Clinical Trials BC Educational Programming

Updated December 2022

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1. About Clinical Trials BC

We support clinical trial investigators, sites, and institutions to ensure a world-class destination for clinical trials.

Focusing on infrastructure and capacity building with a collaborative approach, we enable clinical trial excellence across British Columbia.

Our mission is to maximize the health, educational, and economic benefits of clinical trials to the citizens of British Columbia. We support the institutions, sites, and investigators running trials to do so more efficiently and meet applicable regulatory requirements in one of the most regulated areas globally.

Clinical Trials BC provides province-wide support and access to a range of training, guidance, and resources for clinical research personnel. With a robust educational program, we help British Columbia grow a clinical research workforce with the required skills, knowledge, and training to conduct world-class clinical trials.

Check out our education and training offerings, resources, support, and professional development programs below. You can book us to deliver lectures and workshops at your site/institution or suggest topics that suit your group's training needs.

Contact information and how to book for our education sessions

2. Lectures and Workshops

2.1. Core

Introduction to the Canadian Regulatory Environment

Clinical trials are prospective studies on human participants designed to answer specific questions about biomedical or behavioral interventions, including new treatments and known interventions that warrant further study and comparison. This introductory subtopic provides an overview of the current Canadian regulation structure revealing the influencers on our regulations as they change in the renovation and modernization. The regulations and supporting guidelines, and standards as they apply to the main product sectors are outlined.

The ICH E Family

This introductory module describes the ICH structure and provides an overview of the key and current ICH guidelines relevant to clinical trial conduct: ICH E2A, E3, E7, E8, E9, E11, and E17. Additional ICH guidelines can be added for specialized groups.

E6 Good Clinical Practice Introduction (GCP)

The ICH GCP guidance document is the international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. The document principles have their origin in the Declaration of Helsinki. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected and that the clinical trial data are credible. GCP is incorporated into the Canadian Clinical Trial regulations and is cross-referenced in all of the Canadian guidances for clinical trials across product lines.

E8 General Consideration in Clinical Studies

E8(R2) is the core international Clinical Trials document and foundation of regulations internationally. It was originally implemented in Canada in 1997 and the new version was updated in 2022 as one of the first steps in the modernization of clinical trials. This subtopic highlights content in three areas: the accepted wider range of both study designs and data sources that play a role in drug development, the critical approaches for optimizing study quality which promotes the reliability and efficiency of trials, and thirdly, the advanced patient focus of clinical trials. Introduction to quality by design requirements, identifying the factors that are critical to the quality of a clinical study, and ensuring that risks are proportionate while protecting human subjects and ensuring the reliability of study results are features of this session (1.5-hour lecture).

Good Documentation Practices (GDP)

This is our most popular core course and is essential for all new team members. GDP is the systematic procedure for preparing, reviewing, approving, versioning, recording, storing, and archiving of any research document. This workshop, the second in a series, covers the main components of documentation recording including ALCOAC practices. Common findings and difficult documentation situations will be discussed. Group activities and exercises are included to provide experience and examples of recording practice expectations.

E17 Multi-Regional Clinical Trials (MRCT)

The ICH harmonized guideline was finalized in November of 2017 and implemented in Canada in April of 2019. This guideline provides guidance on general principles on planning and designing multi regional clinical trials. Drug development has been globalized and MRCT for regulatory submission has widely been conducted in ICH regions and beyond. This harmonized international guideline promotes conduct of MRCTs appropriately especially focusing on scientific issues in planning designing MRCTs. The E17 guideline is accepted by multiple regulatory agencies including the members of the ACCESS consortium.

2.2. Advanced

Introduction to Procedural Deviation Management

This is a lively presentation and discussion on *Deviations.* This is a look at deviations from the system level, general processes, and policy through the lens of quality, compliance, and the site research team (1-hour presentation and discussion).

Risk Management 1

Risk management is a part of quality management. This presentation/workshop covers the common nomenclature, principles of risk, simple risk models, grading and mitigation exercises, development, use of risk plans, and risk log activities. Available are "Clinical Trials BC Version 3" supporting tools, resources, and SOPs along with other out-of-province resources to help get you started (2-hour workshop).

Risk Management 2

Managing risks on projects is a process that includes risk assessment and a mitigation strategy for those risks. A risk management plan is designed to eliminate or minimize the impact of risk events or occurrences that may have a negative impact on the study. Identifying risk is both a creative and a structured process. This session involves a guided brainstorming session where the team is asked to identify everything that could go wrong at the site or study level. All ideas are welcome! We then assist your team in starting the development of the site/program-level risk management plan (3-hour small group workshop).

Critical To Quality Factors

The ICH E8(R1) 'General Considerations in Clinical Trials' document ties Quality with Trial conduct and ICH E6(R2) 'Good Clinical Practice'. Critical Quality Factors should be determined for each study. Risks that could impact those Critical to Quality Factors should also be identified. This session covers introductory materials for CtQ basics and application at site and institution level (1-hour lecture).

Quality by Design

Have you wondered what quality in clinical trials really means? The ICH E8(R1) presents us with current concepts to achieve 'Fit for Purpose' data quality as an essential consideration for all clinical trials. The quality of the information generated should be sufficient to support good decision making. It is preferable to build quality into a study and site plan over implementing quality control measures at the site after the fact. This advanced planning is known as Quality by Design. Join us for an introduction to basic QbD concepts (1-hour lecture).

Corrective and Preventative Actions (CAPA)

What do you do with internal site deviations and investigation outcomes requiring follow-up? What is required for follow-up after a site audit or inspection? What are the new GCP E2(R2) site requirements around CAPA? This 2-hour workshop will cover the CAPA regulatory history and requirements, CAPA's central place in the Quality Management System (QMS), sample observations and investigation outcomes needing a CAPA evaluation, CAPA Response Plans and basic CAPA writing. Activities include interactive lecture, group CAPA writing, and group discussion on common BC observations.

Equipment Management and Calibration

This workshop covers Good Manufacturing Practice (GMP), quality management systems and process requirements necessary to satisfy regulatory and industry expectations related to calibration and equipment maintenance, which runs through all product lifecycles. The key components of effective equipment management will be discussed. Groups will have the opportunity to participate in exercises to develop tools to support equipment management for their site. Handouts are included.

Quality Management System (QMS) Overview

Clinical Trials BC's Quality Management System (QMS) is a set of interrelated or interacting systems to direct and control how the quality policies will be implemented and how quality principles and objectives will be achieved. Attend this presentation for an overview of the QMS, its subsystems, and discover why it is important to have a QMS in place (1-hour lecture).

Patient Input and Stakeholder Engagement in Clinical Trials

ICH E8 (R1) describes how consulting with patients and/or patient organizations in the design, planning and conduct of clinical studies helps to ensure that all perspectives are captured. Learn about the general considerations described relevant to patient and other stakeholder engagement and available resources (1-hour lecture).

Compliance Regulatory Influencers, Trends, and Predictions

Compliance with clinical trial regulatory requirements includes ongoing review of set study compliance indicators and an up to date understanding how the regulations are interpreted and applied. This 2023 version highlights current influences, regional and global findings, and compliance trending. This information is used to predict what regulatory agencies and industry care about, what the areas of crackdowns may be, and where shifting resources may be going (1-hour lecture).

Clinical Research Professional Career Advancement

Clinical Trials BC is offering this session as a response to the changing professional requirements resulting from industry change. If you are new to clinical research, working in this area for at least a year and wondering how to further your continuing education or even become certified, this session is for you.

We will cover a variety of education and training options available in BC. Certifications presented will be relevant to all team members responsible for performing study related tasks or oversight for the conduct of a clinical trial at the site level, including the investigator. We will also examine the core competency guidelines for coordinators and investigators and provide details on funding available for certification.

Format: 60-90 minutes. Presentation and workshop formats available.

3. Programs and Courses

3.1. Audit and Inspection Preparedness Program (AIPP)

Compliance to international standards, governmental expectations expressed in regulations and guidelines, granting agency policies, and industry expectations all lead to thorough and rigorous external auditing and inspection processes. The AIPP is a positive first step in to improve compliance. This 7-module course offers a variety of interactive exercises related to preparations, hosting and follow-up of a system-based inspection or audit. The modules expose participants to some of the essential elements of compliance. Research staff members become comfortable with the audit and inspection process when their identified greatest fear has been addressed. The course provides handouts and tools for use and reuse in inspections and audits.

Workshop #1 – Advance Preparation: Be Prepared: From Notice to Knock

This workshop focuses on how to prepare for an upcoming audit or inspection once you have received notice. The session covers: unit, staff, and document preparations along with other useful tips to make sure you are ready when the auditor knocks on the door. The session differentiates between preparing for a qualification audit, sponsor/REB audit and inspection. Activities include interactive lecture, review of specific checklists and preparation plans, and role play.

Workshop #2 – Interview Techniques: Inspection Interview Responses

Auditors get the information they need by reviewing documents and by using a variety of interview techniques. Learn how to effectively respond to general questioning and how to prepare answers in advance for a system-based inspection. This workshop is ideal for personnel who will be hosting an audit or inspection and for staff that will be interviewed. Content includes on site versus remote interviews, general responses, and rules, systems-based, risk-based and QQ techniques. In-person workshop consists of mock audit activities and role play.

Workshop #3 – Hosting Skills and Audit Conduct: The Do's and Don'ts & Exit Meeting

This is a core workshop on hosting and conduct during an audit or inspection from the opening to the closing meetings, and to the exit meeting. Additionally, learn about audit decorum in this workshop. This session is recommended for all staff. The exit meeting is normally the final opportunity for face-to-face communication with the auditor or inspector. Learn how to effectively prepare, take notes, respond to findings, provide feedback, clarify, correct, and negotiate CAPA at this critical meeting. In-person workshop activities include demonstrations, role play, mock audit exercises. The virtual version is in interactive lecture format.

Workshop #4 – Document Handling: Control of Documents

Do you work in a confined, small, or shared workspace? Imagine having to process and handle 300 to 1,700 documents during an inspection. This is a very hands-on, fun training team-based workshop presented in mock audit format. It is a core session on control skills to classify, track and manage the flow of requested documents during and after an inspection. This is a key workshop for remote and hybrid inspection and audit. In-person workshop activities include mock inspection, and role play.

Workshop #5 – Mini Mock Audit

This workshop brings together your skills and experience from the first four workshops. Have your team participate in a mock audit/inspection. You will receive a notice of inspection, preparation guidelines, an on-site inspection/audit, or a hybrid audit along with and an exit meeting. Book your half-day or full-day mock audit. There are limited sessions available per term. Activities include mock inspection and role play.

Workshop #6 – Follow-Up Activities: The Post Audit 5 C's

What is required for follow-up after an audit or inspection? This session covers the five C's: Common Findings in Audit/Inspection Reports, Classifications of findings, Clarifications, Corrections of report findings, and effective CAPA and response writing. Activities include interactive lecture, exercises on classification, CAPA writing, and development of formal responses.

Workshop #7 – AIPP Program Refresher

Do you have an upcoming inspection? Are you still prepared? What is required for a virtual or hybrid inspection? Most regulatory agencies have moved towards online, or online and onsite combination inspections. This 1.5-hour zoom session covers the elements to consider in preparing for inspection, conduct and communications during a virtual or hybrid inspection. Activities include interactive lecture, exercises, and a group discussion and question period.

Certificates will be issued for the sessions attended. Some workshops may not be available for on-site presentation.

3.2. Quality Leadership Program

The Quality Leadership Program was established in 2017. It has been modified and is now in version 2. It is presented as a series of 8 small group sessions in Zoom meeting format. The program introduces preliminary quality concepts and principles and presents overall quality and risk management systems. It is targeted to new Quality Associates (I or II) or designated quality personnel involved in the implementation of Clinical Trial BC's Quality Management System (QMS) program into institutions.

The course will be run over three months from March to May 2023. Attendance is limited and is by application. Registration will open in January 2023.

Learn more and how to register

## 3.3. Quality Management System (QMS) Program

This training program was established by BCCRIN in 2012. It has been modified and is now a Clinical Trials BC's program (version 6). A full-complement QMS with nine systems is available for programs, centres, and institutions within British Columbia. Risk management components are embedded into the quality systems.

Each system includes SOPS, policies, forms and other supporting documents and trackers are customized to fit each institution/instance and the systems. QMS development plans and manuals are prepared with each institution/program along with extensive quality leadership training, conferences, and meetings for implementation and ongoing support.

Clinical Trials BC personnel supports provincial integrated and ongoing quality initiatives and activities for institutions developing quality program. Sessions are run annually with ongoing support. Participation in the Quality Leadership Course and/or Quality Community of Practice is recommended.

4. ASK US Series
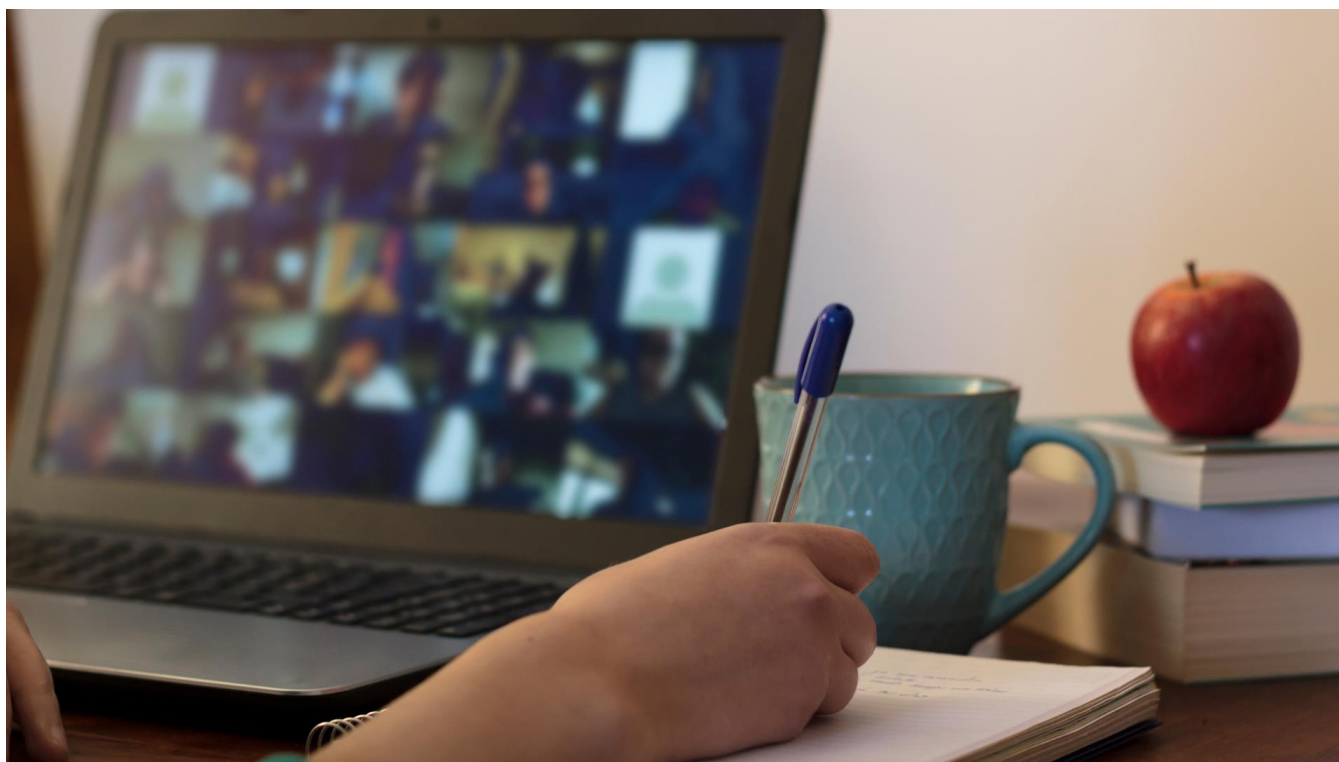
4.1. ASK US Web Shows

The Clinical Trials BC's ASK US Web Shows runs seasonally each year with a summer hiatus. For every "episode", we present on a hot topic question that has come from the BC clinical trials research community. The numbered episodes are hosted and produced by Clinical Trials BC. We present in a variety of formats often with guests or a panel. The content targets key points related to the topic with animated discussion or provoking and thoughtful comments. The web shows are designed to fit into a short noon session. Bring your lunch!

Sessions will be announced in our newsletter and on our calendar of events.

View the recordings of previous relevant ASK US's episodes

4.2. ASK US Forums

The ASK US Forums has been popular since 2011. You can book an ASK US HOT TOPIC session or ASK US ANYTHING session for your own institution and we will do our best to answer your questions.

Contact us

5. Clinical Research Professional Career Development

5.1. Clinical Research Professional (CRP) Certification Program

Achieving certification demonstrates that you have met or exceeded the quality standards required in the industry and have validated your competence. Certification also demonstrates a level of professionalism and indicates a commitment to conduct clinical trials in a safe, ethical manner, and to the standard that is internally recognized.

Clinical Trials BC supports clinical research professionals working at BC academic-based or health authority-affiliated research sites to become certified by the Society of Clinical Research Associates (SoCRA) or the Association of Clinical Research Professionals (ACRP).

For 2023, Clinical Trials BC will offer a partial reimbursement in the amount of **$400** towards CCRP or CCRC examination fees for successful applicants who work for academic health research organizations (health authority, university, non-profit). Funding is available for up to **20 successful applicants**.

Learn more about the program and the reimbursement process

Exam Preparation Sessions

We will be hosting a series of 5 virtual exam preparation sessions in January and February 2023. This series will set you up for exam success and professional designation.

Learn more and register for each of the sessions

Contact us for the recordings of the sessions

Exam Preparation Support

To help you prepare for your certification exam, Clinical Trials BC has put together a bundle of resources, including recordings of a series of consecutive informal exam preparation sessions, practice tests, and access to the **Clinical Research Professional Certification Exam Study Prep** electronic Community of Practice (eCoP) where you can find useful links, recordings, presentation slides, and documents that you can use to help prepare for your exam.

Contact us for access to the eCoP

6. Partnered Training and Resources

6.1. Network of Networks (N2) Resources & CITI-Canada Courses

Clinical Trials BC provides province-wide access to best-in-class tools and resources from the Network of Networks (N2), focused on enhancing clinical research capability and capacity. N2 benefits and courses are available for clinical researchers working in health authorities and academic organizations in BC, as well as for some independent investigators. One of the highlighted benefits of N2 membership is the access to an array of CITI-Canada Program's courses on a variety of research related matters.

The Collaborative Institutional Training Initiative (CITI) training courses, recognized by TransCelerate, are part of an extensive, trackable, and accredited online training program customized for the Canadian clinical research infrastructure.

Access

Each member organization has a designated lead administrator who provides access to N2's resources to their affiliated clinical health researchers or sites.

View the member list

Do you have questions on the BC provincial membership? Or do you need the contact information of the administrator at your institution?

Contact us

For all other questions and CITI-Canada course access:

Contact N2

CITI-Canada Course Listing

- Good Clinical Practice (GCP)
- Health Canada Division 5
- Clinical Research Coordinator (CRC)
- Responsible Conduct of Research (RCR)
- Transportation of Dangerous Goods (TDG)
- Biomedical Research Ethics

Note: Both Division 5 (if you are working with pharmaceuticals, biologics, or radiopharmaceutical products) and GCP training are encouraged after orientation and institutional introductions and before working on a clinical trial. If you are working in a specialized area (i.e. medical device, controlled substances, cannabis), additional documented training is required.

More information on the courses

6.2. ACRP Learning Management System (LMS)

This e-learning platform offered by the **Association of Clinical Research Professionals** (ACRP) is available free of charge to any clinical research professional in BC.

ACRP's e-Learning catalog of 20+ programs offers learners working at clinical research sites in BC a wide variety of training topics on essential components of quality clinical research, with varying intensity levels appropriate for the topics being addressed. This includes training on the new ICH GCP E6(R2), the international industry standard for designing, conducting, and reporting clinical trials.

These programs are designed to ensure that clinical research teams have the training they need to conduct responsible research, minimize risk, and increase efficiency and effectiveness. All courses were developed using modern adult learning principles proven to be effective in enhancing performance.

Since our partnership began, more than 300 BC researchers have signed up for access to the ACRP LMS. We continue to encourage the BC research community to register and complete courses.
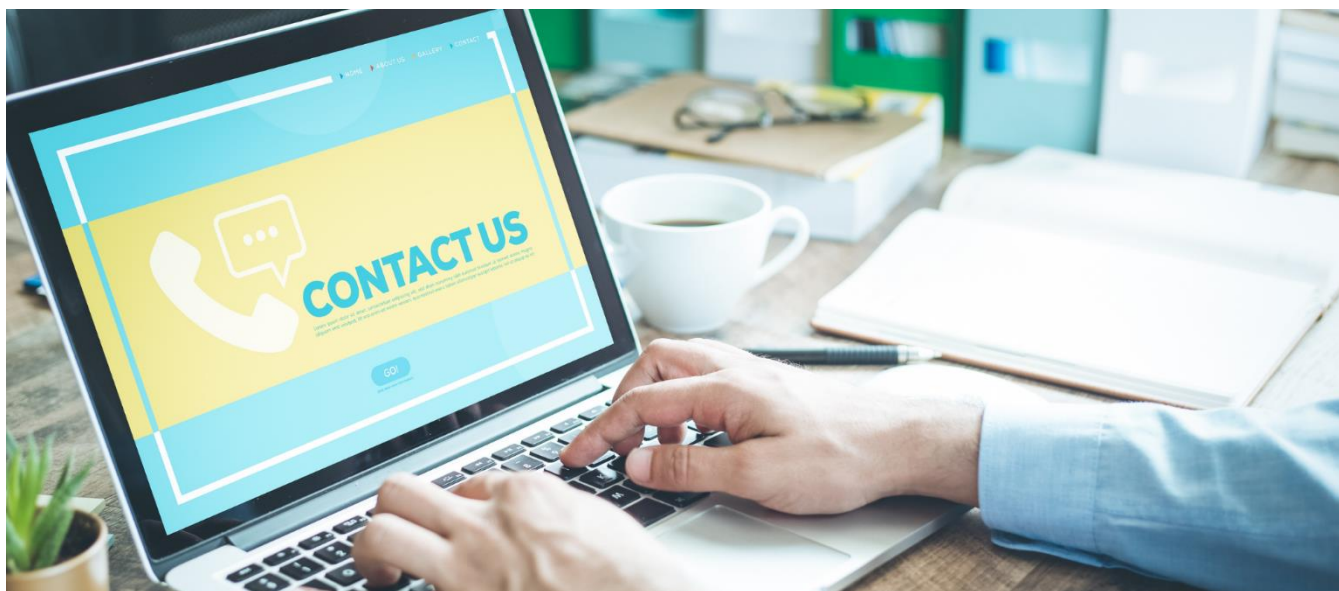
Log in to the ACRP LMS

Access

If you're a new user, you can gain access by contacting us at clinicaltrialsbc@healthresearchbc.ca. Simply send a request along with your first and last name, email address, and research location. Instructions on how to log in and begin training will be provided within one week.

7.   Contact Clinical Trials BC

How to Book a Session at your Organization or Site

If you want to book the above lectures and workshops or have any questions about our education and training offerings, email us at clinicaltrialsbc@healthresearchbc.ca. Please note that some sessions are in-person, virtual, or hybrid format.

General Contact Information

Clinical Trials BC is part of Michael Smith Health Research BC.
For more information, please contact us with the following information:

Address: Suite 200, 1285 West Broadway, Vancouver, BC V6H 3X8
Phone: (236) 521-2064
Website: clinicaltrialsbc.ca
Email: clinicaltrialsbc@healthresearchbc.ca
Twitter: @ClinTrialsBC
Linkedin: linkedin.com/company/clinical-trials-bc

Topic Suggestion

You can suggest topics that we might consider delivering to your institution or research site team members. Please make the suggestions by filling out a short survey with the link below.

Submit topic suggestion