DIA

Canada Annual Meeting

Short Courses October 11 | Meeting October 18-19 | Ottawa, ON Canada

PROGRAM COMMITTEE

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Overview

The DIA's Canada Annual Meeting will deliver a comprehensive overview of the current biopharma and device landscape in Canada, while sharing insights into Canada's broader role in global healthcare product development.

Event Goals and Offerings

- Discuss policy updates and priorities shared directly from Health Canada
- Discover international partnerships with consideration to regulatory, clinical, and safety for drugs and devices
- Address the current issues and opportunities in Canada and beyond
- Pharmacovigilance track added:
  - Additional insights, education and knowledge sharing to analyze relevant challenges and opportunities for professionals in Canada

Targeted Learning Sessions

Track A: Regulatory

Gain a clearer understanding about Health Canada's modernization initiatives with complementary perspectives from industry on:

- Regulatory Review of Drugs and Devices (R2D2)
- Real-World Data and Real-World Evidence
- Innovation and Collaboration in Oncology
- Overview of Health Canada's "Agile Licensing for Drugs"
- Overview of Health Canada's "Agile Licensing for Medical Devices"

Track B: Clinical

- Focused track on clinical research development and operations for industry
- Includes Health Canada's approaches to the modernization of clinical trial regulations, patient contribution to resource development, and its potential to transform the way we conduct clinical research
- Gain insights from industry, regulators, and patients on clinical trial design and conduct
- Review real-world insights into the benefits and challenges of incorporating real-world data/evidence into decisions about clinical trials
- Gain insights on the importance of the transparency of clinical trial information and measures

Track C: Pharmacovigilance

- New to our program this year, this track will provide a comprehensive overview of Canada's regulatory environment in the field of clinical safety and pharmacovigilance for biopharmaceutical products and medical devices
- Enjoy an overview of key considerations for successful risk minimization
- Discuss good Pharmacovigilance Practices (GVP) Inspections, the impact of Vanessa's Law, and the use of AI

Who Should Attend

Professionals involved in:

- Pharmacovigilance
- Clinical Research, Management, Safety & Ops
- Medical Affairs and Communication
- Quality Assurance Control
- Public/Corporate Policy & Regulatory Affairs
- R&D and Risk Management
- Project Management & eSubmissions
- Real-World Evidence and Statistics

Schedule At-A-Glance

Track A: Regulatory **Track B:** Clinical **Track C:** Pharmacovigilance

SHORT COURSE | TUESDAY, OCTOBER 11

All times listed are in EST

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

DAY ONE | TUESDAY, OCTOBER 18

7:00AM-5:00PM	**Meeting Registration**
7:00-8:00AM	**Networking Breakfast**
8:00-8:10AM	**Opening Remarks**
8:10-9:10AM	**Plenary Session:** The Future of Clinical Information Flow: Breaking the Document Paradigm
9:15-10:15AM	**Session 1:** Whatever Happened to the Regulatory Review of Drugs and Devices (R2D2) – 2017-2021?
10:15-10:45AM	**Refreshment and Networking Break**
10:45AM-12:00PM	**Session 2:** Understanding Health Canada's Regulatory Modernization Plans: Agile Licensing for Drugs
12:00-1:15PM	**Networking Luncheon**
1:15-2:30PM	**Session 3:** The What and How of Transparency of Clinical Trial Information
2:30-3:00PM	**Refreshment and Networking Break**
3:00-4:15PM	**Session 4:** Transforming Clinical Trial Design
4:20-5:20PM	**Session 5:** Regulatory Innovation for Health Products: Agile Licensing for Medical Devices
5:20-6:20PM	**Networking Reception**

DAY TWO | WEDNESDAY, OCTOBER 19

7:00AM-3:10PM	**Meeting Registration**
7:00-8:00AM	**Networking Breakfast**
8:00-9:15AM	**Session 6, Tracks A, B:** Real-World Data (RWD) and Real-World Evidence (RWE) in Regulatory Decision Making
8:00-9:15AM	**Session 6, Track C:** Monitoring Post-Market Compliance through GVP Inspections and Proactive Risk Management Projects
9:20-10:35AM	**Session 7 Tracks A, C:** Use of Artificial Intelligence in Pharmacovigilance (PV)
9:20-10:35AM	**Session 7, Tracks B, C:** Key Considerations for Successful Risk Minimization
10:35-11:05PM	**Refreshment and Networking Break**
11:05AM-12:20PM	**Session 8, Tracks A, B:** Innovation and Collaboration in Oncology
11:05AM-12:20PM	**Session 8, Track C:** Vanessa's Law: Impact and Challenges of Mandatory Adverse Reaction Reporting
12:20-1:35PM	**Networking Luncheon**
1:35-2:55PM	**Plenary Session:** Patient Engagement throughout the Product Life Cycle
2:55-3:10PM	**Closing Remarks**
3:10PM	**Meeting Adjourns**

Learning Objectives

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

- Describe Health Canada's Regulatory Review of Drugs and Devices (R2D2), the current status and progress of initiatives achieved, and how they have led to Health Canada's Regulatory Modernization Framework
- Understand Health Canada's plan for regulatory modernization for drugs including the use of Terms and Conditions, Risk Management Plans and Rolling Reviews
- Describe the transparency measures that Health Canada is contemplating to guide and encourage sponsors for clinical trial registration
- Describe adaptive designs in clinical trials and the role that technology can play on remote monitoring, data collection and consent
- Describe key elements of Health Canada's Agile Licensing for Medical Devices, the specific attributes of Health Canada's regulatory innovation plan, and impact on local and global regulatory strategies
- Explain how RWD and RWE can be leveraged to support regulatory decision making
- Discuss what is expected during Health Canada's good vigilance practices (GVP) inspections and proactive compliance monitoring projects (CMPs), including current and future approaches for virtual inspections
- Understand the use and future of artificial intelligence in pharmacovigilance and the expectations from Health Canada
- Describe the FDA Oncology Center of Excellence's mission, vision, and initiatives, and the principal benefits and challenges of Project Orbis
- Explain Health Canada's expectation regarding the implementation of Vanessa's Law and the challenges faced by industry due to its implementation
- Recognize the importance of incorporating the patient voice and experience throughout the drug development life cycle

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

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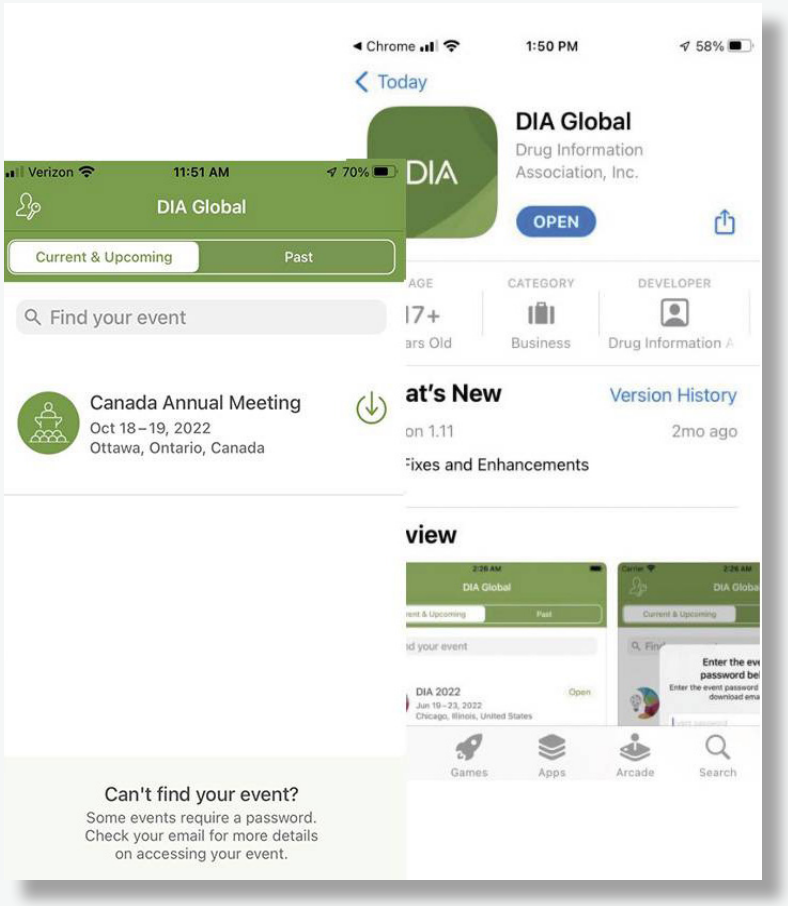
- Agenda at your fingertips
- Network with Attendees, Speakers, Exhibitors
- Frequently Asked Questions answered all in one place!



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Exhibitor Directory

Canada Annual Meeting

October 18-19, 2022

Delta Hotels Ottawa City Centre | Ottawa, ON Canada

DIA

PCI Pharma Services
977 Century Drive
Burlington, ON L7L 5J8
Canada

Contact: Laura Zenker
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https:// www.pci.com
LinkedIn: https://www.linkedin.com/company/pciservices/

PCI is a leading global CDMO, providing clients with integrated, end-to-end drug development, manufacturing and packaging services delivering speed to market and commercial success. Continued investment in both state-of-the-art technology and our people enables us to provide innovative solutions as a bridge between life-changing therapies and patients.

SYSTRAN Software
1615 Murray Canyon Road
Suite 560
San Diego, CA 92108

Contact: ken.behan@systrangroup.com
Phone: +1.858.320.2417
Email: *ken.behan@systrangroup.com*
https://www.systran.us/healthcare-translation-services?hsLang=en
LinkedIn: https://www.linkedin.com/company/166235/admin/

HIPAA-Compliant Medical Machine Translation Services at Scale

Because SYSTRAN's translation servers use machine learning, they can channel HIPAA-protected information through firewalled and compliant platforms. These servers are on your premises, the data on them is owned and controlled by you.

A SYSTRAN server's translation capabilities are unmatched by other healthcare translation options, processing terabits at a time in any of 55 languages, with an immense database of medical terminology.

DIA
Annual Canadian Meeting
Exhibitor Directory

October 18-19 | Delta Hotels Ottawa City Centre
Ottawa, ON, Canada

CAI — Table 8

Contact: David Goodlander
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Email: david.goodlander@cagents.com
https://www.cagents.com
LinkedIn: https://www.linkedin.com/company/caiconnected/mycompany/verification/

We help our customers design, deliver, operate and maintain quality-critical manufacturing (GMP related) or mission-critical facilities. Our engineering, technical and consulting services encompass all aspects of operation: equipment, automation, process, human performance. The result is a superior level of operational performance and reliability.

i4i Inc. — Table 4

Contact: Jack Benson
Phone: 416.504.0141
Email: sales@i4i.com
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i4i is a world leader in structured content solutions – specializing in Global Labelling Compliance.

Connect, control, track, analyze and publish your regulated document content with rich data capture, intelligent reuse, and jurisdictional alignment (CCDS, SPL, QRD, IDMP, XML PM).

We look forward to working together to reduce risk and discover new opportunities with our innovative technology, regulatory expertise and knowledge of evolving standards and Health Authority requirements.

Innomar Strategies Inc. — Table 1

Contact: Mary Speagle (mspeagle@tpireg.com)
Phone: 888.420.5457
Email: marketing@innomar-strategies.com
https://www.innomar-strategies.com/our-integrated-model/regulatory-services
Twitter: https://twitter.com/innomar_ab
LinkedIn: https://ca.linkedin.com/company/innomar-strategies

As part of Innomar Strategies, TPIreg offers expertise in all areas of Regulatory Affairs, Quality Assurance and Safety to the pharmaceutical, biotechnology, natural health product & cosmetic industries. With expertise in all areas of Regulatory Affairs & QA consulting, TPIreg supports a wide variety of therapeutic Gastrointestinal, CNS, Ophthalmology, Cardiovascular, Biosimilars, Rare Disease, Oncology, & medical device fields with submissions to Health Canada, the FDA, etc.

LORENZ Life Sciences Group — Table 2

Contact: Yaprak Eisinger
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Email: mail@lorenz.cc
www.lorenz.cc

LORENZ Life Sciences Group has been developing and marketing software solutions for the Life Sciences market since 1989. LORENZ offers an array of Regulatory Information Management solutions geared towards industry, health authorities and academia that enable compliance enforcement globally. LORENZ's tried and tested portfolio offers Product Registration/IDMP, Submission Assembly, Validation and Management, Publishing/eCTD, Regulatory Planning and Tracking products and related services.

PCI Pharma Services — Table 3

Contact: Laura Zenker
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LinkedIn: https://www.linkedin.com/company/pciservices/

PCI is a leading global CDMO, providing clients with integrated, end-to-end drug development, manufacturing and packaging services delivering speed to market and commercial success. Continued investment in both state-of-the-art technology and our people enables us to provide innovative solutions as a bridge between life-changing therapies and patients.

SYSTRAN Software — Table 7

Contact: ken.behan@systrangroup.com
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https://www.systran.us/healthcare-translation-services?hsLang=en
LinkedIn: https://www.linkedin.com/company/166235/admin/

HIPAA-Compliant Medical Machine Translation Services at Scale
Because SYSTRAN's translation servers use machine learning, they can channel HIPAA-protected information through firewalled and compliant platforms. These servers are on your premises, the data on them is owned and controlled by you.
A SYSTRAN server's translation capabilities are unmatched by other healthcare translation options, processing terabits at a time in any of 55 languages, with an immense database of medical terminology.

TrialAssure — Table 6

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Facebook: https://www.facebook.com/TrialAssure/
LinkedIn: https://www.linkedin.com/company/trialassure

TrialAssure is an award-winning transparency software suite that helps sponsors meet regulatory compliance goals through a flexible, scalable, and streamlined platform that supports trial registration, disclosure, data sharing, anonymization, and plain language summaries.

Zenith PV Solutions Inc. — Table 5

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LinkedIn: https://www.linkedin.com/company/zenith-pv-solutions-inc/?originalSubdomain=ca

Founded on the principles of: Trust, Ownership, Reliability and Speed.

A Global Medical Affairs company specializing in all bilingual Pharmacovigilance aspects including but not limited to: PV self-inspection, GVP audit readiness support, PV department set-up, ICSR processing, medical assessment, MedDRA coding, expedited reporting to health authorities, aggregate reports compilation (ASRs, PSURs), and Medical Information Support for pharmaceutical drugs and advanced biological treatments.