to read and understand large amounts of documentation on regulations and protocols pertaining to the clinical trials they are helping to manage. They need to be detailed thinkers ensuring that often complex instructions are carried out correctly and in a timely manner. They also need strong communication and team building skills in order to ensure that the different subgroups for a set of trials work effectively together.

Language Benchmarks

The majority of communications tasks associated with the required competencies and activities of a competent clinical research associate were found to be between Canadian Language Benchmark levels 8 – 10. This finding is based on a limited sampling of representatives in industry. The actual language benchmark requirements for this occupation within an organization will be subject to the organization's requirements, and the definition of the occupational role within the organization.

Competency Profile

A Clinical Research Associate must be able to:

A. Plan for trial

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Organize and review trial documents	1.1. Contribute to the design of the information and data collection forms to be used in the trial e.g. Informed Consent Forms (ICFs), Case Record Forms (CRF).	
	1.2. Collect and organize the regulatory documents to submit to the Trial Manager for review and approval.	

A Clinical Research Associate must be able to:

B. Prepare for trial launch

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Recommend trial sites	1.1. Use the identified criteria for potential site and investigator suitability assessments.	
	1.2. Locate and assess the suitability of potential trial facilities.	
	1.3. Review and assess the suitability of potential investigators.	
	1.4. Make appropriate investigator and site selection recommendations, in keeping with trial scope and design and obtain approval.	
2. Assess and qualify trial facility and staffing	2.1. Visit the trial site(s).	
	2.2. Meet with site staff.	
	2.3. Review site requirements to run the trial in accordance with trial protocols - equipment, computers, software, clinical supplies.	
	2.4. Review site staff organization and qualifications.	
	2.5. Identify gaps in site requirements, staffing and staff qualifications.	
	2.6. Develop plan to address gaps.	
	2.7. Obtain approval for the planned corrective actions.	
	2.8. Meet with investigator to review findings and explore proposed adjustments.	
	2.9. Achieve consensus on implementing changes needed to address identified gaps.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
3. Prepare sites for trial launch	3.1. Confirm that required changes have been put into place at the trial site.	
	3.2. Distribute trial materials to the trial sites (brochures, documentation, etc).	
	3.3. Confirm that all the resources, all standard checks, and relevant documents are in place at the trial site.	
	3.4. Work with site investigator to address any identified shortfalls.	
4. Conduct Site Initiation Visit (SIV)	4.1. Educate site investigative personnel on trial study conduct, use of trial related tools, and general adherence to Good Clinical Practice and trial protocols.	
	4.2. Educate site administrative personnel on trial study administrative requirements, processes and procedures, use of trial related tools, and general adherence to Good Clinical Practice and trial protocols.	
	4.3. Reinforce application of learned material in site visits or teleconferences.	

A Clinical Research Associate must be able to:

C. Monitor the trial

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Track recruitment of trial participants	1.1. Review and track recruitment levels at the trial sites and update the sponsor study team.	
	1.2. Review characteristics of subjects.	
	1.3. Identify those recruits who are borderline/not well qualified to participate.	
	1.4. Discuss review findings with the site investigator and sponsor study team.	
	1.5. Respect confidentiality in accordance with requirements for confidential/sensitive information.	
2. Monitor the trial progress	2.1. Contribute to and implement the monitoring plan for the trial.	
	2.2. Visit the different trial sites	
	2.3. Ascertain that clinical trials are proceeding according to protocol requirements: trial protocols and procedures, regulatory requirements and Good Clinical Practice.	
	2.4. Ascertain timely and quality clinical trial activities at each assigned investigative site, according to pre-set Key Performance Indicators (KPIs).	
	2.5. Review findings with site investigator and collaborate to address any identified non-conformances.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.6. Identify non-conformances on overall trial objectives and integrity.	
	2.7. Prepare Monitoring Visit Report (MVR) which includes study status, actions taken by the CRA at the site, identification of key issues that need to be addressed by the sponsor study team.	
	2.8. Work with the site to implement recommendations from the sponsor study team of required changes.	
	2.9. Report any transgressions that put patient health/safety at risk to the appropriate internal authorities for appropriate action.	
	2.10. Verifies and reconciles product material inventory levels (e.g. drug accountability).	
	2.11 Organizes/attends investigator meetings.	
3. Verify integrity of trial site data/information	3.1. Confirm each Case Record Form (CRF) represents a patient registered for the trial.	
	3.2. Review Case Record Form (CRF) data to Patient clinical chart (Source Data/Document Verification (SDV)).	
	3.3. Ensure accurate completion of Case Record Forms (CRFs).	
	3.4. Identify and question inaccuracies.	
	3.5. Discuss review results with clinical trial staff and investigators.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.6. Recommend and follow-up on corrective actions to address identified shortcomings in trial site documentation/data.	
	3.7. Maintain a log of noted inaccuracies and responses.	
	3.8. Communicate findings/trends to Trial Manager.	

A Clinical Research Associate must be able to:

D. Coordinate site closure

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Retrieve unused trial product	1.1. Make arrangements with site staff for return of all unused trial product.	
	1.2. Review site inventory/purchase records to ensure all unused product has been returned.	
	1.3. Investigate and report discrepancies.	
2. Retrieve trial equipment owned by the organization	2.1. Make arrangements with site staff for return of trial equipment.	
	2.2. Identify discrepancies.	
3. Collect site study documentation and correspondence, according to the established standard operating procedure (SOP)	3.1. Make arrangements with site staff for return of trial documents.	
	3.2. Recommend that files/documents are appropriately stored in accordance with corporate guidelines/legal requirements for sensitive/confidential information.	
	3.3. Update document log (if applicable).	

A Clinical Research Associate must be able to:

E. Manage trial activities

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Apply project management best practices at the site(s) they're responsible for	1.1. Contribute to the development of the trial project plan.	
	1.2. Monitor progress to plan and achievement of project milestones.	
	1.3. Monitor and mitigate identified risks to ensure the resolution of issues.	
	1.4. Identify and report emerging issues and concerns.	
2. Evaluate performance to trial plan and protocol for the site(s) they're responsible for	2.1. Evaluate progress and performance to established performance indicators.	
	2.2. Identify gaps to sponsor study team and ensure the appropriate corrective actions are taken in collaboration with study site team.	
	2.3. Communicate performance and results to the Trial Manager and management team.	
	2.4. Obtain approval(s) for proposed corrective actions (if needed) or research plan updates.	
	2.5. Communicate updates to plan(s) and expected outcome of any planned corrective actions.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
3. Manage sensitive/confidential information	3.1. Handle confidential information in observance of applicable laws and company policies/procedures (e.g. the *Personal Information Protection and Electronic Documents* Act (PIPEDA).	
4. Establish effective working relationships	4.1. Liaise with doctors/consultants (or investigators)/investigative staff on the conduct of the trial.	
	4.2. Ensure awareness of differences, treat everyone equitably and accommodate special needs.	
	4.3. Recognize the skills and abilities of others.	
	4.4. Use various approaches in response to different individual styles.	
	4.5. Develop an appreciation of the group dynamics at each site.	
	4.6. Promote transparency through communication of ongoing activities with investigative personnel.	
5. Evaluate Investigator performance	5.1. Solicit Investigator perspective on performance relative to agreed upon actions and objectives.	
	5.2. Discuss performance assessment with the Investigator.	
	5.3. Discuss and explore points of difference, and achieve consensus on actions and objectives moving forward and take note of results of discussion.	
	5.4. Advise the Trial Manager of outcome of investigator assessment discussions.	

A Clinical Research Associate must be able to:

F. Address administrative support responsibilities

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Participate in the administering of trial budgets	1.1. Reconcile supplier invoices for payment.	
	1.2. Review and approve investigator/site reimbursement claims for payment, according to agreed milestones.	
	1.3. Monitor expenditures to approved budget, as required.	
2. Prepare and submit required reports	2.1. Write reports according to developed templates, as required.	
	2.2. Distribute reports to appropriate parties.	
	2.3. Keep records or copies of reports.	
3. Monitor trial materials/supplies	3.1. Monitor inventory to project needs and to manage stock.	
4. Make travel plans & arrangements	4.1. Schedule trial site visits.	
	4.2. Determine travel and accommodation needs.	
	4.3. Book travel and accommodations in keeping with company policies.	
	4.4. Submit site visit travel and accommodation expenses once the site visit has been conducted.	

A Clinical Research Associate must be able to:

G. Apply professional practices

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Comply with established policies, procedures and protocols	1.1. Practice and adhere to legislative/regulatory requirements (e.g. International Conference on Harmonization (ICH), Good Clinical Practice (GCP)).	Health Canada, International Conference on Harmonization,
	1.2. Follow established corporate protocols and procedural documentation (e.g., policies, standard operating procedures (SOPs)).	
	1.3. Know the investigative site(s) standard operating procedures (SOPs).	
2. Comply with all applicable regulations, legislation and Good Clinical Practices (GCPs)	2.1. Know and understand applicable rules, regulations and legislation.	
	2.2. Review relevant literature.	
	2.3. Comply with all training requirements.	
	2.4. Work within regulatory framework.	
	2.5. Identify situations that do not align with the regulatory framework.	
	2.6. Recommend corrective action(s) and follow up as required.	
3. Demonstrate scientific experience	3.1. Apply knowledge of the clinical research settings and clinical trial monitoring, as required.	
	3.2. Apply scientific principles and concepts.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.3. Exploit knowledge of regulatory requirements where appropriate (Therapeutic Products Directorate (TPD), Food and Drug Act (FDA), International Conference on Harmonization (ICH) etc.).	
4. Maintain a high level of professional integrity	4.1. Ensure adherence to the requirements of the trial protocol.	
	4.2. Act legally; follow rules and regulations administered by regulatory bodies, such as Health Canada, the Food and Drug Administration, Agriculture and Agri-Food Canada.	
	4.3. Maintain confidentiality (e.g., data, records, intellectual property, client information).	

A Clinical Research Associate must be able to:

H. Demonstrate personal competencies

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Apply critical thinking/problem-solving skills	1.1. Identify and prioritize problems with protocol implementation.	
	1.2. Apply logical and methodical approach to identify and assess the cause(s) of the problem.	
	1.3. Apply knowledge, training and creativity to determine the appropriate course of action.	
	1.4. Oversee implementation of the selected course of action.	
	1.5. Evaluate and report on the effectiveness of the selected course of action.	
2. Organize work	2.1. Plan ahead and work autonomously.	
	2.2. Establish processes/systems/methodologies to enhance effectiveness.	
	2.3. Recognize where templates and standard forms would facilitate productivity and accuracy in data and information collection and management.	
	2.4. Follow Standard Operating Procedures (SOPs), templates, forms, guidance documents, as required.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.5. Demonstrate proficient computer capabilities and abilities with standard business suite products e.g. Microsoft Office and proprietary enterprise solutions e.g. e-Clinical.	
3. Demonstrate attention to detail	3.1. Address follow-ups/issues in a timely manner (e.g. data management query resolution).	
	3.2. Ensure deadlines are met.	
	3.3. Implement document control strategy supported by procedures and appropriate storage/retrieval/security system(s).	
4. Negotiate fairly	4.1. Define the best approach to promote a position.	
	4.2. Articulate the position with clarity.	
	4.3. Understand the positions of the other parties.	
	4.4. Develop a structured analytical approach to identified issues to reach consensus.	
	4.5. Achieve an outcome that is mutually accepted by all parties.	
5. Communicate well and clearly	5.1. Act as the sponsor's ambassador to clinical research site.	
	5.2. Demonstrate an ability to clearly articulate complex issues orally and in writing.	
	5.3. Explain point of view clearly and concisely.	
	5.4. Deliver and adapt message for appropriate audiences.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	5.5. Simplify and explain terms when speaking with parties who may not be familiar with the terminology.	
	5.6. Prepare briefing notes for general presentations and demonstrate group presentation skills.	
	5.7. Ensure ongoing communication between the sponsor and site.	
6. Embrace continuous learning and development	6.1. Allocate time for continuous learning.	
	6.2. Identify opportunities for continuous learning.	
	6.3. Build on 'lessons learned' from past experience.	
	6.4. Keep abreast of relevant science and technology.	
	6.5. Nurture the ability and enthusiasm to learn new skills and techniques.	

Strong Board of Directors

The Board of Directors is composed of experts in the field of HR, CEOs, CFOs and CSOs from across Canada with extensive financial and industry experience representing companies and organizations in Canada's bio-economy. BioTalent Canada is not a membership organization and therefore relies on the guidance provided by its dedicated volunteer Board of Directors.

François Schubert (Chair)
General Manager, Administration
The Research Institute-McGill University Health Centre
Montréal, QC

Janet LeClair (Vice Chair)
Toronto, ON

Paul Braconnier (Treasurer)
President, CEO & Co-founder
Global IQ Inc.
Edmonton, AB

Bob Ingratta (Past Chair)
President
Fast-Trak Strategies
Vancouver, BC

Norma K. Biln
Chief Executive Officer
Augurex Life Sciences Corp.
North Vancouver, BC

Anne-Marie Bonneau
Vice-President & COO
AnexChem Inc.
Montréal, QC

Michael D'Amico
Ottawa, ON

Patrick Girouard
President
AgroNovita Inc.
Ottawa, ON

Denis Kay
Chief Scientific Officer
Neurodyn Inc.
Charlottetown, PE

Steven Klein
Director, Business Development
IRICoR
Montréal, QC

George Michaliszyn
President
Geneva BioSciences
Ottawa, ON

Lucie Morin
Human Resources Senior Advisor
ProMetic Life Sciences Inc.
Mont-Royal, QC

Julia O'Rawe
Head of HR Canada
sanofi aventis and sanofi pasteur
Toronto, ON

Jim Smith
Executive Director
Food Technology Centre
Charlottetown, PE

Lee D. Wilson
Assistant Professor
Department of Chemistry
University of Saskatchewan
Saskatoon, SK

Secretary:
Rob Henderson
Executive Director
BioTalent Canada
Ottawa, ON

Building skills for Canada's bio-economy

www.biotalent.ca • Telephone: 613-235-1402