Clinical Research Data Manager

Clinical Research Data Managers collaborate with project team members as an integral part of the clinical project team to oversee (and participate in, as required) the development of systems used in collecting and organizing the data from clinical research. Their assurance of the accuracy and completeness of data through validation of the information in the database is an integral part of their work. They analyze data and flag trends to ensure the outcome of the research meets the original goal; and to ensure the data is consistent, accurately captured, and complete. They ensure that regulatory requirements are met by documenting the data management process and by auditing the accuracy of clinical trial data and processes while following International Conference on Harmonization Good Clinical Practices (ICH-GCP) and applicable regulatory guidelines. The data manager is also responsible for training and mentoring junior staff.

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

BioTalent™
Canada

Building skills for Canada's bio-economy

Clinical Research Data Manager

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 résumé 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

Get started today

Even before you download the full **Clinical Research Data Manager** 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 Data Manager Skills Profile.

Clinical Research Data Managers come to their role with a bachelor's degree in life sciences, biostatistics, bio-medicine or a related discipline, and with relevant experience working with computer software. As in many bio-economy occupations, a master's degree is an advantage.

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

A. Provide overall project management

- 1. Plan strategically
- 2. Develop data management plan
- 3. Manage data management budget
- 4. Create and maintain data management study file
- 5. Manage data management deliverable timelines
- 6. Manage resource requirements
- 7. Provide input to project management plan
- 8. Review and provide input to monitoring plan
- 9. Provide input to vendor selection
- 10. Manage change management
- 11. Analyze (e) Case Report Form metrics
- 12. Provide study metrics
- 13. Manage data archiving

B. Develop (e)CRFs (electronic Case Report Forms)

- 1. Critically review protocol, as required
- 2. Identify content of (e)CRFs
- 3. Provide guidance on (e)CRF format
- 4. Coordinate (e)CRF review sessions
- 5. Develop (e)CRF completion guidelines
- 6. Manage printing and organization of paper CRFs

C. Manage database development

- 1. Annotate (e)CRFs, as required
- 2. Design forms
- 3. Provide input to test plan
- 4. Test forms
- 5. Develop database validation checks
- 6. Program and test data validation checks
- 7. Develop reports

D. Manage Electronic Data Capture (EDC) platform

- 1. Determine external/internal platform
- 2. Provide Electronic Data Capture developer with project specifications
- 3. Coordinate internal EDC user training
- 4. Define user roles
- 5. Test EDC system
- 6. Manage end-user needs
- 7. Conduct archiving activities, as required

E. Manage Serious Adverse Events (SAE) data

- 1. Set-up Serious Adverse Events database, if required
- 2. Define SAE process
- 3. Train staff on SAE reporting requirements
- 4. Manage SAE events
- 5. Reconcile SAE data

F. Manage data entry process

- 1. Write data entry guidelines
- 2. Train data entry staff
- 3. Oversee data entry
- 4. Ensure audit trail is maintained

G. Manage data quality

- 1. Review data
- 2. Manage data validation process
- 3. Manage import of external data
- 4. Participate in query quality assurance process
- 5. Manage data coding
- 6. Verify audit trail is in place
- 7. Perform database lock procedures
- 8. Participate in database audit
- 9. Provide input in statistical analysis plan (SAP)
- 10. Generate interim listings
- 11. Facilitate data export process (if statistical analysis is done externally)

H. Communicate

- 1. Communicate with internal team members
- 2. Communicate with external stakeholders
- 3. Review and provide input to communication plan
- 4. Maintain communication records and logs
- 5. Observe confidentiality protocol
- 6. Train others
- 7. Develop and deliver data-related presentations

I. Demonstrate personal competencies

- 1. Maintain required regulatory training
- 2. Demonstrate analytical skills
- 3. Apply technical skills
- 4. Demonstrate basic project management knowledge
- 5. Demonstrate time management skills
- 6. Demonstrate attention to detail
- 7. Manage stress
- 8. Demonstrate interpersonal skills
- 9. Demonstrate leadership
- 10. Mentor other data management team members
- 11. Commit to personal and professional development