

# Canada Annual Meeting

October 26-27 | Gatineau, QC

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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.

## Learning Objectives

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

- Evaluate Health Canada's latest regulatory modernization initiatives and their implications for healthcare product development.
- Interpret emerging Canadian and international regulatory expectations, including ICH E6(R3), E8(R1), M15, and evolving M14 principles.
- Strengthen inspection readiness, pharmacovigilance systems, and vendor oversight through risk-based approaches.
- Build cross-functional approaches that improve submission quality, clinical operations, and lifecycle regulatory management.
- Apply practical strategies for implementing AI responsibly across regulatory affairs, clinical development, and pharmacovigilance.
- Integrate digital technologies, structured data, and real-world evidence into regulatory and clinical decision-making.
- Develop strategies that leverage regulatory reliance, harmonization, and international collaboration to accelerate patient access.
- Translate regulatory policy into practical implementation using real-world case studies and lessons learned.

## Why You Can't Miss

- Hear directly from Health Canada leadership through exclusive agency updates, regulatory insights, and the Health Canada Town Hall.
- Gain practical strategies, not just policy updates, for implementing AI, regulatory modernization initiatives, ICH guidance, inspection readiness, and digital transformation.
- Stay ahead of Canada's evolving regulatory landscape with timely discussions on reliance, real-world evidence, structured submissions, precision medicine, and pharmacovigilance.
- Learn from cross-functional experts representing regulatory affairs, clinical development, pharmacovigilance, quality, academia, and technology.
- Build valuable connections with regulators, industry leaders, researchers, patient representatives, and solution providers from across Canada's life sciences ecosystem.

## Who Should Attend

Professionals interested in a comprehensive overview of the current pharmaceutical, medical device, and/or diagnostics landscape in Canada:

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

## Tracks

### Track A: Regulatory

This track delves into Canada's evolving regulatory landscape, providing a platform for exchanging insights, practical use cases, and emerging best practices. Sessions will focus on both current and upcoming regulatory requirements, key policy developments, regulatory convergence and innovative strategies that are influencing life sciences R&D in Canada. Sessions will aim to equip attendees with actionable knowledge to effectively navigate regulatory expectations and enhance the quality of submissions in an increasingly complex environment.

### Track B: Clinical

This track explores the evolving landscape of clinical research development and operations in Canada, offering a platform to exchange insights, real-world applications, and emerging best practices. Sessions will aim to equip attendees with practical knowledge to successfully design and execute clinical programs in an increasingly complex and fast-paced environment.

### Track C: Safety and Pharmacovigilance

This track brings together industry, health authorities, and other stakeholders to share best practices and advance product safety across all product types. Sessions will explore regulatory insights, cross-functional interfaces, and emerging trends and technologies.

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

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

| DAY ONE   MONDAY, OCTOBER 26 |                                                                                                                                                       | 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: Enhancing Regulatory Decisions using The Digital Advantage: AI Driven Insights for Seamless Information Sharing and Earlier Access | Beethoven/Chopin                |
| 10:00AM-10:45AM              | Refreshments, Exhibits, and Networking Break                                                                                                          | Mozart                          |
| 10:05AM-10:35AM              | Case Study Sponsored by Clinevotech                                                                                                                   | Delfosse                        |
| 11:15-12:45PM                | Session 2: CONCURRENT SESSIONS                                                                                                                        | Beethoveen                      |
|                              | Track 1: Move from Reactive to Resilient - Canada's Strategic Vision for Supply Chain Security and Global Harmonization                               | Julien/Gagnon/Walker/Suzor-Cote |
|                              | Track 2: What's New in Clinical Trial Regulation                                                                                                      | Chopin                          |
| 12:00-1:00PM                 | Track 3: Transform PV Workflows: Driving Innovation with AI and Automation to Solve Increasing Demand                                                 | Chopin                          |
|                              | Luncheon, Exhibits, and Networking Break                                                                                                              | Mozart                          |
| 1:00-2:15PM                  | Session 3: CONCURRENT SESSIONS                                                                                                                        | Beethoven                       |
|                              | Tracks 1: Reducing Burden, Accelerating Access - How Health Canada Is Streamlining Regulatory Work                                                    | Julien/Gagnon/Walker/Suzor-Cote |
|                              | Track 2: Manage Trial Evolution: Aligning Patient-Centric DCTs and Digital Governance in Canada                                                       | Chopin                          |

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                        |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
|                                      | <b>Track 3:</b> Trust but Verify - Building and Governing High-Performing PV Partnerships                                                                                                                                                                                                                                                                                                                                                  |                                                        |
| 2:15-3:00PM                          | <b>Refreshments, Exhibits, and Networking Break</b>                                                                                                                                                                                                                                                                                                                                                                                        | Mozart                                                 |
| 2:20-2:50PM                          | <b>Case Study Sponsored by ClaroPV:</b> Building Effective Cross-Functional Partnerships to Strengthen Pharmacovigilance Compliance                                                                                                                                                                                                                                                                                                        | Delfosse                                               |
| 3:00-4:15PM                          | <b>Session 4: CONCURRENT SESSIONS</b><br><b>Track 1:</b> Accelerate Precision Medicine with Model-Informed Drug Development: From Insight to Regulatory Impact<br><b>Track 2:</b> Supporting the Interface Between Community-led Engagement and Researchers: Partners in Clinical Trial Development<br><b>Track 3:</b> Translate Policy into Practice: Applying Health Canada's 2026 Pharmacovigilance Guidance                            | Beethoven<br>Julien/Gagnon/Walker/Suzor-Cote<br>Chopin |
| 4:25-5:40PM                          | <b>Session 5: CONCURRENT SESSIONS</b><br><b>Track 1:</b> Real-World Evidence in Canada: Harnessing RWD for Timely Regulatory & Reimbursement Decisions<br><b>Track 2:</b> Advancing Pediatric Clinical Trials: Innovation, Regulation, and Operational Excellence<br><b>Track 3:</b> Advance Pharmacovigilance Inspection Readiness: From Health Canada GVP Insights to Global Compliance                                                  | Beethoven<br>Julien/Gagnon/Walker/Suzor-Cote<br>Chopin |
| 5:40-6:40PM                          | <b>Networking</b>                                                                                                                                                                                                                                                                                                                                                                                                                          | Mozart                                                 |
| <b>DAY TWO   TUESDAY, OCTOBER 27</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>ROOM</b>                                            |
| 7:30AM-4:15PM                        | <b>Registration</b>                                                                                                                                                                                                                                                                                                                                                                                                                        | Ballroom Foyer                                         |
| 7:30-8:30AM                          | <b>Networking Breakfast</b>                                                                                                                                                                                                                                                                                                                                                                                                                | Mozart                                                 |
| 8:30-9:45AM                          | <b>Session 6: CONCURRENT SESSIONS</b><br><b>Track 1:</b> Navigating AI Capabilities for a Safe Evolution of Regulatory Workflows used to Manage Regulatory Content and Submissions<br><b>Track 2:</b> Advancing Clinical Development with AI - Trends, Applications, and Lessons from the Field<br><b>Track 3:</b> Balancing Promotion and Safety: Canadian Regulatory Expectations and Best Practices                                     | Beethoven<br>Julien/Gagnon/Walker/Suzor-Cote<br>Chopin |
| 9:45-10:30AM                         | <b>Refreshments, Exhibits, and Networking Break</b>                                                                                                                                                                                                                                                                                                                                                                                        | Grand Ballroom Foyer                                   |
| 10:30-11:45AM                        | <b>Session 7: CONCURRENT SESSIONS</b><br><b>Track 1:</b> Optimizing Canadian Submissions: Risk-Based Framework Approach for Package Inserts, XML PM Authoring and CMC Trends<br><b>Track 2:</b> Translating ICH E6(R3) into Action - Perspectives from Regulators, Sponsors, and Operational Teams<br><b>Track 3:</b> From Signal to Action: Managing Safety Risks in Health Products for Self-Selection and Cannabis Without Perfect Data | Beethoven<br>Julien/Gagnon/Walker/Suzor-Cote<br>Chopin |
| 11:30AM-12:45PM                      | <b>Luncheon, Exhibits, and Networking Break</b>                                                                                                                                                                                                                                                                                                                                                                                            | Grand Ballroom                                         |
| 12:45-2:00PM                         | <b>Session 8: CONCURRENT SESSIONS</b><br><b>Tracks 1:</b> Unlocking Global Convergence: Enabling Harmonization and Reliance for Faster Access<br><b>Track 2:</b> Critical to Quality - Operationalizing ICH E8(R1) and E6(R3): From Theory to Practice<br><b>Track 3:</b> Apply Real-World Evidence in Canada - Design, Regulatory Expectations, and Safety Applications                                                                   | Beethoven<br>Julien/Gagnon/Walker/Suzor-Cote<br>Chopin |

|             |                                              |                  |
|-------------|----------------------------------------------|------------------|
| 2:00-2:45PM | Refreshments, Exhibits, and Networking Break | Mozart           |
| 2:45-4:00PM | Session 9 Plenary: Health Canada Town Hall   | Beethoven/Chopin |
| 4:00-4:15PM | Closing Remarks                              | Beethoven/Chopin |

## Continuing Education Credit Allocation

This program is eligible for Attendance Credit. No Continuing Education will be offered.

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Disclosure statements are included with each speaker's biographical sketch.

## Planning Committee

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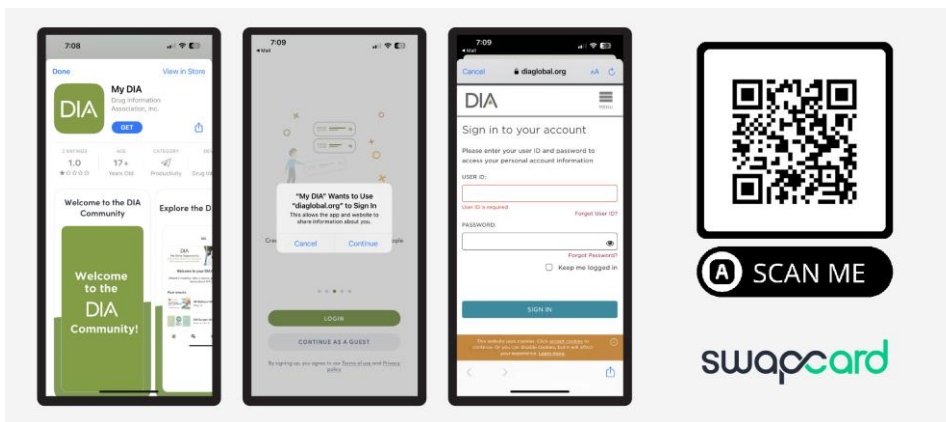
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