Canada Annual Meeting

Short Course: November 5 Virtual
Meeting: November 14-15 | Hilton Lac-Leamy

PROGRAM COMMITTEE

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Overview

The DIA *Canada Annual Meeting* will provide an in-depth exploration of the current pharmaceutical, medical device, and diagnostic landscapes in Canada, emphasizing Canada's pivotal role in global healthcare product development. Offering three specialized tracks on Regulatory, Clinical, and Safety and Pharmacovigilance, the meeting will cover topics spanning from Health Canada's latest regulatory initiatives, international collaboration, and innovative clinical practices to approaches that harness AI in drug safety and increase representation from equity-denied groups.

Attendees will have the opportunity to engage with leaders and experts from academia, regulatory bodies, and the pharmaceutical and medical device industries by gaining insights into best practices, lessons learned, and strategies to address the challenges facing stakeholders in Canada.

Event Goals and Offerings

- Foster an understanding of Health Canada's regulatory frameworks and initiatives
- Encourage collaboration between industry, academia, and regulatory bodies to enhance clinical trial processes
- Highlight the importance of patient engagement and inclusion in research and development
- Showcase advancements in AI and technology that support regulatory and clinical operations
- Provide guidance on best practices and emerging trends in drug safety and surveillance
- Offer educational sessions and workshops to improve skills and knowledge in regulatory affairs and clinical research
- Discuss strategies for effective data sharing and transparency in regulatory submissions
- Highlight Canada's unique advantages in conducting clinical trials and fostering innovation

Tracks

- Track A: Regulatory - The regulatory track provides opportunities for information sharing, use cases, and best practices relating to Canada's regulatory landscape as it applies to regulatory requirements, new developments, and innovation for life sciences R&D
- Track B: Clinical - Today, modern pharmaceutical, medical device, and diagnostic products are advancing at an unprecedented speed. Sessions in this track will focus on clinical research development and operations for industry. Those interested in this track will gain an understanding of Health Canada's approach to the modernization of clinical trial regulations and gain further perspectives from patients and those in the life sciences R&D industry
- Track C: Safety and Pharmacovigilance - Our safety and pharmacovigilance track will provide a comprehensive overview of Canada's regulatory environment in the field of clinical safety and pharmacovigilance for pharmaceutical products and medical devices

Who Should Attend

- Pharmacovigilance & Drug Safety
- Risk Management
- Clinical Research, Management, & Operations
- Regulatory Affairs & Operations
- Medical Affairs & Scientific Communication
- Quality Assurance
- Life Sciences R&D
- Project Management
- Real-World Data & Real-World Evidence
- Data Management

Schedule At-A-Glance (All times listed are Eastern Time)

Track A: Regulatory, Track B: Clinical, Track C: Safety and Pharmacovigilance

VIRTUAL SHORT COURSE | TUESDAY, NOVEMBER 5		ROOM
8:30AM-12:30PM	**Best Practices for Clinical Trial Applications in Canada** **This Short Course requires an additional registration fee. You do not need to be registered for the meeting to attend**	
DAY ONE | THURSDAY NOVEMBER 14		**ROOM**
7:30AM-6:30PM	**Registration**	Ballroom Foyer
7:30-8:30AM	**Breakfast**	Mozart
8:30-8:45AM	**Welcome and Opening Remarks**	Beethoven/Chopin
8:45-10:00AM	**Session 1 Plenary:** Understanding Health Canada's Precision Regulating Initiatives	Beethoven/Chopin
10:00-10:45AM	Refreshments, Exhibits, and Networking Break	Mozart
10:45AM-12:00PM	Session 2: Track A: Health Canada and International Collaboration Initiatives Track B: Why Canada for Conducting Clinical Trials? Track C: Update on Health Canada's PV Guidances and Ongoing Initiatives	Beethoven/Chopin Delfosse Julien/Gagnon/Walker/Suzor-Cote
12:00-1:00PM	**Luncheon, Exhibits, and Networking Break**	Mozart
1:00-2:15PM	Session 3: Track A: HC/HTA Collaboration – Updates and Insights Track B: Equity, Diversity, Inclusion and Accessibility (EDIA) in Trials Track B and Track C: Pre-and Post-marketing Surveillance: Best Practices	Beethoven/Chopin Delfosse Julien/Gagnon/Walker/Suzor-Cote
2:15-3:00PM	**Refreshments, Exhibits, and Networking Break**	Mozart
3:00-4:15PM	Session 4A: Track A: Current and Emerging Regulatory Uses of Real-World Evidence Track B: Decentralized Clinical Trials – Canada's First Case Study and Next Steps Track C: Pharmacovigilance Unleashed: Unlocking PV Best Practices through KPIs and Data Mining	Beethoven/Chopin Delfosse Julien/Gagnon/Walker/Suzor-Cote
4:20-5:35PM	Session 5: Track A: Latest Advancements in AI – A Regulatory Perspective Track B: Harnessing the Potential of AI in Clinical Development and Operations Track C: Innovations within Pharmacovigilance: Shaping the Future of Drug Safety	Beethoven/Chopin Delfosse Julien/Gagnon/Walker/Suzor-Cote
5:35-6:35PM	Networking Reception	Mozart
DAY TWO | FRIDAY, NOVEMBER 15		**ROOM**
7:30AM-4:00PM	**Registration**	Ballroom Foyer
7:30-8:30AM	**Networking Breakfast**	Mozart
8:30-9:45AM	Session 6: Track A and B: Insights into Rare Diseases: Pioneering Pathways for Patient Access and Drug Development Track C: Advancements in Patient Safety and Centricity	Beethoven/Chopin Julien/Gagnon/Walker/Suzor-Cote

9:45-10:30AM	**Refreshments, Exhibits, and Networking Break**	Mozart
10:30-11:45AM	Session 7: Track A: Opportunities and Challenges of Electronic Labelling Implementation Track B: The State of ICH GCP: Moving towards Innovative Approaches in Clinical Trial Operations Track C: Signal or Noise? Decoding the Pharmacovigilance Symphony	Beethoven/Chopin Delfosse Julien/Gagnon/Walker/Suzor-Cote
11:45AM-12:45PM	**Luncheon, Exhibits, and Networking Break**	Mozart
12:45-2:00PM	Session 8: Track A: Fostering Transparency: Health Canada, Industry, and Patient Perspectives on PRCI's Role Track B: Statistical, Modeling and Dose Optimization Considerations for Trial Design Track C: Unveiling the Power and Value of Pharmacovigilance Teams: Pioneering Safety Guardians of the Pharmaceutical World	Beethoven/Chopin Delfosse Julien/Gagnon/Walker/Suzor-Cote
2:00-2:30PM	**Refreshments, Exhibits, and Networking Break**	Mozart
2:30-3:45PM	**Session 9 Plenary:** AI: Investments and Future Outcomes	Beethoven/Chopin
3:45-4:00PM	**Closing Remarks**	Beethoven/Chopin

Learning Objectives

At the conclusion of this conference, participants should be able to:

- Identify Health Canada's Precision Regulating Initiatives and amendments to the Food and Drugs Act to ensure precise regulatory solutions
- Discuss Health Canada's international collaboration initiatives and their impact on regulatory processes and clinical trials
- Determine the unique advantages and challenges of conducting clinical trials in Canada and how it positions itself as a global leader
- Develop strategies to enhance equity, diversity, inclusion, and accessibility in clinical trials, focusing on underrepresented groups
- Evaluate the latest developments in pharmacovigilance, including Health Canada's guidance on adverse drug reaction reporting and post-market surveillance
- Examine the role of artificial intelligence in regulatory processes, clinical development, and pharmacovigilance, and understand the implications for the industry
- Evaluate pathways for drug development and patient access in the rare diseases sector, focusing on regulatory strategies and collaboration opportunities
- Identify decentralized clinical trials, electronic patient medication information, and innovative approaches in clinical trial operations
- Discuss the importance of transparency in regulatory submissions and the role of data anonymization in protecting personal and confidential

Continuing Education Credits

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education with Commendation. The Drug Information Association designates this educational activity for up to 3.25 contact hours or .325 continuing education units (CEUs). UAN: 0286-0000-24-078-L04-P; Type of Activity: Knowledge. DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system.

All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. *** ACPE contact hours/CEUs are only available for the virtual Short Course. If ACPE credit is not requested by Friday, December 20, 2024, the CEU request will not be transmitted through to the CPE Monitor.** Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit www.cpemonitor.net.

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, December 20, 2024.

Drug Information Association (DIA) is accredited by the International Accreditors for Continuing Education and Training (IACET) and offers IACET CEUs for its learning events that comply with the ANSI/IACET Continuing Education and Training Standard. IACET is recognized internationally as a standard development organization and accrediting body that promotes quality of continuing education and training. As an IACET Accredited Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to .3* CEUs for this program. Participants must attend the entire virtual short course to be able to receive an IACET statement of credit. No partial credit will be awarded.
***IACET CEUs are only available for the virtual Short Course.**

Continuing Education Credit Allocation

November 5, 2024, Best Practices for Clinical Trial Applications in Canada: 3.25 contact hours or .325 CEUs, UAN: 0286-0000-24-078-LO4-P; Type of Activity: Knowledge

Statement of Credit

If you would like to receive a statement of credit for the days you attend the conference, you must attend one or both days of the conference, in their entirety, sign in at the DIA registration desk upon arrival, and request CE credit online through My Transcript (see instructions below). Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Wednesday, November 6.**

If you are claiming CE credit for the conference you must:

1. Participate in the virtual short course (in its entirety)
2. Sign into the virtual platform
3. Access your DIA account and select My Transcript to claim your CE credit, available on **Wednesday, November 6**
4. **ACPE credit must be claimed by December 20**

DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials. This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

Disclosure statements are included with each speaker's biographical sketch. The faculty who reported relevant financial relationships with ineligible entities related to the educational content of this CE activity have been mitigated.

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Want to view the detailed agenda? Download DIA's Mobile App!

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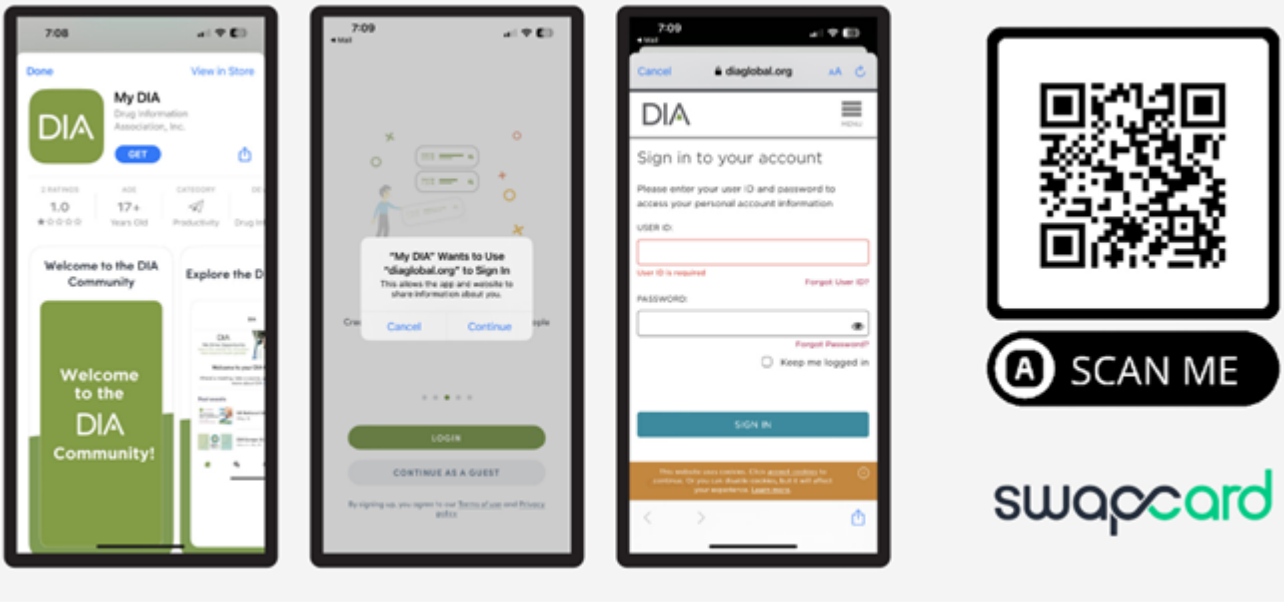
- Ask questions live during sessions through the session chat function



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Follow the instructions on screen, or please see the registration desk/contact NAEvents@DIAglobal.org if you need additional assistance.

DIA 2025 is the premier gathering for industry leaders, regulatory authorities, governmental representatives, academia, innovators, and patients. Set against the vibrant backdrop of Washington, DC, DIA 2025 will beckon stakeholders from around the world to converge, collaborate, and catalyze transformative change within the life sciences realm.

At DIA 2025, we will transcend boundaries, inviting diverse voices to the table to address both local and global challenges. From regulatory hurdles to technological innovations, from healthcare disparities to patient-centric solutions, our agenda is comprehensive and forward-thinking.

DIA

EXHIBITOR DIRECTORY

Canada Annual Meeting

NOVEMBER 14-15, 2024

3 BOULEVARD DU CASINO,

GATINEAU, QC J8Y 6X4, CANADA

DIA

3 BOULEVARD DU CASINO, GATINEAU, QC J8Y 6X4, CANADA

November 14-15, 2024
Hilton Lac-Leamy | Gatineau, QC J8Y 6X4, Canada

CAPRA

Website: *https://www.capra.ca*
LinkedIn: https://www.capra-canadian-association-of-professionals-in-regulatory-affairs/posts/?feedView=all

The **Canadian Association of Professionals in Regulatory Affairs (CAPRA)** is a non-profit organization that serves the pharmaceutical, biologics, medical device, cosmetic and natural health product industries in Canada.

We foster **learning**, **networking and professional excellence** of our members.

We will build and strengthen relationships with governmental agencies, scientific experts and industry educators in order to create an affordable, professionally fulfilling and academically enriching environment for our members.

INNOMAR STRATEGIES INC.

Website: *https://www.innomar-strategies.com/our-integrated-model/regulatory-services*
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Innomar Strategies offers expertise in all areas of Regulatory Affairs, Quality Assurance and Drug Safety services to the pharmaceutical, biotechnology, natural health product and cosmetic industries at each stage of the product lifecycle. Innomar supports a wide variety of therapeutic areas such as gastrointestinal, CNS, ophthalmology, cardiovascular, biosimilars, rare disease, oncology as well as medical devices, with submissions to Health Canada, the FDA and other quasi regulatory bodies.

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Website: *https://www.intrinsik.com*
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Intrinsik provides regulatory and scientific advice to help you identify the most efficient drug development and registration pathways in a timely manner. As a science-based consulting firm with clients from all over the world, Intrinsik supports the development of a wide range of human health products, including small molecules, biologics, NHPs, and cosmetics from the preclinical stage through to market and the post-approval phase.

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LORENZ Life Sciences Group has been developing and marketing software solutions for the Life Sciences market for over 30 years.

The LORENZ Regulatory Information Management solutions address industry, health authorities and academia to ensure compliance enforcement worldwide.

LORENZ's proven portfolio offers:

- Product Registration/IDMP,
- Submission Assembly,
- Validation and Management,
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- Regulatory Planning and Tracking products and related services.

Interoperability between LORENZ products and **third-party solutions**, as well as the ability to automate processes, allow LORENZ customers to enhance operational efficiencies.

LORENZ has a strong customer base worldwide, with over 1700 paid installations in 48 countries, including 14 agencies.

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Founded in 2007, Regxia is a regulatory consulting firm serving the pharma & biotech industries.

We provide outsourced RA ,QA and PV operations, conduct promotional/medical materials reviews, dossier reviews, NDA/NDS & IND/CTA, eCTD and XML PM publishing; and provide CMC consulting.
New! e-PV Module for RegDocs365 has been developed in collaboration with Court Square Group to empower smaller companies with the tools they need to easily manage ADRs and reporting.

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Zenith PV is a bilingual Canadian company specializing in all PV and Med Info aspects including but not limited to: PV self-inspection and GVP audit readiness support, PV department set-up, bilingual ICSR processing, medical assessment, MedDRA coding, CIOMS narrative writing, expedited reporting, aggregate reports compilation (ex. ASRs, PSUR) & Med Info support for a wide ranges of pharmaceutical drugs.