



Michael Smith

**Health
Research BC**

CLINICAL TRIALS BC



CLINICAL TRIALS BC EDUCATIONAL PROGRAMMING

Updated November 2021

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Lecture & Workshop Series

Feature Lectures

E8(R1) – General Principles in Clinical Trials **New ***

The original version of E8 was adopted in Canada in 1998. Since then, there have been significant changes in four main areas. There is a much wider range of both study designs and data sources that play a role in drug development. The approaches for optimizing study quality which promotes the reliability, efficiency, and patient focus of clinical trials have advanced. We are much more apt at identifying the factors that are critical to the quality of a clinical study, ensuring that risks are proportionate while protecting human subjects and ensuring the reliability of study results. Attend this presentation to brush up on the changes to this core ICH document, which is the foundation of the ICH efficacy group. (1.5-hour lecture).

Learning Objectives

The learner will be able to:

- Describe internationally agreed-upon principles and practices to facilitate regulatory acceptance
- Understand the elements of quality that are considered in the design and conduct of clinical studies, including:
 - Identification of factors critical to the quality of the study
 - Management of risks to those factors during study conduct
- Identify the types of clinical studies performed during the product lifecycle
- Be familiar with the ICH Efficacy Family of Guidelines

Risk Management Workshop - Part 1

ICH E6 (R2) has been approved in Canada and in full effect as of April 1, 2019. It includes the requirements for risk management as 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 2” supporting tools, resources, and SOPs along with other out-of-province resources to help get you started (2-hour workshop).

Learning Objectives

The learner will be able to:

- Conduct basic risk identification and mitigation strategies
- Identify the site training requirements associated with implementation of risk management
- Understand the impact on the site or program
- Identify access points for readily available resources



Risk Management Workshop - Part 2 **New ***

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 the risk events – 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).

Learning Objectives

The learner or team will:

- Identify the common study or site-specific risks
- Participate in the risk management planning process for a study or site
- Use of the tools and resources available to start the development of a site or study risk management plan

Parts 1 and 2 can be done in a one-day combination with advance booking.



Learning from the Canadian Clinical Research Participant Experience

The Canadian Clinical Research Participation Survey led by Clinical Trials BC aimed to engage and learn from 1,000 patients and study volunteers about their experience with clinical trials. This presentation/workshop will be of interest to clinical research investigators, coordinators, nurses, and recruitment team members. Trial sponsors, CROs and SMOs will also hear valuable feedback to inform their programs. Patient groups may be interested in learning about these findings.

(1-3 hours – presentation, workshop, forum or webinar options, or 1-hour pre-recorded webinar)

Learning Objectives

The learner will be able to:

- Describe Canadians attitudes and beliefs about clinical trials
- Identify study design elements that may reduce or are barriers to participation
- Understand the influence of cohort demographics on participation decision making
- Identify areas that could improve the participant experience in clinical trials



Regulatory Environment: Influences, Changes and Trends 2022 **New ***

There is a lot going on this year! Part of ongoing compliance with regulatory requirements includes understanding how the regulations are interpreted. Keeping abreast of the influences, global findings and trends is the best way to determine what regulatory agencies and industry care about, what the areas of crackdowns may be and where shifting resources may be going. This session presents:

- Major influences from the last two years, with takeaways tips on what to expect or watch for (based on new ways of conducting trials virtually, new programs, new and interim regulations, and new technologies or initiatives)
- Top 10 Trends: The focus and problem areas over the last two years with compliance initiatives to prevent or avoid them
- Current findings from the most influential regulatory agencies and Canada with a global summary

Learning Objectives

- List the major influencers on compliance
- Identify the top trends and problem areas
- Understand the impact of the current findings on practice



Clinical Research Professional Career Development

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, as developed by ACRP, and provide details on funding available for certification.

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

Investigators Training Program (ITP)

Clinical Trials BC will be hosting the new version of the internationally recognized Investigator Training Program (ITP). The date(s) for this course will be announced. The course is targeted to new investigators.



Special Site Quality Series

In response to the approval of the ICH E8R1 document on General **Considerations** in Clinical Trials' we have put together a special series with content on quality from our other programs. The series will run from November 2021 to April 2022. The following topics will be presented for site level interest. Institutional level quality content for implementation will still be covered in the Quality Leadership Program Course. For the dates and registration of this special series please visit the Clinical Trials BC Events page [here](#)



E8(R1) EDUCATIONAL SESSIONS

November 2021 - March 2022

Location: Zoom Webinar
Institutional Booking Available

Educational Sessions

E8(R1) General Considerations in Clinical Trials

The original version of E8 was adopted in Canada in 1998. [On October 6, 2021, E8R1 was approved by the ICH](#). There have been significant changes in four main areas. Attend this presentation to brush up on the changes to this core ICH document, which is the foundation of the ICH efficacy group (1-hour lecture).

Target group

General research teams

Pre- requisite

None

Learning Objectives

The learner will be able to:

- Describe internationally agreed-upon principles and practices to facilitate regulatory acceptance.
- Understand the elements of quality that are considered in the design and conduct of clinical studies, including:
 - Identification of factors critical to the quality of the study.
 - Management of risks to those factors during study conduct.
- Identify the types of clinical studies performed during the product lifecycle.
- Be Familiar with the ICH Efficacy Family of Guidelines.

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. SQAS based adaptable systems include Quality manual, Standard Operational Procedures, forms, logs, and other supporting quality documents. Attend this

presentation to have an overview of the QMS, its subsystems, and why it is important to have a QMS in place (1-hour lecture).

Target group

Quality managers, quality specialists, senior coordinators, research directors.

Pre- requisite

None

Learning Objectives

The learner will be able to:

- Identify elements of the QMS
- Understand the relationship of QMS to Quality and Risk requirements
- Be familiar with Quality related terms and nomenclature

Risk Management

ICH E6R2 has been approved in Canada and has been in full effect as of April 1, 2019, and includes the requirements for risk management as part of quality management. Risk Management ties in with the new E8R1 document on 'General Considerations for Clinical Trials' making this a must know area. This presentation covers the common nomenclature, principles of risk, simple risk models, grading and mitigation exercises, development, use of risk plans and risk log activities. Available "Clinical Trials BC Version 2" supporting tools, resources and SOP are identified along with other out-of-province resources to help get you started (1.5-hour lecture).

Target group

Research teams, program/site managers.

Pre- requisite

None

Learning Objectives

The learner will be able to:

- Conduct basic risk identification and mitigation strategies.

- Identify the site training requirements that will be associated with implementation of risk management.
- Understand the impact on the site or program.
- Identify access points for readily available resources.

Introduction to Critical to Quality Factors

The ICH E8R1 'General Considerations in Clinical Trials' document ties Quality with Trial conduct and ICH E6R2 '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).

Target group

Intermediate level research team staff and QA personnel.

Pre- requisite

Risk Management training is helpful but not necessary.

Learning Objectives

The learner will:

- Recognize key terms associated with CtQ
- Describe the process of identification to review of CtQ
- Understand the relationship of CtQ with risk
- Identify some common CtQ for a site

Patient Input & 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).

Target group

Intermediate level research team staff, recruitment, or patient engagement specialists

Pre- requisite

None – Intro to ICH E8 (R1) is helpful

Learning Objectives

The learner will:

- Recognize how patients can help identify the Critical to Quality Factors
- Describe the various stakeholders who should be engaged in study design
- Understand the value that appropriate and early consultation with patients has on feasibility
- Know how to locate resources to support effective engagement

Introduction to Quality by Design

Have you wondered what quality in clinical trials really means? The ICH E8R1 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 advance planning is known as Quality by Design. Join us for an introduction to basic QbD concepts (1-hour lecture).

Target group

Intermediate level research team staff and QA personnel

Pre-Requisites

CQI or CAPA training is helpful but not necessary

Learning Objectives

The learner will:

- Recognize basic terms and terminology related to 'Quality by Design'
- Understand the principles of QBD and association with continuous quality improvement.(CQI) and risk management (RM) at the site level
- Will recognize the shift from quality control (QC) to CQI

ASK US Series

ASK US WEBSHOW

The Clinical Trials BC's **ASK US WEBSHOW** 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. 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.

ASK US FORUMS

The ASK US Forums has been popular since we started them at BCCRIN (One of Clinical Trials BC's predecessors) beginning in 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. These sessions are currently available in online format.

SEASON 2 - 21/22

CLINICAL TRIAL AUDIT & INSPECTION PREPAREDNESS:

"ARE YOU STILL READY?"

MODERATOR: JEAN SMART - CLINICAL TRIALS BC REGULATORY AFFAIRS & QUALITY OFFICER

Alison Drummond - Syreon Corp
Quality Assurance Manager

Karen McGillivray - BC Cancer
Quality Assurance and Process Improvement Specialist

Sasha Pavlovich - VCHRI
Clinical Research Quality Assurance Specialist

TUESDAY, SEPTEMBER 28, 2021
12 P.M - 1 P.M PACIFIC TIME
ZOOM WEBINAR

ASK US SERIES

Clinical Trials BC
British Columbia Academic Health Science Network

Video thumbnails (top to bottom): Karen McGillivray, Sasha Pavlovich, Alison Drummond, Jean Smart

Ask Us Forum Topics

- ASK US Anything! - Open forum. Always offered. We are in the hot seat.
- Introduction to Quality by Design – what is QbD? How does it relate to E8R1 and E6R2 and the site? **New ***
- Introduction to Critical to Quality Factors – What is CtQ? How does it link to ICH E8, risk management and the site? **New ***
- ICH E17 Multi-Regional Clinical Trials (MRCT) – What is all the buzz and how does this link with ICH E5?
- Quality Management Systems Overview – What is QMS and how does it work at a site?
- Clinical Trial Participation – Barriers and Facilitators.
- Training and Qualification Basics – What are the core and recommended training requirements for a site, and where are the resources?
- Where do I go from here? CT Professional Development Opportunities and Workplace Advancement.

Sessions will be announced in our newsletter and on our calendar of events. Alternatively, you can contact us to request or book a general session for your group.

To view the recordings of previous ASK US Series webinars. Please follow the link below:

[Click here](#)

Clinical Trials Introductory Training

We have an introductory set of training materials for new researchers, new research team members and new supporting personnel. The training program includes training modules and supporting materials on a Clinical Trials BC eCoP (Electronic Community of Practice). Please contact us at clinicaltrialsbc@healthresearchbc.ca for access.

The modules include:

- Regulatory Introduction (Canadian regulatory environment, Historical Documents).
- Core ICH (E6-Good Clinical Practice, E8-General Considerations in Clinical Trials, E17-Multi-Regional Clinical Trials).
- Research Teams (Roles and Responsibilities, Training and Qualifications).
- Records (Essential Documents, Good Documentation Practices).
- Special Topics (Safety, Investigational Product, Data).

These modules include access to supporting reference documents, condensed notes, recorded sessions, slides, and self-quizzes.

For more information about access to the eCoP, please contact us at:

clinicaltrialsbc@healthresearchbc.ca

Audit & Inspection Preparedness Program (AIPP)

This program was updated in 2020.

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: Interactive lecture, review of specific checklists and preparation plans, 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.

Covered: On site versus remote interviews, general responses, and rules, systems-based, risk-based and QQ techniques.

Activities: Mock audit activities, 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.

Activities: Demonstrations, Role play, mock audit exercises, interactive lecture

Workshop #4 – Document Handling: Control of Documents During an Inspection

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.

Activities: 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: Mock inspection and role play

Workshop #6 – Follow-Up Activities: The Post Audit 5 C's: Common Findings, Classifications, Clarifications, Corrections & CAPA

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: Interactive lecture, exercises on classification and CAPA writing

Workshop #7 – AIPP Program Refresher New *

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. There is plenty of time for questions via the chat.

Activities: Interactive lecture, Exercises and Group discussion

Training Certificates will be issued for the sessions attended. Some sessions including the mock audit are currently unavailable for on-site presentation.

Clinical Trials Quality Management System (QMS) Training Program

This Training Program was established by BCCRIN in 2012. It has been modified and is now a Clinical Trials BC program (version 5). 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.



Clinical Trials Quality Leadership Training Program

The Clinical Trials BC Quality Leadership Training Program was established in 2017. It has been modified and is now a in version 2. It is presented as a series of small group sessions (8) in Zoom meeting format. The program introduces preliminary quality concepts and principles and links to overall quality and risk management. It is targeted to new Quality Associates or quality personnel involved in the implementation of Clinical Trial BC quality Systems into institutions.

The course will be run over three months from January to April. 2022. Attendance is limited and is by application.



QUALITY LEADERSHIP COURSE

January - April 2022

Limited attendance
Submit your application
Before December 6, 2021
At 5:00 PM

Core Workshops

Core workshops are a permanent series and are always available for training of new research staff.

Core Workshop 1

Introduction to ICH Guidance Documents – E Family Basics for Clinical Trials New*

This introductory module describes the ICH structure and provides an overview of the key 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.

Core Workshop 2

The Canadian Regulatory Environment

Are you having difficulty navigating the acts, guidance's, regulations and influencing bodies? Join us for a one-hour whirlwind presentation on how this puzzling environment works.

Learning Objectives:

- Identify the bodies that govern clinical trials externally
- Identify the bodies that govern clinical trials within Canada
- Understand the types of documents and their hierarchy
- Awareness of the Canadian trends and interpretation of the regulations
- Navigate the location of pertinent websites and documents

Core Workshop 3

Good Documentation Practices (GDP) Records

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.

Learning Objectives:

- Identify the main compliance findings associated with records.
- Understand the general principles associated with GDP.
- Name the criteria associated with ALCOAC.
- Demonstrate ability to record, make corrections, prepare explanatory notes, and handle a late entry.

Training guide, documentation samples and tools provided.

Core Workshop 4

Privacy and Security in Clinical Research

Privacy nomenclature, the Canadian regulatory framework and the privacy principles are introduced. Several case studies demonstrate privacy risk assessment and risk mitigation elements, privacy documentation requirements, tips for handling and reporting privacy incidents and common privacy problems in Clinical Trials.

Learning Objectives:

- Understand the privacy and security nomenclature for research.
- Familiarize with the Canadian regulatory framework for privacy, provincially and federally.
- Understand the 10 general privacy principles.
- Knowledge of Privacy impact analysis and risk considerations for research study and projects.
- Know documentation and reporting requirements for minor and serious breaches.
- List some common privacy incidents and prevention skills for clinical trial research.

Core Workshop 5

Quality and the Calibration & Maintenance of Equipment in Clinical Trials

This workshop covers 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.

Learning Objectives:

- List the key sections and content of an Equipment Calibration and Equipment procedure.
- Familiarization of quality tools to provide record of effective equipment management.
- Identify examples of specialized equipment that may require on-site validation, frequent maintenance, or a study-specific procedure.
- Name the equipment-related components necessary to ensure compliance
- Identify the main components of a Vendor Qualification System



CTBC Workshops and Lectures Bank

Clinical Trials BC maintains an archive of lectures. Staff are available to speak on topics of interest or provide an update on any previous specialized topic that has been presented that relates to clinical trials. We are also happy to take suggestions for new topics.

Other Education and Training Offerings

Network of Networks (N2)

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

CITI Courses available include:

- Good Clinical Practice (GCP) Basic.
- Good Clinical Practice (GCP) Refresher.
- Biomedical Research Ethics.
- Social and Behavioral Research Ethics.
- Health Canada Division 5: Drugs for Clinical Trials Involving Humans.
- Transportation of Dangerous Goods/International Air Transport Association (TDG/IATA).
- Responsible Conduct of Research .
- Privacy and Security for Personal Health Information (PHI).

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 Courses](#)

Information on your provincial N2 membership: clinicaltrials@healthresearchbc.ca

All other questions and CITI course access: n2@n2canada.ca

This Clinical Trials BC initiative is made possible through a provincial membership agreement funded by Michael Smith Health Research BC

ACRP learning management system (LMS)

We continued to maintain an organizational license to the ACRP (Association of Clinical Research Professionals) learning management system. This program offers learners working at clinical research sites in BC a suite of e-learning courses developed by ACRP. The lessons include a wide variety of training topics on essential components of quality clinical research with varying intensity levels appropriate for the topics being addressed. Our Education Coordinator makes this collection of 24 courses available quickly and efficiently to ensure 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 people 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 ACRP LMS here.](#)

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 login and begin training will be provided within one week.

This Clinical Trials BC initiative is made possible through a license agreement funded by Michael Smith Health Research BC

Clinical Research Professional Certification Program

General Information & Reimbursement:

Clinical Trials BC supports clinical research professionals working at academic-based BC clinical research sites to achieve professional certification. 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 quality standards.

For 2022, Clinical Trials BC is offering a partial reimbursement in the amount of \$350 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.

Exam Preparation

Clinical Trials BC has a variety of options to help to prepare for your examination. Please visit our website for up to date information

Find out more about the Clinical Research Professional (CRP) Certification Funding program and the reimbursement process [here](#)

About Clinical Trials BC



Clinical Trials BC advances British Columbia's development as a world-class destination for clinical trials across our province's hospitals, research institutions and communities.

Our mission is to maximize the health, educational, and economic benefits of clinical trials to the citizens of BC.



Clinical Trials BC is an operational unit of [Michael Smith Health Research BC](#)

For more information, please contact us with the following information:

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Linkedin: linkedin.com/company/clinical-trials-bc