



Clinical Research Associate

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.

Learn more about the role of a Clinical Research Associate by downloading the full skills profile for free at www.biotalent.ca/profiles.



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BioTalent Canada's Bio-economy Skills Profiles

Biotechnology's fusion of science and business creates unique requirements for jobs in the sector. Candidates often need skills suited both to the lab and the boardroom. As a result, occupational descriptions from other sources or sectors don't always fit the bio-economy exactly. That's why, in partnership with industry stakeholders, BioTalent Canada has developed skills profiles specific to the bio-economy—a project that will continue with the ongoing addition of other functions over time.

Each profile includes a definition of the occupation, a list of competencies and associated tasks, a summary situational analysis, language benchmarks, and essential skills.

Who can use these profiles?

Easy to use and interpret, our *Bio-economy Skills Profiles* were created to meet the needs of a wide range of audiences.

Here's how you might use them if you're an:

Employer: Develop job descriptions, performance evaluation criteria, professional development programs, succession plans, team building initiatives and recruitment plans.

Job seeker: Identify your professional development needs, tailor your resume for a specific position, prepare for interviews and interpret job descriptions.

Educator: Build industry-oriented curricula to help produce job-ready graduates.

Student: Grow your understanding of employers' expectations and choose the right educational programs to equip yourself with the skills for success.

Validated by industry

BioTalent Canada created its *Bio-economy Skills Profiles* in consultation with industry to accurately capture the needs of biotechnology companies and produce truly practical, relevant resources. These profiles summarize the high-level skills required for each occupational profile and itemize in detail the common

tasks associated with each function. Because the profiles are comprehensive, not every skill may be required for a single position: instead, the profiles present the full sets of skills that could be expected of a person in a given role within companies at various stages of development.

Information you can trust

BioTalent Canada is the country's source for reliable, objective and accurate information on skills development and human resources in the bio-economy. Our aim as Canada's biotechnology sector council is to deliver the human resources tools, information and skills development resources industry needs to ensure an adequate supply of job-ready people.

Understanding the bio-economy

Canada's bio-economy is engaged in the research, development, commercialization and manufacturing of biotechnology products. The bio-economy is constantly expanding as new technologies and techniques are applied to an ever-broader range of industries and sectors including:

Agriculture	Genomics
Aquaculture	Human and Animal Health
Bioenergy	Industrial
Bioinformatics	Life Sciences
Bioproducts	Medical Devices



Biosciences	Nanotechnology
Environment	Natural Resources
Food Processing	Nutraceuticals
Forestry	Pharmaceuticals

Bio-economy Competency Profile Checklist

Clinical Research Associates combine an education in science with business and administrative skills and project management expertise. They have knowledge of clinical research trial protocols and ethical standards, and hold a bachelor or master's degree in a scientific or medical field.

Building on these, a **Clinical Research Associate** must be able to:

A. Plan for trial

- 1. Organize and review trial documents

B. Prepare for trial launch

- 1. Recommend trial sites
- 2. Assess and qualify trial facility and staffing
- 3. Prepare sites for trial launch
- 4. Conduct Site Initiation Visit (SIV)

C. Monitor the trial

- 1. Track recruitment of trial participants
- 2. Monitor the trial progress
- 3. Verify integrity of trial site data/information

D. Coordinate site closure

- 1. Retrieve unused trial product
- 2. Retrieve trial equipment owned by the organization
- 3. Collect site study documentation and correspondence, according to the established standard operating procedure (SOP)



E. Manage trial activities

- 1. Apply project management best practices at the site(s) they're responsible for
- 2. Evaluate performance to trial plan and protocol for the site(s) they're responsible for
- 3. Manage sensitive/confidential information
- 4. Establish effective working relationships
- 5. Evaluate Investigator performance

F. Address administrative support responsibilities

- 1. Participate in the administering of trial budgets
- 2. Prepare and submit required reports
- 3. Monitor trial materials/supplies
- 4. Make travel plans & arrangements

G. Apply professional practices

- 1. Comply with established policies, procedures and protocols
- 2. Comply with all applicable regulations, legislation and Good Clinical Practices (GCPs)
- 3. Demonstrate scientific experience
- 4. Maintain a high level of professional integrity

H. Demonstrate personal competencies

- 1. Apply critical thinking/problem-solving skills
- 2. Organize work
- 3. Demonstrate attention to detail
- 4. Negotiate fairly
- 5. Communicate well and clearly
- 6. Embrace continuous learning and development



Get started today

Even before you download the full **Clinical Research Associate Skills Profile**, get a sense of the information it contains and how you might use it in your work. Attached here is a quick-reference checklist that summarizes the core skills required for the position and the common tasks associated.

Go to www.biotalent.ca/profiles and download the complete Clinical Research Associate Skills Profile.

