Clinical Trial Manager

National Occupational Standard Summary

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Definition of occupation| **Clinical Trial Manager**

The Clinical Trial Manager (CTM) works for Clinical Research Organizations (CROs) and/or sponsors and is responsible for the overall management of clinical trials. Duties and responsibilities will vary somewhat between the two types of organizations. Depending on the organization, they may also be referred to as Clinical Study Managers, Clinical Study Leads, Clinical Team Managers, Clinical Operations Leads, Clinical Operations Managers, or Clinical Research Managers.

At a Sponsor organization that employs the services of specialized CROs, the CTM's duties are more focused on providing the necessary oversight to ensure that the statement of work for the clinical trial and all contractual obligations are being followed by the CROs. At a sponsor organization that does not employ the services of specialized CROs, the duties and responsibilities will be broadly similar to the duties at a CRO.

The CTM is responsible for the start-up, implementation, conduct, and close-out of clinical trials. Start-up related tasks include but are not limited to the identification, qualification, and activation of clinical trial sites. The CTM reviews the study protocol and guidelines to ensure that country-specific requirements are properly outlined. The CTM may be accountable for overseeing submissions to regulatory authorities and Research Ethics Boards (REB).

Throughout the study, the CTM is responsible for the study progress (schedule, budget, resources, enrollment targets, etc). The CTM ensures that the study is well-executed by coordinating and collaborating with cross-functional teams and resources, managing external vendors (where applicable), managing risks, communicating with stakeholders, training staff, and resolving issues that arise during any aspect of the study (e.g., drug distribution, enrollment, site-level regulation, technical difficulties, interpersonal conflicts, etc.). Where plans need to be modified, the CTM proposes changes to minimize cost/schedule/scope variances.

The CTM may be responsible for overseeing the work of Clinical Research Associates (CRAs) and is involved in training them, reviewing their work, performing quality control visits, motivating the team, providing constructive feedback, conducting performance reviews, allocating work, and helping them to resolve issues.

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, generally in life sciences, health sciences, nursing, pharmacy, or the equivalent, is the minimum (higher level degrees such as a Masters or PhD are not uncommon)
- Generally, minimum five years of experience working in a clinical trial environment (e.g., clinical trials management, study start-up, clinical monitoring, etc.) is required (for candidates with higher-level credentials, the time required may be shorter)
- Detailed understanding of the operational, regulatory, ethical, and general methodological aspects of clinical trials
- Detailed understanding of Good Clinical Practices (GCP), International Council on Harmonization (ICH), and the regulatory requirements of the countries involved in the trial
- Detailed understanding of Tri-Council Policy Statement (TCPS2) that governs medical human research in Canada
- Understanding of basic medical terminology
- Knowledge of the therapeutic area in which trials are being conducted is an asset
- Project management experience or training is an asset
- Strong computer skills, including electronic data capture (EDC) systems, Clinical Trial Management Systems (CTMS), Interactive Web-Based Response Systems (IWRS), electronic Trial Master Files (eTMF), other Electronic Document Management Systems, and MS-Office products

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

CLINICAL TRIAL MANAGER COMPETENCY SUMMARY

Competencies	Complexity Level Required			
	1 Foundational	2 Operational	3 Specialist/ Manager	4 Expert/ Executive
Core				
Clinical Trial Oversight		■		
Stakeholder Management		■		
Team Management		■		
Technical				
Project Planning		■		
Study Start-up and Site Recruiting		■		
Clinical Trial Monitoring		■		
Clinical Trial Financial Management		■		
Clinical Document Management		■		
Industry Regulatory Competencies				
See note below*		■		
Personal and Professional				
Leadership		■		
Verbal Communication		■		
Written Communication		■		
Teamwork/Collaboration		■		
Problem Solving		■		
Detail Oriented		■		

*Note: due to the nature of the role, and the fact that regulatory and ethical compliance is fundamental to every aspect of the work, the industry panel consulted on this role has recommended that the regulatory components should be articulated for each competency, rather than called out separately in this section

Core competencies

Clinical Trial Oversight
Applies effective clinical trial and project management processes to ensure that the clinical trial is executed in compliance with the protocol and study documents, SOPs, and all regulatory and ethical requirements as well as within acceptable budget, timeline, schedule, and performance requirements.

Stakeholder Management
Applies sound customer service and management practices to ensure internal and external stakeholders' needs and objectives are supported within the constraints of the clinical trial process.

Team Management
Applies effective leadership and people management skills in order to direct and motivate the trial team, ensuring that the trial is conducted efficiently, effectively, and in accordance with all applicable guidelines and regulations, SOPs, and ethical requirements.

Technical competencies

Project Planning
Applies knowledge of clinical trial processes and requirements in order to participate in planning the clinical trial start-up, execution, and close-out necessary to achieve trial objectives with minimal risk.

Study Start-up and Site Recruiting
Applies knowledge of the trial requirements and conducts site feasibility to identify, recruit, qualify, contract, and initiate/activate qualified sites to participate in the trial.

Clinical Trial Monitoring
Applies knowledge of study protocol, regulations, and contractual requirements in order to ensure that site monitoring visits are conducted and discrepancies are identified and rectified so that the trial requirements are met.

Clinical Trial Finanical Mangement

Applies effective project accounting skills to ensure that clinical trials are properly budgeted and expenditures are accounted for, minimizing variances.

Clinical Document Management

Applies comprehensive knowledge of ICH GCP documentation standards and other regulatory and ethical requirements in order to ensure the compliance of all study documentation.

Personal and professional competencies

Leadership

Exhibits personal accountability for outcomes of the trial and provides guidance and support to members of the trial team through encouragement and communication.

Verbal Communication

Applies effective verbal communication processes to present complex technical concepts in a clear and compelling manner that ensures understanding, appropriate action, and project success.

Written Communication

Applies effective writing skills to present complex technical subject matter in a clear and compelling manner that ensures understanding, appropriate action, and project success.

Teamwork/Collaboration

Applies sound teamwork processes to foster cooperation and collaboration across diverse internal and external stakeholder groups, enabling effective and efficient project execution, creative and effective problem solving, and fostering a shared approach to project success.

Problem Solving

Applies knowledge of requirements and uses effective problem-solving techniques in order to identify and quantify issues, understand their root cause(s), develop and analyze possible solutions, consult subject-matter experts and sponsor where appropriate, and select the most appropriate solution in order to resolve problems successfully.

Detail Oriented

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.

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- ✓ Build a job description
- ✓ Plan professional development
- ✓ Map career progression and succession planning
- ✓ Benchmark compensation

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