



National Occupational Standard for
Clinical Data Manager



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1 ACKNOWLEDGEMENTS

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2 A COMPETENCY FRAMEWORK FOR INDIVIDUALS WORKING IN THE BIO-ECONOMY

2.1 What is a National Occupational Standard?

In Canada, National Occupational Standards are industry-developed and validated documents that identify and group tasks/competencies associated with a particular occupation. They also describe the knowledge and skills that a worker must demonstrate to be considered competent.

The former Alliance of Sector Councils (TASC) outlined 11 guiding principles for creating National Occupational Standards (NOS). NOS for the Canadian bio-economy meet all 11 principles and are developed to meet the current and future human capital management needs of the Canadian bio-economy.

2.2 How are we defining a competency?

We define a competency as *a set of related behaviors that describe successful performance in a designated area. It is a behavioural expression of how people integrate knowledge, skills, attributes, and attitudes to produce a value-adding result in a defined situation.*

The competency statement includes a description that integrates skills, knowledge, and actions into a sequence of activities that deliver a value-added product or service.

Performance Indicators is the term we use for the behaviours grouped under each competency that describe the level of mastery the incumbent role must demonstrate when executing a task.

For this project, we have organized the competencies into four categories.

Core Competencies are those competencies that describe the "essence of the role" — that is, they are the one to three most critical competencies that may be applicable across multiple roles in a function or job family. All levels of personnel in this function would typically share them. These competencies may also act as qualifiers that differentiate the function from other functions.

Technical Competencies are those competencies related to specific roles or professions that enable an individual to work, function, and succeed in that role. They address the various responsibilities that job incumbents encounter in a role. For example, a surgeon's technical competencies would encompass multiple surgical tools, techniques, and conditions that could be part of the position. Similarly, technical competencies for a lawyer would contain various legal situations that they encounter in the context of a particular field of practice.


Regulatory Competencies are those competencies that describe compliance with prescribed practices and mandated obligations under applicable laws, regulations, and industry standards. They ensure that critical work processes are implemented and integrated into all work activities. They are of absolute importance where economic behaviours can impact human conditions.

Personal/professional Competencies are those competencies that enable an individual to be successful working with others and fulfilling their responsibilities in a work context. Personal and professional competencies are not necessarily role specific.

2.3 Levels of complexity of work

It is important to recognize how the complexity of work varies along an organizational continuum. At one end of this continuum is low-complexity, clearly-defined, task-driven work. At the other end of the continuum is work that is higher in complexity, not as well-defined, and requires higher-level thinking and decision-making skills and a greater degree of autonomy. Results are recognised over a longer period of time and are more difficult to assess.

Figure 1 Demonstrates how the level of complexity changes with the role responsibilities

Complexity Level	Examples of Work at Different Complexity Levels	Typical Roles/Titles
Most Complex	Construct and pursue worldwide strategic plans in large corporations.	CEOs of the largest trans-global corporations
	Construct and pursue worldwide strategic plans.	C-suite executives at multi-national organizations
	Lead the accumulated impact of multiple business units.	C-suite executive at large, multi-location organizations
	Optimize the function of a single business unit or corporate support staff.	General manager; plant manager
	Manage multiple, interdependent projects; balance resources among departments.	Engineering manager
	Plan and carry out sequential projects while considering contingencies and alternatives.	Maintenance manager
	Accumulate information to diagnose and anticipate problems; proactive; notice trends.	Maintenance technician
Least Complex	Follow predefined procedures; seek help when encountering an obstacle. The ability to anticipate problems is not expected.	Maintenance labourer

We define the complexity levels within the profiles at four levels:

Foundational — performance focus is on the execution of procedures and tasks involving own job role.

Operational — performance focus includes some discretion in the planning and executing of work. The work typically includes assessing the quality of the work outcomes and taking corrective action to ensure quality.

Specialist — performance focus is on translating goals and standards to team members and ensuring that work done under the person's responsibility area complies with all corporate standards.

Strategic — performance focus is on leading work and the accumulated impact of work in an independent business unit or across a whole organization. The impact of work at this level is often not visible until the medium to longer term.

The following example illustrates the different complexity levels within a profile.

<p>Competency Name: Research Ethics</p> <p>Competency Definition: Exercises integrity and professionalism to ensure all research is performed responsibly in keeping with the ethical principles of beneficence and nonmaleficence.</p> <p>Competence at this level is demonstrated when the Research Manager:</p>			
<p>Performance Indicators</p>			
<p>Foundational</p>	<p>Operational</p>	<p>Specialized</p>	<p>Strategic</p>
<p>Diligently follows research procedures and protocols mandated by legitimate authorities and professional organizations.</p>	<p>Regularly monitors own actions and decisions to ensure they align with professional and organizational values.</p>	<p>Holds self and staff accountable to the organization's values, ensuring compliance with the policies and procedures related to scientific ethics and rules of conduct.</p>	<p>Fosters an organizational culture of integrity and ethical business practices by unwavering personal example.</p>

2.4 Overview methodology for the development of national occupational standards

National occupational standards were developed using a multi-step process.

Step	Description	Result/Output
1	Identify critical roles in the bio-economy through primary and secondary research.	List of 50 key roles
2	Create draft profiles with critical competencies for the roles, performance, and knowledge indicators.	Draft profiles
3	Review the draft profiles with industry subject matter experts to refine the competencies, performance, and knowledge indicators.	Reviewed profile with design inputs from industry experts
4	Further validation and review by industry via online focus group.	Validated profiles by industry experts
5	Broader validation of the draft profiles via national online surveys.	Occupational Standards validated on a national level by experts from the different sectors
6	Addition of the Essential Skills and Canadian Language Benchmark (ES/CLB) ratings.	Nationally validated NOS profiles with ES/CLB profile for each NOS

3 CLINICAL DATA MANAGER COMPETENCY FRAMEWORK

3.1 Competency diagram for Clinical Data Manager

Competencies		Complexity Level				Complexity Level Legend
		1	2	3	4	
Core Competency						1. Foundational
1	Data Management – Planning					2. Operational
2	Data Management – Operations/Execution					3. Specialist/Manager
Technical Competencies						4. Expert/Executive
3	Project Management					
4	Data Review					
5	Training					
6	Stakeholder Relationship Management					
Industry Regulatory Competencies						
7	Industry Compliance					
Personal and Professional Competencies						
8	Team Coordination					
9	Communication					
10	Critical Thinking					
11	Attention to Detail					
12	Problem Solving					

3.2 Definition of occupation

The Clinical Data Manager acts as the operational lead for all data management activities for the assigned projects, and ensures they are effectively carried out from project start to closeout. This includes designing case report forms(CRF), and then the collection, storage, integration, review and reconciliation and transfer of clinical trial data. The Clinical Data Manager serves as the primary contact for Data Management on the Core Study Team and the technical leader on all data management aspects for project(s) including start-up, maintenance, close-out activities, and development of Data Management Plans, User Acceptance Testing (UAT) Plans, and Quality Management (QM)plans that will deliver accurate, timely, consistent, and high-quality clinical data. In some cases, they may also oversee the work of vendor organizations involved in clinical trial data management activities.

Clinical Data Managers work closely with the statistics and science teams but are generally not involved in analysis or interpretation of the data collected. They generate and analyze metrics to identify trends in data-related issues. Clinical Data Managers may also be involved in clinical database programming in organizations where this type of training is provided.

The 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

3.3 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's Degree in Natural Health/Life Sciences, or Health Informatics; Clinical Research Certification is common in combination with an undergraduate degree.

- 2+ years of Clinical Data Management experience and a minimum of 1 year of leading studies in a Contract Research Organization (CRO) setting or a combination of CRO/Sponsor environment. This could be clinical database programming, or in a junior data management position
- Experience with: Electronic Data Capture (EDC) systems for data entry and/or configuration, other data collection tools, data management methodologies and technologies, clinical database build, paper or electronic case report form (eCRF) design and validation specifications creation for capturing data in pharmaceutical and/or medical device clinical trials
- Knowledge of clinical data requirements and ICH/Good Clinical Practices is mandatory
- Knowledge of medical terminology relevant to the trial is an asset
- Proficiency in MS Windows navigation, standard office suite tools (word processing, advanced spreadsheet skills, presentations, e-mail applications).
- Effective oral, written and presenting communication skills.
- Strong project management skills and knowledge of project management methodologies
- Demonstrated leadership skills.
- CCDM Certification (Certified Clinical Data Manager) an asset

3.4 Core competencies list for Clinical Data Manager

3.4.1 Data Management — Planning

Plans the data management process(es) and procedures that will be used to support the protocol and requirements of a clinical trial in order to ensure data quality and integrity will be maintained.

Competency in this role is demonstrated when the individual:

- Serves as a key subject matter expert on topics related to data management activities, including specific activities and processes for study start-up.
- Prepares or reviews standard plans (e.g., Project Plan, Data Management Plan, Operational Oversight Plan, Systems Integration Plan, User Acceptance Testing (UAT) Plan, etc.) to support the clinical trial.
- Designs the database for the clinical trial.
- Designs, develops, and reviews Electronic Case Report Forms (eCRFs), annotations, eCRF Completion Instructions, and Validation Specifications based on standard of care, the Clinical Study Protocol, and input from the study team.
- Conducts UAT on data collection tools to flag any issues or missed instructions.

Knowledge required for competency at this level:

- In-depth knowledge and understanding of clinical trial data management concepts, practices, processes, and procedures; established data management best practices; relevant issues related to or impacting clinical data management, as well as industry guidance, conventions, and standards
- Knowledge of data review/reconciliation activities and utilization of dashboards, metrics, generated reports, and trackers in order to monitor data arrival and review status
- Understanding of client management processes
- Basic knowledge of health/medical terminology

3.4.2 Data Management — Operations/Execution

Contributes to the overall success of a clinical trial by ensuring data collection, storage, cleaning, transfer, and reporting processes are followed as defined in plans and study protocol. Also takes a lead role in the management of quality control and governance processes concerning all data management-related aspects of the study throughout the duration of the trial.

Competency in this role is demonstrated when the individual:

- Acts as Functional Lead for Data Management including acting as the primary contact for anything related to data management activities.
- Supports study data management and data cleaning processes on an ongoing basis, applying study specific documents and conventions such as data review, double data entry, query issuing and resolution, data reconciliation, coding, etc.
- Works proactively throughout the trial to optimize the data collection, storage, and management processes.
- Coordinates the work of the assigned Data Management/Data Operations team.
- At sponsor organization, oversees CRO/vendor data management activities.
- Liaises and manages communication with the clients and/or data safety management board (DSMB).
- Maintain value of data through application of FAIR (Findable, Accessible, Interoperable, Reusable) principles.
- Informs relevant functions of results and leads proper communication between functions, Quality Control manager, and others in order to ensure any and all data-related issues are reconciled.
- Performs general administration tasks such as user access and account management
- Reviews and implements study-related protocol or data capture changes.
- Assists in the preparation of the Review Report.
- Identifies, mitigates, and manages risks associated with data management throughout a clinical trial.

Knowledge required for competency at this level:

- In-depth knowledge and understanding of clinical trial data management concepts, practices, processes, and procedures; relevant issues related to or impacting clinical data management; established data management best practices as well industry guidance, conventions, and standards
- Knowledge of data review/reconciliation activities and utilization of dashboards, metrics, generated reports, and trackers in order to monitor data arrival and review status
- Knowledge of the WHODrug and MedDRA dictionaries
- Knowledge of Clinical Data Interchange Standards Consortium (CDISC) interoperability standards
- Knowledge of Clinical Data Acquisition Standards Harmonization (CDASH) requirements
- Working knowledge of various software packages programs (e.g., Oracle Clinical, Medidata Rave, Inform, iDataFax, Phase Forward, Clintrial, REDcap, Medrio, etc.)

- Understanding of client management processes
- Basic knowledge of health/medical terminology

3.5 Technical competencies list for Clinical Data Manager

3.5.1 Project Management

Applies sound principles of project management to oversee the efficient execution of project plans and to ensure on-time, on-budget deliverables that meet the quality expectations of the client and the contract.

Competency in this role is demonstrated when the individual:

- Formulates and executes a project plan within their areas of responsibility.
- Allocates work and deliverables across the project team to ensure scope, schedule, cost, and quality requirements are met, and optimizes assigned resources in order to execute the project plan.
- Applies tracking metrics within their area of responsibility to identify issues so they can be addressed with minimal impact to schedule, cost, and quality.
- Makes recommendations for improvements to project processes within their area of responsibility to improve efficiency and/or effectiveness.

Knowledge required for competency at this level:

- Detailed knowledge of project management methodologies and processes that support the clinical trial operation
- Working knowledge in the preparation of status reports and presentations for senior management levels
- Working knowledge of emerging industry or technology trends or issues that may impact project execution

3.5.2 Data Review

Uses data surveillance tools and strategies to provide aggregate level reviews designed to identify patterns or anomalies in data to ensure high quality results.

Competency in this role is demonstrated when the individual:

- Proactively conducts quality checks on data to ensure data quality and integrity.
- Engages with other team members (internal and external) to address data quality issues and trends.
- Issues and resolves queries (data clarifications) to address inconsistent/missing data.
- Reports data quality issues and solutions to appropriate management authority so that remedial action is taken.

Knowledge required for competency at this level:

- Knowledge of clinical data management processes and tools
- Working knowledge of data quality review and reporting processes

3.5.3 Training

Applies comprehensive knowledge of clinical data systems to train personnel on electronic data capture (EDC) system, eCRF completion, and quality control processes in order to ensure proficiency and minimize errors in data collection and storage.

Competency in this role is demonstrated when the individual:

- Provides training and direction and acts as a resource to staff assigned to these projects (Investigator meetings, CRO training, CRA training, site-level initiation training, etc.).
- Trains staff and site users on technical procedures or software program usage.
- Writes data capture guidelines and newsletters.

Knowledge required for competency at this level:

- Knowledge of data entry procedures and data cleaning tasks
- Knowledge of Electronic Data Capture (EDC) systems
- Knowledge in technical data management competencies via participation in internal and external training seminars
- Knowledge of effective verbal and visual presentation approaches
- Instructional design and delivery approaches

3.5.4 Stakeholder Relationship Management

Ensures customer's needs and objectives are supported by consulting and providing clinical data management services.

Competency in this role is demonstrated when the individual:

- Works collaboratively and effectively as the project and client liaison, including managing and reporting on project status, schedule, and other project metrics.
- Anticipates, proactively prevents, and mitigates potential risks. When risks actualize, reviews problem areas with stakeholders, consults subject matter experts, addresses deviations, investigates causes, and analyzes trends.
- Proactively engages with stakeholders across the business to understand their needs and influence their understanding of decisions made in data management function.
- Informs stakeholders of status of key deliverables and acts on changing milestones.
- Provides overall planning, oversight, coordination, and related due diligence, analysis, reporting, and recommendations which have a direct impact on decisions related to data collection, human resource allocation, and timelines.
- Acts as the first point of contact for all data management related queries and concerns.
- Acts as a resource and subject matter expert to staff assigned to these projects.
- Confers with end users and other vendors to define or implement clinical system requirements such as data release formats, delivery schedules, and testing protocols.

Knowledge required for competency at this level:

- Demonstrated knowledge in customer service that meets high quality standards and high levels of customer satisfaction
- Demonstrated expertise in data management and project management processes
- Strong communication, consulting, and negotiation skills

3.6 Industry regulatory competencies list for Clinical Data Manager

Note: Regulatory compliance is a factor that underpins all aspects of the Clinical Data Manager's role.

3.6.1 Industry Compliance

Monitors to ensure results and assessments are properly documented, maintained, and in keeping with regulatory reporting requirements, industry standard guidelines, and any other timelines or requirements in order to maintain compliance.

Competency in this role is demonstrated when the individual:

- Performs duties in compliance with SOPs, GCP, and ICH guidelines in accordance with regulatory and ethical standards.
- Ensures complete, accurate, and timely documentation for all projects/studies according to established guidelines.

Knowledge required for competency at this level:

- Extensive knowledge and understanding of SOPs, GCP, and ICH guidelines in accordance with regulatory, contractual, and ethical standards

3.7 Personal and professional competencies list for Clinical Data Manager

3.7.1 Team Coordination

Acts as a resource for decision-making by providing support and contributing expertise, evaluation, and advice in areas such as performance improvement, customer service delivery and consulting, operational and business process improvement reviews and related analytical process, data utilization, and reporting requirements. Also facilitates consensus with stakeholders as needed and identifies viable objectives, directions, and options.

Competency in this role is demonstrated when the individual:

- Provides work direction, manages timelines in cooperation with other personnel assigned to projects, and ensures that service and technical standards are met.

- Coordinates tasks, deliverables, and timelines with other vendors and departments, including the biostatistics and statistical analysis system (SAS) programming team, and clinical database programmers.
- Effectively leads the work of data management project staff and communicates effectively with staff at all levels within the organization, both orally and in writing.
- Organizes and prioritizes workload to meet deadlines.
- Provides advice and support to clinical researchers and other stakeholders with development of the clinical trial database.

Knowledge required for competency at this level:

- Effective, practical knowledge of facilitation, communication, and negotiation tactics in order to achieve consensus and buy-in, resolve conflict, and deliver high quality data
- Comprehensive knowledge of process management and analysis

3.7.2 Communication

Employs effective written, verbal, and visual communication principles to ensure clear, timely, and accurate information transfer to appropriate individuals in order to support decision making and appropriate action.

Competency in this role is demonstrated when the individual:

- Prepares reports, memoranda, and other written materials that are content-appropriate for the intended audience and fit for purpose.
- Reports study status and issues to stakeholders and sponsor.
- Conducts internal and external training.
- Assists system users with troubleshooting technical issues (electronic data capture).
- Prepares formal and informal presentations, briefings, and other forms of audio-visual information that are content-appropriate for the intended audience and fit for purpose.
- Employs verbal and non-verbal techniques to ensure understanding and appropriate action.
- Employs active listening techniques to ensure clarity and understanding in oral communications and to gather project requirements.

Knowledge required for competency at this level:

- Knowledge of effective verbal communication approaches
- Knowledge of active listening approaches
- Knowledge of effective questioning techniques
- Knowledge of visual communication and presentation techniques
- Knowledge of effective written communication techniques
- Knowledge of appropriate technological tools for effectively producing written, visual, and oral communication media and for interacting with and engaging the audience

3.7.3 Critical Thinking

Applies accumulated knowledge of clinical research, personal experience, and lessons learned from previous studies in order to prevent future problems. Analyzes the protocol and the stakeholders' needs, clarifies requirements, and develops solutions for complex data management issues that arise during the planning and execution of clinical trials. Also captures lessons learned from previous experience and adapts them to new contexts in order to facilitate effective problem-solving and risk management.

Competency in this role is demonstrated when the individual:

- Follows an iterative process for understanding issues and making decisions as well as employing creative thinking for solving problems.
- Articulates and defends the factors that are incorporated into their analyses and decisions.

Knowledge required for competency at this level:

- Ability to perform inductive and deductive reasoning

3.7.4 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.

Competency in this role is demonstrated when the individual:

- Detects errors/omissions/incongruities in collected data (data review).
- Detects inconsistencies (across tables) during data reconciliation.
- Drafts and reviews plans and guidelines to ensure clarity and syntax consistent formatting.
- Designs forms and annotations to ensure all required data is collected with minimal room for error for users.
- Crafts queries to ensure clarity.
- Designs validation specifications that ensure that all data fields are addressed.

Knowledge required for competency at this level:

- Consistent demonstration of inherent traits, characteristics, and behaviours/practices

3.7.5 Problem Solving

Demonstrates commitment to responsible performance throughout the duration of the study and to personal responsibility and transparency by holding to a high ethical standard for proper and consistent performance.

Competency in this role is demonstrated when the individual:

- Gathers all pertinent information to gain a deep understanding of the issue and its implications before developing a plan of action.
- Applies systems thinking, inductive reasoning, and deductive reasoning approaches to understand root causes.
- Applies brainstorming and other creative techniques to develop potential solutions.
- Seeks external assistance to help develop and vet different options.
- Applies quantitative and qualitative measures to select the best option.
- Implements solutions to mitigate the impact of actualized risks.
- Monitors the solutions during application to ensure their effectiveness.
- Documents and shares lessons learned.

Knowledge required for competency at this level:

- Understanding of systems thinking and critical thinking
- Ability to perform deductive and inductive reasoning
- Knowledge of brainstorming techniques
- Knowledge of problem solving techniques
- Understanding of collaborative processes for idea generation
- Knowledge of analytical processes
- Knowledge of root cause analysis processes
- Knowledge of communication skills

3.8 Essential Skills for Clinical Data Manager

Essential Skills (ES) are foundational skills required for all types of work. They are not technical skills, but the core skills people need to acquire knowledge and complete workplace tasks and daily activities.

Understanding the ES requirements for a role can allow individuals to compare their skills to those required, assist training/learning providers in developing appropriate supports to ensure ES levels are developed during training, and provide employers with an additional tool for determining who/how to place in particular roles.

Human Resources and Skills Development Canada has defined Essential Skills as follows:

- Reading
- Document Use
- Numeracy, which is further divided into:
 - Money math; Scheduling, budgeting, and accounting math; Measurement and calculation math; Data analysis math.
 - Several different factors related to estimations, including the presence of a set procedure, the number of items being estimated, the consequences of errors in estimation, the amount of information missing, and the accuracy required.
- Writing
- Oral Communication
- Thinking Skills, which are further divided into:

- Problem Solving
- Decision Making
- Critical Thinking
- Job Task Planning and Organizing
- Finding Information
- Significant Use of Memory
- Digital Skills
- Working with Others
- Continuous Learning

Most of the ES have levels based on complexity, and a role can be analyzed to determine the appropriate levels of ES. The exceptions are noted below:

- "Working with Others" does not have a complexity rating: it simply describes the ways in which the role would be required to interact with other people, either internally within the organization or externally (i.e., with clients, customers, or the public).
- "Continuous Learning" does not have a complexity rating: it describes the types of learning expected in the context of the role (e.g., on the job, being mentored by others, formal training as part of the job, etc.).

NOTE: as of January 2020, ESDC was undertaking a comprehensive review of ES with the intent of adding additional skills, refining existing ones (particularly digital skills) and better aligning ES with similar approaches used in other countries. However the detail was not finalized in time to be used, therefore the profiles developed for this project follow existing standards as of December 2019.

3.9 Canadian Language Benchmark for Clinical Data Manager

Canadian Language Benchmarks (CLB) are a 12-point scale for task-based language proficiency descriptors which were originally developed as a guide for measuring the teaching and assessment of English as a Second Language (ESL) learners in Canada. Since they

were originally developed, the Canadian Centre for Language Benchmarks (CCLB) has continued to refine CLB, and it now includes scales for both English and French language proficiency.¹

The CLB has been validated against both the Common European Framework for Language (CEFL) and the American Council for the Teaching of Foreign Languages (ACTFL) benchmarks and is considered accurate for high-stakes evaluation².

The ES levels for Oral Communication were developed with reference to the Canadian Language Benchmarks³. Comparative work to determine the alignment between the CLB and other Essential Skills has been ongoing, with recent work providing additional alignment with the ES for Oral Communication in both spoken and listening domains, Reading, Writing, and Document Use.⁴

CCLB has developed a set of crossover tables that align CLB ratings with ES ratings for reading, writing oral communication and document use.

Clinical Data Manager ES/CLB Profile

Essential Skills	Equivalent CLB Level	ES Level				
		1	2	3	4	5
Reading	Reading: 11–12	1	2	3	4	5
Document Use	Reading: 11–12 Writing: 11–12	1	2	3	4	5
Writing	Writing: 10–12	1	2	3	4	5
Oral Expression	Speaking: 11–12 Listening: 11–12	1	2	3	4	5

¹ Centre for Canadian Language Benchmarks. Theoretical Framework for The Canadian Language Benchmarks And *Niveaux De Compétence Linguistique Canadiens*. CCLB. Ottawa 2015. p8

² Centre for Canadian Language Benchmarks. Canadian Language Benchmarks: English as a Second Language for Adults, CCLB. Ottawa 2012 p.II

³ Essential Skills Research Group. Readers Guide to the Essential Skills. ESDC. Ottawa ND. p57

⁴ Canadian Centre for Language Benchmarks. Relating Canadian Language Benchmarks to Essential Skills: A Comparative Framework. 2015, p3

Essential Skills	Equivalent CLB Level	ES Level				
		1	2	3	4	5
Numeracy	n/a	1	2	3	4	5
Thinking Skills – Problem Solving	n/a	1	2	3	4	
Thinking Skills – Decision Making	n/a	1	2	3	4	
Thinking Skills – Job/Task Planning and Organizing	n/a	1	2	3	4	
Thinking Skills – Significant Use of Memory	n/a	Types 1,2,3				
Thinking Skills – Finding Information	n/a	1	2	3	4	
Digital Skills	n/a	1	2	3	4	5
Working with Others	n/a	See Below				
Continuous Learning	n/a	See Below				

Explanation of the Essential Skills and the Canadian Language Benchmark for Clinical Data Manager

Reading: ES 5 CLB: 11–12

Clinical Data Managers read and interpret complex clinical data (such as WHODrug and MedDRA dictionaries), industry guidance and conventions, and standards documents. They synthesize and aggregate information from various operational reports to guide their actions while managing the data collection and recording functions of the clinical trial. They must be able to discern anomalies in written information and take appropriate action based on their interpretation. Reading can include technical and scientific materials related to the trial, ethical and regulatory documentation, sampling data, technical documentation related to data collection and storage software and hardware, and other complex medical, scientific, and/or legal documents.

Document Use: ES 5 CLB: Reading: 11–12, Writing: 11–12

Clinical Data Managers must interpret a variety of clinical trial documentation in both paper and digital formats. They find and process information from data collection forms and read and interpret textual, graphical, and numerical information to effectively manage the clinical trial data collection and storage functions.

Writing: ES 4 CLB: 9

Clinical Data Managers collaborate with multiple stakeholders through written correspondence, email, internal memos, etc. These can range from short, simple, and repetitive/routine documents (in paper and electronic formats) to more detailed technical plans and reports detailing the data collection and storage protocols to be used in the trial, reports on data security/privacy, data integrity, data quality, and other technical information. The information conveyed may be used by others to change their own work and processes; therefore, accuracy and attention to detail is critical. Common documents include status reports, internal memoranda, data capture guidelines, instructions/procedures for staff, and other job-related materials. They may use basic health, medical, and scientific terminology in the production of these reports.

Oral Expression: ES 4 CLB: Speaking: 11–12, Listening: 11–12

Clinical Data Managers serve as a primary contact for Data Management on the Core Study Team from project start to close-out, and they work closely with the statistics and science team. Interactions range from one-on-one to larger group communications. They must be able to conduct high quality, accurate, culturally informed presentations to peers, more senior personnel, and subordinate team members within their organization. Presentations to external stakeholders are rare. They must employ active listening techniques and other feedback mechanisms to ensure understanding.

Numeracy: ES 3 (Money Math: 3, Scheduling, Budgeting and Accounting: 3, Measurement & Calculation: n/a, Data Analysis: 3)

Clinical Data Managers monitor the budgeted and actual performance of the data collection and storage processes used in the clinical trial. Tasks may require a combination of operations or multiple applications of single operations that may include several steps of calculation using known or easily sourced variables.

Thinking Skills: ES 3

Thinking skills are subdivided into five domains:

- Thinking Skills — Problem Solving
- Thinking Skills — Decision Making
- Thinking Skills — Job/Task Planning and Organizing
- Thinking Skills — Finding Information
- Thinking Skills — Significant Use of Memory

- **Thinking Skills — Problem Solving: ES 3**

Clinical Data Managers solve relatively complex problems related to data collection, storage, and retrieval. They troubleshoot data collection and data integrity issues in large databases and large datasets. There may be a standardized problem solving process, but it is customized to meet the specific parameters of each problem and the relationships between the variables may not be clear.

- **Thinking Skills — Decision Making: ES 2**

Clinical Data Managers make decisions related to the integrity of data collection, storage, and retrieval. The decisions are not inconsequential and can have significant ramifications (time, money, reputation) for the organization, potentially resulting in significant re-work if the wrong decision is made. Decisions that will have future impact are made with incomplete or uncertain information. Generally, decisions related to data management can use standardized and established processes, but their practitioners have leeway in how these decision frameworks are used and will modify processes to fit the parameters of each individual case.

- **Thinking Skills — Job/Task Planning and Organizing: ES 3**

Clinical Data Managers have generally well-defined roles, but within that structure they have a lot of discretion for how they sequence, plan, and execute their work. Any disruptions (which can be caused by human error, technology breakdown, or other

factors that are unforeseen/unpredictable) must be handled in stride, often resulting in a completely new plan for executing the work in order to minimize disruption and variances. The data manager must coordinate activities within the data management team, but also with the activities of the trials they are supporting, which results in dynamic replanning and reprioritizing of activities on a day-to-day basis.

- **Thinking Skills — Finding Information: ES 3**

Clinical Data Managers are required to seek information from both paper and digital sources to solve problems, inform their work, troubleshoot data management issues, and minimize disruption to the operations they support. Information is from known sources, but due to the nature of the systems used, it may be difficult to locate and must be interpreted once found in order to be useful.

- **Thinking Skills — Significant Use of Memory: Types 1, 2, 3**

To ensure effective, accurate, and ethical clinical trial studies, Clinical Data Managers must memorize, retain, and use clinical trials project information through one or all of the following methods:

- Purposeful memorization of procedures, codes, parts numbers, memorization through repetition (Type 1)
- Remembering information for brief periods, e.g., minutes or hours (Type 2)
- Unique events in which learning occurs from exposure (Type 3)

Digital Skills: ES 4

Clinical Data Managers must use a variety of sophisticated software tools to develop and execute data management tasks for the study. This can include clinical database programming, working with various software packages programs (e.g., Oracle Clinical, Medidata Rave, Inform, iDataFax, Phase Forward, Clintrial, REDCap, Medrio, etc.), designing case report forms (CRF) and electronic case report forms (eCRF), conducting data entry and configuration in Electronic Data Capture (EDC) tools, working with electronic data collection tools, building clinical trial databases, and designing and validating specifications creation for capturing data in pharmaceutical and/or medical device clinical trials.

Working with Others: Work Context 2, 3 & 4

The following work contexts and functions are relevant to the Clinical Data Manager role:

- Works independently (Work Context 2)
- Works jointly with a partner or helper (Work Context 3)
- Work as a member of a team (Work Context 4)

Clinical Data Managers are required to demonstrate exceptional leadership skills as an operational lead for all data management activities for assigned projects, serve as a primary contact for Data Management on the Core Study Team and the technical leader on all data management aspects for projects from start to completion, works closely with statistics and science teams, liaison with multiple stakeholders, provide training and direction and customer service, and act as a resource to staff to anticipate and proactively prevent potential risks.

They may also be involved in supervisory or leadership activities, as follows: Functions 1–5 & 8–12

- Participate in formal discussions about work processes or product improvement (S/L Function 1)
- Have opportunities to make suggestions on improving work processes (S/L Function 2)
- Monitor the work performance of others (S/L Function 3)
- Inform other workers or demonstrate to them how tasks are to be performed (S/L Function 4)
- Orient new employees (S/L Function 5)
- Select contractors and suppliers (S/L Function 8)
- Assign routine tasks to other workers (S/L Function 9)
- Assign new or unusual tasks to other workers (S/L Function 10)
- Identify training that is required by or would be useful for other workers (S/L Function 11)
- Deal with other workers' grievances or complaints (S/L Function 12)

Continuous Learning: Types of Learning: 1, 2, 3 How Learning Occurs: 1, 2, 3, 4, 5, 6

Type of learning may include:

- Training in job-related health and safety (Type 1)
- Obtaining and updating credentials (Type 2)
- Learning about new equipment, procedures, products, and services (Type 3)

The learning may occur:

- As part of regular work activity (Context 1)
- From coworkers (Context 2)
- Through training offered in the workplace (Context 3)
- Through other forms of self-study (Context 4):
 - At work
 - On worker's own time
 - Using materials available through work
 - Using materials obtained through a professional association or union.
 - Using materials obtained through worker's own initiative
- Through offsite training (Context 5):
 - During working hours at no cost to the workers
 - Partially subsidized
- With costs paid by the worker (Context 6)

4 REFERENCES

Gathering the data

The development of the National Occupational Standards started with a review of existing information for the role. This review process included: referencing books, job postings, websites, articles, and BioTalent Canada's existing skills profiles to create the first draft. After several iterations via written feedback, focus groups and a national survey with subject matter experts, the National Standards were developed. The following are sources consulted during the creation of the **Clinical Data Manager** profile:

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"Clinical Data Managers - Job Description." MyPlan.com, <https://www.myplan.com/careers/clinical-data-managers/description-15-2041.02.html>.

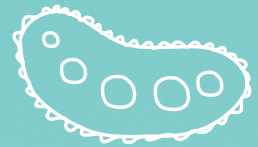
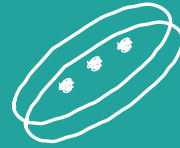
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During the research period, several job posting boards were reviewed for this profile.

You already have a stellar team. Here's how to enhance their key skills.



PROFESSIONAL DEVELOPMENT

- Essential Skills Fundamentals
 - Introduction to the Bio-economy, Reading, Writing, Numeracy, Document Use, Communication, Collaboration, Problem Solving
- Technical Skills Fundamentals
 - Scientific Report Writing, GLP, GCP, GMP, QA/QC



Give your team the BioReady™ Edge

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

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March 2022.



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