CAPRA ACPR
Canadian Association of Professionals in Regulatory Affairs
Association canadienne des professionnels en réglementation

Clinical Trial Application: Navigating the Canadian Regulatory Roadmap

In this one-day event, Health Canada will engage Regulatory Affairs professionals from academia, industry, and consultancy sectors in an informative dialogue focused on Clinical Trial Applications (CTA).

Representatives from the Biologics and Genetic Therapies Directorate will discuss common issues that arise from CTA review and provide guidance on best practices for CTA filings. The Therapeutic Products Directorate will present on upcoming efforts to renew the clinical trials framework. In addition, the Regulatory Operations and Enforcement Branch will share ongoing compliance programme development related to clinical trial site assessment.

Attendees will have an opportunity to pose questions and exchange ideas with Health Canada delegates towards improving the efficiency of clinical trial evaluation and monitoring.

June 27, 2019

The Westin, Toronto Airport
950 Dixon Road
Toronto, Ontario M9W 5N4

Topic Descriptions

Legislative Modernization of Clinical Trials in Canada

An overview will be provided of new legislative provisions recently introduced by the federal government in Bill C-97 for modernizing Canada's clinical trial framework for drugs, medical devices and certain foods for special dietary purposes.

Modernization of Clinical Trials Regulations

This presentation will discuss Health Canada's plans to modernize the regulations of clinical trials in order to introduce a risk-based approach and afford greater flexibility in the safe development of innovative therapies.

Efficient Strategies for Preparing Your CTA

Every CTA is assessed for completion and compliance against relevant guidances such as the "Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications." The BGTD Office of Regulatory Affairs will recount common deficiencies resulting in clarifaxes or processing holds early in the CTA review period and provide useful tips on how to obviate the need for these information requests.

Best Practices for CTA Filings: How to Improve Your Quality Package

A Quality reviewer from BGTD will discuss key considerations for submitting a comprehensive quality package. Additionally, the speaker will discuss the most common issues encountered during CTA review, and provide advice to ensure an efficient review process.

Considerations for Clinical Review of CTA

The presentation will focus on the preparation of submissions to facilitate an efficient and timely review, so that information requests are minimized where a risk-benefit can be established based on the stage of clinical development. Proper filing will allow Health Canada to determine if the trial is structured to meet its objectives, determine if it is in the best interests of subjects, and determine the adequacy of the safety and monitoring plans in accordance with Division 5 of the Food and Drugs Regulations. Additionally, components of a good submission will be discussed, such as:

- Components of a good protocol
- Important aspects of an Investigator's Brochure
- Informed Consent Forms (ICFs) that meet regulatory requirements (accurate risk declaration)
- Safety monitoring plans to mitigate risks present throughout the conduct of a trial

Health Canada's Clinical Trial Inspection Program

An overview will be provided of Health Canada's Clinical Trial Inspection Program, including compliance trends, program updates, transparency, and Canada's implementation of ICH E6 (R2). Representative from the Regulatory Operations and Enforcement Branch will also give an introduction to GUI-0100: Guidance Document - Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trial Involving Human Subjects."

PROGRAM AGENDA

7:30 – 9:00 am	**Registration and Breakfast**
9:00 – 9:15 am	**Welcoming Remarks**
9:15 – 9:45 am	**Legislative Modernization of Clinical Trials in Canada** *David K. Lee – Chief Regulatory Officer* *Assistant Deputy Minister's Office, Health Products and Food Branch*
9:45 – 10:15 am	**Modernization of Clinical Trials Regulations** *Carole Légaré, MD – Director* *Office of Clinical Trials, Therapeutic Products Directorate*
10:15 – 10:30 am	**Combined Q&A**
10:30 – 10:45 am	**AM Break**
10:45 – 11:30 am	**Introduction to the Clinical Trial Inspection Program** *Hocine Abid – National Manager* *Clinical Trial and Biological Product Compliance, Regulatory Operations and Enforcement Branch (ROEB)*
11:30 – 12:00pm	**Common Observations in Clinical Trial Inspection** *Flora Noitsis – Clinical Trial Compliance Specialist* *Clinical Trial and Biological Product Compliance, ROEB*
12:00 – 1:00 pm	**Lunch**
1:00 – 1:45 pm	**Efficient Strategies for Preparing Your CTA** *Winnie Fung, MASc – Senior Regulatory Affairs Officer* *Office of Regulatory Affairs, Biologic & Genetic Therapies Directorate (BGTD)*
1:45 – 2:30 pm	**Best Practices for CTA Filings: How to Improve Your Quality Package** *Andrea Marie Ibrahim, MSc – Biologist / Evaluator* *Cytokines Division, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, BGTD*
2:30 – 2:45 pm	**PM Break**
2:45 – 3:30 pm	**Considerations for Clinical Review of CTA** *Adam Buffone, MSc – Senior Clinical Evaluator* *Clinical Trials and Drug Safety Division, BGTD*
3:30 – 3:55 pm	**Full panel discussion**
3:55– 4:00 pm	**Closing Remarks**

CTA Symposium Registration & Fee

Symposium Fee (*Includes continental breakfast, breaks and lunch)*:

1. CAPRA Member: $450 (includes HST)
2. Non-member: $525 (includes HST)
3. Vendor Rate (one person): $900 (includes HST)
4. Vendor Rate (two persons): $1100 (includes HST)

A limited number of spaces are available for students at $200. Proof of full-time registration in a Regulatory programme is required at the time of booking (HST Registration No. 85475 8349RT0001).

Registration Procedure:

Registration will be accepted **ONLINE ONLY** at www.capra.ca/meetings.html. **Credit card payment is available only with on-line registration prior to the registration deadline of June 21st, 2019.** On the payment site, please use the name and address that matches the card.

If you wish to pay by cheque, payment must be received by June 24th, 2019. Please mail the cheque, with a list of registrants and company name, to:

CAPRA
2425 Matheson Boulevard East
7th Floor, Suite 795
Mississauga, Ontario L4W 5K4

Please Note: Registration will be open from **April 24, 2019 to June 21st, 2019**. Participants may be substituted, but no refunds will be issued.

Hotel Information:

Rooms are subject to availability– please ensure you make your reservation early!

1) Book with Westin before **June 7, 2019** for a CAPRA rate of $179.00/night (plus applicable tax and fees). Complimentary wireless high-speed internet included. Parking is an additional $10.00CAN/day (plus applicable tax).

Reservations can be made by contacting the hotel directly and stating they are part of CAPRA 1-866-837-5184.

Disclaimer
CAPRA reserves the right to make amendments to the conference (including but not limited to identity of speakers, topics, locations, timing of speakers) without notice to you. In the event that the conference is cancelled for any reason whatsoever, such reason not within the control of CAPRA, CAPRA shall not be liable for any cost or loss otherwise incurred.