DUE BY FRIDAY, JUNE 28

DIA Annual Canadian Meeting

NOVEMBER 5-6 | HILTON LAC-LEAMY | GATINEAU, QC CANADA



CALL FOR ABSTRACTS - SUBMISSION DEADLINE: FRIDAY, JUNE 28

ABSTRACT OVERVIEW AND TOPICS:

The DIA Annual Canadian Meeting will deliver a comprehensive overview of the current bio-pharma and device landscape in Canada, while sharing insights into Canada's broader role in global healthcare product development. From policy updates and priorities shared directly from Health Canada, to sessions on international work sharing to key regulatory and clinical considerations for biologics and biosimilars, you will have the exclusive opportunity to address the current issues and opportunities in Canada and across the globe.

We are accepting abstracts for 20-minute presentations (speakers), 90-minute sessions (session chairs), and 3.5-hour pre-meeting short courses (instructors). When visiting the DIA website to submit your abstract, be sure to select the correct abstract type (presentation, session, or short course).

Suggested topics include, but are not limited to:

IMPROVING REVIEW AND ACCESS OF DRUGS AND DEVICES

- · Exploring New Pathways to Market
 - · International worksharing
 - · Use of foreign reviews/decisions to support drug submissions
 - · Early scientific advice from stakeholders in drug access
 - Pathways used by other regulatory jurisdictions (advantages and challenges)
- · Leveraging Partnerships in the Drug Access Chain
 - · Prioritizing work to better meet healthcare system needs
 - Aligning the Health Canada review with that of the Health Technology Assessment body
 - · Strengthening the sharing and use of Real World Data/Real World Evidence
- Regulatory Renewal
 - · Biologics/biosimilars
 - Generic drugs/Canadian reference products
 - · Special access program renewal
 - · Vanessa's Law implementation update
 - Opioids
 - Environmental assessment regulations
 - Confidential business information
 - · Patented medicine prices review board
 - Cost recovery
- Medical Devices Challenges and Opportunities
 - Early advice and interaction with the regulator
 - Post-market regulatory changes
 - · Strengthening the use of Real World Evidence for devices

CLINICAL TRIAL DESIGN AND RESEARCH

- Adaptive clinical trial design application and effect on product lifecycle
- How to appropriately choose endpoints that will meet regulators, payers, and Health Technology Assessments needs
- · Surrogate endpoints
- Use of Real World Data
- · Combination product clinical trial design
- · Novel approaches in clinical trial recruitment
- Clinical trial data transparency
- · Wearables in clinical trials
- Artificial intelligence and/or machine learning in clinical research
- · Post-market studies, including:
 - Deferred pediatric studies
 - Drug utilization studies
 - · Non-interventional studies registries

PATIENT CARE/PATIENT VOICE/ENGAGEMENT

- Natural health products and over the counter products Plain Language Labeling
- Self-care markets, nonprescription products when the patient is the one selecting the product what considerations need to be made from various perspectives
- What are the roles of patient advocates and patient associations and how
 have they become a strong stakeholder in adding value to conversations at
 regulator, payer, international levels, etc.; how are patient associations included
 in conversations and how do patient associations want to be included in
 conversations?

POLICY DEVELOPMENT AND DIRECTION

- How to effectively collaborate and engage in policy, including collaborating with Health Canada
- · How to critically review draft health authority guidance documents
- Cannabis

PERSONALIZED MEDICINE

- · Screenings for diseases
 - · Biomarker use in clinical trials
- Genetic testing
- Gene editing

SMALL AND MEDIUM SIZED ENTERPRISES

- Navigating Regulatory Processes
- Novel Collaboration agreements
- Bridging industry and academia

GENERICS

- Intellectual Property considerations
- · Innovation in how policy is applied
- · Innovation in manufacturing and supply chain management

DIGITAL

- Best practices for social media use in patient engagement compliance, legal, regulatory, and medical considerations
- · Promotion and advertising in social media
- How to incorporate the patient voice addressing the growing number of patient entry databases
- · Digital health
- Artificial Intelligence
- · Emerging technologies

RISK COMMUNICATION

- · Crisis management
- How to ensure regulatory message stays on point

Abstract Submission Deadline: Friday, June 28

Notification: Friday, July 12

Final PowerPoint Presentations Due: Monday, October 14

Meeting Dates: November 5-6

Location: Hilton Lac-Leamy, Gatineau, QC Canada

Please Submit All Abstracts Online At: <u>DIAglobal.org/Abstract</u>

Questions? Contact Susan Benedetti at susan.benedetti@diaglobal.org

CALL FOR ABSTRACTS

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GENERAL SUBMISSION REQUIREMENTS

(Please read the following instructions carefully; incorrect or incomplete abstracts will not be considered.)

- 1. All abstracts must be submitted online to **DIAglobal.org/Abstract**.
- 2. Title must reflect the abstract content accurately and concisely.
- Preference will be given to submitted abstracts that address real-life applications and case-studies.
- 4. Final PowerPoint presentations for all accepted abstracts will be due to DIA to be reviewed by the Committee and included on the DIA website for registered attendees. Should you choose to submit an abstract for consideration, please mark your calendars with the deadline.
- Presentations should not overtly endorse or recommend a specific product or service. For-profit organizations or industry logos are no longer permitted to be included in slide presentations, per ACCME Standards for Commercial Support.
- 6. Time allotted for individual presentations will be approximately 15-20 minutes. Final timing will be determined by the session chair and based on the number of presentations selected for the session.

- 7. DIA will provide complimentary meeting attendance for the selected speaker.
- 8. Please note: Only one speaker per presentation will be allowed. Any exceptions to this policy must be discussed with the DIA office in advance.

REQUIRED DOCUMENTATION FOR ALL ABSTRACTS

- Participant Disclosure Information: all abstract authors must disclose any relevant financial relationships with any commercial interest associated with this activity that exist or have existed within the past 12 months, as well as any discussion of unlabeled or unapproved drugs or devices. If you are proposing an abstract on behalf of the author, as the submitter you will not be asked to disclose. However, should the abstract be accepted, the author will be informed that he or she must complete and submit a Participant Disclosure in order to participate in the program.
- All submitters and authors must agree to the DIA Speaker
 Authorization for Use of Presentation Materials in order for the
 abstract to be a part of the Program. Accepted abstracts will be
 available on DIA's website for attendee download after the event.

SUBMISSION GUIDELINES

The following information will be requested at the time of submission. **DIAglobal.org/Abstract**

To streamline your submission process and avoid possible delays, DIA strongly encourages you to submit your abstract as early as possible. **Do not wait until the last day.**

Prepare your abstract before you access the DIA website. Abstract information should be copied and pasted from a prepared document as plain text. **All of the below fields are required.**

Author Information. The following information will need to be completed

Prefix: Country:

First Name: Address Line:

Middle Name: City:

Last Name: State/Province:

Name Suffix: Zip/Postal Code:

Degrees: Phone:

Job Title: Email:

Company:

NOTE: If you are submitting on behalf of the author, you are considered the SUBMITTER and will need to complete the required information for yourself AND also for the AUTHOR. Submitters will be the contact regarding the status of the abstract. If you are submitting your own abstract, you are considered the AUTHOR and will be the direct contact for this abstract.

Abstract Title (maximum 125 characters, including spaces)

Titles should briefly describe the focus of the abstract as well as accurately reflect the content of the abstract.

Primary Interest Area

Select the interest area that best relates to your abstract.

Keywords (Maximum 100 characters, including spaces)

Provide one or more keywords to highlight your abstract. Examples of keywords: Personalized Medicine, Health Technology Assessment, Clinical Trial Agreements.

Level of Difficulty (Select one):

- Basic: Appropriate for individuals new to the topic/subject area.
- Intermediate: Appropriate for individuals who already have a basic understanding of the topic/subject area.
- Advanced: Appropriate for individuals with an in-depth knowledge of the topic/subject area.

Objective (Maximum 300 characters, including spaces)Provide a one-sentence statement of the abstract's objective.

Learning Objectives (maximum 400 characters, including spaces) Please provide two to three learning objectives that clearly explain what participants should be able to do after attending this presentation. For a list of suggested verbs to create these objectives, please select the Learning Objectives link.

Abstract Details (maximum 2,000 characters, including spaces)

Please provide complete details about your abstract. Information such as scientific, technical, process issues, design/methods, results/outcomes, case-studies, statistics, key findings, etc., that would support your abstract should be included here. This information will be used by the Program Committee to learn more about the purpose of your abstract.

Abstracts will be reviewed, and authors will be notified of results by Friday, July 12