



CALL FOR ABSTRACTS

ABSTRACT SUBMISSION DETAILS AND GUIDELINES SUBMISSION DEADLINE: APRIL 30

Are you a professional involved in the regulatory, clinical or safety and pharmacovigilance functional areas within a company or organization working on pharmaceuticals, drugs, medical devices, and/or diagnostics in Canada? If so, DIA wants to hear from you!

To ensure that we have the most comprehensive and cutting-edge program, we are seeking abstract submissions from professionals like yourself, who are pushing the boundaries in their respective fields. We encourage you to submit abstracts that reflect the latest trends, innovations, and best practices in regulatory, clinical or safety and pharmacovigilance in Canada. We will be accepting the following formats:

- Presentations: 15-20-minute presentation to be bundled with other presentations to create a session
- Sessions: 60-75-minute total session

- Workshop: 60-minute workshop delivered in an interactive/simulation or role-playing format
- Short Courses: three-hour interactive workshop delivered in a small group format (these will be delivered virtually and require a separate fee from attendees)

The Canada Annual Meeting Program Committee is seeking abstracts on the following topics (keep in mind, business use cases and lessons learned are encouraged in all topic areas). Please note that this meeting is attended by many regulatory, clinical and safety professionals, service providers, and health authority representatives, and therefore, topics in addition to those listed below, that you feel are relevant, may be submitted for evaluation and possible selection.

Regulatory Track:

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.

- Building a regulatory operations team: expanding infrastructure and skill sets, training, and managing increasing demands
- Challenges and opportunities for drug development in special populations, therapeutic areas or health conditions (e.g., pediatric development plan, rare diseases, etc.)
- Chemistry, manufacturing, and controls (CMC) development and challenges
- Cross-functional dependencies on regulatory data (e.g., transparency, market access, etc.)
- Data standards and governance
- Digital transformation of regulatory (e.g., XML implementation, e-labeling, automation, cloud collaboration, project management updates)
- Diversity and inclusion regulatory topics
- Drug establishment license (DEL)
- Drug shortages
- Early access programs
- Global development and filing strategies
- Health authority, industry, and trade group vision and collaborations
- Implementation of new ICH guidelines (e.g., ICH M13A – Bioequivalence for Immediate Release Solid Oral Dosage Forms)
- Inspection preparation and readiness
- International collaboration (e.g., ACCESS, Project Orbis)
- Operationalization and implementation of AI
- Payer, health technology assessment (HTA), and patented medicine review board (PMPRB) perspectives on pricing and reimbursement
- Planning, tracking and management of regulatory activities and information
- Professional development topics as they apply to the regulatory functional area (e.g., core competencies for RA professionals of the future)
- Regulatory dossier development best practices (e.g., writing, cross referencing, etc.)
- Regulatory intelligence and regulatory strategy
- Regulatory modernization
- Regulation, policy and guidance updates
- Submissions relying on third party data
- Utilization of real-world data (RWD) and real-world evidence (RWE)
- Development challenges for small and medium sized organizations

Clinical Track:

Today, modern pharmaceuticals, drugs, biologics, advanced therapies, medical devices, and diagnostic products are advancing at an unprecedented speed. Sessions in this track will focus on clinical research development and operations for industry.

- Advanced therapy medicinal product (ATMP) challenges
- Budgeting: understanding fair market value
- Building a clinical operations team: expanding infrastructure and skill sets, training, and managing increasing demands
- Clinical operations and logistics: planning, tracking, and metrics
- Clinical trial modernization (e.g., use cases and best practices)
- Cybersecurity considerations and compliance with international privacy rules in clinical trials and its impact on the bottom line
- Decentralized clinical trials (DCTs)
- Digital health technologies (DHTs)
- Effective patient engagement strategies
- Effective recruitment, retention, and engagement strategies for clinical operations
- Equity, diversity, inclusion, anti-racism, and accessibility (EDIAA)
- Ethics review process and timeline in Canada
- Expanded access clinical trials draft guidance
- Highlighting the advantages of conducting clinical trials in Canada
- Implementation of effective strategies that support clinical operations

- Innovation in clinical program design (e.g., master protocols and decentralized studies)
- Inspection preparation and readiness
- Investigation of medical devices, diagnostics, and combination products
- New guidance for co-packaged drug products
- Partnerships/outourcing
- Patient consent (e.g., types of consent and the challenges that exist)
- Patient-focused endpoint development
- Planning clinical supply logistics (e.g., e-labeling)
- Professional development topics as it applies to the clinical functional area (e.g., soft skills)
- Quality management systems and quality control best practices
- Special populations (e.g., pediatric, rare disease, geriatric, historically underrepresented, etc.)
- Speeding up clinical development (e.g., modeling and simulation, extrapolation to different populations, etc.)
- Statistical considerations for trial design (e.g., adaptive design studies)
- Understanding, working with, and closing the gap between generations in clinical operations (from Baby Boomers to Gen Alpha)
- Use of AI and artificial data in clinical development

Safety and Pharmacovigilance Track:

Our safety and pharmacovigilance (PV) track will provide a comprehensive overview of Canada's regulatory environment in the field of clinical safety and pharmacovigilance for pharmaceutical products, drugs, medical devices, and diagnostics.

- Adverse event (AE) reporting
- Aggregate reports (ASRs, PBRERs)
- Agile regulations and their effects on pharmacovigilance
- Building a pharmacovigilance and drug safety team: expanding infrastructure and skill sets, training, and managing increasing demands
- Data privacy and how it pertains to pharmacovigilance
- Effective patient engagement strategies as they apply to pharmacovigilance and drug safety
- Good pharmacovigilance practices (GVP)
- How effectiveness checks on risk minimization measures will impact Canada
- How health authorities utilize reported information
- How marketing authorization holders (MAH) process reportable data
- Implementation of effective strategies that support pharmacovigilance and drug safety operations
- Insights and challenges of switching safety databases
- International collaboration and harmonization in pharmacovigilance and drug safety
- Managing quality of cases within an outsourced pharmacovigilance model
- Notification of foreign risk actions
- Patient support programs
- Pharmacovigilance for digital media and market research
- Pharmacovigilance for medical devices, diagnostics, combination products, and low risk products
- Pharmacovigilance for over the counter (OTC) or consumer healthcare companies (e.g., challenges and implications for public health and biopharma companies)
- Reportable information required by different health authorities
- Risk management plans (RMPs) (e.g., implementation of the new guidance document)
- Risk management strategies and implementation
- Successful use cases demonstrating the effective integration of artificial intelligence (AI) and new technologies (e.g., automation) into pharmacovigilance and drug safety applications

Abstract Submission Deadline:
Wednesday, April 30

Notification: Week of June 30

Final PowerPoint Presentations Due:
October 6

Meeting Dates: October 27-28

Please submit all abstracts online at:
DIAGlobal.org/Abstracts

Questions: Contact Lynda Fisher, Project Manager, Lynda.Fisher@DIAGlobal.org

CALL FOR PRESENTATION ABSTRACTS

SUBMISSION DEADLINE: APRIL 30

GENERAL SUBMISSION REQUIREMENTS

- All submissions must be submitted online
- For complete submission requirements and to submit your abstract go to DIAglobal.org/Abstracts

SUBMISSION TIPS

- Ideal submissions will contain practical content and shared experiences
- Theoretical topics and content is acceptable, however, it should be supported with proof of concepts and use cases
- Diverse topics and sessions are welcomed and encouraged within the scope of the meeting
- Please select the track that best fits with your proposal. If your topic is relevant to more than one track, please indicate that in your abstract summary as cross-track sessions are available
- Abstracts should be written using clear language and descriptions to provide enough clarity for the selection committee to review and understand

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.

SUBMISSION GUIDELINES

Submitting a PRESENTATION ABSTRACT (All abstracts must be submitted online)

15-20-minute presentation, bundled with other presentations to create a session. Abstract author is considered the presenter (co-presenters are not permitted) and will be responsible for:

- Adhering to the program development guidelines and timelines
- Working with chair and other presenters in creating a balanced program offering
- Preparing and delivering a PowerPoint presentation

Submitting a SESSION ABSTRACT (All abstracts must be submitted online)

60-75-minute total session. Abstract author will be responsible for:

- Adhering to the program development guidelines and timelines
- Recruiting speakers and ensuring good representation/diversity in their selection. Maximum of 3 speakers per session
- Working with the Session Chair to communicate with speakers regarding their role in the session

Submitting a WORKSHOP ABSTRACT (All abstracts must be submitted online)

60-minute total workshop. Abstract author will be responsible for:

- Adhering to the program development guidelines and timelines
- Ensuring the workshop provides onsite learning in the form of activities or demonstrations

Submitting a SHORT COURSE ABSTRACT (All abstracts must be submitted online)

Three-hour, interactive presentation delivered in small group format. Abstract author is considered the Short Course Lead Instructor and will be responsible for:

- Adhering to the program development guidelines and timelines
- Recruiting co-instructors and ensuring good representation/diversity in their selection
- Communicating with co-instructors regarding their role in the short course and reviewing presentation materials (note: PowerPoint presentations are required from each instructor)
- Managing the short course, including the facilitation of audience questions and interactions

SUBMISSION GUIDELINES

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

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 in advance of accessing 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

Abstract Information

Abstract Title: (125 characters including spaces)

Track: Choose from the drop down

Keywords: Provide one or more keywords to highlight your abstract. Examples of keywords: Personalized Medicine, Health Technology Assessment, etc. (100 characters)

Level of Difficulty: Beginner, Intermediate, or Advanced

Learning Objectives: Provide 2-3 learning objectives that clearly explain what participants should be able to do after attending this event. For a list of suggested verbs to create these objectives, [click here](#). (400 Characters)

Overview: *Please provide 2-3 sentences summarizing your abstract. This summary will be used as the overview description in the DIA program for marketing purposes (250 Characters including spaces)

Abstract Details: *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 proposal should be included here. This information will be used by the Program Committee to learn more about the purpose of your abstract. Is there an interactive component to your topic? If so, please indicate in the abstract details how you would be able to include an interactive learning experience for attendees. (2000 Characters including spaces)

Submit Your Abstract at DIAglobal.org/Abstracts