Clinical Trials BC
British Columbia Academic Health Science Network

2019 Clinical Trials BC Syllabus
Spring and Summer Lecture and Workshop Series

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Contact us at:
E-mail: info@clinicaltrialsbc.ca or jsmart@bcahsn.ca
Phone: 236-521-2064

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Spring and Summer Lecture and Workshop Series

2019 Feature Lectures

Feature Lecture 1

Risk Management

ICH E6R2 has been approved in Canada and is 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 and use of risk plans & risk log activities. Available Clinical Trial BC Version 2 supporting tools and resources and SOP are identified along with other out of province resources to help get you started.

Learning Objectives

The learner will be able to:

- Do 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

Feature Lecture 2

HC Guidance 0100

The long-awaited release of Health Canada Guidance 0100 will occur in 2019. Guide 0100 is Health Canada's interpretation of the regulations pertaining to: MRCT, CTA Process and E6R2 and records content as suggested in the 2017 DRAFT. This walk through and discussion presentation will go over the highlights, interpretation and associated resources. This session will be listed as Core for 2020.

Learning Objectives

- The learner will be able to:
- List the main sections of the guidance
- Understand the impact of the interpretation and changes on practice
- Identify access points for additional resources

Feature Lecture 3

Learning From the Canadian Clinical Research Participant Experience

Clinical Trials BC recently completed analysis of the Canadian Clinical Research Participation Survey, which aimed to engage and learn from 1000 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 and patient groups may be interested to learn about these findings.

1 to 3 hr – 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

Feature Lecture 4

Presentation: Canadian Regulatory Environment: Influences, Changes and Trends 2019

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 - with takeaways tips on what to expect or watch for (based on new programs, new regulations, 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 2018) in the site and sponsor categories.

Learning Objectives:

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

Feature Lecture 5

ICH- E6 (R2) GCP - Implementation Impact and Resources

ICH E6 (R1) stood as the standard for International Good Clinical Practice since 1996. ICH E6R2 has been approved in Canada and is full effect as of April 1, 2019. The impact is widespread at all levels (national, provincial, sponsor, institution and sites). This presentation covers the revisions in relation to the impact on systems and process and notable other changes. The resources that are available or in development provincially and nationally to assist with the implementation are identified and described. There is a handout on the 26 E6R2 changes.

Learning Objectives

- The learner will be able to:
- List the main changes to E6 GCP
- Identify the site training requirements that will be associated with the change
- Understand what the impact of the changes will be on practice

- Identify access points for resources

This will be listed as a Core Presentation in 2020.

ASQ US Series

The **ASQ TOPIC** series and **JUST ASQ US** (Ask Study/Site Questions) forums were popular under the former BCCRIN dating back to 2011. The 2019 Sessions are designed to fit into a short time session. Bring your lunch! These are short presentations on key points with equal time to ask questions.

HOT ASQ US TOPICS 2019:

Quality Management Systems Overview – What is QMS and how does it work at a site?

Recruitment: Barriers and Incentives

Training and Qualification Basics - What are the Core and recommended training requirements for a site and where are the resources?

ICH E17 MRCT (Multi-Regional Clinical Trials) – What is all the buzz and how does this link with ICH E5

Guidance 0100 - Short Notes

Where do I go from here? – CT Professional Development Opportunities and Workplace Advancement

The 'Just ASQ Us' FORUM Dates and ASQ HOT TOPICS will be announced in our newsletter.

Investigators Only Series (IOS)

IOS Module 1

Investigator Responsibilities

The first module in the six module series starts with investigator responsibilities including resources, communications, budget, contracts and obligations. It includes written materials, slides and exercises. There is time allotted for discussion and questions. This module is designed for small groups to encourage interaction.

Clinical Trials BC will provide training certificates for this module on site.

IOS Module 2

Investigator Oversight

The second module in the series covers investigator oversight for study activities. Documentation, data collection (paper, electronic and hybrid), study conduct and flow, Investigational product handling and administration, compliance site closures and reporting are the topics covered. Written materials, slide and exercise are included with listing of helpful resources to aid in oversight and successful conduct of the study at a site.

Note: IOS Modules 3-7 will be available for the Fall Winter Syllabus of 2019/2020

Module 3 Recruitment and Retention	Module 5 Safety
Module 4 Site QC Monitoring Audit and Inspection	Module 6 Regulations, Standards and Guidances
Module 7 CTBC Resources, Support and Team Development	

Clinical Trials BC Audit & Inspection Preparedness Program (AIPP) 2018 Version

AIPP 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

AIPP 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 vs. remote interviews, general responses and rules, Systems- based, Risk-based and QQ techniques)

Activities: Mock audit activities, Role Play

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

This is a core workshop on hosting and conduct during an audit or inspection. Learn audit decorum. This session is recommended for all staff.

Activities: Demonstrations, Role play, Mock audit exercises, Interactive lecture

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

Do you work in a confined, small or shared work space? Imagine having to process and handle 300 to1700 documents during an inspection. This is a very 'hands on' fun training 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

AIPP Workshop #5 – Exit Meeting

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 'mock' meeting.

Activities: Demonstrations, Role play and Mock exit meeting

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 writing.**

Activities: Interactive lecture, Exercises on Classification and CAPA writing

The Program comes with access to an audit kit, tools and access to the Clinical Trials BC AIPP Manual V3 and workshop handouts at sessions. Training Certificates are issued at the end of the series.

Clinical Trials BC Quality Management System Training Program

This Training Program was established with BCCRIN in 2012. It has been modified and is now CTBC version 4. A full compliment QMS with nine systems is available for programs, centres and institutions within British Columbia. Risk management components are imbedded into the quality systems. Each system includes SOPS, Policies, forms and other supporting documents and trackers are customized to fit each institution or 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

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.

Core Workshop 2

Privacy and Security in Clinical Research

Privacy nomenclature, the Canadian regulatory framework and the privacy principals 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 3

Introduction to ICH Guidance Documents - The Basics for Clinical Trials

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 4

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.