Table of Contents

© BioTalent Canada 2010

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 Clinical Research Data Manager.

Occupational Definition

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

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

© BioTalent Canada 2010

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.

© BioTalent Canada 2010

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

© BioTalent Canada 2010

needs areas.

Situational Analysis

The role of a Clinical Research Data Manager may differ greatly depending on the size of the company, scope of work, and industry subsector in which they are employed. Those working for smaller companies will often wear multiple 'hats' and may be required to have additional skills that someone performing this role for a larger company would not require. Working as part of a project team, they design and implement applications which support clinical research, such as auditing tools which monitor the accuracy of clinical coding. Clinical Research Data Managers interpret and validate data, prepare utilization analyses, and may on occasion, collect and analyze information for special projects. In doing these tasks, they monitor compliance with policies and procedures and offer suggestions on ways to improve the processes.

Clinical Research Data Managers enter, log, track, and file Case Report Forms (CRFs), work to ensure timely delivery for the collection and quality control of CRF and non-CRF pages for e-submission, and support the Clinical Data Coordinator (CDC) in database testing and quality control. They create collection instruments, set up databases, and track and manage data flow. They work to ensure the validity of clinical trials and the subsequent formatting of them for statistical purposes. With guidance from the project team, Clinical Research Data Managers establish data review and entry guidelines based upon the selected protocol, document data validation and formatting procedures, and define batch-ending programs. They also assist in the review of interim and final data listings prior to transmission to other groups for inclusion in interim and final reports.

Depending on the requirements of their company, Clinical Research Data Managers may be required to operate Oracle PL/SQL (Procedural Language/Structured Query Language) and SAS (statistical software) programming, query builders, and report writers. They should also be familiar with basic Clinical Data Management Systems, such as Oracle Clinical which is specifically used by Clinical Research Data Managers to define and validate protocols used in various clinical studies.

Clinical Research Data Managers require excellent interpersonal skills given that they often must coordinate with several departments when analyzing clinical data. They should also have superior organizational and analytical skills.

Clinical Research Data Managers must ensure they follow company policy, standard operating procedures, and most importantly, regulatory requirements when putting data management procedures into practice. They collaborate with both internal and external resources to ensure consistency in methods and approaches used, in interpretation of data as well as in the review and evaluation of improved methods, operations, or technology implementation.

© BioTalent Canada 2010

Clinical Research Data Managers must be diligent, detail-oriented individuals who are able to work independently as well as part of a team. They should be technically and analytically adept, and should promote integrity in their work. They must be able to communicate effectively, and be proficient decision makers.

Entry into the occupation of Clinical Research Data Manager is based primarily on a post-secondary degree, preferably in a relevant scientific field such as biology, chemistry, or biochemistry, while some positions request a degree in Computer Science or relevant training instead. A minimum of 1 to 2 years' related experience is usually preferred in hiring, although some companies may be willing to train new students or graduates. Related experience may include formal training in Good Laboratory Practices, Good Clinical Practices, and WHMIS; knowledge of database applications, spreadsheet design, and report writing software. Additionally, proof of accuracy and acceptable spelling in a technical or clinical typing test may be conducted.

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		

According to Essential Skills interviews conducted, current Clinical Research Data Managers stress the importance of Thinking Skills, Working with Others, and Reading. Interviewees concurred that Clinical Research Data Managers must be diligent, detail-oriented individuals who are able to work independently as well as part of a team. They should be technically and analytically adept, and should promote integrity in their work. They must be able to communicate effectively, and be proficient decision makers.

© BioTalent Canada 2010

Language Benchmarks

Clinical Research Data Managers need to work as an integral part of the clinical research project team and will need an upper language level CLB of 9.

© BioTalent Canada 2010

Competency Profile

A Clinical Research Data Manager must be able to:

A. Provide Overall Project Management

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Plan strategically	1.1 Meet with senior management or with project manager to discuss the overall plan for the study	
	1.2 Highlight goals for the study	
	1.3 Highlight key issues in the study	
	1.4 Participate in kick-off meeting	
2. Develop data management plan	2.1 Write overview	
	2.2 Provide timelines and milestones	
	2.3 Define responsibilities of study team	
	2.4 Define data flow	
	2.5 Define critical data	
	2.6 Define query process	
	2.7 Define turn-around time	
	2.8 Define coding procedures	
	2.9 Define self-evident corrections	
	2.10 Develop data (including lab data) transfer plan	
	2.11 Define quality assurance process	
	2.12 Outline electronic case report forms [(e) CRFs]	
	2.13 Complete review and approval process	
3. Manage data management budget	3.1 Provide input to or develop the cost estimate	
	3.2 Manage budget as per agreed-upon plan	
	3.3 Set up contingency plans	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.4 Track budget performance	
	3.5 Provide or analyze budget reports	
	3.6 Flag any budget risks to study team	
	3.7 Provide updated estimates or suggestions to bring budget back on track	
	3.8 Initiate change management as required	
4. Create and maintain data management study file	4.1 Open a file or set up a data shell	
	4.2 Identify project specific filing structure	
	4.3 Observe company policies and procedures for filing	International Conference on Harmonization (ICH) Good Clinical Practices (GCP) Health Canada
	4.4 Review to ensure that the file is updated	
	4.5 Audit and maintain file	
5. Manage data management deliverable timelines	5.1 Provide input to or develop data management timelines	
	5.2 Obtain feedback on timelines from data management team members	
	5.3 Identify key deliverables	
	5.4 Identify critical path	
	5.5 Identify parallel steps	
	5.6 Use time management software, as required	
	5.7 Identify project timeline risks	
	5.8 Develop contingency or mitigation plan	
	5.9 Inform the team when project risks occur	
	5.10 Provide suggestions and take corrective action to bring study timelines back on track	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	5.11 Initiate change management as required	
6. Manage resource requirements	6.1 Estimate resource requirements	
	6.2 Define resource needs for data entry	
	6.3 Analyze resource usage for effort versus completion	
	6.4 Consider effort and duration	
	6.5 Secure resources	
	6.6 Identify resource risk	
	6.7 Develop contingency or mitigation plan	
	6.8 Inform team when resource risks occur	
	6.9 Provide suggestions to bring resource use back on track	
	6.10 Initiate change management as required	
7. Provide input to project management plan	7.1 Review the study protocol	Refer to Project Management Institute (PMI.org) website for developing templates
	7.2 Familiarize yourself with company templates	
	7.3 Provide input to draft project management plan	
	7.4 Convene study team meeting	
	7.5 Obtain input from team members	
	7.6 Obtain approval and sign off, as required	
8. Review and provide input to monitoring plan	8.1 Provide input to monitoring schedule, as required	
	8.2 Provide guidance for Source Document Verification (SDV) guidelines	
	8.3 Outline the query resolution process	
	8.4 Outline communication plan	
	8.5 Assess resource peaks based on CRF (Case Report Form) collection timing by monitors	
9. Provide input to vendor selection	9.1 Identify requirements for vendors	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	9.2 Identify options for vendors	
	9.3 Provide input to request for proposal (RFPs)	
	9.4 Assess vendor capabilities and budget proposal	
	9.5 Provide feedback and recommendation to project team	
	9.6 Audit vendor performance	
10. Manage change management	10.1 Once a change to project deliverables has been identified, provide new estimates (e.g. process, timeline, budget) for impact of change to team	
	10.2 Initiate change management approval process	
	10.3 Obtain approval for change	
	10.4 Communicate change to team	
	10.5 Update project plan, timelines and budget, as required	
11. Analyze Electronic (e) Case Report Form metrics	11.1 Define set of metrics, for example: • Expected number of CRF pages • CRFs completed by sites and visits • CRFs collected/reviewed • Number of adverse events • Randomized subjects by treatment	
	11.2 Analyze (e) CRF completion progress	
	11.3 Assess remaining CRFs to be processed against final CRF collection date	
12. Provide study metrics	12.1 Assess what type of metrics are needed with team	
	12.2 Agree upon timing and frequency of reports	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	12.3 Provide reports as per agreed-upon timing, for example: • Total number of patients in database • Total number of adverse events • Total number of screen fail patients • Percent completions of all patients • Report on number of enrolled/randomized	
	12.4 File reports	
	12.5 Respond to feedback on reports	
13. Manage data archiving	13.1 Identify archiving needs and requirements	Company policy International Conference on Harmonization (ICH) Good Clinical Practices (GCP) Health Canada
	13.2 Identify company archiving policies	
	13.3 Identify what regulatory files are versus internal study files	
	13.4 Define storage media	
	13.5 Secure external archiving vendor, as required	
	13.6 Seek approval to work with archiving process	
	13.7 Archive files	

© BioTalent Canada 2010

A Clinical Research Data Manager must be able to:

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

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Critically review protocol, as required	1.1 Assess randomization needs, as required	International Conference on Harmonization (ICH) Good Clinical Practices (GCP) 21CFR-11
	1.2 Assess data and required collection frequency as per protocol	
	1.3 Assess critical safety data	
	1.4 Communicate with team for any project-specific needs	
	1.5 Provide suggestions for potential protocol improvements	
2. Identify content of (e)CRFs	2.1 Review and identify company templates to be used	
	2.2 Identify flags for pertinent safety data	
	2.3 Identify the appropriate Serious Adverse Event form to be used	
	2.4 Identify number and schedule of CRFs	
	2.5 Identify unique versus repeat pages	
	2.6 Identify content for each CRF, for example: • Demographics • Patient and site numbering system • Treatment-related information	
	2.7 Identify points of observation	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.8 Identify log forms	
	2.9 Develop (e)CRF flow	
	2.10 Finalize draft CRF content	
3. Provide guidance on (e)CRF format	3.1 Identify the format, paper or (e)CRF	
	3.2 Assess cost versus study needs, as required	
	3.3 Provide suggestion to team on format	
4. Coordinate (e)CRF review sessions	4.1 Identify reviewers	
	4.2 Provide reviewers with documentation	
	4.3 Establish process document (e.g., number of drafts, review timelines)	
	4.4 Obtain feedback	
	4.5 Incorporate feedback, where applicable	
	4.6 Issue next draft process document	
	4.7 Obtain final approval	
5. Develop (e)CRF completion guidelines	5.1 Identify format of guidelines, as guidelines will differ depending on format (paper or electronic)	
	5.2 Draft completion guidelines based on study requirements, for example: • Required fields • Type of response • Demographic specifications	
	5.3 Identify reviewers	
	5.4 Establish review process	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	5.5 Obtain feedback	
	5.6 Incorporate feedback, where applicable	
	5.7 Issue next draft	
	5.8 Obtain final approval	
	5.9 Provide input to education and training related to developing (e)CRFs, as required	
6. Manage printing and organization of paper CRFs	6.1 Identify quantity to be printed	
	6.2 Identify number of copies [No Carbon Required (NCRs)]	
	6.3 Identify vendors	
	6.4 Assess cost versus allowable budget	
	6.5 Decide on vendor	
	6.6 Assess timelines for printing	
	6.7 Obtain prototype	
	6.8 Review prototype	
	6.9 Provide feedback on prototype	
	6.10 Approve final version	
	6.11 Provide approval for printing	
	6.12 Determine method of distribution	
	6.13 Distribute CRF	

© BioTalent Canada 2010

A Clinical Research Data Manager must be able to:

C. Manage Database Development

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Annotate (e)CRFs, as required	1.1 Establish coding for data fields	
	1.2 Define type of response for each field, for example: • Boolean • Categoric • Integer • Real numbers • Date	
	1.3 Establish valid ranges	
	1.4 Define required fields and logic (e.g., "If male, pregnancy test not required")	
	1.5 Confirm accuracy of calculation fields, as required	
2. Design forms	2.1 Develop fields as per annotated CRFs	
	2.2 Include format considerations for ease of entry	
	2.3 Define list of options	
3. Provide input to test plan	3.1 Define test data	
	3.2 Define type of testing (e.g., completion, validation, ranges)	
	3.3 Define timelines for testing	
	3.4 Apply company test policies or procedures	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
4. Test forms	4.1 Assign tasks to team members	
	4.2 Supervise testing	
	4.3 Observe timelines	
	4.4 Seek approval for CRFs	
5. Develop database validation checks	5.1 Follow annotated CRFs	
	5.2 Establish required edit checks (screen checks)	
	5.3 Determine whether checks are auto or manual	
	5.4 Develop text for auto queries	
	5.5 Follow company policies	
	5.6 Review with team members to ensure completion and quality assurance	
	5.7 Apply data validation format to data management plan	
6. Program and test data validation checks	6.1 Code or program queries, as required	
	6.2 Test queries	
7. Develop reports	7.1 Define reports needed as per study requirement for manual queries	
	7.2 Define frequency and content for each report	
	7.3 Oversee programming of reports	
	7.4 Oversee and participate in testing of reports	

© BioTalent Canada 2010

A Clinical Research Data Manager must be able to:

D. Manage Electronic Data Capture (EDC) Platform

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Determine external/internal platform	1.1 Consider platform capabilities	International Conference on Harmonization (ICH) Good Clinical Practices (GCP) 21CFR-11 Canadian Regulatory Requirements Therapeutics Product Directorate Federal Drug Agency, as applicable
	1.2 Assess financial constraints	
	1.3 Decide on platform	
	1.4 Provide guidance for vendor contract	
2. Provide Electronic Data Capture developer with project specifications	2.1 Provide annotated CRFs (Case Report Forms)	International Conference on Harmonization (ICH) Good Clinical Practices (GCP) 21CFR-11 Canadian Regulatory Requirements Therapeutics Product Directorate Federal Drug Agency, as applicable
	2.2 Provide randomization model	
	2.3 Outline timelines and major deliverables	
	2.4 Communicate project scope	
	2.5 Provide protocol	
	2.6 Provide lab ranges	
	2.7 Provide serious adverse event (SAE) form	
	2.8 Outline SAE notification specifications	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.9 Define which completed (e)CRFs (electronic Case Report Forms) are required to be printed as per clinical study report (CSR)	
3. Coordinate internal EDC user training	3.1 Identify internal EDC users	International Conference on Harmonization (ICH) Good Clinical Practices (GCP) 21CFR-11 Canadian Regulatory Requirements Therapeutics Product Directorate Federal Drug Agency, as applicable
	3.2 Identify level of training required	
	3.3 Assess who should be trained as trainers	
	3.4 Coordinate training sessions	
	3.5 Conduct training	
4. Define EDC user roles	4.1 Define roles, in conjunction with study team, for example: • Data Entry Personnel/Site Coordinators • Principal Investigator • Monitor • Project Manager • Data Manager • Safety Manager	International Conference on Harmonization (ICH) Good Clinical Practices (GCP) 21CFR-11 Canadian Regulatory Requirements Therapeutics Product Directorate Federal Drug Agency, as applicable
	4.2 Assign access levels to each role	
	4.3 Identify users for each role	

© BioTalent Canada 2010

5. Test EDC system	5.1 Provide input for test plan	International Conference on Harmonization (ICH) Good Clinical Practices (GCP) 21CFR-11 Canadian Regulatory Requirements Therapeutics Product Directorate Federal Drug Agency, as applicable
	5.2 Provide test data	
	5.3 Test each access level to ensure it is working properly	
	5.4 Test system for user requirements	
	5.5 Provide EDC test feedback	
	5.6 Retest as required	
	5.7 Approve system to go live	
	5.8 Launch EDC system	
6. Manage end-user needs	6.1 Define user approval process	International Conference on Harmonization (ICH) Good Clinical Practices (GCP) 21CFR-11 Canadian Regulatory Requirements Therapeutics Product Directorate Federal Drug Agency, as applicable
	6.2 Train end users, as required	
	6.3 Maintain training records	
	6.4 Grant user access, as required	
	6.5 Remove user access, as required	
	6.6 Provide access to training database, as required	
	6.7 Assess retraining, as required	

© BioTalent Canada 2010

7. Conduct archiving activities, as required	7.1 Provide CRF archiving disks to study sites	International Conference on Harmonization (ICH) Good Clinical Practices (GCP) 21CFR-11 Canadian Regulatory Requirements Therapeutics Product Directorate Federal Drug Agency, as applicable
	7.2 Print completed CRFs as required by Clinical Studies Report	
	7.3 Archive database	

© BioTalent Canada 2010

A Clinical Research Data Manager must be able to:

E. Manage Serious Adverse Events (SAE) Data

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Set-up Serious Adverse Events database, if required	1.1 Identify SAE data collection platform	International Conference on Harmonization (ICH) Good Clinical Practices (GCP) Health Canada
	1.2 Identify SAE data collection points	
	1.3 Set up SAE database	
	1.4 Test SAE database	
	1.5 Approve SAE database	
2. Define SAE process	2.1 Outline SAE process	International Conference on Harmonization (ICH) Good Clinical Practices (GCP) Health Canada
	2.2 Specify SAE communication flow	
	2.3 Specify SAE reporting requirements	
3. Train staff on SAE reporting requirements	3.1 Train all project staff on SAE reporting requirements	International Conference on Harmonization (ICH) Good Clinical Practices (GCP) Health Canada
	3.2 Document SAE training attendance	
	3.3 File SAE training documentation in master file for the study	
	3.4 Ensure study site staff is trained on SAE reporting requirements	
	3.5 Document study site staff training	

© BioTalent Canada 2010

	3.6 Ensure site staff training documentation is filed in the investigator site file	
4. Manage SAE events	4.1 Ensure relevant team members are informed of SAEs when they are reported by the study site	International Conference on Harmonization (ICH) Good Clinical Practices (GCP) Health Canada
	4.2 Assess if all required SAE data was submitted by the study site	
	4.3 Communicate with study site and/or monitor to obtain additional SAE data as required	
	4.4 Ensure medical monitor is informed of all initial and follow-up SAE data	
	4.5 Ensure regulatory team is informed of SAEs as they occur	
	4.6 Identify regulatory SAE reporting requirements	
	4.7 Report SAE to regulatory bodies, as required	
	4.8 Report expedited SAEs to study sites, as required	
5. Reconcile SAE data	5.1 Review SAE database against clinical database	
	5.2 Identify database discrepancies	
	5.3 Issue queries to resolve discrepancies	
	5.4 Apply query responses to databases	
	5.5 Conduct reconciliation to ensure databases match	

© BioTalent Canada 2010

	5.6 Ensure database changes are communicated to and reviewed by the data coder, thesaurus manager or dictionary manager	
	5.7 Provide additional information to regulatory, safety, or surveillance team, as required	
	5.8 Ensure all SAE documentation is filed in the trial master file	

© BioTalent Canada 2010

A Clinical Research Data Manager must be able to:

F. Manage Data Entry Process

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Write data entry guidelines	1.1 Identify required data fields	
	1.2 Identify general issues in data entry	
	1.3 Identify study-specific issues (e.g., if answer to assessment A is 'Yes', assessments B and C must be completed)	
	1.4 Provide succinct instruction for data entry in fields	
	1.5 Outline self-evident corrections	
	1.6 Outline how to deal with unknown or unavailable data	
	1.7 Identify format for entry into fields	
	1.8 Define process for double data entry	
	1.9 Identify timelines for data entry [e.g., within 48-hours of receipt of CRFs (Case Report Forms)]	
2. Train data entry staff	2.1 Review data entry guidelines with data entry staff	
	2.2 Decide on training method	
	2.3 Train data entry staff on protocol	
	2.4 Train data entry staff on Serious Adverse Events (SAE) process	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.5 Train data entry staff on CRFs	
	2.6 Document all data entry training	
	2.7 Ensure training documentation is filed in the master file for the study	
3. Oversee data entry	3.1 Ensure data entry staff is entering data as per timelines	
	3.2 Address any double data entry findings, as required	
	3.3 Retrain staff, as required	
	3.4 Ensure quality specifications are met, as per data entry guidelines	
	3.5 Ensure query responses are properly entered	
	3.6 Identify peak resource requirements and obtain additional data entry staff, as required	
	3.7 Provide support to data entry staff, as required	
4. Ensure audit trail is maintained	4.1 Perform quality control checks to ensure audit trail requirements are met	
	4.2 Document quality control issues and corrective actions	
	4.3 Follow-up with or retrain staff, as needed	
	4.4 Ensure quality control findings are filed in the master file for the study	

© BioTalent Canada 2010

A Clinical Research Data Manager must be able to:

G. Manage Data Quality

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Review data	1.1 Review first CRFs (Case Report Forms) prior to data entry	
	1.2 Review data within established timeline after data entry	
	1.3 Identify and resolve any issues that arise through first data received	
	1.4 Apply type-1/self-evident corrections	
2. Manage data validation process	2.1 Run system validation to generate queries	
	2.2 Generate ad hoc reports	
	2.3 Analyze ad hoc reports	
	2.4 Issue queries	
	2.5 Forward queries to sites and monitors	
	2.6 Review query responses	
	2.7 Re-issue queries, as required	
	2.8 Close queries	
	2.9 Communicate most frequent queries with monitors and provide guidance or training to avoid re-occurrence	
3. Manage import of external data	3.1 Collect local laboratory ranges	
	3.2 Enter local laboratory ranges in database	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.3 Identify data import requirements, for example: • Central laboratory • Central electrocardiograms (ECGs) • Interactive voice response system (IVRS)	
	3.4 Identify required fields to consider as completed	
	3.5 Identify data formats	
	3.6 Ensure programming resources are available	
	3.7 Inform programming resources of import timelines and frequency	
	3.8 Request programmer to provide ad hoc report to quality control data imports	
	3.9 Test data import	
	3.10 Quality check data import	
	3.11 Implement imports	
	3.12 Ensure process corresponds with the data transfer plan	
4. Participate in query quality assurance process	4.1 Provide quality assurance with listing of processed queries	
	4.2 Review quality assurance findings	
	4.3 Address quality assurance issues	
	4.4 Ensure documents are filed in the master file for the study	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
5. Manage data coding	5.1 Define coding procedures and coding dictionary to be used, for example: • Medical Dictionary for Regulatory Activities (MedDRA) • World Health Organization (WHO) Drug	International Conference on Harmonization (ICH) Good Clinical Practices (GCP) Health Canada
	5.2 Confirm the fields to be coded	
	5.3 Confirm licenses are valid	
	5.4 Perform coding as per organization's set-up	
	5.5 Perform coding as per study-specific timelines	
	5.6 Obtain oversight from medical monitor, as required	
	5.7 Issue coding queries	
	5.8 Review coding query responses	
	5.9 Reissue coding queries, as required	
	5.10 Close coding queries	
6. Verify audit trail is in place	6.1 Ensure adherence to requirements for documentation of data change	
	6.2 Identify issues	
	6.3 Follow-up and resolve issues	
	6.4 Document findings and corrective action	
	6.5 Ensure findings and documentation is filed in the master file for the study	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
7. Perform database lock procedures	7.1 Confirm all data has been received	
	7.2 Confirm all queries have been resolved	
	7.3 Ensure investigator has approved all data submitted	
	7.4 Confirm all coding is complete and coding classifications have been reviewed by the medical monitor	
	7.5 Confirm all SAEs (Serious Adverse Events) have been reconciled	
	7.6 Run final validation listing	
	7.7 Confirm database is ready to lock	
	7.8 Obtain approvals for database lock	
	7.9 Lock database	
8. Participate in database audit	8.1 Be familiar with database audit plan	
	8.2 Provide working copies of paper CRFs to quality assurance	
	8.3 Address any audit findings	
	8.4 Reopen and correct database, as required	
	8.5 Issue queries, as required	
	8.6 Provide quality assurance with query responses	
	8.7 Apply query responses to database	
	8.8 Follow locking procedures	
	8.9 Ensure audit findings and corrective action documentation is filed in the master file for the study	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	8.10 Ensure audit findings are discussed with study team	
9. Provide input to statistical analysis plan (SAP)	9.1 Ensure data collected meets statistical requirements	
	9.2 Provide feedback to study team, as required	
	9.3 Implement database changes, as required	
	9.4 Ensure SAP is in line with protocol	
10. Generate interim listings	10.1 Run report listings	
	10.2 Review listings and flag potential data trends	
	10.3 Review listings for inconsistencies	
	10.4 Obtain statisticians' feedback on listings	
	10.5 Assess need for additional quality control checks	
	10.6 Initiate additional quality control checks	
	10.7 Issue queries, as required	
	10.8 Forward queries to sites and monitors	
	10.9 Review query responses	
	10.10 Re-issue queries, as required	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	10.11 Close queries	
	10.12 Communicate most frequent queries with monitors and provide guidance and training to avoid re-occurrence	
	10.13 Assess need for additional listings	
	10.14 Develop additional listings, as required	
11. Facilitate data export process (if statistical analysis is done externally)	11.1 Identify data export requirements	
	11.2 Identify media, for example: • FTP • CD-ROM • On-line	
	11.3 Develop data export program	
	11.4 Run test of data export	
	11.5 Apply programming corrections, as required	
	11.6 Run final data export	

© BioTalent Canada 2010

A Clinical Research Data Manager must be able to:

H. Communicate

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Communicate with internal team members	1.1 Ensure timely and respectful communication with internal team members, for example: • Project Manager • Statistician • Monitor • Safety Manager • Medical Monitor • Data Entry Person	
	1.2 Communicate with the whole team or with individuals, as necessary, for example: • Provide direction on tasks needed • Provide updates on task completion status • To coordinate activities	
	1.3 Communicate through multiple forms of media, for example: • Telephone • Face-to-face • E-mail • Webinars	
	1.4 Ensure internal team members adhere to the project communication plan	

© BioTalent Canada 2010

2. Communicate with external stakeholders	2.1 Ensure timely and respectful communication with external stakeholders, for example: • Vendors • Principal Investigators • Medical Monitors • Study Coordinators	
	2.2 Communicate with external stakeholders as a group or individually	
	2.3 Communicate through multiple forms of media, for example: • Telephone • Face-to-face • E-mail • Webinars	
	2.4 Ensure external team members adhere to the project communication plan	
3. Review and provide input to communication plan	3.1 Ensure plan fits with data management work flow	
	3.2 Identify escalation path	
4. Maintain communication records and logs	4.1 Ensure decision making communication is documented and filed in the master file for the study, as required	
5. Observe confidentiality protocol	5.1 Be familiar with and adhere to organization's confidentiality protocol	
	5.2 Ensure patient confidentiality requirements are maintained	
	5.3 Ensure no study confidential information is disclosed	
	5.4 Ensure breaches to confidentiality are reported and followed-up appropriately	

© BioTalent Canada 2010

© BioTalent Canada 2010

6. Train others	6.1 Define training needs	
	6.2 Develop training content	
	6.3 Perform training	
	6.4 Maintain and update training logs	
7. Develop and deliver data-related presentations	7.1 Use electronic presentation methods	
	7.2 Give face-to-face presentations	
	7.3 Adapt and deliver appropriate message for internal and external audiences	
	7.4 Develop presentations	
	7.5 Develop and deliver speeches	
	7.6 Demonstrate presentation skills	

© BioTalent Canada 2010

A Clinical Research Data Manager must be able to:

I. Demonstrate Personal Competencies

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Maintain required regulatory training	1.1 Ensure up-to-date training, for example: • Good Clinical Practices (GCP) • Safety training, as required • Good Pharmacoepidemiological Practices (GPP), as required • Therapeutic Indication, as needed • Company Standard Operating Procedures (SOPs) • Electronic Data Capture (EDC)	
2. Demonstrate analytical skills	2.1 Identify problem or issue at stake	
	2.2 Use accepted analytical tools	
	2.3 Formulate clear recommendations that address the interest of various stakeholders	
	2.4 Understand the implications and scientific limitations of the results obtained	
	2.5 Demonstrate innovative thinking	
3. Apply technical skills	3.1 Apply basic statistical knowledge	
	3.2 Demonstrate expertise in computer and web-based applications, for example: • Microsoft Word, Excel, PowerPoint • Oracle • Access • Web browsers	

© BioTalent Canada 2010

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.3 Demonstrate ability to query databases using Structured Query Language (SQL) language, as necessary	
	3.4 Demonstrate ability to perform ad hoc programming, as necessary	
4. Demonstrate basic project management knowledge	4.1 Identify critical path for data management tasks	
	4.2 Identify and deliver on data management timelines	
	4.3 Identify and deliver on budget requirements	
	4.4 Identify risks and manage as they occur	
	4.5 Identify and manage resources	
	4.6 Identify scope changes; implement and document change management as needed	
5. Demonstrate time management skills	5.1 Prioritize and manage tasks	
	5.2 Allocate time appropriately	
	5.3 Identify additional resources to assist in completing tasks	
	5.4 Delegate, when possible	
	5.5 Demonstrate mental flexibility	
6. Demonstrate attention to detail	6.1 Complete documents with minimal revisions	
	6.2 Scrutinize data to ensure maximum data quality	
	6.3 Execute tasks carefully and accurately	

© BioTalent Canada 2010

	6.4 Demonstrate ability to rapidly identify inconsistencies and apply corrective actions where needed	
7. Manage stress	7.1 Uphold good communication practices while working under stressful conditions	
	7.2 Keep physically and mentally healthy	
8. Demonstrate interpersonal skills	8.1 Listen to understand diverse opinions	
	8.2 Recognize group dynamics	
	8.3 Share personal opinion or understanding	
	8.4 Seek 360° feedback on working relationships	
	8.5 Use variable approaches to respond to individual styles	
	8.6 Demonstrate sensitivity	
	8.7 Understand peoples' motives, interests and backgrounds	
	8.8 Listen to peoples' feedback	
	8.9 Demonstrate ability to identify champions/allies when implementing strategies	
	8.10 Apply and look for win-win solutions	
9. Demonstrate leadership	9.1 Make timely, informed decisions	
	9.2 Justify decisions and be accountable	
	9.3 Follow through	
	9.4 Be approachable	
	9.5 Lead by example	
	9.6 Recognize personal strengths and seek	

© BioTalent Canada 2010

	guidance or expertise, as required	
10. Mentor other data management team members	10.1 Provide guidance to data entry staff	
	10.2 Motivate team members	
	10.3 Identify areas for improvement	
	10.4 Identify champions	
	10.5 Provide opportunities for growth	
	10.6 Encourage growth in others	
11. Commit to personal and professional development	11.1 Read or watch appropriate media and informative materials	
	11.2 Attend and actively engage in industry conferences	
	11.3 Attend and actively engage in current sector/industry association events	
	11.4 Network	
	11.5 Share information within company	
	11.6 Keep current with technology	
	11.7 Maintain technical aptitude	
	11.8 Continually update scientific and regulatory knowledge	
	11.9 Read applicable journals	
	11.10 Keep applicable certifications up-to-date	

© BioTalent Canada 2010