AbSPORU
Alberta SPOR SUPPORT Unit

Leadership in Patient-Oriented Research: Pragmatic Clinical Trials Certificate

2023 Fall Course Outline

Course Description

The Leadership in Patient-Oriented Research: Pragmatic Clinical Trials Certificate is designed to integrate currently available training while providing additional content, learning strategies, and practical application exercises using real-world and Alberta-specific examples. The content has been designed and approved by an Advisory Committee of leading experts in clinical trials in Alberta and is presented in a chronological sequence that is intended to mirror the progression of a clinical trial.

Learning Outcomes

At the conclusion of the certificate program the participants will be able to:

- Employ a common understanding of information required to work on clinical trials in Alberta
- Develop and apply knowledge of specific regulations, good clinical practice, research ethics, and trial management into their own practice
- Identify the resources and structure of clinical trials processes in Alberta
- Identify and integrate POR principles into practice

Certificate Staff

Diane Christensen – Course Coordinator
Program Coordinator, Capacity Development Platform

Dr. Michelle Nelson – Course Preceptor

Chloe Burnett – Course Supervisor
Associate Director, Capacity Development Platform

CIHR IRSC
ALBERTA INNOVATES

Methods of Instruction

The PCT Certificate will take place over 17 weeks in a fully online learning environment, utilizing both asynchronous and synchronous content delivery methods. This is a 48-hour certificate with additional external content integrated into the program. It is anticipated that learners will spend approximately 3-4 hours per week on module content. The time commitment may vary by week as some module content is inevitably slightly heavier or lighter than others and individual knowledge of module topics will vary.

During homework weeks that are composed of external content for completion, the number of hours required to complete this material may exceed the weekly estimate; however, deadlines for submission of this content will allow learners multiple weeks to complete and submit.

Canvas

The PCT Certificate uses Canvas as our learning management system. All content within the course will be housed within this system. If you encounter any difficulties with Canvas, please refer to the Day 1 PowerPoint or contact Diane Christensen.

Zoom

Synchronous sessions will be hosted over the video conferencing platform Zoom. Links will be provided ahead of the session. It is encouraged that learners test their connectivity prior to the session's scheduled start time. All synchronous sessions aside from the Course Introduction day and the Course Wrap-up day will take place from 12pm to 1pm on Thursdays, per the course schedule.

Assessment

The certificate is based on a pass/fail model. This format allows learners to engage with the material, participate in activities, discussions, and assignments as a way to make the content applicable to your work in clinical trials, rather than to meet a designated mark or letter grade. However, learners will be provided with criteria to ensure that they are completing assignments correctly and within the expectation of what is considered a “pass”.

An overall grade of 75% is required to pass the course. Grading schemes may be found in the rubrics section of Canvas. Assignments are due on Sundays at 23:59/11:59pm MT per the schedule.

Participation: 20% of total grade

Learners are required to attend the opening and concluding days of the certificate. These days are September 6 and January 10th, respectively. Any conflicts or anticipated absences must be communicated ahead of time to the course coordinator. A certificate will not be granted if either day is missed with an unexcused absence. To achieve full marks in this category, learners will also need to attend three additional lunch-and-learn

synchronous sessions. These sessions take place on Thursdays for specific modules and are an hour in length, running from 12pm to 1pm MT. A list of synchronous sessions, dates, and topics may be found in the schedule.

Discussion Posts: 20% of total grade

There are four discussion post assignments in this course. These assignments are marked on a complete/incomplete basis. In order to successfully complete a discussion board assignment, you must craft your response to the respective prompt as well as post a reply to another learner.

Group Work/Case Studies: 20% of total grade

At the beginning of the course, you will choose a case study topic and complete assignments within a group of 5-6 other learners. For each assignment you will apply what you are learning to the Case Study scenario and design strategies for patient-oriented research at each stage. Review the presentation materials, resources, and literature summaries to design the POR/PE component of each assignment.

Final Presentation: 30% of total grade

The final presentation is a group presentation that summarizes your group assignments and discusses one topic to address in further detail. Groups will be expected to describe how they would approach the activities utilizing both POR strategies and clinical trials processes/regulations as discussed throughout the certificate.

External Content: 10% of total grade

External content acts as a supplement in this course and takes the form of Proof of Completion submissions. Alongside the two prerequisites for this course, there are three other external modules to be completed throughout the duration of the course.

Communication

Communication will primarily take place through Canvas in the form of course announcements. Canvas also has a messaging system built in which we encourage you to use in lieu of traditional email.

Be mindful of writing style and be respectful in online interactions. Be aware when reading posts that social cues of vocal tone and body language are absent; to avoid misinterpretation or assumptions, we encourage an open environment where learners can ask for more information, request clarification, or demonstrate an opposing view in a respectful manner.

AbSPORU
Alberta SPOR SUPPORT Unit

Course Schedule

Below is an outline of the live sessions and assignment schedule. This schedule is subject to change; learners will be notified of any adjustments.

Week	Module Title	Synchronous Content	Assignments	
1 *Sept 4 - Sept 10*	Introduction	Introduction to the Certificate *Sept 6, 10am - 3pm MT*	Sept 10	TCPS-2 CITI Canada: GCP Introduction
2 *Sept 11 - Sept 17*	External Content			
3 *Sept 18 - Sept 24*	Investigator/Industry Protocols and Minding the Gap	Mind the Gap: What is so important about being pragmatic? *Sept 21, 12pm - 1pm MT*	Sept 24	Health Canada Div 5 Ethics Overview
4 *Sept 25 - Oct 1*	HIA and FOIP		Oct 1	AHS: Health Info Act FOIP: Focus on Privacy
5 *Oct 2 - Oct 8*	Legal Considerations for Clinical Trials		Oct 8	GCP/ICH Review
6 *Oct 9 - Oct 15*	Privacy Issues in Health Research	Privacy Issues in Health Research *Oct 12, 12pm - 1pm MT*		
7 *Oct 16 - Oct 22*	Delegation Logs and Training	Delegation Logs & Training *Oct 19, 12pm - 1pm MT*	Oct 16	PE Lit Review
8 *Oct 23 - Oct 29*	Introduction to the Clinical Trials Management System	Introduction to the Clinical Trials Management System Q&A *Oct 26, 12pm - 1pm MT*		
9 *Oct 30 - Nov 5*	Planning and Designing a Budget	Planning and Designing A Budget: Industry Sponsored Trials *Nov 2, 12pm - 1pm MT*		
10 *Nov 6 - Nov 12*	Recruitment and EDI	Recruitment *Nov 9, 12pm - 1pm MT*	Nov 12	Budget Preparation
11 *Nov 13 - Nov 19*	Informed Consent		Nov 19	Recruitment Plan

12 *Nov 20 - Nov 26*	Data Collection Tools and SGBA+	RedCap Workshop *Nov 23, 12pm - 1pm MT*	Nov 26	Informed Consent
13 *Nov 27 - Dec 3*	Investigational Product Handling and Accountability			
14 *Dec 4 - Dec 10*	Reporting Requirements: Protocol Deviation & Adverse Events	Reporting Requirements: Protocol Deviations & Adverse Events *Dec 7, 12pm - 1pm MT*		
15 *Dec 11 - Dec 17*	Maintaining Documents for Audit & Inspections		Dec 17	Protocol Deviations
WINTER/HOLIDAY BREAK				
16 *Jan 2 - Jan 7*	Final Reporting, Archiving & Closing Accounts		Jan 7	Final Presentation
17 *Jan 8 - Jan 14*	Course Wrap-up	Course Wrap-up *Jan 10, 10am - 12pm MT*		