Seneca POLYTECHNIC

2024-2025

CLINICAL RESEARCH (CRQC)

About the Program

This one-year certificate program, you will learn research design concepts, analysis and the quality assurance required for daily operations in the clinical research field. You will examine clinical studies across the pharmaceutical, medical device and natural health product sectors that give the competitive edge required in this dynamic industry. In this hands-on program, you will work alongside industry professionals and develop a network of contacts ahead of graduation.

Part-time option is available > (http://www.senecapolytechnic.ca/ce/technology/health-care/clinical-research.html)

Credential Awarded

Ontario College Graduate Certificate

Duration

2 Semesters (1 Year)

Starts

January,May, September

Program and Course Delivery

This program is offered online. Students learn remotely and do not need to come to campus. Online learning can be synchronous – scheduled class time with professors – or asynchronous – no scheduled class time, with all learning independent.

Skills

Throughout this program you will develop the following skills:

- Conduct research design concepts
- Analysis and quality assurance of daily operations in clinical trials development process for products such as drugs, medical devices, biopharmaceuticals and natural health products
- Identify the roles and responsibilities of the different positions within the clinical research processes
- Learn to incorporate ethical practices

Work Experience

Optional Work Term

Students meeting all academic requirements may have the opportunity to complete an optional work term(s) in a formal work environment. The work term(s) is similar in length to an academic semester and typically involves full-time work hours that may be paid or unpaid. In programs with limited work term opportunities, additional academic requirements and a passing grade on a communication assessment may be required for eligibility. Eligibility for participation does not guarantee a work position will be secured. Additional fees are required for those participating in the optional work term stream regardless of success in securing a work position.

Review eligibility requirements for work-integrated learning (https://www.senecapolytechnic.ca/employers/seneca-works/work-integrated-learning/eligibility.html)

Your Career

Graduates of the program can explore the following career options:

- Clinical research assistant
- Clinical research associate
- Clinical records associate
- Clinical trials monitor

Affiliations and Associations

- Clinical Research Association of Canada (CRAC)
- Network of Networks (N2)
- Consortium of Academic Programs in Clinical Research (CoAPCR)
- Association of Clinical Research Professionals (ACRP)

Program of Study

Course Code	Course Name	Weekly Hours
Semester 1		
CRP100	Clinical Trial Regulations	3
CRP101	Introduction to Drug Development/ Clinical Trials	3
CRP104	Clinical Study Administration	3
CRP108	Clinical Trial Design and Pharmacology	3
CRP113	GCP - Good Clinical Practice and Ethics	3
PQA712	Introduction to Clinical Quality Assurance	3
TWC714	Technical Writing and Communication I - Clinical Research	3
WTP100	Work Term Preparation *	1
Work-Integrated Learning Term		
CRQ441	Clinical Research, Work Term *	30
Semester 2		
CRP106	Monitoring Clinical Research	3
CRP109	Clinical Research Data Management	3
CRP110	Medical Writing and Clinical Research Project	3
CRP112	Clinical Auditing and Critical Analysis	3

* Work-Integrated Learning option only

Program Learning Outcomes

This Seneca program has been validated by the Credential Validation Service as an Ontario College Credential as required by the Ministry of Colleges and Universities.

As a graduate, you will be prepared to reliably demonstrate the ability to:

- Apply Health Canada and FDA regulations to clinical research.
- Explain the product development process for products such as drugs, medical devices, biopharmaceuticals and natural health products.
- Identify the roles and responsibilities of the different positions (Principle Investigator, Clinical Research Associate, Clinical Research Monitor, Study Participant) within the clinical research process.
- Communicate professionally both orally and in writing within the clinical research environment.
- Create documentation examples that are integral to clinical research.
- Interpret data collected in clinical lab procedures.
- Describe Good Clinical Practices as they apply to different aspects of the Clinical Trial.
- Analyze the principles of quality assurance as they apply all aspects of clinical research.
- Assess the compliance of clinical trial aspects to regulatory requirements (GCP, CLP, GMP).
- Incorporate ethical practices in all stages of the clinical trial.
- Compare and summarize international regulations, clinical requirements and best practices for the clinical research process.
- Design a clinical study for a given drug, medical device, biopharmaceutical and/or natural health product that complies with industry and government standards and protocols.

Admission Requirements

- Post-secondary diploma or degree or equivalent in life sciences, nursing or a closely related field of study. Postsecondary studies must include physical sciences courses such as chemistry and biology.
- English proficiency (https://www.senecapolytechnic.ca/registrar/canadian-applicants/admission-requirements/english-proficiency.html) for graduate certificates

Canadian citizens or permanent residents educated outside of Canada must provide a World Education Services (WES) or ICAS Canada credential evaluation.

Pathways

As a leader in academic pathways, we offer a range of options that will allow you to take your credential further in another Seneca program or a program at a partner institution.

To learn more about your eligibility, visit the Academic Pathways (https://www.senecapolytechnic.ca/pathways.html) web page.

Last updated: July 31, 2024 at 4:13 p.m.