Canada Annual Meeting

Virtual Short Course: Tools and Methods | October 22
Meeting: October 27-28 | Hilton Lac-Leamy

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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

- Bring together regulators, industry, patients, and academia to exchange perspectives on Canada's role in global regulatory science
- Highlight the latest developments in regulation, safety, labeling, trial modernization, and digital transformation
- Strengthen partnerships between Health Canada, international regulators, industry leaders, and patient representatives
- Provide learning opportunities across regulatory, clinical, and safety domains to expand participant knowledge and expertise
- Create space for peer-to-peer exchange through plenaries, breakouts, and dedicated networking sessions

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.
- 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
- Clinical Research, Management, & Operations
- Medical Affairs & Scientific Communication
- Life Sciences R&D
- Real-World Data & Real-World Evidence
- Risk Management
- Regulatory Affairs and Operations
- Quality Assurance
- Data Management

VIRTUAL SHORT COURSE | WEDNESDAY, OCTOBER 22		
10:00AM-2:00PM	**Tools and Methods to Evaluate the Effectiveness of Risk Minimization Measures** **This Short Course requires an additional registration fee. You do not need to be registered for the meeting to attend**	
DAY ONE | MONDAY, OCTOBER 27		**ROOM**
7:30AM-6:30PM	Registration	Ballroom Foyer
7:30-8:30AM	Networking Breakfast	Mozart
8:30-8:45AM	Welcome and Opening Remarks	Beethoven/Chopin
8:45-10:00AM	Session 1 Plenary: Advancing Regulatory Innovation: Canada's Role in Global Collaboration	Beethoven/Chopin
10:00-10:45AM	Refreshments, Exhibits, and Networking Break Sponsored by Bayshore Specialty Rx	Mozart
10:45AM-12:00PM	Session 2 Track A: Evolving Regulatory Landscapes: Key Updates in Health Canada's Regulations, Policies, Guidance and Compliance Framework Track B: Re-Defining Patient-Centric Clinical Research Track C: From Duplication to Innovation: Modernizing ICSR Collaboration	Beethoven/Chopin Delfosse Julien/Gagnon/Walker/Suzor-Cote
12:00-1:00PM	Luncheon, Exhibits, and Networking Break	Mozart
12:15-12:45PM	Roundtable Discussions Each day's networking luncheon offers both open seating and focused roundtable discussions. Each topic listed below will be hosted at a designated table led by a moderator. If you're passionate about one of these subjects or would like to exchange ideas with peers who share similar interests, we invite you to join a designated table to enjoy both your meal and an engaging conversation. **T&C Implementation and Further Discussion hosted by Kristen Zorn, Health Canada** This fall, Health Canada will be consulting on two guidance documents that explain the new broad terms and conditions (T&C) authorities that will come into effect on April 1, 2027. The Roundtable session will be an opportunity to ask questions about how T&Cs will be implemented, including the processes and timing, and how T&Cs for submissions based on promising evidence of efficacy will replace the current Notice of Compliance with Conditions policy. **More on Health Canada's Management of Workload and Backlog hosted by Elana Cherry, Health Canada** At the DIA Canada Annual 2025 Meeting, Health Canada will present an overview of its current challenges and strategic responses related to the growing backlog in drug submissions. Since 2022, both the Pharmaceutical Drugs Directorate (PDD) and the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) have experienced significant increases in submission volume and complexity, compounded by staffing limitations and incomplete data packages. Despite internal efficiency measures, capacity constraints have persisted, prompting increased feedback from industry stakeholders requesting greater predictability and transparency, enhanced flexibility in the review process, stronger international collaboration, and timely updates to guidance and policy. Stakeholder workshops held in September led to a collaborative action plan focused on transparency, communication improvements, and increased flexibility. The roundtable discussion is an opportunity for more detailed discussion about shared responsibility, ongoing engagement, and balancing short-term actions with long-term sustainability. Health Canada looks forward to hearing your thoughts and ideas as part of this ongoing dialogue.	Mozart

	What is your Regulatory Affairs Career Development Path? hosted by My Dang, Cencora, Marcia Sam, Regeneron and Melanie Cote, Otsuka Pharmaceutical Development & Commercialization Inc. 3 Regulatory Affairs professionals will be briefly sharing their experience in regulatory affairs and answering any question the attendees would have to give them ideas for their own career development. **Meet Your Health Canada Clinical Trial Reviewers: Collaborating Towards a Successful Clinical Trial Application hosted by Katherine Soltys, Health Canada and Sophie Hamel, Health Canada** To answer any questions you may have on Health Canada's clinical trial application (CTA) process, representatives from Health Canada's Office of clinical trials will host a roundtable on the preparation for a successful CTA **Canada on the International Stage hosted by Kelly Robinson, Health Canada** Kelly Robinson (Director General, PDD) would discuss topics related to Health Canada's participation in various international collaboration initiatives.	
1:00-2:15PM	Session 3 Track A: Evolution of Labelling Track B: Optimizing Clinical Trial Operations: Strategy, Sites, and Smart Recruitment Track C: Advancing Access and Automation for Canadian Medical Information	Beethoven/Chopin Delfosse Julien/Gagnon/Walker/Suzor-Cote
2:15-3:00PM	Refreshments, Exhibits, and Networking Break Sponsored by Bayshore Specialty Rx	Mozart
3:00-4:15PM	Session 4 Track A: Health Canada, the Industry, and the Future of Oncology Approvals Track B: Rebuilding Trust and Awareness in Clinical Trials Track C: Patient Support Programs and Drug Safety: Compliance, Reporting, and Optimization	Beethoven/Chopin Delfosse Julien/Gagnon/Walker/Suzor-Cote
4:25-5:40PM	Session 5 Track A: Navigating Submissions Relying on Third Party Data (SRTDs) Track B: Navigating the Quality by Design and Inspection Process for Enhanced Safety and Result Reliability of Clinical Trials Track C: Health Canada Pharmacovigilance Updates	Beethoven/Chopin Delfosse Julien/Gagnon/Walker/Suzor-Cote
5:40-6:40PM	Networking Reception	Mozart
DAY TWO | TUESDAY, OCTOBER 28		**ROOM**
7:30AM-3:40PM	Registration	Ballroom Foyer
7:30-8:30AM	Networking Breakfast	Mozart
8:30-9:45AM	Session 6 Track A: Advancing Digital Submissions: Transforming Documents into Data in Regulatory Affairs Track B: Canada Now – Together Track C: Advancing Pharmacovigilance Through Artificial Intelligence: From Real-World Data to Practical Applications	Beethoven/Chopin Delfosse Julien/Gagnon/Walker/Suzor-Cote
9:45-10:30AM	Refreshments, Exhibits, and Networking Break Sponsored by Bayshore Specialty Rx	Mozart
10:30-11:45AM	Session 7 Track A: Navigating the Novel: Multi-faceted Challenges in Rare Disease Treatment in Canada Track B: Building the Backbone: Clinical Research Workforce Development in Canada Track C: Post-Market Drug Evaluation in Canada: The Role of Canada's Drug Agency PMDE Program	Beethoven/Chopin Delfosse Julien/Gagnon/Walker/Suzor-Cote

11:45AM-12:45PM	Luncheon, Exhibits, and Networking Break	Mozart
12:00-12:30PM	Roundtable Discussions Each day's networking luncheon offers both open seating and focused roundtable discussions. Each topic listed below will be hosted at a designated table led by a moderator. If you're passionate about one of these subjects or would like to exchange ideas with peers who share similar interests, we invite you to join a designated table to enjoy both your meal and an engaging conversation. **Uncovering the Bottleneck in the Canadian Clinical Trials Ecosystem by Suzie Talbot, Diex Research, Jean-Francois Leger, Sanofi and Bruno Battistini, University of Ottawa** The panelists from Session 3B will continue the discussion around the challenges and opportunities related site feasibility, selection, and recruitment using AI. **Meet Your Health Canada Clinical Trial Inspectors: Collaborating Towards a Successful GCP Inspection hosted by Kevin Donato, Health Canada and Hocine Abid, Health Canada** To continue on the topic of a proportionate risk-based inspection approach, Health Canada's clinical trial Inspectors will host a roundtable on the inspection process and preparation for a successful clinical trial inspection. **Documents to Data, Advancing Digitization – Current Status and Future Vision hosted by Todd Georgieff, RWS** Join us to continue a discussion about enabling real-time, data- and content-based submissions based on interoperability standards including HL7 FHIR, CDISC, OMOP and others. **A Closer Look at Canada's Post-Market Drug Evaluation Program hosted by Michael Paterson, Institute for Clinical Evaluative Sciences and Tarry Ahuja, Canada Drug Agency** Join us for a roundtable discussion that offers a deeper exploration of Canada's Drug Agency Post-Market Drug Evaluation (PMDE) Program, its key stakeholders, and its role in supporting evidence-based decision-making. The session will also highlight CoLab — a national expert network — including its structure and collaborative contributions to post-market drug evaluation. **Meet Your Health Canada Clinical Trial Reviewers: Collaborating Towards a Successful Clinical Trial Application hosted by Katherine Soltys, Health Canada and Sophie Hamel, Health Canada** To answer any questions you may have on Health Canada's clinical trial application (CTA) process, representatives from Health Canada's Office of clinical trials will host a roundtable on the preparation for a successful CTA.	Mozart
12:45-2:00PM	Session 8 Track A: Devise Effective Regulatory Strategy: Using the Lens of Regulatory Intelligence Track B: Clinical Trial innovation and modernization: The Future of Clinical Trials Track C: From Self-Care to Surveillance: Emerging Tools for Detecting Safety Signals	Beethoven/Chopin Delfosse Julien/Gagnon/Walker/Suzor-Cote
2:10-3:25PM	Session 9 Plenary: Embracing AI: Practical Approaches to Transforming Clinical, Regulatory Affairs, and Post-Approval Activities	Beethoven/Chopin
3:25-3:40PM	Closing Remarks	Beethoven/Chopin

Learning Objectives

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

- Describe Health Canada's evolving regulatory priorities and their role in advancing global collaboration and public health
- Recognize trends in clinical research modernization, including patient engagement, trial accessibility, and innovative study approaches
- Identify current and emerging frameworks in safety and pharmacovigilance that support compliance, data quality, and patient protection
- Assess the impact of international and multi-stakeholder collaboration on regulatory innovation, clinical trials, and patient access
- Discuss the role of technology and digital transformation (e.g., AI, automation, data-driven submissions) in shaping the future of regulatory affairs, safety, and clinical development
- Explain strategies for workforce and professional development to strengthen Canada's position in the global research and regulatory ecosystem

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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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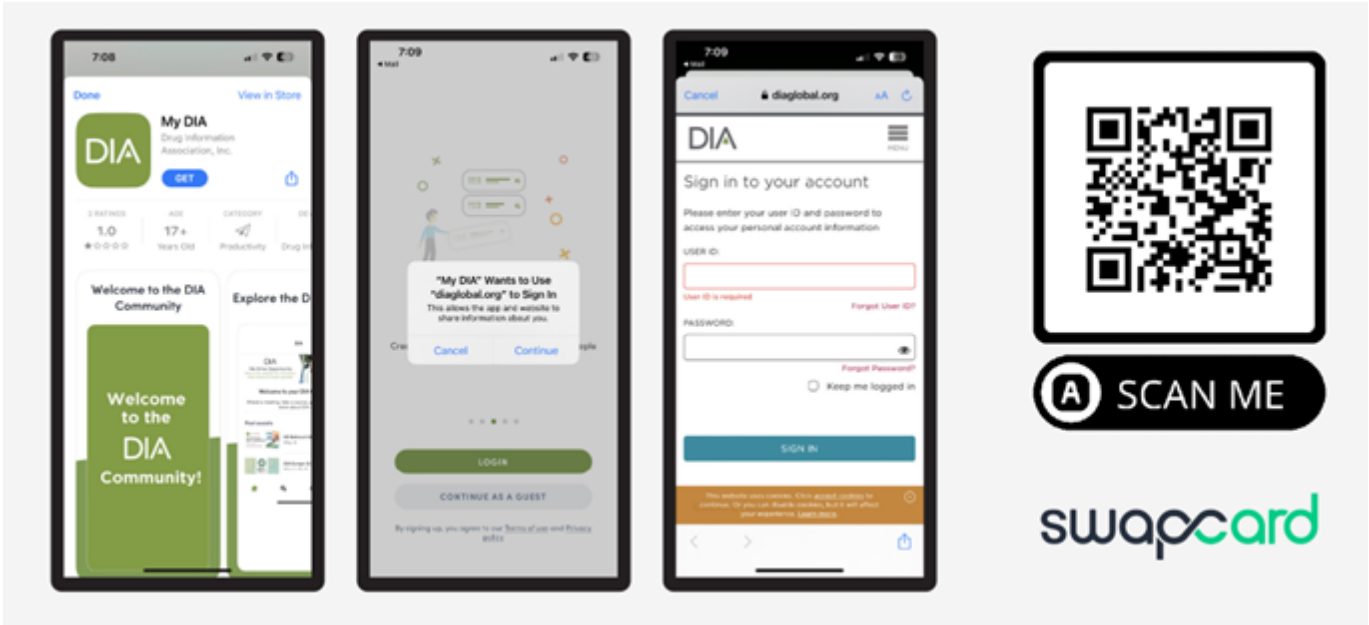

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DIA 2026 is the premier gathering for industry leaders, regulatory authorities, governmental representatives, academia, innovators, and patients. Set against the vibrant backdrop of Philadelphia, PA, DIA 2026 will beckon stakeholders from around the world to converge, collaborate, and catalyze transformative change within the life sciences realm.

At DIA 2026, 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.