Health Canada Regulatory and Clinical Modernization Initiatives Virtual Workshops – May 18 and 20, 2021

There will be two virtual interactive workshops where Health Canada officials will provide attendees with information on regulatory modernization initiatives being undertaken within the Department. The first session will focus on Regulatory Innovation Agenda, Regulatory Modernization in Compliance and Enforcement, and Advanced Therapeutic Products, while the second session will focus on 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.

These regulatory initiatives were 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 Organizations
- Clinical Data Management/Pharmacovigilance
- Research and Development

Please share the news of this event within your organization.

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

CAPRA Virtual Symposium
May 18 and 20, 2021

Session 1: Regulatory Innovation at Health Canada, Regulatory Modernization in Compliance and Enforcement, and Advanced Therapeutic Products – May 18, 2021

8:50 - 9:00 am	***Logging into Virtual Workshop Session # 1***
9:00 - 9:05 am	**Welcoming Remarks**
9:05 - 9:20 am	**Regulatory Innovation at Health Canada: Advancing agile regulations for drugs and devices** Elizabeth Toller - Executive Director, Regulatory Innovation, Assistant Deputy Minister's Office, Health Products and Food Branch
9:20 - 9:40 am	**Regulatory Modernization in Compliance and Enforcement** Catherine Hudon, Director, Compliance Policy and Regulatory Affairs, Regulatory Operations and Enforcement Branch Dr. Hocine Abid - National Manager, Clinical Trial and Biological Product Compliance, Regulatory Operations and Enforcement Branch
9:40 - 9:55 am	**Q&As**
9:55 - 10:05 am	**Break**
10:05 - 10:35 am	**Advanced Therapeutic Products** Kenneth Joly – Policy Analyst, Office of Policy and International Collaboration, Biologic and Radiopharmaceutical Drugs Directorate, Health Products and Food Branch
10:35 - 11:05 am	**Q&As**
11:05 am - 12:05 pm	**Feedback Discussion (Questions will be provided by ATP at a later date)**
12:05 - 12:15 pm	**Closing Remarks**

Session 2: Clinical Trial Modernization- May 20, 2021

8:30 - 8:40 am	***Logging into Virtual Workshop Session 2: Clinical Trial Modernization***
8:40 - 8:45 am	**Welcoming Remarks**
8:45 - 9:10 am	**Modernizing Health Canada's Clinical Trial Framework** Dr. Daniel Keene – Associate Director, Office of Clinical Trials, Therapeutic Products Directorate, Health Products and Food Branch
9:10 - 9:30 am	**Modernizing Medical Device Clinical Trial Regulations: An Approach to Foster an Environment to Support More Innovative Trials** Marie-Pierre Desrosiers - Scientific Evaluator, Bureau of Investigational Testing Authorization, Special Access Program and Post-Market Surveillance, Medical Devices Directorate, Health Products and Food Branch Alana Hendry - Senior Policy Analyst, Bureau of Policy, International Programs, and Stakeholder Relations, Medical Devices Directorate, Health Products and Food Branch
9:30 – 9:45 am	**Regulatory Modernization of Clinical Trials – An Industry Perspective** Lisa Chartrand - Director, Regulatory Strategy and Policy, Hoffmann-La Roche Limited on behalf of Innovative Medicines Canada
9:45 - 10:50 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: Where are you presently registering trials? And what are the barriers if any to registration?
10:50 - 11:00 am	**Break**
11:00 - 12:00 pm	**Session 2: Round Table Discussion of Key Questions and Plenary Feedback** Q4: In the future, what changes do you perceive could occur in the design and conduct of clinical trials in Canada? Q5: What are the lessons learned from COVID-19 response in moving forward with Clinical Trial Modernization? Q6: What is your anticipated pipeline in clinical trials in the short / medium / long term in Canada? Q7: Do you anticipate an increase in the number of clinical trials in particular areas?
12:00 - 12:10 pm	**Burning Questions via Chat Function**
12:10 - 12:15 pm	**Closing Remarks**

Workshop Registration & Fee

Workshop Fee:

1. CAPRA Member: $450 (includes HST) for online access.
2. Non-member: $520 (includes HST) for online access.
3. A limited number of spaces are available for students at $260. 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 with on-line registration prior to the registration deadline of May 5, 2021. 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 May 14, 2021. 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 8, 2021 to May 5, 2021. Participants may be substituted, but no refunds will be issued.

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.