Clinical Trials BC 2020 Educational Programming

Clinical Trials BC

British Columbia Academic Health Science Network

October 2020 Version 1

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Contents

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. We plan to study conduct that is proportionate to the risks to these quality factors, thereby 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 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. 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 “Clinical Trials BC Version 2” supporting tools, resources and SOP are identified 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 that will be 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 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.

Learning from the Canadian Clinical Research Participant Experience

Clinical Trials BC recently completed an analysis of the Canadian Clinical Research Participation Survey, which 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:

- 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 2020

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 2019 and 2020, 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 (November 2019) in the site and sponsor categories.

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 available funding for certification in 2020-21.

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 in Fall 2020 (rescheduled due to postponement in Spring 2020). The course is targeted to new investigators.

ASK US SERIES

The **JUST ASQ US** (Ask Study/Site Questions) forums were popular at BCCRIN (Clinical Trials BC's predecessor) beginning in 2011. These sessions consist of brief presentations containing key points with equal time to ask questions. They are designed to fit into a short session. Bring your lunch!

Hot Ask Us Topics 2020-21:

- Ask us anything! Open forum.
- Guidance 0100 – This session covers the highlights, interpretation, associated resources and answers any questions you may have about Part C, Division 5 of the Food and Drug Act.
- ICH E17 MRCT (Multi-Regional Clinical Trials) – 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 session for your group.

RAPID CLINICAL TRIALS TRAINING FOR COVID-19

Clinical Trials BC launched its new COVID-19 Rapid Response Training Program in April 2020. This program was developed for new researchers, new research team members and new supporting personnel who will be involved in COVID-19 clinical trials.

The training program includes training modules and supporting materials on a Clinical Trials BC eCoP (Electronic Community of Practice) established for COVID-19 Rapid Training.

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 CTBC's Response to COVID-19, please see our resource page.

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 New *

This workshop brings together your skills and experience from the first four workshops. Have your team participate in a mock audit/inspection. Your 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 – Virtual and Hybrid Inspections New *

What is required for a Virtual or Hybrid inspection? Most regulatory agencies have moved towards online, or online and onsite combination inspections. This session covers the elements to consider in preparing for inspection, conduct and communications during a virtual or hybrid inspection.

Activities: Interactive lecture, Exercises and Group discussion

The AIPP Program comes with access to the Version 5 audit kit, course handouts, tools at sessions and access to the Clinical Trials BC AIPP Manual V5 during training. Training Certificates will be issued for the sessions attended.

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.

The new CTBC Quality ECOP, supports provincial integrated and ongoing quality initiatives and activities.

CORE WORKSHOPS

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

Core Workshop 1

Privacy and Security in Clinical Research New *

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 2

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 3

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

Core Workshop 4

Good Documentation Practices (GDP) Records

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.

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.

Courses available include:

- Good Clinical Practice (GCP) Basic
- Good Clinical Practice (GCP) Refresher
- Biomedical Research Ethics

- Social and Behavioural 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 in Life Sciences
- Responsible Conduct of Research in Physical Sciences
- Privacy and Security for Personal Health Information (PHI)

Note: GCP training is encouraged after orientation and institutional introductions

More Information on Courses

Information on your provincial N2 membership: info@clinicaltrials.ca
All other questions and CITI course access: n2@n2canada.ca

This Clinical Trials BC initiative is made possible through a provincial membership agreement with BC AHSN, funded through the BC SUPPORT Unit's Training & Capacity Development initiative.

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 eLearning catalog of 30+ programs cover the essentials of clinical research, including the new "Introduction to Good Clinical Practice" eLearning course, which provides training on the new ICH GCP E6(R2) as the international industry standard for designing, conducting, and reporting clinical trials. 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 info@clinicaltrialsbc.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 provincial membership agreement with BC AHSN, funded through the BC SUPPORT Unit's Training & Capacity Development initiative.

CLINICAL RESEARCH PROFESSIONAL CERTIFICATION PROGRAM

General Information & Reimbursement:

Clinical Trials BC offers clinical research professionals at BC-based academic research sites with financial and resource support to become certified by the Society of Clinical Research Associates (SoCRA) and the Association of Clinical Research Professionals (ACRP).

For 2020, we are pleased to offer a partial reimbursement in the amount of $350 towards clinical research examination fees for up to 25 successful applicants who work for academic health research organizations. Funding is provided by the BC SUPPORT Unit.

Exam Preparation:

To help you prepare, Clinical Trials BC will hold a series of consecutive informal exam preparation sessions. The sessions will be recorded and available along with materials until December 2020.

Please contact Sarah Hanif at shanif@bcahsn.ca for more information or with your questions about these programs. Details about the 2021 program to be announced in late-2020.

More details: https://www.clinicaltrialsbc.ca/clinical-research-professional-certification/

ABOUT CLINICAL TRIALS BC

Clinical Trials BC advances British Columbia's development as a world-class destination for clinical trials (a type of health research that studies a test or treatment given to people) 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 the British Columbia Academic Health Science Network (BC AHSN).

For more information, call us at 236-521-2064 , email info@clinicaltrialsbc.ca or follow us on Twitter (@ClinTrialsBC) and Linkedin.