National Occupational Standard for

Pre-Clinical/Clinical Trial Project Manager

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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.

Competency Name: Research Ethics **Competency Definition:** Exercises integrity and professionalism to ensure all research is performed responsibly in keeping with the ethical principles of beneficence and nonmaleficence. Competence at this level is demonstrated when the **Research Manager**:			
Performance Indicators			
Foundational	Operational	Specialized	Strategic
Diligently follows research procedures and protocols mandated by legitimate authorities and professional organizations.	Regularly monitors own actions and decisions to ensure they align with professional and organizational values.	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.	Fosters an organizational culture of integrity and ethical business practices by unwavering personal example.

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 PRE-CLINICAL/CLINICAL TRIAL PROJECT MANAGER COMPETENCY FRAMEWORK

3.1 Competency diagram for Pre-Clinical/Clinical Trial Project Manager

Competencies		Competency Level			
		1	2	3	4
Core Competency					
1	Research Ethics			■	
2	Information Management			■	
Technical Competencies					
3	Feasibility Assessments			■	
4	Project Plan Development			■	
5	Contractor Performance Management			■	
6	Budget and Cost Management			■	
7	Project Team Management			■	
8	Risk Management			■	
9	Scope of Work Management			■	
10	Quality Management			■	
11	External Stakeholder Management			■	
12	Reporting			■	
13	Project Close-Out			■	
Industry Regulatory Competencies					
14	Document Management			■	
Personal and Professional Competencies					
15	Communication			■	
16	Problem Solving			■	

Competency Level Legend

1. Foundational
2. Operational
3. Specialist/Manager
4. Expert/Executive

3.2 Definition of occupation

The Clinical Project Manager is responsible for managing clinical trial projects through the clinical trial lifecycle following all applicable legislation as required by the clinical trial sponsor organization, country regulations, and/or provincial requirements. The project manager is responsible for all the project management functions from the feasibility phase, selection, and approval to execution and close-out of clinical trials. Core to the success of the project is developing the project plan of execution, compiling the project team, setting the budget and schedule, and managing the achievement of project milestones against the approved project parameters.

The Clinical Project Manager also acts as the main point of communication to the project stakeholders. They ensure that informing participants, identifying problems, and solving the problems are taking place through competent specialists. They also ensure the timely delivery of all related reports, documents and records, as required, and that all related reports are delivered on time and documents and records are managed as required.

This 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.

- Project Management experience and/or designation
- Minimum a bachelor's degree in biology, health, life sciences, or bioengineering
- More advanced degrees (MS, MBA, PhD) are strongly recommended
- Working knowledge of Good Clinical Practice (GCP)
- Ability to work with institutional review boards (IRBs) and ethical committees (ECs)
- Experience in clinical research and/or experience as a Clinical Research Professional

3.4 Core competencies list for Pre-Clinical/Clinical Trial Project Manager

3.4.1 Research Ethics

Ensures that all participating team members, including those downstream of the project, have the experience, qualifications, and competence required to deliver a project, using appropriate research methods and conducting research in a transparent and accountable manner which respects the participants involved in the trial.

Competency in this role is demonstrated when the individual:

- Designs, develops, and implements methods appropriate for achieving the aims of the research project.
- Maintains respect for participants by ensuring participant consent and confidentiality and minimizing potential risk and harm.

- Manages data security throughout the project lifecycle.
- Governs the use of facilities and resources as appropriate for the research.
- Ensures that amendments, renewals, and adverse events are submitted and approved.

Knowledge required for competency at this level:

- Understanding of the function and role of the appropriate regulatory bodies, funding bodies, and Directorates
- Knowledge of the roles and responsibilities of the Biologists and Genetic Directorate (BGTD)
- Ability to identify the applicable Ethics Board for approval of clinical trials
- Knowledge of the stipulations of Division 5 of the Food and Drugs Act and Regulations

3.4.2 Information Management

Governs and controls the quality of data collection, capturing, analysis, archiving, and access to the data and clinical trial information in order to ensure the delivery of conclusions and results from answering the clinical trial questions by appropriately qualified and competent people in compliance with regulations.

Competency in this role is demonstrated when the individual:

- Ensures the identification of data collection and archiving protocols.
- Trains and qualifies team members to collect, enter, and transfer the data.
- Applies and uses the correct data collection methodologies to maintain privacy and respect for the participants.
- Designs, controls, and validates the data management system.
- Stores data and information in a way that restricts access to people with appropriate authorization levels.

Knowledge required for competency at this level:

- Knowledge of personal information protection and electronic document management regulations

3.5 Technical competencies list for Pre-Clinical/Clinical Trial Project Manager

3.5.1 Feasibility Assessments

Ensures the completion of feasibility studies and confirms that trials can be executed within the cost and schedule to deliver the required results.

Competency in this role is demonstrated when the individual:

- Delivers feasibility assessments and ensures the site feasibility is confirmed.
- Ensures the feasibility study is conducted to mandatory requirements as reflected in the regulatory and institutional standards.
- Confirms the feasibility of the participant population for the study.
- Obtains collaboration and input from a multidisciplinary team to validate clinical operations, relevance and quality of information, and possible sites in future markets.

Knowledge required for competency at this level:

- Working knowledge of the International Conference of Harmonization Technical and Related Regulatory Requirements of Pharmaceuticals for Human Use (ICH) Guidelines for Good Clinical Practice
- Ability to identify the applicable Ethics Board for approval for clinical trials
- Working knowledge of the stipulations of Division 5 of the Food and Drugs Act and Regulations

3.5.2 Project Plan Development

Defines the project execution plan by finalizing the scope, schedule, technical specifications, method of execution, and resources required to deliver a project within schedule and budget.

Competency in this role is demonstrated when the individual:

- Collaborates with the stakeholders to develop the project deliverables, targets, and performance standards.
- Develops the different work process flows related to governance, decision making, reporting, and risk management.
- Uses input from the project content and knowledge experts to compile the work breakdown structure.

- Develops the project schedule and allocates time, resources, and responsibilities to execute the different project deliverables.
- Creates and assembles an Advisory Board.
- Defines the different reporting commitments within the team, suppliers, and stakeholders.

Knowledge required for competency at this level:

- Detailed knowledge of project management systems

3.5.3 Contractor Performance Management

Applies the contract standards and requirements to manage contractor performance, ensuring successful project delivery.

Competency in this role is demonstrated when the individual:

- Ensures all stakeholders and their roles and influence on the project deliverables are understood and defined.
- Delivers agreements that describe responsibilities and terms of collaboration, govern intellectual property rights, and dispute resolution mechanisms.
- Informs stakeholders and ensures compliance to terms and conditions.
- When contractors are breaching the contract terms and conditions, reports appropriately and implements corrective action with assistance of the appropriate disciplines.

Knowledge required for competency at this level:

- Knowledge of contract management

3.5.4 Budget and Cost Management

Applies estimating, forecasting, and project finance principles in order to budget, control costs, and manage cash flow, ensuring the execution of the project within approved budgets.

Competency in this role is demonstrated when the individual:

- Develops detailed budgets, taking into consideration the project scope, resource requirements, limitations, risks, and liabilities.
- Accurately captures, monitors, reviews, and controls project costs and recoveries.
- Develops a cost control baseline by adding escalations and contingencies to address uncertainties.
- Requests and approves reallocations of funds and budget amendments.
- Implements corrective action to reduce cost and correct non-authorized expenditures or late recoveries.
- Identifies anomalies and corrects errors to produce effective cost management reports.
- Initiates timely and effective close-out of project budget after completion with specific reference to warranties and claims.

Knowledge required for competency at this level:

- Knowledge of project budgeting and cost management principles

3.5.5 Project Team Management

Aligns the team members' skills, competencies, and strengths with the project objectives to maintain a cohesive, high-performing team and manages performance to ensure all team members perform work at the expected level of excellence.

Competency in this role is demonstrated when the individual:

- Ensures understanding and alignment of duties, responsibilities, and deliverables for the core project team and representatives of external agencies.
- Balances team members’ competencies to allocate work so that individuals and the team are optimally set up to learn and execute the work.
- Fosters team spirit and collaboration by acknowledging contributions and efforts of individuals to team effectiveness.
- Determines the strengths and weaknesses of the team through performance appraisals and applies corrective action and mentorship where needed to ensure the expected level of performance.
- Applies fair-minded decision-making to terminate or reallocate people who, even after constant support, cannot work and achieve their objectives within the team.

- Identifies development needs in the project team and uses training and development programs to ensure the required competencies within the team.

Knowledge required for competency at this level:

- Detailed knowledge of multidisciplinary expert team management

3.5.6 Risk Management

Completes a thorough analysis of the project conditions, identifying risks and implementing risk management strategies in order to maintain effective project performance.

Competency in this role is demonstrated when the individual:

- Develops an early project risk profile to ensure risk mitigation strategies are built into the project plan of execution and maintains the profile throughout the project lifecycle.
- Educates and coaches project team members on identifying and mitigating potential risks.
- Monitors the results of implemented risk mitigation plans to ensure the effectiveness of corrective action plans.
- Evaluate and understands the insurance requirements, warranties, and maintenance schedules versus potential exposure in order to guide and approve risk mitigation plans.
- Implements prompt and effective risk response initiatives to mitigate the effect of uncontrollable risk incidents.

Knowledge required for competency at this level:

- Knowledge of risk assessment models.
- Understanding of informed consent processes and requirements (ICP)
- Working knowledge of serious adverse event identification and capturing (SAE)
- Detailed knowledge of SAE reporting guidelines and requirements
- Knowledge of applicable safety update reports

3.5.7 Scope of Work Management

Manages the project scope of work by adhering to the clinical trial design and project plan as approved by the applicable Research Ethics Board (REB) and securing required changes as defined in the contracted scope change procedures.

Competency in this role is demonstrated when the individual:

- Communicates the scope of work to all project teams during the project kick-off.
- Identifies deviances and scope creep to the approved project scope and implements corrective action to contain the project to the approved scope of work.
- Ensures the project team and subcontractors are aligned with the approved scope of work, schedule, and budget.
- Implements project-specific processes to capture, facilitate, review, and approve change requests.
- Communicates and documents all approved and rejected changes and ensures the execution of all changes by the project team, subcontractors, and vendors.

Knowledge required for competency at this level:

- Understanding of the restrictions introduced by the funding agents
- Working knowledge of project management principles and an understanding of how scope creep reduces project efficiency
- Ability to identify the applicable Ethics Board for approval for clinical trials
- Thorough understanding of change management practices

3.5.8 Quality Management

Implements repeatable and auditable processes to confirm the data generation and management is done according to the approved standards and good clinical practice guidelines to ensure the quality of clinical trials.

Competency in this role is demonstrated when the individual:

- Develops, implements, and/or follows a consistently applied quality control plan throughout the project to ensure compliance to the clinical trial criteria.

- Ensures implementation of and compliance to standard operating procedures (SOPs), approved protocols, institutional policies, and good clinical practices.
- Ensures that the data generated complies with the specified protocols.
- Confirms that the data collected from case report forms are accurately captured, stored, and transferred.
- Ensures that the data analyzed matches the data collected.

Knowledge required for competency at this level:

- Knowledge of clinical trial quality management models
- Thorough understanding of SOPs used in clinical trials
- Understanding of the different regulations in specific jurisdictions
- Working knowledge of ICH GCP

3.5.9 External Stakeholder Management

Applies the principles of active listening, soliciting of participation, and recognition of contributions in order to ensure all identified stakeholders respond positively to support the delivery of project results.

Competency in this role is demonstrated when the individual:

- Identifies significant stakeholders that can impact the quality of the project deliverables,
- Maintains a level of communication with all significant individuals to ensure they are informed about the project.
- Leverages the energy and the essential skills available within the stakeholder community to support the cost, schedule, and quality objectives of the project goals.
- Ensures that stakeholders' involvement remains focussed on the stakeholder role requirements.

Knowledge required for competency at this level:

- Knowledge and understanding of how people react within larger workgroups within project teams and task teams
- Solid knowledge and understanding of a framework or model that will explain the different team roles for stakeholders in a project

3.5.10 Reporting

Applies the agreed project reporting practices, plans, and schedules in order to inform stakeholders about project deliverables, status, and related information, enabling support and required decision making.

Competency in this role is demonstrated when the individual:

- Complies with the project reporting protocols.
- Confirms that all stakeholders understand their reporting requirements.
- Delivers project progress and financial reports to the project sponsor, manager, and identified stakeholders.
- Ensures that trial sponsors/applicants report any serious or adverse events to the appropriate regulatory agencies.
- Audits and takes corrective action to confirm that reporting is done according to project requirements.
- Reviews all requests for academic publishing and obtains approvals, as required.

Knowledge required for competency at this level:

- Detailed knowledge of the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)
- Knowledge of the different reporting processes and tools as required by Health Canada and appropriate Regulatory Agencies
- Knowledge of project progress reporting and tools

3.5.11 Project Close-Out

Reviews all deliverables, targets, procedures, performance standards, and regulatory requirements to compile, and develops the project close-out procedure and checklist to confirm completion of all project endpoints and obligations.

Competency in this role is demonstrated when the individual:

- Compiles a study close-out checklist and communicates it to all project members for compliance.
- Ensures all study participants are informed of the trial close-out as well as alternative suppliers of support, if required.
- Informs all regulating bodies and ethical committees about the project’s completion.
- Reviews and confirms completion of all data submission and verification.

- Verifies the shipment, long term storage, and/or destruction of applicable biological specimens or pharmaceutical products in compliance with the contract and protocol requirements.
- Audits and confirms all documents and data are finalized, signed off, managed, and/or stored as per the required procedures.
- Ensures financial close-out.

Knowledge required for competency at this level:

- Working knowledge of Canadian Records Management Regulations
- Understanding of the Standards for Electronic Documents and Records Management
- Knowledge of different reporting processes and tools as required by Health Canada and other Regulatory Agencies
- Understanding of the Canada Consumer Product Safety Act requirements regarding preparing and maintaining documents
- Working knowledge of archival and storage regulations

3.6 Industry regulatory competencies list for Pre-Clinical/Clinical Trial Project Manager

3.6.1 Document Management

Establishes and/or follows the document management procedures to enable the identification, safe storage, and retrieval of those documents that individually and collectively permit evaluation of the conduct of the project and the quality of the data produced to confirm compliance with the standards of Good Clinical Practice.

Competency in this role is demonstrated when the individual:

- Establishes a document management procedure at the beginning of the project and a master file that is maintained throughout the project.
- Retains updated and completed documents as required by the relevant institutional and regulatory agencies.
- Manages applicable document security and access control.
- Manages document versions according to regulations.
- Ensures management of personal information complies with privacy regulations.

Knowledge required for competency at this level:

- Working knowledge of ICH E6 Guidance for industry

3.7 Personal and professional competencies list for Pre-Clinical/Clinical Trial Project Manager

3.7.1 Communication

Delivers communication that improves understanding of goals and objectives to capture interest, direct action, and generate support.

Competency in this role is demonstrated when the individual:

- Develops an overall project communications strategy and plan.
- Delivers multi-mode communications that convey a clear understanding, appropriate to the different target groups and situations.
- Manages the flow of information to and from the project team and tests to verify dissemination process and interpretation.
- Creates an organizational chart and lists roles, responsibilities, and reporting relationships to share with project team members and stakeholders in order to facilitate and guide communication within the project team.
- Adapts communications with respect to cultural, educational, and technical levels of the audience.

Knowledge required for competency at this level:

- Knowledge of effective communication models and conflict management

3.7.2 Problem Solving

Recognizes when there is a problem and collects and reviews relevant information to make decisions and implement actions that solve the problem.

Competency in this role is demonstrated when the individual:

- Monitors project workflows to detect deviations and collects information to define problems correctly as they occur.

- Applies knowledge of the skills and competencies in the organization to compile a team responsible for assessing and determining the root cause of the problem.
- Manages conflicts within the team to ensure that diverse views are considered when alternative solutions are generated.
- Consults with the team and chooses solutions that address the root cause that will best contribute to achieving project outcomes in a practical and timely manner.
- Directs and manages the implementation of selected solutions even when unpopular actions need to be implemented.
- Reviews the outcomes of corrective action to confirm the problem is solved.
- Updates procedures and takes action to prevent similar problems from occurring in the future by training/coaching teams regarding the changed procedures.

Knowledge required for competency at this level:

- Knowledge of the roles, responsibilities, and decision-making powers of each of the team members
- Working knowledge of problem-solving tools and techniques

3.8 Essential Skills for Pre-Clinical/Clinical Trial Project 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 Pre-Clinical/Clinical Trial Project 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 evaluation[2].

The ES levels for Oral Communication were developed with reference to the Canadian Language Benchmarks[3]. 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.

Pre-Clinical/Clinical Trial Project Manager ES/CLB Profile

Essential Skills	Equivalent CLB Level	ES Level				
Reading	Reading: 10–11	1	2	3	4	5
Document Use	Reading: 7–8 Writing: 7–8	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				
Writing	Writing: 9–10	1	2	3	4	5
Oral Expression	Speaking: 11–12 Listening:11–12	1	2	3	4	
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 Pre-Clinical/Clinical Trial Project Manager

Reading: ES 4 CLB: 10–11

Pre-Clinical/Clinical Trial Project Managers read and interpret a variety of technical documents such as project plans, contracts, non-disclosure and confidentiality agreements, company policies and procedures, and professional standards (PMI, etc.).They read to gather information from multiple sources to solve problems, inform decisions, and manage their work.

Document Use: ES 3 CLB: Reading: 7–8, Writing: 7–8

Pre-Clinical/Clinical Trial Project Managers access and interpret a wide variety of technical documentation and information in both printed and electronic form. Information can be textual, graphicalal, and/or numerical in format. Locating specific information requires them to recognize and use particular sources, but these sources are generally known and provided as part of their job.

Writing: ES 4 CLB: 9–10

Pre-Clinical/Clinical Trial Project Managers write reports to management to detail the progress of projects and communicate with team members and support staff through a variety of written methods, including email, text or other IM communication vehicles, memos, and written SOPs and directives. They produce written plans and budgets to secure and/or justify support (funding, resources) for specific projects.

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

Pre-Clinical/Clinical Trial Project Managers communicate with stakeholders at all levels of the organization, as well as with external suppliers/vendors, in the course of their duties. They work within an interdisciplinary team, and must be adept at communicating complex technical information to a wide variety of audiences. They contribute to peer forums, provide information to inform the decisions of senior managers and other stakeholders, instruct junior personnel in techniques and technologies, and solicit feedback from project staff and other stakeholders. Additionally, they make presentations to senior management, negotiate with external vendors , providers, and/or clients, and may be called upon to communicate and explain the technical details of projects to non-technical audiences.

Numeracy: ES 4 (Money Math: n/a, Scheduling, Budgeting and Accounting: 4, Measurements: n/a, Data Analysis: 3)

Pre-Clinical/Clinical Trial Project Managers are directly involved in the budgeting process for projects, as well as accounting for expenditures during project execution, conducting earned-value analysis on projects to facilitate billing and invoicing activities, and managing the costs associated with external vendors and suppliers. On sophisticated projects, they analyze data to determine critical paths, allocate and balance personnel and resources, calculate and mitigate variances from project plans, and determine alternative approaches to project execution to ensure variances are minimized.

Thinking Skills:

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**

Pre-Clinical/Clinical Trial Project Managers solve problems related to project execution. These problems have a limited number of variables, and the relationships between these variables is known. There are established processes for solving most problems, but it is up to themto determine which process to follow. Solutions can be evaluated, and once effects are known the Project Managers determine what, if any, additional changes need to be made to minimize variances and bring projects back under control.

- **Thinking Skills — Decision Making: ES 3**

Pre-Clinical/Clinical Trial Project Managers make decisions that can have significant financial repercussions for their organization, such as rescoping and rescheduling work, issuing change orders, requesting engineering changes, etc. These decisions require them to

exercise judgement, and complete and unambiguous information is not always available to support the decision-making process. Reversing these decisions comes at significant cost.

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

Pre-Clinical/Clinical Project Managers' primary function involves the detailed planning and monitoring of the work of many different individuals involved in a project. They have significant discretion over how they spend their own time, and they manage their own work within the constraints of the particular project as well as the established processes and standards of their profession. Resource management and allocation across multiple departments or projects is common, as is rebalancing work when individuals are committed to multiple projects and delays and rescheduling occur.

- Thinking Skills — Finding Information: ES 3

Pre-Clinical/Clinical Project Managers access a number of information sources in their work. These sources include project reports, progress metrics, costing information, and project plans and budgets. The type of information sought and the usual source of that information is generally well known. Information collected is often repurposed, or input into other systems, to support decision-making and on-going project management activities.

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

Pre-Clinical/Clinical Project Managers must memorize, retain, and use 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: 3

Pre-Clinical/Clinical Project Managers utilize standard office productivity software tools (Word processing, spreadsheets, presentations, etc.), electronic communication tools (email, text, instant messaging, video conferencing, etc.) and set up and use specialized project management tools and software in the performance of their duties.

Working with Others: Work Contexts 2, 3 & 4

The following work contexts and functions apply to the Pre-Clinical/Clinical Project Manager role:

- Works independently (Work Context 2)

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

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 off-site 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 Pre-Clinical/Clinical Trial Project Manager profile:

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

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