Health Canada Regulatory and Clinical Modernization Initiatives Workshop

In this one-day interactive workshop, Health Canada will provide attendees with information on Regulatory and Clinical Trial Modernization initiatives. Attendees will have the opportunity to raise questions and participate in round table discussions with Health Canada officials on the modernization initiatives.

Key elements of proposed regulatory modernization include:

- Establish a coherent risk-based approach
- Afford greater flexibility in the safe development of innovative therapies
- Streamline processes toward greater efficiency and clarity
- Align with international best practices regarding oversight and public access to trial information.

This regulatory initiative was introduced by Health Canada in its Health and Biosciences Sector Regulatory Review Roadmap.

This event will be of interest to:

- Regulatory Affairs professionals from NHP, medical devices, pharmaceuticals/biologics as well as veterinary drugs
- Clinical Research
- Contract Research Organization
- Clinical Data Management/Pharmacovigilance
- Research and Development

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

CAPRA Symposium
April 24, 2020 Toronto

Westin Toronto Airport
Westin Toronto Airport Hotel
950 Dixon Rd
Etobicoke, ON
M9W 5N4

Workshop Agenda

7:30 – 9:00 am	***Registration and Breakfast***
9:00 – 9:05 am	**Welcoming Remarks**
9:05 - 9:20 am	**Overview of Health Canada's Regulatory Modernization** Dr. Fiona Frappier - Senior Policy Analyst, Office of Policy and International Collaboration, Biologics and Radiopharmaceutical Drugs Directorate
9:20 – 9:45 am	**Modernizing Health Canada's Clinical Trial Framework: Toward a Flexible, Risk-Based Approach** Dr. Daniel Keene - Senior Medical Officer and Manager, Office of Clinical Trials, Biologics and Radiopharmaceutical Drugs Directorate **Investigational Testing Authorizations: General Overview Medical Devices** Dr. Rany Shamloul **-** Senior Scientific Evaluator; Investigational Testing and Special Access Programme Division, Medical Devices Directorate
9:45 – 10:45 am	**Session 1: Round table discussion of key questions and plenary feedback:** Q1: What do you see as the barriers to conducting a clinical trial in Canada? What are the possible solutions? (e.g. participating in international trials, virtual trials, etc.) Q2: What are the factors that need to be considered in determining the degree of risk associated with a clinical trial? Q3: What degree of regulatory oversight should there be on high risk trials?
10:45 – 11:00 am	***Break***
11:00 – 12:00 pm	**Round table discussion of key questions and plenary feedback** Q4: Where are you presently registering trials? And what are the barriers if any to registration? Q5: In the future, what changes do you perceive could occur in the design and conduct of clinical trials in Canada
12:00 – 1:00 pm	***Lunch***
1:00 - 1:30 pm	**Consultation on International Conference on Harmonization E6 (R3): Good Clinical Practice** Dr. Carole Legare - Director of the Office of Clinical Trials, Therapeutic Products Directorate
1:30 – 2:15 pm	**Session 2: Round table discussion of key questions and plenary feedback** The ICH is working on the revision of the E6(R2) Guideline "Good Clinical Practice" (GCP) with a view to addressing the application of GCP principles to the increasingly diverse trial types and data sources being employed to support regulatory and healthcare related decision-making on drugs, and provide flexibility whenever appropriate to facilitate the use of technological innovations in clinical trials. Additional information may also be found in ICH Reflection Paper on "GCP Renovation".
2:15 – 2:30 pm	***Break***
2:30 – 3:15 pm	**Advanced Therapeutic Products** Julie Gervais - Manager Office of Policy and International Collaboration, Biologics and Radiopharmaceutical Drugs Directorate

	Regulatory Modernization in Compliance and Enforcement Kim Dayman-Rutkus - Senior Policy Advisor, Regulatory Operations and Enforcement Branch Dr. Hocine Abid - National Manager, Clinical Trial and Biological Product Compliance, Regulatory, Operations and Enforcement Branch (ROEB)
3:15 – 3:55 pm	**Session 3: Round table discussion of key questions and plenary feedback** Q6: In addition to the factors in the legislation (risks & benefits, novelty compared to previously approved products and other controls in place through provincial and territorial legislation), what other factors should be considered before deciding to add a product to the ATP pathway? Market readiness, healthcare system needs, health system readiness, etc. Q7: Do you have any suggestions on how to engage stakeholders during the iterative development of requirements for selected candidates? Q8: Part of the role of the new concierge service will be to maintain awareness of novel & complex products in the healthcare landscape, to identify potential future candidates for the ATP pathway. What recommendations do you have for how the Concierge Service can stay current on emerging technologies?
3:55 - 4:00 pm	**Closing Remarks**

Workshop Registration & Fee

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

1. CAPRA Member: $525 (includes HST) or $450 (Includes HST) for online access*
2. Non-member: $600 (includes HST) or $530 (Includes HST) for online access*
3. Vendor Rate (one person): $1160 (includes HST)
4. Vendor Rate (two persons): $1360 (includes HST)

* Online access only applies to presentation and panel discussions.

A limited number of spaces are available for students at $300. 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 https://capra.ca/en/meetings **Credit card payment is available with on-line registration prior to the registration deadline of April 17, 2020.** 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 April 17, 2020. Please mail the cheque, with a list of registrants and company name, to:

CAPRA
7111 Syntex Drive, 3rd Floor, #364
Mississauga, ON L5N 8C3
Tel: 289-290-4355

Please Note: Registration will be open from **March 9, 2020 to April 17, 2020**. Participants may be substituted, but no refunds will be issued.

Hotel Information:

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

1) Individual Reservations with Westin via Phone: 1-866-837-5184 before **March 27, 2020** for a CAPRA rate of $169.00/night (plus applicable tax and fees). Guests making such reservations must identify themselves as members of CAPRA group. Complimentary wireless high-speed internet included and Parking.

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.