DIA

DIA Annual Canadian Meeting

Short Course: October 18 | Conference: October 19-20 | Virtual

PROGRAM COMMITTEE

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Overview

The *DIA Annual Canadian 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. From policy updates and priorities shared directly from Health Canada to sessions on international work sharing and partnerships, to key regulatory, clinical, and safety considerations for drugs and devices, you will have the exclusive opportunity to address the current issues and opportunities in Canada and across the globe. This meeting presents three tracks: Regulatory, Clinical, and Pharmacovigilance (NEW). Our new pharmacovigilance track, previously its own meeting, broadens the scope of this meeting and will provide additional insights, education and knowledge sharing for our attendees to discuss and analyze the relevant challenges and opportunities for professionals working in the field in Canada.

Highlights

- Track Listing
- **Regulatory:** Gain a clearer understanding of Canada's regulatory landscape through our regulatory track. You'll hear about Health Canada's modernization initiatives with complementary perspectives from industry on advanced therapeutic products (ATPs), medical devices, good manufacturing practices (GMP) virtual inspections, pediatric medicines, and international collaborations.
- **Clinical:** Today, modern biopharmaceutical and device 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, including case studies of how patients have contributed to resource development and how decentralized trials have the potential to transform the way we conduct clinical research. Take your level of understanding a step further and explore our other sessions including an industry perspective on good clinical practices (GCP) in relation to clinical trial site GCP audits and clinical trial compliance (CTC) inspections. Our attendees in this track will be able to gain real-world insights into the benefits and challenges of incorporating real-world data and real-world evidence into a whole range of decisions about clinical trials.
- **Pharmacovigilance:** As a new edition to our programming this year, our pharmacovigilance 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. Our pharmacovigilance track will kick off with an overview from representatives of various regulatory agencies, where they'll share lessons learned from COVID-19 and their thoughts on the future challenge of risk-management planning in a post-pandemic world. Subsequent sessions will cover topics such as good pharmacovigilance practices (GVP) inspections, post-market surveillance, the use of artificial intelligence in pharmacovigilance, and general data protection regulation (GDPR) and its implications.

Who Should Attend

Professionals in pharmaceutical and device industries, regulatory agencies, and academia involved in:

- Clinical Data Management/eClinical
- Comparative Effectiveness/Health Technology Assessment
- Clinical Safety/Pharmacovigilance
- Clinical Research
- Document Management/eSubmissions
- Medical Communications
- Outsourcing
- Project Management
- Public Policy/Law/Corporate Compliance
- Quality Assurance Control
- Regulatory Affairs
- Research and Development
- Statistics

Schedule At-A-Glance

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

SHORT COURSE | MONDAY, OCTOBER 18

Sessions held in ET

9:30AM-12:30PM	**Short Course:** Introduction and Update on Eurasian Economic Union Regulatory Environment and Electronic Drug Registration Format **This course requires an additional registration fee.*

DAY ONE |TUESDAY, OCTOBER 19

10:00-11:00AM	**Opening Remarks and Plenary Session**
11:00-11:15AM	Break
11:15AM-12:30PM	**Session 1:** Concurrent Breakout Sessions **Track A:** Modernizations Initiatives: Advanced Therapeutic Products (ATPs) **Track B:** Canada's Approach to COVID-19 Vaccine Development and Approval **Track C:** Pharmacovigilance and Risk Management Post-Pandemic: Lessons Learned and Future Perspectives
12:30-1:00PM	Break / Visit the Virtual Exhibit Hall
1:00-2:15PM	**Session 2:** Concurrent Breakout Sessions **Track A**: Health Canada Activities in the Medical Devices Area During the COVID-19 Pandemic **Track B:** Clinical Trials Innovation in Canada **Track C:** Round Table on GVP Inspections
2:15-2:45PM	**Exhibitor Event:** Coffee Corner hosted by i4i inc.: XML PM - Canada Joins the Growing Global Movement to Strengthen Patient Health and Safety Through More Structured Product Information - Separate RSVP required
2:15-2:45PM	Break / Visit the Virtual Exhibit Hall
2:45-4:00PM	**Session 3:** Concurrent Breakout Sessions **Track A:** Virtual Good Manufacturing Practices (GMP) Inspections **Track C:** Post-Market Surveillance

DAY TWO | WEDNESDAY, OCTOBER 20

9:15-10:00AM	**Exhibitor Session:** Round Table Session Hosted by Innomar Strategies: Drug Submissions Relying on Third-Party Data/Literature Based Submissions for Prescribing Medicines: An Update - Separate RSVP required
10:00-11:15AM	**Session 4:** Plenary – Bridging Gaps: Diversity, Equity, and Inclusion in Drug
11:15-11:30AM	Break / Visit the Virtual Exhibit Hall
11:30AM-12:45PM	**Session 5:** Concurrent Breakout Sessions **Track A:** Improving Access to Pediatric Medicines and Formulations in Canada **Track B:** GCP Inspections: An Abbvie Case Study **Track C:** Utility of Artificial Intelligence in Pharmacovigilance
12:45-1:15PM	Break / Visit the Virtual Exhibit Hall
1:15-2:30PM	**Session 6:** Concurrent Breakout Sessions **Track A:** International Collaboration via the Access Consortium: Health Canada and Industry Perspective **Track B:** Real-World Data and Real-World Evidence **Track C:** General Data Protection Regulation (GDPR) and It's Implications
2:30-3:00PM	Break / Visit the Virtual Exhibit Hall
3:00-4:30PM	**Session 7:** Adapting Health Product Advertising Oversight to the Digital Environment and Closing Remarks
4:30PM	Meeting Adjourns

Learning Objectives

At the conclusion of this meeting participants should be able to:

- Describe the current and evolving regulatory environment in Canada
- Summarize current methods used in clinical trials, patient engagement, and improving market access
- Discuss approaches on international harmonization, work sharing, and implementation of current guidelines
- Review the various levels of transparency needed to maintain compliance in pre- and post-market activities

Track A: Regulatory **Track B:** Clinical **Track C:** Pharmacovigilance Sessions held in ET

SHORT COURSE | MONDAY, OCTOBER 18

9:30AM-12:30PM

Short Course: Introduction and Update on Eurasian Economic Union Regulatory Environment and Electronic Drug Registration Format **This course requires an additional registration fee.*

Instructor
Christina Stavrinidis, Senior Manager Regulatory Operations, Gilead Sciences, Ireland

From 31st December 2020, new marketing authorization applications for medicinal products to the Economic Area of Eurasia (EAEU) need to follow the electronic EAEU submission format. In addition, follow-up submissions must be compliant before 31st December 2025.

Therefore, pharmaceutical companies should start converting their existing approved EAEU applications into this new electronic format. Moreover, applications that do not yet have an existing approved EAEU application should now start their application directly in this new electronic format.

For these actions to occur it is essential to have a clear understanding of what the new electronic EAEU submission format entails. This session provides a general overview as well as highlight the key guidelines which underpin this new formatting structure. It will address the differences and similarities between the electronic EAEU format in comparison to the ICH eCTD format. Furthermore, it will look into the different validation options available as well as specifically address some of the key factors that must be taken into account to ensure a technically valid EAEU submission.

Throughout the session, I will also refer to my real-time experiences as Project Manager for various submission publishing projects highlighting some of the best practices that are recommended during a submission publishing project detailing how to go from electronic PDF documents to a valid eCTD submission.

At the conclusion of this short course, participants should be able to

- Describe the general structure of an electronic EAEU submission
- Write the differences and similarities between the EAEU electronic submission format and the ICH eCTD format
- Outline aspects that are needed in order to publish technically compliant electronic EAEU submission

DAY ONE |TUESDAY, OCTOBER 19

10:00-11:00AM

Opening Remarks and Plenary Session

Session Chair
Judith Mergl, MSc, Director, Regulatory Affairs and Operational Services, AbbVie Corporation, Canada

The world around us is quickly changing. Emerging technologies are dramatically altering the health landscape, while health products are becoming ever more complex and personalized. This keynote will kick off the DIA Canada Annual Conference by discussing Health Canada's role as regulator in the face of the evolving health and biosciences ecosystem. Elizabeth Toller will speak to the key change drivers

behind this evolution, the need for greater regulatory agility in response, and the implications of the COVID-19 pandemic.

The keynote address will be followed by a presentation on innovative global regulatory strategies using a case study that will provide practical regulatory recommendations on how to speed up drug development and reduce drug development costs while meeting high quality drug approval standards set by Health Authorities. A blueprint for product development with appropriate regulatory interactions will be shared followed by a discussion of regulatory incentives and pathways that may be leveraged for product development. At the conclusion of this session, participants should be able to

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

- Understand the key drivers of change in the health and biosciences sector requiring greater regulatory agility, and the impacts of COVID-19 on these change drivers
- Identify major obstacles in drug development and learn how to productively engage with Health Authorities (Health Canada, EMA and FDA) during global drug development to bring drugs to the market in an efficient manner

Speakers
Elizabeth Toller, MA, Associate Director General, Policy, Planning and International Affairs, Health Canada

Oxana Iliach, PhD, Senior Director Regulatory Strategy, Certara/Synchrogenix, Canada

11:00-11:15AM **Break / Visit the Virtual Exhibit Hall**

11:15AM-12:30PM **Session 1:** Concurrent Breakout Sessions

Track A: Modernizations Initiatives: Advanced Therapeutic Products (ATPs)

Session Chair
Samar Darwish, MSc, MBA, Director Drug Regulatory Affairs, Boehringer Ingelheim, Canada

Products are becoming increasingly complex (e.g. AI, machine learning, advanced cell therapy, 3-d printed products), and many of these products are challenging the current regulatory system and need innovative and agile solutions to enable access to these products. These Advanced Therapeutic products (ATPs) are becoming a reality and several of these transformative therapies have been approved by major and midsized authorities.

In this session, you will hear from Health Canada on the progress of the implementation of the Advanced Therapeutic Products (ATP) pathway, the identification of ATP candidates and the timelines of implementation of the first pilot ATP pathway. In addition, you will learn from an industry perspective on what is different about cell and Gene therapies, their science, their benefits, and challenges, as well as the regulatory landscape impacting the future of these promising therapies. The session will conclude with a panel discussion and a Q&A session.

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

- Recognize what makes cell and Gene therapies different from traditional therapies
- Discuss the opportunities and challenges of ATPs
- Describe the Health Canada proposed ATP pathway

Advanced Therapeutic Products
Kenneth Joly, MS, Policy Analyst, Office of Policy and International Collaboration, BRDD, Health Canada

Cell and Gene Therapies/ATMPs: Where are We?
Chin Koerner, MS, Executive Director, Regulatory Policy, Novartis Pharmaceuticals Corporation

Panelist
Nicole Mahoney, PhD, Executive Director, Regulatory Policy and Intelligence, Novartis Pharmaceuticals Corporation

Track B: Canada's Approach to COVID-19 Vaccine Development and Approval

Session Co-Chairs
Deborah Danoff, MD, Medical Evaluator, Health Canada

Fiona Frappier, PhD, Senior Policy Analyst, Health Canada

The vaccine development, regulatory review and public health response to COVID-19 have been unprecedented. The innovation and regulatory life cycle frames all aspects of the introduction and revision of therapeutics in Canada. The COVID-19 epidemic has required many innovations to meet Canadian and worldwide needs. This has included a nimble approach to vaccine development and regulatory activities. This presentation provides an in depth perspective on these innovations. Discussion will include success, lessons learned and impact on regulations post pandemic. Using case studies, we will explore both the MAH and regulatory authority perspectives.

At the conclusion of this session, participants should be able to

- Recognize the regulatory changes that permitted expedited approval of COVID-19 vaccines
- Learn about the impact (timing, resources, unexpected difficulties) of the regulatory changes
- Consider how these changes may inform future regulatory approaches

Health Canada's Regulatory Response to COVID-19
Celia Lourenco, PhD, Director General, Biologic and Radiopharmaceutical Drugs Directorate, HPFB, Health Canada

Pfizer-BioNTech COVID-19 Vaccine Overview
Aline Silahian, BPharm, Associate Director Regulatory Affairs, Pfizer Canada, Inc., Canada

Speakers
Leslie Madden, MBA, Head of Regulatory Affairs, Canada, Moderna

Ron Boch, Vice President, Biotechnology, and Industry Affairs, BIOTECanada

Track C: Pharmacovigilance and Risk Management Post-Pandemic: Lessons Learned and Future Perspectives

Session Co-Chairs
Marilyne Chamoun, MSc, Acting Manager, Marketed Pharmaceuticals Bureau, Health Canada

Patrick Fandja, **MSc, MBA**, Director, Bureau of Biologics, Radiopharmaceuticals and Self-care Products, Health Canada

In this session, representatives from regulatory agencies (EMA, FDA and Health Canada) will discuss their perspectives on lessons learned from the pandemic, and how they will shape the future of pharmacovigilance and risk management planning.

At the conclusion of this session, participants should be able to

- Gain a global understanding of the lessons learned from the pandemic
- Identify changes to PV/RM practices that should be adopted/considered post-pandemic

Speakers

Kate Browne, MSc, RPh, Signal Management Lead, European Medicines Agency, The Netherlands

Gerald Dal Pan, MD, MHS, Director, Office of Surveillance and Epidemiology, CDER, FDA

Kelly Robinson, MSc, Director General, Marketed Health Products Directorate, Health Canada

12:30-1:00PM **Break / Visit the Virtual Exhibit Hall**

1:00-2:15PM

Session 2: Concurrent Breakout Sessions

Track A: Health Canada Activities in the Medical Devices Area During the COVID-19 Pandemic

Session Chair
Patrick Fandja, **MSc, MBA**, Director, Bureau of Biologics, Radiopharmaceuticals and Self-care Products, Health Canada

At the onset of the COVID-19 pandemic, Health Canada introduced a number of innovative and agile regulatory measures to facilitate access of medical devices needed for COVID -19, to Canadians and healthcare workers. These measures cover the lifecycle of medical devices; clinical trials for COVID-19, In Vitro diagnostic testing devices for COVID-19, post-market surveillance, Medical Device Establishment Licences and Inspection. The objective of this session is to provide an overview of Health Canada's activities in the medical devices area during the COVID-19 pandemic.

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

- Outline Health Canada's activities in Clinical Trials and Post-market surveillance of COVID-19 devices
- Gain awareness of COVID-19 testing technologies approved by Health Canada
- Outline Health Canada's activities in Medical Establishment Licences and Inspection during COVID-19 Pandemic

Clinical Trials and Post-market Surveillance of COVID-19 Medical Devices
Tanya Ramsamy, PhD, Executive Director, Medical Device Directorate, Health Canada

COVID-19 Testing Devices
Christine Leckie, A/Executive Director, Medical Device Directorate, Health Canada

Medical Devices Establishment Licenses and Inspections
Marie Odile N Gomis, Manager, Regulatory Operations and Enforcement Branch, Health Canada

Track B: Clinical Trials Innovation in Canada

Session Co-Chairs
Fiona Frappier, PhD, Senior Policy Analyst, Health Canada

Mandy Collier, Health Products and Food Branch, Health Canada

Clinical trials continue to try new and innovative approaches to improve trial outcomes and patient health, and the need to modernize the way we regulate these trials in Canada has become clear. This session will provide an overview of Health Canada's approach to modernization of clinical trial regulations, include case studies of how patients have contributed to resource development and describe how decentralized trials have the potential to transform the way we conduct clinical research. The objective of this session is to provide an overview of how industry, government and research organizations are aiming to modernize clinical development.

At the conclusion of this session, participants should be able to

- Outline Health Canada's Clinical Trial Modernization Initiative
- Describe new approaches to decentralized trials
- Address patient considerations in improving clinical trials

Health Canada's Approach to Clinical Trial Modernization
Carole Legare, MD, Director, Office of Clinical Trials, TPD, Health Canada

Engaging Patients and the Public with Clinical Trials: Two Case Studies to Demonstrate Resources and Tools to Help Your Work
Dawn Richards, PhD, Director, Patient and Public Engagement, Clinical Trials Ontario, Canada

Modernizing Clinical Trials Through the Global Adoption of Decentralized Clinical Trials
Scott Askin, Global Program Regulatory Director, Innovation, Novartis Pharma AG, Switzerland

Track C: Round Table on GVP Inspections

Session Chair
Agnes Jankowicz, MSc, Executive Director, PV, Certus PV Services Inc., Canada

The Good Pharmacovigilance Practices (GVP) Inspection program is intended to verify that health product manufacturers meet the requirements of the Food and Drug Regulations pertaining to ADR reporting. In this session, you will learn from the Inspectorate about GVP inspection trends observed during the fiscal year 2020-2021 and on-going initiatives within the Program. In addition, you will also hear firsthand from an Industry perspective what to expect from a virtual GVP inspection and how to prepare for a GVP inspection.

At the conclusion of this session, participants should be able to

- Identify most common inspection findings observed in recent Health Canada GVP inspections
- Understand what is expected during Health Canada GVP inspections
- Understand how to best prepare for a GVP inspection

Speaker
Marc-André Giguère, Senior Corporate Regulatory and Enforcement Advisor, Health Canada

2:15-2:45PM

BONUS SESSION: Coffee Corner hosted by i4i inc.: XML PM – Canada Joins the Growing Global Movement to Strengthen Patient Health and Safety Through More Structured Product Information

Global Health authorities continue to develop new requirements for submissions throughout the product development lifecycle. Standards, pilots and initiatives are currently underway in all major markets and include, amongst others, SPL, XML PM, IDMP, PQ CMC, and ePI, many of which are leveraging XML technology to achieve their information exchange and interoperability goals. Health Canada is currently transitioning to the mandatory requirement for encoded product information in the new XML PM format to support the health and safety of Canadian families through improved product information.

Click here to RSVP

Featured Topics:

- Overview of global initiatives
- Benefits of structured product information
- Health Canada's initiative – XML PM

Moderators:
Gilles Durot, Senior Director, Global Life Sciences Solutions, i4i inc.

Jacqueline Bruner, Senior Director, Encoding Technology, i4i inc.

2:15-2:45PM

Break / Visit the Virtual Exhibit Hall

2:45-4:00PM

Session 3: Concurrent Breakout Sessions

Track A: Virtual Good Manufacturing Practices (GMP) Inspections

Session Co-Chairs
Yatika Kohli, PhD, MBA, Executive Director, Global Regulatory Affairs,NoNO Inc., Canada

Kristin Willemsen, MS, Vice President Scientific and Regulatory Affairs, Food Health and Consumer Health Products of Canada

During COVID-19, Health Canada has made a variety of changes to the regulatory approval process. These changes include conducting remote (virtual) evaluations in lieu of on-site inspections and issuing electronic licenses, replacing the traditional paper-based license. This session will include a presentation from Health Canada with updates on the recent changes and practices and presentations from industry with their experience, challenges, and practices for preparing and conduct of virtual GMP inspections.

At the conclusion of this session, participants should be able to

- Understand Health Canada's current approach for Virtual inspections
- Gain awareness of the challenges of and preparing for and conduct of remote evaluations
- List the Do's and Don'ts of preparing for regulatory inspection- especially in a virtual environment

Drug Product Compliance and Enforcement Post Pandemic
Kim Godard, PhD, Director, Health Product (Drug) Inspection and Licensing, Health Canada

Melanie Bhangoo, MS, Manager GMP Inspection Central, Health Canada

Considerations for Preparing for a Virtual Inspection
Trevor Aldridge, Senior Director, Quality, and Compliance, Brevitas Consulting, Inc., Canada

Preparing for a Pre-approval Inspection – A Case Study
Michael Schunk, DVM, Principal, Michael Schunk Biologics Consulting, Canada

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Track C: Post-Market Surveillance

Session Co-Chairs
Marcia Bailey, RN, BSN, MHS, Associate Director, Pharmacovigilance Scientist, Sierra Oncology, Inc., Canada

Caroline Croteau, PhD, RPh, Country Safety Lead, Pfizer Canada Inc.

Deborah Danoff, MD, FRCP, Medical Evaluator, Health Canada

Post market surveillance requires close collaboration between industry and the regulatory authorities. To that end, Health Canada has reached out to industry to understand concerns related to proposed changes to Risk Management Plan requirements, with a focus on the Canadian addendum. At the same time, industry is exploring innovative methods to gain additional information and facilitate risk mitigation for newer therapies.

This session will explore approaches to post market surveillance from the perspectives of both industry and regulatory authorities.

By the end of this session, participants should be able to:

- Describe the extension of patient support programs to include both generics and brand name products
- Outline how extra solicited reports / patient support programs can mitigate risk
- Summarize key points in Health Canada data on industry perspectives on strengths and limitations of proposed revisions to guidance on risk management plans

Pharmacovigilance Signal Detection and Information Monitoring for COVID-19 Vaccine Using Social Listening
Manfred Hauben, MD, MPH, Senior Director Product Safety Surveillance and Reporting, Pfizer Inc.

Speaker
Paul Litowitz, MBA, RAQC, Manager, Public and Regulatory Affairs Outreach Section, Health Products Surveillance and Epidemiology Bureau, Health Canada

DAY TWO | WEDNESDAY, OCTOBER 20

9:15-10:00AM

BONUS SESSION: Round Table Session Hosted by Innomar Strategies: Drug Submissions Relying on Third-Party Data/Literature Based Submissions for Prescribing Medicines: An Update

This session will focus on literature- based submissions for new drugs in Canada and prescription medicines in Australia.

Topics that will be covered are as follows:

- Overview of process (similarities and differences between jurisdictions)
- Experience to date with illustrative case studies
- Considerations
- Future directions

Click here to RSVP

Moderator
Mary Speagle, Senior Director, Regulatory Affairs, TPIreg, a part of Innomar Strategies

10:00-11:15AM

Session 4: Plenary – Bridging Gaps: Diversity, Equity, and Inclusion in Drug

Session Co-chairs
Marilyne Chamoun, MSc, Acting Manager, Marketed Pharmaceuticals Bureau, Health Canada

Samar Darwish, MSc, MBA, Director, Drug Regulatory Affairs, Boehringer Ingelheim, Canada

Biological and social differences can impact the way that drugs function in different populations. Even when clinical trials include large and diverse samples, certain populations continue to be under-represented due to various reasons. This session will bring together the regulator, industry and other perspectives and will discuss challenges in ensuring equitable inclusion in clinical trials and potential solutions.

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

- Describe Health Canada's Sex and Gender Based Analysis + (SGBA+) strategy
- Identify challenges related to the inclusion of a diverse population in drug development that takes into account differences related to sex, gender, age, ethnicity and vulnerable populations
- Discuss strategies, innovative approaches to improve representation and increase diversity and equity in drug development

Speakers
Alysha Croker, PhD, Manager, Office of Pediatrics and Patient Involvement, Health Canada

RADM Richardea Araojo, DrMed, PharmD, MS, Associate Commissioner for Minority Health, Director, Office of Minority Health, FDA

Kaveeta Vasisht, PharmD, MD, Associate Commissioner for Women's Health, Director of the Office of Women's Health, FDA

Kim Fookes, Global Head, Diversity and Inclusion in Clinical Trials, Novartis Pharmaceuticals

11:15-11:30AM

Break / Visit the Virtual Exhibit Hall

11:30AM-12:45PM

Session 5: Concurrent Breakout Sessions

Track A: Improving Access to Pediatric Medicines and Formulations in Canada

Session Chair
Patrick Fandja, Director, Bureau of Biologics, Radiopharmaceuticals and Self-care Products, Health Canada

This session will bring together the industry, clinician and regulator to discuss the challenges and opportunities to improve access to the pediatric medicines and formulations in Canada.

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

- Discuss lessons learned from regional policy reform that has shaped pediatric medicines development globally
- Discuss the opportunities and challenges related to pediatric formulations
- Outline Health Canada's initiatives aimed at improving access to pediatric medicines

The Role of Pediatric-focused Policies in Improving Access to Pediatric Medicines
Christina Bucci-Rechtweg, MD, Global Head, Maternal Health and Pediatric Regulatory Policy, Novartis Pharmaceuticals Corporation

Canada Needs a Pediatric Framework to Best Serve our Children
Andrea Gilpin, PhD, MBA, MS, General Manager, The Rosalind and Morris Goodman Family Pediatric Formulations Centre, Canada

Speaker
Alysha Croker, PhD, Manager, Office of Pediatrics and Patient Involvement, Health Canada

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Track B: GCP Inspections: An Abbvie Case Study

Session Chairs
Judith Mergl, Director, Regulatory Affairs and Operational Services, AbbVie Corporation, Canada

Consistent with other jurisdictions, Health Canada inspects approximately 2% of all clinical trial sites in Canada on a yearly basis. The mandate of these onsite clinical trial site inspections ensures participants in clinical trials are not subjected to undue risks, data is generated appropriately per GCPs, appropriate complaints investigations, and compliance with Division 5 of the Food and Drug Regulations - Drugs for Clinical Trials. This session will highlight the differences between Clinical Trial site GCP and Clinical Trial Compliance Sponsors audits.

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

- Distinguish between clinical trial site GCP audits and Sponsor CTC (Clinical Trial Compliance) inspections
- Gain and apply key learnings and insights from recent CTC inspections

Insights from a Regulatory Monitoring Perspective
Amber McLeod, PhD, Lead, Regulatory Affairs, AbbVie Corporation, Canada

Insights from a Clinical Site Management and Monitoring Perspective
Reena Gill, MHP, Senior Clinical Operations Manager, AbbVie Corporation, Canada

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Track C: Utility of Artificial Intelligence in Pharmacovigilance

Session Chair
Caroline Croteau, PhD, RPh, Country Safety Lead, Pfizer, Inc., Canada

Pharmaceutical companies are actively pursuing automated solutions to address the challenge of managing increasing volumes of safety-related data from multiple sources. Different Artificial Intelligence (AI) and technology tools – such as robotic process automation (RPA), and natural language processing (NLP) are being assessed and applied by different companies across the pharmacovigilance (PV) continuum. Validation of such applications remains an area of focus with interest from Regulatory Agencies worldwide. This session will provide an overview of the potential uses of AI in pharmacovigilance activities, provide concrete examples from the Pharma Industry as well as Health Canada's view on the topic and results from a survey conducted on this subject earlier this year.

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

- Understand how AI can be leveraged in pharmacovigilance and define AI, RPA, and NLP
- Outline how pharma organizations are using AI as part of PV activities, including limitations and validation
- Understand Health Canada's regulatory perspective on applying AI to pharmacovigilance strategies

Intelligent Automation Opportunities in Pharmacovigilance – The TranCelerate Group
Claudia Schaffer, RN, Head Case and Vendor Management, Merck Healthcare KgaA, Germany

Oeystein Kjoersvik, Product Owner and Business Analyst, Merkc & Co., Inc., Czech Republic

Embrace Automation in Pharmacovigilance Experience
Bhavin Patel, PharmD, RPh, Senior Director, Drug Safety, Pfizer, Inc.

Applied Data Science in Modern Pharmacovigilance
John Pietzsch, DrSc, Head of PV Data Science and Insight Generation, Bayer AG, Germany

Health Canada Regulatory Perspective and Industry Survey
Marc-André Giguère, Senior Corporate Regulatory and Enforcement Advisor, Health Canada

12:45-1:15PM **Break / Visit the Virtual Exhibit Hall**

1:15-2:30PM **Session 6:** Concurrent Breakout Sessions

Track A: International Collaboration via the Access Consortium: Health Canada and Industry Perspective

Session Co-Chairs
Yatika Kohli, PhD, MBA, Executive Director, Global Regulatory Affairs, NoNO Inc., Canada

Mandy Collier, Director, Health Products and Food Branch, Health Canada

This session will focus on the Australia, Canada, Singapore, Switzerland, and United Kingdom (Access) Consortium New Active Substance Work Sharing Initiative. Health Canada, on behalf of the Access Consortium regulatory partners, will share its experience and metrics to date, including perspectives on the strengths, challenges, and considerations for the future. The session will also include presentations on the industry's perspectives. Innovative Medicines Canada (IMC) will share the findings of its survey of members' experiences with submissions reviewed through this initiative. In addition, a specific case study will highlight the activities and timelines experienced by a company involved in the first Access Consortium four-way work-sharing initiative.

At the conclusion of this session, participants should be able to

- Explain the goals of the Access Consortium New Active Substance Work Sharing Initiative (NASWSI) and its current status
- Understand the benefits, challenges, and opportunities of participation in the NASWSI from a regulator's perspective
- Gain awareness of the advantages, limitations, and recommendations to enhance participation in the NASWSI from an industry perspective

Speaker
Jeffrey Skene, MSc, Division Chief, Monoclonal Antibodies, Health Canada

Innovative Industry's Experience with ACCESS
Laura King, MBA, Head, Regulatory Affairs, Novartis Pharmaceuticals Canada Inc., Canada

The First ACCESS (Formerly Known as ACSS) Consortium Four-Way New Active Substance Work Sharing Initiative (NASWSI) Experience
Rose Mary Cianflone, MSc, Regulatory Affairs Specialist, Novartis Pharmaceuticals Canada Inc., Canada

Track B: Real-World Data and Real-World Evidence

Session Chairs:
Judith Mergl, MSc, Director, Regulatory Affairs and Operational Services, AbbVie Corporation, Canada

In a market that is constantly adapting and adjusting to healthcare needs, real-world evidence (RWE) is increasingly becoming important for regulatory and reimbursement decision-making. RWE, in relation to the real-world data that is collected in combination with the advancement of artificial intelligence-based analytics platforms, has led to the real-time analysis of data to better understand and gain insights on disease, approaches to treatment, and how to substantiate coverage decisions. RWE is now becoming integrated throughout the product development lifecycle, and this session will explore new and innovative applications of RWE and provide insights through case examples and practical applications on how stakeholders are leveraging RWE to advance healthcare knowledge and decision-making. This session will provide a high-level overview of the evolving regulatory landscape for RWD/RWE from a Health Canada, CADTH, and industry perspective.

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

- Gain a greater awareness of Health Canada's international collaborations in the COVID-19 space that are leveraging RWE and observational studies
- Provide an overview of premarket challenges with RWE as well as a high-level overview on details and limitations regarding some recent examples submitted by sponsors in the premarket setting
- Discuss "lessons learned" from current uses of RWE, and how these can be applied for other future HTA applications

Post-Market Utilization of RWE at Health Canada: Progress to Date and International Collaborations Leveraging RWE for COVID-19
Melissa Kampman, PhD, MS, Acting Manager and Senior Epidemiologist, Marketed Health Products Directorate, Health Canada

Premarket RWE Examples and Challenges: Regulatory Perspective
Andrew Raven, MSc, Manager for Biostatistics, Epidemiology, and Phamacometrics Unit, HPFB, Health Canada

Speakers
Nicole Mittmann, PhD, Chief Scientist and Vice President of Evidence Standards, Canadian Agency for Drugs and Technologies in Health (CADTH), Canada

Yonghua Jing, Senior Director/Team Lead, Real-World Evidence Analytics, AbbVie

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Track C: General Data Protection Regulation (GDPR) and It's Implications

Session Chair
Marcia Bailey, RN, BSN, MHS, Senior Manager, Pharmacovigilance, Sierra Oncology, Canada

Although this privacy and security law was passed by the European Union (EU) in 2018, GDPR affects organizations anywhere in the world that process the personal data of EU citizens or residents. GDPR violators can face significant fines and penalties, so aside from legal, dutiful, and reputational obligations to protect patient data, there are also strong financial incentives for enterprises to be GDPR compliant. This session aims to provide insights and considerations on how to maintain GDPR compliance.

At the conclusion of this session, participants should be able to

- Summarize the purpose of GDPR
- Identify what is required for an organization to be GDPR Compliant
- Describe GDPR implications in clinical trials (verbal patient consent, data collection from patients/vendors/sites)
- Recognize potential GDPR issues concerning clinical trials and retrospective studies

GDPR and It's Impact on Running Clinical Trials in the EU
Bradley Norton, Managing Director and Senior Consultant, MWB Consulting Limited/Pharma Data Protection Services, United Kingdom

GDPR in Clinical Trials: Major Points to Consider and Practical Examples
Carmen DiMarino, JD, Executive Director, Assistant General Counsel, Europe, Zogenix International Limited, United Kingdom

Panelist
Samuel Allan, GDPR Consultant, MWB Consulting Limited/Pharma Data Protection Services, United Kingdom

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2:30-3:00PM **Break / Visit the Virtual Exhibit Hall**

3:00-4:30PM

Session 7: Adapting Health Product Advertising Oversight to the Digital Environment and Closing Remarks

Session Chair

Kristin Willemsen, MS, Vice President, Scientific and Regulatory Affairs, Food, Health and Consumer Health Products Canada, Canada

Misinformation is becoming a threat to public health and the healthcare system, particularly given the prevalence of inaccurate health information online. Given Canadians and healthcare practitioners are increasingly seeking out digital information about health products to inform choices, how can Health Canada keep up and enforce against misleading health product information online? In this session, you will hear from the Marketed Health Products Directorate about how they modernized policies and regulatory oversight, and tools and processes to adapt to the digital environment. These initiatives are intended to increase compliance and enforcement of the Food and Drugs Act, the Controlled Drugs and Substances Act and their associated regulations. Opportunities to further improve oversight will also be discussed.

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

- Apply the revised policy that distinguishes between promotional and non-promotional messages to digital forms of communication
- Identify how Health Canada harnessed artificial intelligence to increase surveillance and enforce against misleading COVID claims, and how this new process is being piloted to address misleading NHP advertising
- Anticipate future measures to improve oversight of health product advertising and promotions

Overview of Distinction Policy

Alain Musende, PhD, Manager, Section for Transparency and Advertising Regulatory Surveillance, Marketed Health Products Directorate, Health Canada

Taking Action on Misleading COVID-19 Related Claims

Rim Lejmi Mrad, PhD, Supervisor, Section for Transparency and Advertising Regulatory Surveillance, Marketed Health Products Directorate, Health Canada

4:30PM

Meeting Adjourns