

Short Courses: October 30, November 2 | Virtual

Meeting: November 7-8 | Ottawa Conference and Event Centre



## TRACK CHAIRS

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## Overview

The DIA *Canada Annual Meeting* will deliver a comprehensive overview of the current pharmaceutical, medical device, and/or diagnostic landscapes in Canada, while sharing insights into Canada's broader role in global healthcare product development and is separated into three tracks: Regulatory, Clinical and Pharmacovigilance. This meeting will connect attendees with leaders and experts in academia and those involved in the regulatory, clinical, and pharmacovigilance functional areas in the pharmaceutical and medical device industry to explore best practices, lessons learned, and problem-solving strategies effecting stakeholders in Canada.

## Event Goals and Offerings

- Discuss policy updates and priorities shared directly from Health Canada
- Stay up to date with emerging trends and technologies effecting life sciences professionals in Canada
- Establish and foster relationships with life sciences professionals in Canada.
- Gain additional insights, education, and knowledge to analyze relevant challenges and opportunities for life sciences professionals in Canada

**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: Pharmacovigilance**

Our 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

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

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

## Schedule At-A-Glance

All times listed are in EST

## SHORT COURSE | MONDAY, OCTOBER 30

1:00-4:30PM **Virtual Short Course: Tools and Methods to Evaluate the Effectiveness of Risk Minimization Measures**

*\*This course requires a separate registration fee. You do not need to be registered for the full conference to attend this Short Course.*

## SHORT COURSE | THURSDAY, NOVEMBER 02

9:00AM-12:30PM **Virtual Short Course: Global Advertising and Promotion – Considerations for Compliance and Success**

*\*This course requires a separate registration fee. You do not need to be registered for the full conference to attend this Short Course.*

## DAY ONE | TUESDAY, NOVEMBER 07

## ROOM NAMES

7:30AM-6:00PM	<b>Meeting Registration</b>	Atrium, outside Room 106CD
7:30-8:30AM	<b>Networking Breakfast</b>	Room 106EFG
8:30-8:55AM	<b>Welcome and Opening Remarks</b>	Room 106CD
8:55-10:00AM	<b>Session 1 Plenary:</b> The Future of Therapeutic Products Development: Current Emerging Trends and Technologies	Room 106CD
10:00-10:40AM	<b>Refreshments, Exhibits, and Networking Break</b>	Room 106EFG
10:40AM-12:10PM	<b>Session 2, Tracks A, B, C:</b> Advancing Agile Regulations for Drugs: Updates from Health Canada	Room 106CD
12:10-1:10PM	<b>Luncheon, Exhibits, and Networking Break</b>	Room 106EFG
1:10-2:10PM	<b>Session 3, Tracks A, B, C:</b> Integrating Equity, Diversity and Inclusion Across the Drug Product Lifecycle	Room 106CD
2:10-2:50PM	<b>Refreshments, Exhibits, and Networking Break</b>	Room 106EFG
2:50-4:05PM	<b>Session 4:</b>  <b>Track A:</b> Innovation in Therapeutic Product and Device Development  <b>Track B:</b> Key Changes to the ICH E6 R3 Guidelines  <b>Track C:</b> Creating a Safer Framework for Medicines Use in Pregnant and Breastfeeding People	Room 106CD Room 118E Theatre Hall 201
4:15-5:30PM	<b>Session 5:</b>  <b>Track A:</b> Accelerating Access to Medicines Through Collaboration  <b>Track B:</b> Optimizing Clinical Trials Operationally in Canada  <b>Track C:</b> Notification of Foreign Actions: Challenges and Best Practices	Room 106CD Room 118E Theatre Hall 201
5:30-6:30PM	<b>Networking Reception</b>	Room 106EFG

<b>7:30AM-4:00PM</b>	<b>Meeting Registration</b>	Atrium, outside Room 106CD
<b>7:30-8:30AM</b>	<b>Networking Breakfast</b>	Room 106EFG
<b>8:30-9:45AM</b>	<b>Session 6:</b>	
	<b>Track A:</b> Nitrosamine Impurities – What's New and Where Do We Stand?	Room 106CD
	<b>Track B:</b> Decentralized Clinical Trials	Room 118E
	<b>Track C:</b> Good Pharmacovigilance Practices Inspection Readiness	Theatre Hall 201
<b>9:45-10:30AM</b>	<b>Refreshments, Exhibits, and Networking Break</b>	Room 106EFG
<b>10:30-11:45AM</b>	<b>Session 7:</b>	
	<b>Track A:</b> Advancements in Regulatory Data Transformation	Room 106CD
	<b>Track B:</b> Clinical Trials: Focus on Patients, Innovation and Automation	Room 118E
	<b>Track C:</b> Artificial Intelligence (AI) in Pharmacovigilance	Theatre Hall 201
<b>11:45AM-12:45PM</b>	<b>Luncheon, Exhibits, and Networking Break</b>	Room 106EFG
<b>12:45-2:00PM</b>	<b>Session 8:</b>	
	<b>Track A:</b> Do You Have a Handle on Data Transparency? Best Practices for Management and Public Release of Clinical Data and Confidential Business Information	Room 106CD
	<b>Track B:</b> Clinical and Commercial Challenges of Emerging Therapies: Lessons Learned from Psychedelics and Cannabinoids	Room 118E
	<b>Track C:</b> When Quantity Affects Quality: The Consequences of Overreporting	Theatre Hall 201
<b>2:00-2:40PM</b>	<b>Refreshments, Exhibits, and Networking Break</b>	Room 106EFG
<b>2:40-3:55PM</b>	<b>Session 9 Plenary:</b> How to Make Good Decisions Quickly	Room 106CD
<b>3:55-4:10PM</b>	<b>Closing Remarks</b>	Room 106CD
<b>4:10PM</b>	<b>Meeting Adjourns</b>	

# Learning Objectives

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

- Contextualize the Agile Licensing for Drugs initiative within Health Canada's (HC's) Regulatory Innovation Agenda
- Identify key themes and feedback heard during HC's consultation period, including the use of terms and conditions, risk management plans, and rolling reviews
- Describe current efforts to increase equitable drug development and regulatory systems
- Identify regulatory frameworks and policies to support advanced therapeutic products and devices in Canada
- Gain insights on international collaboration initiatives in place to support timely access to medicines in Canada
- Define specific attributes of HC's regulatory requirements on HC's Nitrosamines Impurities Guidance and utilization of international collaboration to inform regulatory requirements and decisions
- Gain insights on how to optimize clinical trials operationally in Canada
- Identify the most common good pharmacovigilance practices (GVP) inspection findings
- Gain insights on considerations around global collaboration and reliance regarding digital advancements in regulatory data transformation
- Identify key elements of effective clinical supply chain
- Define transparency requirements for sponsors and expectations from regulators

## Continuing Education Credits



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.

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If you are claiming CE credit for the short course you must:

1. Virtually attend the short course in its entirety
2. Complete the post-assessment with a passing score of 80% or better and complete the program evaluation
3. Access your DIA account and select My Transcript to claim your CE credit, available on **Friday, November 3, 2023**.

### To access My Transcript:

- Visit DIAglobal.org, select "Sign in" and you will be prompted for your user ID and password
- Under EVENTS select "Continuing Education"
- Select the blue "My Transcript" button followed by "Credit Request" to process your credit request for the course

## 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.

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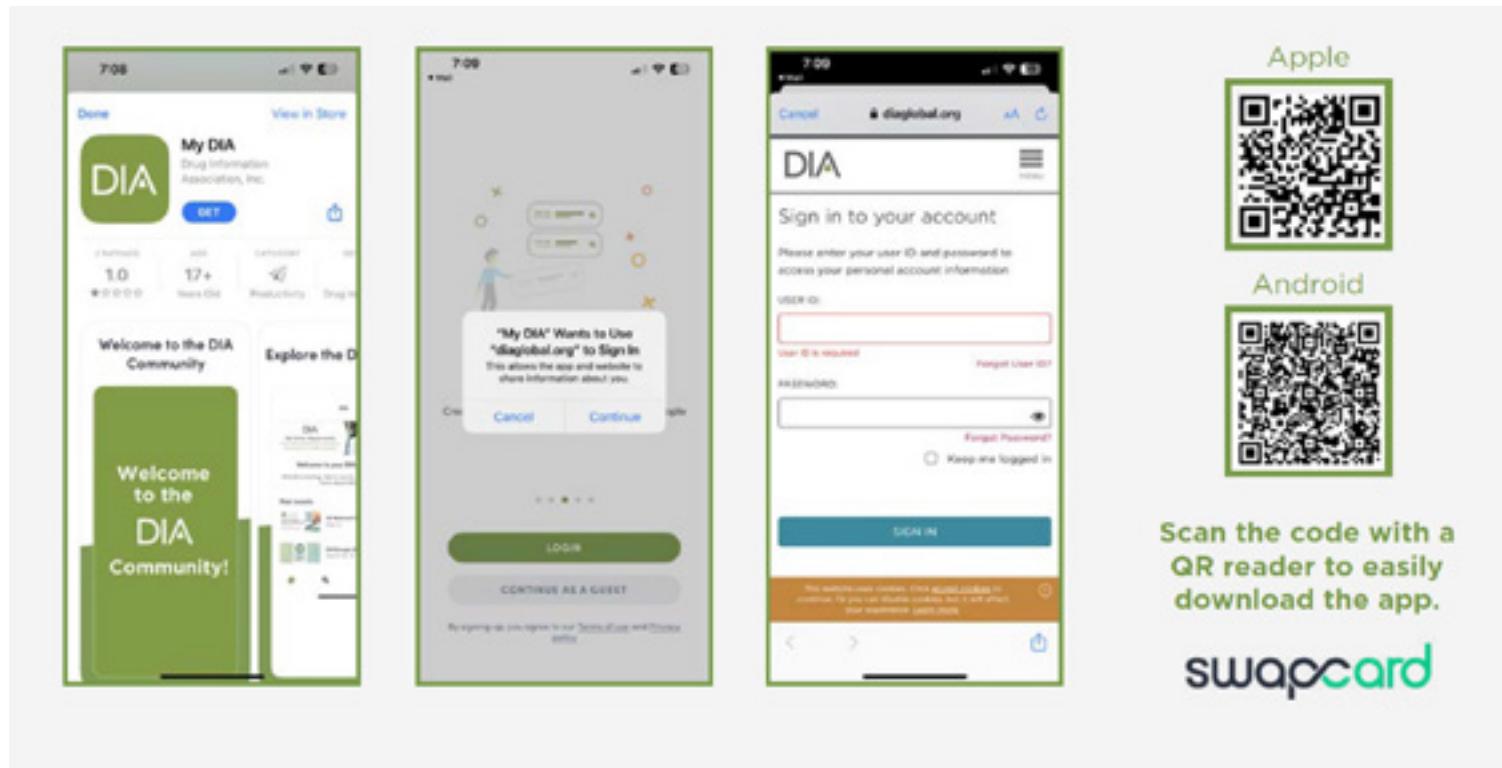
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## Want to View The Detailed Agenda?

Download DIA's Mobile App!

### DIA Global App

- DIA Global App is run through Swapcard
- App is available in Apple and Android app stores (search for **My DIA**)
- Access for all attendees, speakers, and exhibitors registered for Canada Annual Meeting 2023. There is single sign-on for SwapCard - individuals will be redirected to login with their DIA Username and Password.
- You are unable to login in with multiple devices on the same account so individuals cannot share username/password



### Highlights of the My DIA App

- Create "My Agenda" with your personal sessions
- Browse and bookmark speakers, sessions, and exhibitors so they can access with one touch
- Access helpful information from the conference
- Find exhibitors on the floor plan, view their information, etc.
- Send and receive meeting invites from conference participants
- Share DIA 2023 experiences through photos, posts, and more