Hilton Lac-Leamy

Nov 14, 2024 7:30 AM - Nov 15, 2024 4:10 PM

3 Boulevard du Casino, Gatineau, QC J8Y 6X4, Canada

Canada Annual Meeting

The Canada Annual Meeting offers three tracks, Regulatory, Clinical, Safety and Pharmacovigilance!

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Print Agenda

Day 1 Nov 05, 2024

8:30 AM — 12:00 PM

Short Course: Best Practices for Clinical Trial Applications in Canada

Day 2 Nov 14, 2024

7:30 AM — 8:30 AM Mozart

Networking Breakfast

7:30 AM — 6:30 PM Ballroom Foyer

Registration

8:30 AM — 8:45 AM Beethoven/Chopin

Welcome and Opening Remarks

8:45 AM — 10:00 AM Beethoven/Chopin

Session 1 Plenary: Understanding Health Canada’s Precision Regulating Initiatives

In this plenary session, Health Canada representatives will provide an overview of recent amendments to the Food and Drugs Act, which will enable precise regulatory solutions to a variety of potential situations.
Where a situation requiring action has been identified and where the requirements of the legislation have been met, the new authorities would enable the Minister of Health to make a Ministerial Order to:

- Put in place targeted exemptions from specific regulatory requirements, while adding conditions as appropriate to ensure that health and safety standards are met
- Rely on information or decisions from select regulatory authorities to satisfy specific regulatory requirements
- Put in place supplementary rules for certain therapeutic products to protect against potential health risks or adverse effects

These are adaptable tools which could be used in a variety of situations; for example, to maintain product availability in the event of a shortage, remove barriers that create areas of unmet need or address potential health risks or adverse effects.

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

- Understand the changes to the Food and Drugs Act
- Discuss the first use cases under Precision Regulating
- Describe Precision Regulating and its regulatory impact to industry

Track: General Session

Session Chair(s)

Katalin Bertenyi, MSc

Manager, Centre for Blood, Blood Products and Biotherapeutics
Health Canada, Canada

Katalin Bertenyi is the manager of the Clinical Evaluation Division - Endocrine and Metabolic Diseases, situated in CBBB in the Biologic and Radiopharmaceutical Drugs Directorate of Health Canada. Her team is responsible for the evaluation of biologics for endocrine and metabolic diseases, including rare diseases. She has over 20 years of experience with Health Canada, in the clinical evaluation of biologic and pharmaceutical drugs in the areas of reproduction, urology, oncology, endocrinology and metabolism, as well as experience in regulatory affairs, and clinical trials for medical devices and pharmaceutical drugs. Katalin holds a B.Sc. (Honours) in Biotechnology/Biology and a M.SC in Biology, both from Carleton University in Ottawa.

My Dang, MBA

Director/Consultant, Regulatory Affairs
Cencora, Canada

My is a Director of Regulatory Affairs at Innomar Strategies, a division of Cencora. She started out her career in healthcare working at Sunnybrook and Women`s Health College in their laboratory and then transitioned into the pharmaceutical industry. With over 20 years' experience, My has worked on regulatory submissions for human and animal drug products, covering a variety of therapeutic areas and overseeing both RA and QA responsibilities. She enjoys coaching and mentoring team members and shares a true passion for her work. M? has been an active CAPRA member over the years and is currently a Board of Director member and Chair of the Dinner Meeting Committee. She had spearheaded the NOC and eNOC publications and presented webinars.

Speaker(s)

Speaker

Alysha Croker, PhD

Director, Centre for Policy, Pediatrics and International Collaboration, BRDD
Health Canada, Canada

Dr. Alysha Croker is the Director of the Centre for Policy, Pediatrics and International Collaboration, Health Products and Food Branch, Heath Canada. In this position, Dr. Croker is responsible for developing ways to increase access to safe and effective health products for pediatric populations in Canada, among other files. Previously, Dr. Croker managed the Canada Excellence Research Chair and the Canada First Research Excellence Fund programs for Canada's federal research funders. She also led the development of the CIHR's training and equity strategies where she received the Innovation Award. Dr. Croker has a PhD from Western University where she studied the molecular mechanisms of breast cancer metastasis and therapy resistance.

Speaker

Patricia Dechman

Acting Director, Strategic Horizontal Policy Division
Health Canada, Canada

Patricia Dechman is the Acting Director of the Strategic Horizontal Policy Division in the Health Products and Food Branch of Health Canada. She is responsible for strategic policy and planning coordination, Cabinet and Parliamentary Affairs and international engagement, working closely with program areas across HPFB. Patricia has been with Health Canada since 2017, with previous positions at the Privy Council Office and the Competition Bureau. She holds a Bachelor of Arts degree with a double major in International Development Studies and Spanish.

10:00 AM — 10:45 AM Mozart

Refreshments, Exhibits, and Networking Break

10:45 AM — 12:00 PM Beethoven/Chopin

Session 2, Track A: Health Canada and International Collaboration Initiatives

Session 2, Track A: Health Canada and International Collaboration Initiatives

Track: Track A: Regulatory

Session Chair(s)

My Dang, MBA

Director/Consultant, Regulatory Affairs
Cencora, Canada

My is a Director of Regulatory Affairs at Innomar Strategies, a division of Cencora. She started out her career in healthcare working at Sunnybrook and Women`s Health College in their laboratory and then transitioned into the pharmaceutical industry. With over 20 years' experience, My has worked on regulatory submissions for human and animal drug products, covering a variety of therapeutic areas and overseeing both RA and QA responsibilities. She enjoys coaching and mentoring team members and shares a true passion for her work. M? has been an active CAPRA member over the years and is currently a Board of Director member and Chair of the Dinner Meeting Committee. She had spearheaded the NOC and eNOC publications and presented webinars.

Speaker(s)

Speaker

Maxime Sasseville, PhD, MSc

Manager
Health Canada, Canada

Dr Maxime Sasseville is manager of Oncology Division 2 within Health Canada and his team of scientific and clinical evaluators is responsible for pre-market drug risk/benefit assessment for drugs for the treatment of haematological and oncological diseases. Dr Sasseville has 15 years of experience in the regulatory and scientific evaluation of new drugs in different therapeutic areas including oncology, metabolism and reproduction. He is also part of a number of initiatives for Health Canada related to improving Patient-Reported Outcomes use in regulatory decisions [SISAQOL Consortium and PROTEUS Consortium] or to foster international collaboration among regulatory agencies [ACCESS and ORBIS].

Speaker

Patricia Oliveira Pereira Tagliari, LLM, MPH

Associate Director of the Second Directorate
ANVISA, Brazil

Patricia Oliveira Pereira Tagliari holds a master's degree in Public Health (Global Health and Health Diplomacy) from the National School of Public Health (2014), specializations in Health Regulation and Surveillance (2010) and Health Law (2007), both from Fiocruz, and a degree in International Affairs from the University of Brasilia (2004). She is currently a government employee, specialist in health regulation and surveillance, at the Brazilian Health Regulatory Agency - Anvisa. From April 2020 to the present date, Ms. Tagliari has served as Associate Director at Anvisa. Prior to that, she served as Advisor at Anvisa's Office of Inspection and Health Surveillance and as the Head of Anvisa's International Affairs Office.

Speaker

Christopher Colwell, MPA

Vice President, International Government and Regulatory Affairs
US Pharmacopeia, United States

Chris Colwell is Vice President, International Government & Regulatory Affairs at the United States Pharmacopeia (USP). He leads a team that develops USP's position on public policy and regulatory affairs issues related to its mission to improve global health through public standards.Chris' prior experiences span technical and policy work across pharmaceuticals and medical devices in government, private sector and NGO sectors. He has worked at the US FDA, Merck & Co., Inc (known as MSD outside of the U.S. and Canada), Becton Dickinson (BD) and the Biotechnology Innovation Organization (BIO). Chris received his Masters in Public Policy from Georgetown University and a B.S. in Chemical Engineering from the Pennsylvania State University.

10:45 AM — 12:00 PM Delfosse

Session 2, Track B: Why Canada for Conducting Clinical Trials?

This interactive, moderated session will highlight the advantages of conducting clinical trials in Canada. It will begin with short talks from several perspectives: a clinical trials infrastructure organization; a Canadian site; a Sponsor; and a CRO. Following these framing talks, attendees will have the opportunity to engage in an interactive discussion with the session moderator and speakers.

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

- Recognize some of the factors that make Canada an appealing and competitive country for clinical trials, from different stakeholder perspectives
- Share perspectives on real and perceived barriers to conducting clinical trials in Canada
- Illustrate some of the unique benefits and truths regarding the conduct of clinical trials in Canada that can be used as a unified message to the global market

Track: Track B: Clinical

Session Chair(s)

Marie-France Goyer, MSc

Director, Clinical Operations
Abcellera, Canada

As Director of Clinical Operations at AbCellera, I am passionate about and proud to be working on clinical trials because they help to improve and save the lives of patients in need. I have more than 20 years of experience in Clinical Research. Before joining AbCellera, I spent 5 years as a Director of Clinical Operations at Merck, working in Oncology and General Medicine portfolios. Before moving to Merck, I worked as a Clinical / Sr. Clinical Project manager on the Asthma/Allergy, Cardiovascular, and HIV portfolios at Schering Canada. I completed a master's degree in Drug Development from Université de Montréal.

Rebecca Barnes, MS

Executive Director
Network of Networks (N2), Canada

Rebecca began as a bench cancer researcher and over the past 15 years has worked in different leadership roles, all related to enhancing health research capacity through sustainable systems, processes and robust stakeholder engagement. Prior to joining N2 she was responsible for helping lead the Canadian Tissue Repository Network and overseeing research engagement for the Vancouver Island Health Authority by serving as lead of the CIHR Strategy for Patient Oriented Research (SPOR) initiative within the Vancouver Island region. She also worked as Director of the University of Victoria's Office of the Vice-President Research and Innovation. She holds a Bachelor of Science (Biology) and a Masters (Environmental Toxicology/Carcinogenesis).

Speaker(s)

Highlighting the advantages of conducting clinical trials in Canada

Sonia Brodie, MS

VP Clinical Research
Healthtech Connex, Canada

As VP Clinical Research with the Centre for Neurology Studies and National Research Lead for MAPS Canada, Sonia is a neuroscientist, Clinical Research Professional, leader, and a long-standing research nerd. She has a wealth of experience in Phase II-IV trials in pharmaceuticals, medical devices, digital health, and psychedelics, and is passionate about finding efficient ways to bridge the gap between research and reality in clinically meaningful and accessible ways.

Canada's Competitiveness – Clinical Trials Infrastructure Organization Perspective

Susan Marlin, MSc

President & CEO
Clinical Trials Ontario, Canada

Susan Marlin is the President and CEO of Clinical Trials Ontario (CTO), an organization established in 2012 to improve the environment for conducting clinical trials. Prior to joining CTO she was the Associate Vice-Principal of Research at Queen's University and worked for many years with the National Cancer Institute of Canada Clinical Trials Group. Susan has engaged in research ethics over the years serving on research ethics boards. She was President of the Canadian Association of Research Ethics Boards and is currently a member of several boards and committees supporting clinical research and innovation in health care.

Canada's Competitiveness – Canadian site perspective

Michael Barr

Director of R&D
Apex Trials, Canada

Michael Barr has worked for Apex Trials for 7 years. During this time he lead a medical diagnostic device development project as the director of R&D. This project received over $2 million dollars of public and private funding. This diagnostic project lead to Michael's designing and being the lead Sponsor of an observational study during the peak of COVID. Not only was it the peak of COVID, the patients were nursing women. It was a complete success. Michael now leads business development for Apex Trials. Prior to Apex, Michael worked for a cider start-up in Toronto as employee number one. Michael also worked for Sanofi Pasteur at the Connaught campus manufacturing the vaccine for whooping cough. Apex Trials is based in Guelph, ON.

Canada's Competitiveness – Sponsor Perspective

Tammy Kruger, RN

National Site Engagement Lead / Clinical Research

GlaxoSmithKline (GSK), Canada

Beginning my career as a Registered Nurse, I later shifted to research before joining GSK as a Clinical Research Associate, working in diverse therapeutic areas. After 20 years, I progressed to Site Engagement Lead, and most recently, National Site Engagement Lead, overseeing a team of CRAs. Outside of work, I enjoy spending time at our cabin with family and friends, either golfing or relaxing by the lake.

Canada's Competitiveness – CRO Perspective

Stephane Michel, MSc

Associate Strategic Site Solutions Director / Patient and Site Centric Solutions
IQVIA Canada, Canada

With more than 20 years of experience in Clinical Research, I have occupied various positions at IQVIA, in Clinical Operations (CRA, Clinical Lead), project management (Project Lead) and now within the Strategic Site Solutions team, working closely with IQVIA partner sites to support them in their current studies and to identify the best possible study opportunities for the PIs of their network. I mainly specialized in CNS studies (Alzheimer's Disease, Parkinson's Disease) in my last few years in Site Management but participates in multiple international trials across all phases and across a large variety of therapeutic areas.

10:45 AM — 12:00 PM

Julien/Gagnon/Walker/Suzor-Cote

Session 2, Track C: Update on Health Canada's PV Guidances and Ongoing Initiatives

Information session on ongoing Health Canada post market initiatives for risk management plans. This session will include a presentation on global perspectives on risk management and increased need for real-world evidence to support decision-making post marketing. There will also be an update on Agile Regulations for Risk Management Plans (RMP) and best practices when preparing/updating an RMP for a Canadian product followed by a broad panel discussion.

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

- Understand the requirements for RMP submission under upcoming Agile Regulations
- Best practices for RMP submission to Health Canada
- Gain a global perspective on risk management

Track: Track C: Safety/Pharm

Session Chair(s)

Randy Levitt, PhD

Director, Pharmacovigilance and Medical Affairs
Paladin Pharma Inc., Canada

Randy Levitt is the Director of Pharmacovigilance and Medical Affairs at Paladin. He is also the local compliance champion and works closely with the legal and compliance teams at Endo, the parent company of Paladin. He joined Paladin in 2011 as Manager, Scientific Communications and Publications after Paladin's acquisition of Labopharm, where he had worked in the medical department since 2008. Randy completed his undergraduate and graduate degrees at McGill University, graduating with his PhD in Experimental Medicine in 2006.

Nadiya Jirova, MSc

Manager, Bureau of Biologics, Radiopharmaceuticals and Self-Care Products
Health Canada, Canada

Nadiya Jirova is a manager for the Bureau of Biologics, Radiopharmaceuticals and Self-Care Products within the Marketed Health Products Directorate of Health Canada. Her section is responsible for post marketing surveillance of biotechnology products including blood, cells, tissues and organ products. She is also leading a team responsible for post market surveillance of Monoclonal Antibodies for COVID-19. She has over 15 years of experience in pharmacovigilance and risk management for biologic and pharmaceutical drugs working within Health Canada. Nadiya holds a Bachelor's degree in Biochemistry from McGill University and a Master's degree in Pharmaceutical Sciences with specialization in Drug Development from the University of Montreal.

Speaker(s)

Risk Management Plans – Modernization of Review Processes and Best Practices

Marie-Therese Bawolak, PhD

Manager, Bureau of Biologics, Radiopharmaceuticals and Self-Care Products
Health Canada, Canada

Marie-Thérèse Bawolak is a Manager in the Marketed Health Products Directorate at Health Canada. She holds a B.Sc. in Pharmacology from Université de Sherbrooke, and a M.Sc. and a Ph.D. in Experimental Medicine, from Université Laval. Marie-Thérèse joined Health Canada as a Scientific Evaluator in 2011. She has experience in the pharmacovigilance and risk management of both biologic and pharmaceutical products. Marie-Thérèse is currently leading modernization activities related to Risk Management Plan reviews at Health Canada.

Current and Future State in Risk Management

Rania Mouchantaf, PhD

A/Executive Director, Marketed Pharmaceuticals Bureau, MHPD
Health Canada, Canada

Dr. Rania Mouchantaf is A/Executive Director at the Marketed Health Products Directorate at Health Canada with over 20 years of experience in academic, industry and regulatory experience . Before entering the public service she worked in the private sector, however her interest in public health led her to join the federal government at Health Canada where she has assumed different roles in assessment, management and strategic policy development from both a pre and post market perspective in the area of safety, efficacy and quality Her education includes a Bachelor

degree in Microbiology and Immunology and a doctorate degree in Pharmacology and Therapeutics from McGill University.

12:00 PM — 1:00 PM

Luncheon, Exhibits, and Networking Break

1:00 PM — 2:15 PM Beethoven/Chopin

Session 3, Track A: HC/HTA Collaboration – Updates and Insights

Time to patient access for Canadian medicines is a lengthy process. Pharmaceutical Regulatory Affairs professionals play a crucial role in this process. There have been recent initiatives undertaken to facilitate time to patient access for Canadian medicines via collaboration amongst industry, Health Canada, Health Technology Assessment agencies and government (policy makers). This session will provide updates and insights on the current initiatives and progress. This session will also address role of Regulatory Affairs in generating the value story and proactive ways to positively impact the process.

Learning Objective :

- Understand progresses made on collaboration between Health Canada and Health Technology Assessment agencies and recent introduction of innovative approaches to facilitate access (eg, Real World Evidence and time-limited recommendation)
- Understand how these initiatives are being utilized by industry and the opportunities and challenges
- Understand Regulatory Affairs professionals' role, contributions and opportunities to shape the Canadian reimbursement process

Track: Track A: Regulatory

Session Chair(s)

Louise Blythe, MS, MSc

VP & Head, Regulatory Affairs
Bayer Inc. Canada, Canada

Louise Blythe has been with Bayer Canada Inc. since 2021 as the VP and Head of Regulatory Affairs for the pharmaceuticals division. With over 25 years of broad therapeutic experience in the biopharmaceutical industry, Louise is dedicated to supporting access to innovative medicines for patients. Louise has a Master of Science degree in Pharmacology from the University of Toronto, and an Honours Bachelor of Science degree in Life Sciences from Queen's University.

Tharany Ganesh, MSc

Head, Regulatory Affairs
AstraZeneca Canada Inc., Canada

Tharany Ganesh has been with AstraZeneca since 2006, holding progressive roles in Regulatory Affairs, Quality Assurance and Patient Safety. She has worked in several different therapy areas including Oncology, Cardiovascular, Respiratory, Vaccines and Infectious Diseases, Gastrointestinal and Neuroscience during her career at AstraZeneca and is the current Head of Regulatory Affairs for the Canadian business. Tharany holds a Master of Biotechnology degree from the University of Toronto, and an Honours Bachelor of Science degree from the University of Waterloo.

Speaker(s)

Health Canada and HTA Collaboration – A Multi-Faceted Partnership

Melissa Hunt, MSc

Director
Health Canada, Canada

Melissa Hunt joined Health Canada in 2005. She holds a Bachelor of Science in Life Sciences from Queen's University and a Master of Science in Pharmacology from the University of Toronto. Prior, Melissa worked for several years within the pharmaceutical industry. At Health Canada she has been a Scientific Evaluator and a Manager in the Marketed Pharmaceuticals and Medical Devices Bureau within the Marketed Health Product Directorate (MHPD), as well as a member of the core team for the Health Products and Food Branch "Regulatory Review of Drugs and Devices" initiative. Since 2018 she has held the position of Director of the Bureau of Metabolism, Oncology and Reproductive Sciences within the Pharmaceutical Drugs Directorate.

Innovative Pathways to HTA

Matthew McDonald, PhD, MSc

Acting Director, Pharmaceutical Policy and HTA
Canada's Drug Agency, Canada

Dr. Matthew McDonald is the Acting Director of Pharmaceutical Policy and HTA, a directorate within the Evidence Products and Services Business Unit at Canada's Drug Agency. He has been involved in the launching of CDA-AMC's nonsponsored reimbursement reviews and the Formulary Management Expert Committee. Both initiatives provide tools for payers to reimburse new indications for older drugs, or re-visit previous recommendations for older drugs to increase treatment options and advise payers on formulary management.

Industry Perceptions and Experiences with HC/HTA Aligned Reviews

Emily Roome, JD

Director, Legal Services

Innovative Medicines Canada, Canada

Emily is passionate about strengthening the health and wellbeing of her community and the environment. She is a barrister and solicitor licensed by the Law Society of Ontario since May 2020, and became a Certified Information Privacy Professional–Canada in February 2023. Emily has spent her legal career working with Canada's innovative pharmaceutical industry. As Director, Legal Services at Innovative Medicines Canada, Emily supports the Association's legal, ethics and regulatory departments. Emily is also on the Board of Directors for the Health Products Stewardship Association and Ottawa Community Doula Access.

The Role of the Regulatory Professional in HTAs

Myriam Antoun, MBA

Global Head of FSP Regulatory Affairs
PPD, Part of Thermo-Fisher Scientific, Canada

Myriam is a seasoned professional with over 25 years of experience across commercial and medical roles in the CRO and pharmaceutical industries. She currently serves as the Global Head of the PPD FSP Regulatory Business Unit, leveraging her vast experience, dual BSc. in Biochemistry/Chemistry and MBA. Prior to her current role, she led the Global Regulatory Affairs team at IQVIA Biotech, and held significant positions at PPD and Pfizer. Myriam is recognized for her positive presence, adaptive leadership style, and people-focused approach. She has a proven track record of assembling, engaging, and developing high-performing global teams, applying her originality, insight, and interpersonal warmth to unify, inspire and teach others.

1:00 PM — 2:15 PM Delfosse

Session 3, Track B: Equity, Diversity, Inclusion and Accessibility (EDIA) in Trials

Equity, diversity, inclusion and accessibility (EDIA) in clinical trial participants is an important topic to ensure the benefits of trials are shared by everyone. Clinical trials have often lacked representation from various equity-denied groups and Canada is well positioned to conduct clinical trials in a way that addresses these historical shortfalls. In this session, speakers will describe strategies to help sites and sponsors in improving EDIA in clinical trials, including early patient and community engagement, site selection, and use of AI and technology. Two communities this session will focus on are new immigrants to Canada, and members of the sexually and gender diverse community.

Learning Objective :

- Understand how to implement equity, diversity, inclusion and accessibility strategies in clinical trials, including through early planning and use of AI and technology
- Develop strategies that promote inclusion for new immigrants in clinical trials
- Explore barriers in the clinical trial landscape that lead to exclusion of sexual and gender diverse people and identify inclusive practices throughout the trial pathway from design to delivery

Track: Track B: Clinical

Session Chair(s)

Rebecca Barnes, MS

Executive Director
Network of Networks (N2), Canada

Rebecca began as a bench cancer researcher and over the past 15 years has worked in different leadership roles, all related to enhancing health research capacity through sustainable systems, processes and robust stakeholder engagement. Prior to joining N2 she was responsible for helping lead the Canadian Tissue Repository Network and overseeing research engagement for the Vancouver Island Health Authority by serving as lead of the CIHR Strategy for Patient Oriented Research (SPOR) initiative within the Vancouver Island region. She also worked as Director of the University of Victoria's Office of the Vice-President Research and Innovation. She holds a Bachelor of Science (Biology) and a Masters (Environmental Toxicology/Carcinogenesis).

Speaker(s)

Strategies to Bridge the Diversity, Equity and Inclusion Gap in Clinical Trials

Sabrina Ramkellawan

Chief Operating Officer
AxialBridge, Canada

Sabrina Ramkellawan started her career as a registered nurse with critical care speciality. She has 25 years of clinical trial experience working for Pharma, CROs & research sites. Sabrina has experience conducting clinical trials with novel therapeutics, devices & digital health products. Sabrina is also the President/Board Director at Clinical Research Association of Canada. Through AxialBridge she is supporting a DIGITAL Supercluster Canadian Government award to develop an APP Technology to improve diversity in participant recruitment and retention in clinical trials. Sabrina is the COO at AxialBridge that supports biotech/pharma, CROs, & sites navigate regulatory, strategic advisory and clinical operations to conduct clinical trials.

Bridging the Gap: Advancing New Immigrant Participation in Clinical Trials to Enhance Diversity

Munaza Jamil

Faculty, Applied Clin Research Program
McMaster University/N2 [canada], Canada

Munaza has 24 years of experience in the world of clinical trials. She is passionate about EDI principles, integrating them into all her work, with a special focus on the inclusion of immigrants in clinical trials. She is on Faculty at McMaster University, where she teaches in the Applied Clinical Research Program. She chairs the N2 Public Engagement Committee, where she champions many EDI initiatives. She is also on the executive board of ACRP Canada.

Queering Clinical Trials: Cultural Sensitivity from Bench to Bedside

Kim Meeking

Lead for Content, Community and Collaborations
Queering Cancer, Canada

Kim Meeking is the co-lead for Queering Cancer, a grassroots partnership dedicated to improving cancer care for sexual and gender diverse (SGD) individuals. Kim holds a Master's in Clinical Health Research and is a radiation therapist by background. They have over 10 years of experience managing oncology clinical trials at the site level and with CROs, along with 5+ years in the non-profit sector. Kim's interests focus on fostering inclusivity in clinical trials and enhancing cancer care for SGD populations through collaborative partnerships, rigorous research, and innovative knowledge mobilization.

1:00 PM — 2:15 PM

Julien/Gagnon/Walker/Suzor-Cote

Session 3, Tracks B & C: Pre- and Post-marketing Surveillance: Best Practices

In this session health Canada will provide practical guidance for several areas of pre- and post-market surveillance. This session will provide practical advice on reporting Adverse Drug Reactions (ADRs) from various sources. The session will kick off with the Canada Vigilance is Health Canda's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products marketed in Canada. A second presentation will give an overview of Health Canada's Vigilance framework for cannabis and cannabis products and reporting ADRs to the Canada Vigilance Program. This session will conclude with two presentations from the pre-market and post-market inspectorate program, the Good Clinical Practices Inspection program and the Good Pharmacovigilance Practices (GVP) Inspection program to address common industry questions to address common industry questions including tips on how to prepare for GVP inspections.

Learning Objective :

- Identify cases that must be reported to Health Canada under Food and Drug Regulations
- Identify cases that must be reported under the Cannabis Regulations
- Describe Inspectorate's expectations during Health Canada GCP inspections
- Describe Inspectorate's expectations during Health Canada GVP inspections

Track: Track C: Safety/Pharm

Session Chair(s)

Nadiya Jirova, MSc

Manager, Bureau of Biologics, Radiopharmaceuticals and Self-Care Products
Health Canada, Canada

Nadiya Jirova is a manager for the Bureau of Biologics, Radiopharmaceuticals and Self-Care Products within the Marketed Health Products Directorate of Health Canada. Her section is responsible for post marketing surveillance of biotechnology products including blood, cells, tissues and organ products. She is also leading a team responsible for post market surveillance of Monoclonal Antibodies for COVID-19. She has over 15 years of experience in pharmacovigilance and risk management for biologic and pharmaceutical drugs working within Health Canada. Nadiya holds a Bachelor's degree in Biochemistry from McGill University and a Master's degree in Pharmaceutical Sciences with specialization in Drug Development from the University of Montreal.

Myriam Salem, MSc

Good Pharmacovigilance Practices National Coordinator
Health Canada, Canada

Myriam Salem is currently coordinating the Good Pharmacovigilance Practices inspection Program at Health Canada. She previously worked as a pharmacovigilance scientific manager and a senior scientific evaluator for several years. She was involved in the implementation of several policies leading to a strengthened post market oversight of opioid products in Canada. Prior to joining Health Canada, she held various positions in the pharmaceutical industry and academia. She is a biochemist by training and holds a master's degree in pharmacology from Université de Montréal and a master's degree in Pharmacovigilance and Pharmacoepidemiology. She is the chair of the PIC/S GVP international working group on Artificial Intelligence-Machine learning.

Speaker(s)

Best Practices on Reporting Adverse Reactions from Various Sources

Silas Da Graça, MSc

A/Manager, Adverse Reaction Monitoring and Information Section
Health Canada, Canada

Silas Leitao da Graca is currently the acting manager of the Adverse Reaction Monitoring and Information Section within the Marketed Health Products Directorate of Health Canada. Silas holds a Bachelor's degree in Biomedical sciences and a Master's degree in Pharmaceutical Sciences with specialization in Drug Development from the University of Montreal.

GVP Inspection Trends, Ongoing Initiatives, and Best Practices

Fadi Sader, PhD

Regional Regulatory Compliance and Enforcement Officer
Health Canada, Canada

Biochemist by training, Fadi started at Health Canada in 2020, and has been involved in Compliance verification and now in Good Pharmacovigilance Inspection. As GVP Inspector, he is responsible for conducting GVP inspections and participate in the day to day of the Health Canada's GVP inspection program. Prior to joining Health Canada, Fadi

completed his Ph.D. in Biochemistry and molecular medicine at the Université de Montréal, which gives him experience not only in the regulatory field but also in academics and fundamental sciences.

Health Canada's Vigilance Framework for Cannabis and Cannabis Products

Safia Hassan

Scientific Evaluator
Health Canada, Canada

Safia Hassan is a Scientific Evaluator within the Pharmacovigilance Division of Health Canada's Office of Cannabis Science and Surveillance. Her division leads Health Canada's vigilance framework for cannabis and cannabis products. Before joining this division, Safia has held various positions the public sector and the private sector, including the Microbiology Laboratories of the Canadian Food Inspection Agency and the R&D Division of Abbott Point of Care, a subsidiary of Abbott. Safia holds a Bachelor's degree in Biomedical Sciences from the University of Ottawa and is completing a Master's degree in Epidemiology from the University of Montreal.

Speaker

Representative Invited

Health Canada, Canada

Dr Hocine Abid is currently the national manager for Health Canada's clinical trial compliance program that oversees the inspections of clinical trials. Before this, Hocine occupied different roles in various within Health Canada such as manager of the good manufacturing inspection program, the Inspectorate regional manager for Ontario, overseeing Health Products Compliance and Enforcement programs, Head of the medical cannabis program overseeing the evaluation and the delivery of authorizations to possess and produce cannabis for medical purposes. Dr Hocine Abid is an international medical doctor graduate. Hocine also holds an MBA and a Graduate Diploma in public administration.

2:15 PM — 3:00 PM

Refreshments, Exhibits, and Networking Break

3:00 PM — 4:15 PM Beethoven/Chopin

Session 4, Track A: Current and Emerging Regulatory Uses of Real-World Evidence

Stakeholders ranging from academics, industry, regulators, and health care providers have long recognized the opportunity of using real-world data (RWD) to evaluate the benefits and risks of medical products. Leveraging fit-for-purpose real world evidence (RWE) to support regulatory decision-making continues to gain ground. This session will focus on the perceived gaps in the evidence generation process and potential opportunities for future development and harmonization of RWE.

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

- Understand the regulatory limitations of RWE
- Predict future directions to improve RWE use in regulatory decision-making
- Highlight examples of successful regulatory decisions that were supported by RWE

Track: Track A: Regulatory

Session Chair(s)

My Dang, MBA

Director/Consultant, Regulatory Affairs
Cencora, Canada

My is a Director of Regulatory Affairs at Innomar Strategies, a division of Cencora. She started out her career in healthcare working at Sunnybrook and Women`s Health College in their laboratory and then transitioned into the pharmaceutical industry. With over 20 years' experience, My has worked on regulatory submissions for human and animal drug products, covering a variety of therapeutic areas and overseeing both RA and QA responsibilities. She enjoys coaching and mentoring team members and shares a true passion for her work. M? has been an active CAPRA member over the years and is currently a Board of Director member and Chair of the Dinner Meeting Committee. She had spearheaded the NOC and eNOC publications and presented webinars.

Brenda Gryfe, MSc

Regulatory Consultant
Flying Moose Technologies , Canada

Brenda Gryfe is a Regulatory Affairs Consultant with over 30 years' experience. Ms. Gryfe has a business-focused understanding of Regulatory Affairs, gained from experience across several mid-sized pharmaceutical companies, and over ten years in consulting. Ms. Gryfe has guided Regulatory teams through a variety of strategically complex regulatory processes. She also provides support to promotional material development teams with regulatory advice and review services for the Canadian drug advertising environment. Since her research as a pharmacist at U of Toronto, in seniors' understanding of prescription drug labels, Ms. Gryfe retains a particular interest in labeling and patient education materials.

Speaker(s)

Speaker

Andrew Raven, MSc

Manager for Biostatistics, Epidemiology, and Pharmacometrics Unit, HPFB
Health Canada, Canada

Andrew Raven joined Health Canada in 2004. He holds a Bachelor of Science in Molecular Biology and Genetics and a Master of Science in Mathematics and Statistics both from the University of Guelph. He has previously worked as a biostatistician and senior biostatistician, assessing study design and conduct as well as statistical methodologies and analyses in pre-market prescription drug submissions at the Pharmaceutical Drugs Directorate (PDD) (formerly TPD). He has been manager of the Biostatistics, Epidemiology, and Pharmacometrics Unit of PDD since 2015.

Speaker

John Concato, MD, MPH, MS

Associate Director for Real-World Evidence Analytics, OMP, CDER
FDA, United States

Dr. John Concato is Associate Director for Real-World Evidence Analytics in the Office of Medical Policy, Center for Drug Evaluation and Research, FDA. As an internist and epidemiologist, his responsibilities related to real-world evidence (RWE) include developing internal Agency processes, interacting with external stakeholders, and coordinating demonstration projects as well as guidance development. Dr. Concato joined FDA from Yale School of Medicine and the U.S. Department of Veterans Affairs, where he was a clinician, educator, independent investigator, research center director, and Professor of Medicine. He has a BE degree from The Cooper Union, MD & MS degrees from New York University, and an MPH degree from Yale University.

Canadian Case Study of RWE used to Support Efficacy for Labelling

Christopher Petengell, MD, MSc

Chief Medical Officer
Pentavere, Canada

3:00 PM — 4:15 PM Delfosse

Session 4, Track B: Decentralized Clinical Trials – Canada's First Case Study and Next Steps

The global COVID-19 pandemic has catalyzed substantial advancements in the establishment and execution of decentralized clinical trials (DCTs) in Canada. This session will offer a glimpse into the experiences and findings from Canada's first fully decentralized trial. Furthermore, we will delve into a proposed framework for hybrid DCTs, sharing experiences to date, lessons learned, and a vision for the future. Keeping our commitment to patient-centricity, we will also discuss the perceived advantages and challenges of DCTs from the perspectives of patients, caregivers, and their families.

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

- Describe different DCT models and understand methods to implement them
- Discuss the advantages and challenges with implementing DCTs

- Recognize the patient perspective when implementing DCTs

Track: Track B: Clinical

Session Chair(s)

Stephanie Anderson, MS

Associate Director, Regulatory Affairs
Intrinsik Corp., Canada

Stephanie Anderson is an Associate Director of Regulatory Affairs at Intrinsik Corp. She has been a part of the pharmaceutical/biotechnology sector since 2010 and now leads a dedicated team of Regulatory Affairs professionals. Stephanie has led a broad range of regulatory activities from clinical development to post-registration license maintenance across a wide range products and therapeutic areas. Stephanie has experience with FDA, Health Canada, EMA, BfArM, and MHRA. Stephanie has a Master of Science degree in Biochemistry and Physiology from the University of Western Ontario.

Speaker(s)

Operational Implementation of Decentralized Clinical Trials advances participant-centric research

Aneta Woroniecka-Osio, MD

Decentralized Clinical Trial Strategy Development Lead
Bayer HealthCare Pharmaceuticals, Canada

Aneta Woroniecka-Osio has obtained her Medical Doctor degree from Medical University in Wroclaw, Poland. Upon completing her postgraduate training in Clinical Research she has joined Medical and Scientific Affairs at Bayer Canada. Aneta has over 15 years of industry experience, has held global roles of increasing responsibilities leading large phase III programmes in Clinical Development and Operations. Aneta also has experience in ICH-GCP study audit and regulatory inspections. In her current role Aneta leads development of operational framework focusing on DCT metrics; DCT implementation and advancing acceptance of DCT globally. She is passionate about science and innovative solutions to enable participation in clinical trials.

CRAFT Hybrid DCT Model and Experience to Date

Roel Schlijper-Bos

Clinical Research Unit Manager
BC Cancer, Canada

Roel Schlijper-Bos is the Clinical Trials & Research Unit Manager at BC Cancer – Prince George and is an uninvited guest on the traditional, ancestral, and stolen lands of the Lheidli T'enneh First Nations. After completing his residency program in Radiation Oncology in the Netherlands, he completed a 2-year Radiation Oncology fellowship at BC Cancer. He has been the CRU manager since early 2021 and has been involved in growing the clinical trials & research program at Centre for the North. His focus lies on expanding the systemic trials program in Prince George,

improve Indigenous Cultural Safety both in- and outside clinical trials, and creating a team culture that is inclusive, meaningful, innovative, and encouraging.

Participant Perception of Decentralized Clinical Trials and Next Steps

Dawn P. Richards, PhD

Director, Patient and Public Engagement
Clinical Trials Ontario, Canada

Dawn Richards, PhD, is the founder of Five02 Labs Inc., and Director of Patient and Public Engagement at Clinical Trials Ontario. With a PhD (Analytical Chemistry) from the University of Alberta and experience in different roles over 25 years, it is her diagnosis with rheumatoid arthritis in 2006 that led her to combine her passion for science with making the most of her diagnosis. In her role at CTO, Dawn is charged with executing on CTO's strategic pillar of patient and public engagement.

Patient and Public Perceptions in Canada About Decentralized and Hybrid Clinical Trials: "It's About Time We Bring Trials to People"

Maureen Smith, MEd

Member
Clinical Trials Ontario College of Lived Experience, Canada

Maureen's passion for patient engagement and patient partnered research stems from a diagnosis with a rare disease during childhood and frequent flyer status with the healthcare system. She has benefitted both from participating in pediatric and adult clinical trials and collaborating with trialists as a patient partner and is especially interested in advancing youth and family engagement. In June 2023 Maureen was appointed Adjunct Professor at the University of Toronto Dalla Lana School of Public Health, a recognition of the of the expertise she has acquired in patient engagement as a person with lived experience.

Patient and Public Perceptions in Canada About Decentralized and Hybrid Clinical Trials: "It's About Time We Bring Trials to People"

Emily I McIntosh, PhD

College of Lived Experience Member
Clinical Trials Ontario, Canada

Emily has a Ph.D. in Biomechanics from the University of Guelph. Her use of primary research to make complex health decisions helped save her life when she was faced with a brain cancer diagnosis. She now guides other patients through their diagnoses and is passionate about research translation and health equity.

3:00 PM — 4:15 PM Julien/Gagnon/Walker/Suzor-Cote

Session 4, Track C: Pharmacovigilance Unleashed: Unlocking PV Best Practices through KPIs and Data Mining

This game-changing session will unravel the secrets of effective key performance indicators (KPIs) and their powerful application in the realm of pharmacovigilance. Industry experts will provide a deep dive into innovative solutions that seamlessly support pharmacovigilance integration activities during company acquisitions and product in-licensing deal. Additionally, the session offers exclusive insights from a health agency perspective on KPIs, providing a comprehensive understanding of this critical aspect of pharmacovigilance.

Learning Objective :

- Analyze the critical role of Key Performance Indicators (KPIs) in optimizing pharmacovigilance processes
- Demonstrate the application of data mining techniques to uncover valuable insights and drive informed decision-making in pharmacovigilance activities
- Evaluate strategies for seamlessly integrating pharmacovigilance operations during company acquisitions and product in-licensing deals, aligning with industry best practices

Track: Track C: Safety/Pharm

Session Chair(s)

Mei Lam, BSN, RN

Canada PV Manager/Safety Regional Country Contact
Haleon, Canada

Mei Lam is the Pharmacovigilance Manager for Haleon Canada. She has over 15 years in industry, primarily in Pharmacovigilance (PV). In addition to PV, Mei has experience in medical information, medical affairs, and global deviation management. Mei is a registered Nurse in Ontario who volunteers for the Region of Peel Public Health Unit.

Vanessa Zapata

Associate Director, Regional Pharmacovigilance Officer
Merck Canada Inc., Canada

Vanessa Zapata started her career in the pharmaceutical industry in 1998. For 12 years, she fulfilled different roles in the Clinical research field. In 2011, she moved to Pharmacovigilance where she has held various roles of increasing responsibility. She currently fulfills a position of Associate Director, Regional Pharmacovigilance at Merck Canada Inc. She also is the business owner of the company's Global Pharmacovigilance training that gets assigned annually to more that 115 000 employees and external partners around the world.

Speaker(s)

Innovative Solutions to Support PV Integration Activities in Company Acquisitions and Product In-license Deals

Stephanie Stankiewicz, MBA

Director, Drug Safety
Merck Sharp & Dohme LLC, United States

Stephanie Stankiewicz currently works with the Merck Pharmacovigilance (PV) Partner Strategy and Management team as a Director of Drug Safety and is based in the US. She currently leads a team responsible for the PV implementation and integration of business deals, such as acquisitions and in-licensing. She has over 25 years of experience in PV, with various roles within case processing, safety database support, as well as safety database configuration. Stephanie holds a Bachelor of science degree in Biology from the College of St. Elizabeth and MBA from Centenary University.

Effective KPIs and their application in PV

Manar Hammood, MSc

Founder and Director of PV Operations
Zenith PV, Canada, Canada

A Visionary Founder & Director of PV Operations at Zenith PV, a leading firm in PV. Under her leadership, Zenith PV excels in providing cutting-edge solutions to meet Health Canada stringent standards. With extensive experience across Canada & Europe, Manar brings unique blend of traditional and innovative practices to PV. Her commitment to advanced technology drove Zenith PV's rapid growth, supporting pharma and hospitals. Through her strategic acumen, Manar established robust operational framework and a culture of continuous improvement. She is recognized as a transformative figure in a typically conservative discipline, pushing boundaries to enhance patient outcomes, forward-thinker, and a sought-after thought leader and speaker in PV.

Speaker

Fadi Sader, PhD

Regional Regulatory Compliance and Enforcement Officer
Health Canada, Canada

Biochemist by training, Fadi started at Health Canada in 2020, and has been involved in Compliance verification and now in Good Pharmacovigilance Inspection. As GVP Inspector, he is responsible for conducting GVP inspections and participate in the day to day of the Health Canada's GVP inspection program. Prior to joining Health Canada, Fadi completed his Ph.D. in Biochemistry and molecular medicine at the Université de Montréal, which gives him experience not only in the regulatory field but also in academics and fundamental sciences.

4:20 PM — 5:35 PM

Beethoven/Chopin

Session 5, Track A: Latest Advancements in AI – A Regulatory Perspective

In the rapidly evolving field of artificial intelligence (AI), regulatory professionals are encouraged to engage with ongoing developments in AI regulatory frameworks and explore how AI can be leveraged within their practices. This session will delve into the emerging AI regulatory framework and its implications for regulatory professionals. Through industry use cases, participants will gain insights into real-world AI experiences in Regulatory Affairs. The session will also address the benefits, challenges and risks associated with the implementation of AI.

Learning Objective :

- Explore Health Canada's emerging artificial intelligence (AI) regulatory framework and its potential impact on regulatory processes
- Discuss industry use cases to illustrate the application of AI in Regulatory Affairs
- Recognize the benefits, challenges and risks related to the implementation of AI

Track: Track A: Regulatory

Session Chair(s)

Louise Blythe, MS, MSc

VP & Head, Regulatory Affairs
Bayer Inc. Canada, Canada

Louise Blythe has been with Bayer Canada Inc. since 2021 as the VP and Head of Regulatory Affairs for the pharmaceuticals division. With over 25 years of broad therapeutic experience in the biopharmaceutical industry, Louise is dedicated to supporting access to innovative medicines for patients. Louise has a Master of Science degree in Pharmacology from the University of Toronto, and an Honours Bachelor of Science degree in Life Sciences from Queen's University.

Melanie Cote, MS

Senior Manager, Global Regulatory Affairs
Otsuka Canada Pharmaceutical Inc., Canada

Melanie Cote works as a Senior Manager, Global Regulatory Affairs at Otsuka and has been in the industry for more than 20 years. After graduating with a bachelor's degree in biochemistry, she worked for a few years in analytical development for various biotechnology companies. She later completed a DESS in drug development, focusing on CMC, and has a Master of Pharmaceutical Sciences from the Université de Montréal. In 2010, Melanie fell into the field of Regulatory Affairs and moved to the UK shortly after where she worked in European regulatory for 2 years. Back home since 2013, Melanie has focused on Canadian regulatory. She is thrilled to be part of DIA Canada Annual Meeting program committee for her second year.

Speaker(s)

AI Initiatives – Use Cases

Benny Ling, MSc

Senior Scientific Evaluator, Marketed Pharmaceuticals Bureau
Health Canada, Canada

Benny Ling is a senior scientific reviewer in the Marketed Pharmaceuticals Bureau in Health Canada. He holds a Master's degree in Pharmacology and Toxicology from the University of Western Ontario and has been working in Health Canada for over 20 years. Benny is the Health Canada representative at the on the CIOMS Working Group XIV on Artificial Intelligence in Pharmacovigilance and the LLM Taskforce.

Demystifying AI in Healthcare

Sridevi Nagarajan, PhD

DIA Communities Lead for AI in Healthcare
Independent, United Kingdom

An influential and data-driven executive professional with a robust background in the Pharmaceutical and Public Health sectors, bringing a unique blend of expertise in leading digital transformation initiatives and leveraging data to guide corporations through complex business changes. Recognized as a thought leader/industry expert in the data, digital health, and AI ecosystem, excelling at understanding industry trends and developing strategic perspectives to guide digital health and AI partnerships and investments. High-level analytical skills and deep expertise in drug development, clinical, safety and regulatory processes, data management, digital innovation, and governance.

AI Initiatives – Use Cases

Carrie Ku, MSc

Head of Regulatory Affairs
sanofi-aventis Canada Inc, Canada

Carrie Ku has been at Sanofi since 2014. Her team is responsible for the regulatory filings for the Specialty Care, General Medicines and Vaccines business units. Carrie has over 25 years experience in the pharmaceutical industry, mostly in regulatory affairs, but also in quality assurance, medical affairs, medical information and drug safety. Carris has a Master of Science (pharmacy) degree and a Bachelor's of Pharmacy degree, both from University of Toronto.

4:20 PM — 5:35 PM Delfosse

Session 5, Track B: Harnessing the Potential of AI in Clinical Development and Operations

Significant progress has been made in the application of artificial intelligence (AI) and machine learning (ML) in all aspects of research and development. Our speakers will shed light on how AI is currently being used in clinical development and operations, discuss the constraints of its use, and explore its potential future uses.

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

- Define the current advancements in AI and ML use in clinical development and operations
- Determine when AI tools can be used in clinical development
- Outline limitations of AI in clinical development and operations

Track: Track B: Clinical

Session Chair(s)

Stephanie Anderson, MS

Associate Director, Regulatory Affairs
Intrinsik Corp., Canada

Stephanie Anderson is an Associate Director of Regulatory Affairs at Intrinsik Corp. She has been a part of the pharmaceutical/biotechnology sector since 2010 and now leads a dedicated team of Regulatory Affairs professionals. Stephanie has led a broad range of regulatory activities from clinical development to post-registration license maintenance across a wide range products and therapeutic areas. Stephanie has experience with FDA, Health Canada, EMA, BfArM, and MHRA. Stephanie has a Master of Science degree in Biochemistry and Physiology from the University of Western Ontario.

Speaker(s)

Harnessing AI for Smarter Clinical Trials: A Guide to Innovation and Execution

Diana Avramioti, MBA, MSc

COO
Sorintellis, Canada

Ms. Diana Avramioti is the Chief Operating Officer of Sorintellis Group and a seasoned professional in the pharmaceutical industry, specializing in drug development, reimbursement strategies, and pharmaco-economics. She holds an MBA from HEC Montreal and a Master's in Health Economics and Market Access from the University of Montreal. Prior to joining Sorintellis, Diana worked internationally with AMARIS Consulting in London (UK) and Toronto, as part of the Health Economics and Outcomes Research (HEOR) team. She later transitioned to the pharmaceutical industry, where she served as Senior Associate in Market Access at PENDOPHARM, leading strategic initiatives to optimize pharmaceutical reimbursement in Canada.

Harnessing the Potential of AI: from Hype to Reality

Representative Invited

Nova in Silico, France

François-Henri Boissel is a seasoned executive with over 20 years of experience in the financial services and life sciences industries. He is the co-founder and former CEO of Novadiscovery, a leading provider of in-silico drug discovery solutions. Prior to founding Novadiscovery, François-Henri spent four years with investment bank Lehman Brothers in London and Tokyo. Now an Ambassador for Nova In Silico, François-Henri is tasked with

developing and deepening relationships with Sponsors and Strategic Partners to source and expand new business opportunities. François-Henri holds an MSc in Management from ESSEC Business School.

Harnessing AI in the Clinical Practice: the Good, the Bad and the Ugly

Sonny Kohli, DrMed, FRCP

Vice President, Medical Affairs
Khure Health, Canada

Dr. Sonny Kohli practices Internal Medicine and Critical Care in Ontario, Canada and is Faculty at McMaster University. For 15+ years, he has explored how AI and digital technology can responsibly address the problems that plague our healthcare system. Sonny's passion was fueled by his global relief work and desire to improve healthcare access for the marginalized; experiences that inspired him to co-found and lead Cloud DX to Canada's first ever XPRIZE for their "Star Trek" inspired medical tricorder called "Vitaliti". He is currently the VP of Medical Affairs at Khure, an AI co-pilot for doctors; former VP of Roche Pharma; CF trained Flight Surgeon; and a 2008 CSA astronaut candidate and ISU alumnus, where he deployed IRIS on the ISS.

4:20 PM — 5:35 PM Julien/Gagnon/Walker/Suzor-Cote

Session 5, Track C: Innovations within Pharmacovigilance: Shaping the Future of Drug Safety

The session will explore automation opportunities within pharmacovigilance, leveraging existing and rapidly evolving technology. Attendees will gain insights into how technologies such as Artificial Intelligence (AI) can enhance drug safety processes, improving efficiency and reduce the risk of human errors. The discussion will cover various automation model and key factors in evaluating their suitability across different pharmacovigilance workflows. Additionally, a case study will illustrate the practical considerations and impact of integrating automation into existing practices / processes.

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

- Define "Artificial Intelligence" and the models of automation
- Demonstrate the potential to integrate automation and/or AI to pharmacovigilance systems and workflows
- Identify risks associated with the use of new technology

Track: Track C: Safety/Pharm

Session Chair(s)

Daniel Greco, PharmD, RPh

Associate Director of Patient Safety
Bristol-Myers Squibb Company, Canada

Daniel Greco is the Associate Director of Patient Safety at Bristol Myers Squibb, with a specialization in Risk Management. In this capacity, Daniel has led substantial changes to the risk management program responsible for overseeing the risks associated with thalidomide and its derivatives in Canada. He earned his H.BSc. and PharmD from the University of Toronto, and is presently pursuing a Masters in Pharmacovigilance and Pharmacoepidemiology through the Eu2P program. Moreover, Daniel is practicing as a licensed Pharmacist in the province of Ontario, where he has gained invaluable firsthand experience in direct patient care.

Nadia Mian, MS

Senior Manager, Pharmacovigilance
Ipsen Biopharmaceuticals Canada Inc., Canada

Nadia Mian is currently working as the head of local pharmacovigilance for the affiliate office at Ipsen Biopharmaceuticals Canada. With over 20 years of successful experience in the Biotech/Pharmaceutical industry and expertise in Pharmacovigilance and Clinical research, she has a diverse range of experiences in different therapeutic areas: Neuroscience, Oncology, Hematology, Immunology, Renal disease and Rare diseases. She holds a Master's degree in Pharmaceutical Science, Biopharmacy from King's College, University of London, UK.

Speaker(s)

Speaker

Brian Dreyfus, MPH

Senior Director
Bristol-Myers Squibb Company, United States

Brian Dreyfus is currently a Senior Director and the Solid Tumor Oncology Epidemiology Lead at Bristol Myers Squibb. Prior to joining BMS, Brian led the epidemiology team at Decision Resources. Brian has a Master in Public Health from Boston University and is completing his DrPH from Indiana University.

Speaker

Indy Ahluwalia

PV Consultant
Truliant Consulting, United Kingdom

Indy Ahluwalia is a PV professional who has been in the industry for 15 years. Working in different aspects Indy first started out as a Drug Safety Associate, then moved to the technology side. He has previously worked for Eisai, Amgen, Gilead and Perficient he then moved to work in software companies My Meds and Me and then PVAI. He know works for management consulting firm Truliant Consulting.

Speaker

Ricardo Pasquel Cook, MD

Safety Team Lead
Pfizer, Canada

Ricardo works as a Safety Team Lead at Pfizer Drug Safety Unit Canada and has been with the company since 2022. He has been working in the industry for 14 years in the Montreal area. A couple of years after graduating as a Physician in Peru, Ricardo moved to Canada and started working in Pharmacovigilance and Medical Information in 2010 to later focus on his new passion, Pharmacovigilance and Drug Safety. He has completed different Pharmacovigilance trainings including the PV course by Kusuri Canada Corp., GVP course at Cegep Gerald Godin in Montreal and Preclinical Safety Assessment and Pharmacovigilance given by the Uppsala University. He is very excited to participate on the DIA Canada this year.

5:35 PM — 6:35 PM

Networking Reception

Day 3 Nov 15, 2024

7:30 AM — 8:30 AM — Mozart

Networking Breakfast

7:30 AM — 4:00 PM — Ballroom Foyer

Registration

8:30 AM — 9:45 AM — Beethoven/Chopin

Session 6, Track A and B: Insights into Rare Diseases: Pioneering Pathways for Patient Access and Drug Development

This session will discuss the challenges in rare disease drug development and provide updates on some exciting programs aimed at advancing therapeutic options for rare diseases. It will focus on Health Canada's National Strategy for Drugs for Rare Diseases, RareKids-CAN Pediatric Rare Disease Clinical Trials and Treatment Network, and the Critical Path Institute's Rare Disease Cures Accelerator - Data Analytics Program. These initiatives aim to increase accessibility and affordability of effective drugs, collect data to support better understanding of rare diseases, and provide drug development tools to address unmet needs in rare disease research.

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

- Describe the rare diseases space and how it has evolved in Canada over time
- Discuss Health Canada’s current Regulatory environment for rare diseases
- Identify opportunities to collaborate with various initiatives focused on supporting development of new drugs for rare diseases

Track: Track A & B

Session Chair(s)

Brenda Gryfe, MSc

Regulatory Consultant
Flying Moose Technologies , Canada

Brenda Gryfe is a Regulatory Affairs Consultant with over 30 years’ experience. Ms. Gryfe has a business-focused understanding of Regulatory Affairs, gained from experience across several mid-sized pharmaceutical companies, and over ten years in consulting. Ms. Gryfe has guided Regulatory teams through a variety of strategically complex regulatory processes. She also provides support to promotional material development teams with regulatory advice and review services for the Canadian drug advertising environment. Since her research as a pharmacist at U of Toronto, in seniors’ understanding of prescription drug labels, Ms. Gryfe retains a particular interest in labeling and patient education materials.

Amber McLeod, PhD

Immunology, Virology, and Specialty Head, Regulatory Affairs
Abbvie Corporation, Canada

Amber McLeod has held the role of Head of Immunology, Virology, and Specialty at AbbVie since May 2020. In this role, she leads a team of Regulatory Affairs professionals focused on filing and obtaining approval for biopharmaceutical drug submissions with Health Canada, spanning clinical development and commercial products in the fields of Immunology, Virology, Neuroscience, and Specialty Care. Amber joined Abbott in January 1999. Over her 25-year tenure with Abbott/AbbVie, she has held various roles of increasing responsibility, leading and managing numerous regulatory filings, approvals, and product launches across diverse therapeutic areas. Amber holds a Doctorate in Pharmacology and Therapeutics from McGill University.

Alysha Croker, PhD

Director, Centre for Policy, Pediatrics and International Collaboration, BRDD
Health Canada, Canada

Dr. Alysha Croker is the Director of the Centre for Policy, Pediatrics and International Collaboration, Health Products and Food Branch, Heath Canada. In this position, Dr. Croker is responsible for developing ways to increase access to safe and effective health products for pediatric populations in Canada, among other files. Previously, Dr. Croker managed the Canada Excellence Research Chair and the Canada First Research Excellence Fund programs for Canada's federal research funders. She also led the development of the CIHR's training and equity strategies where she received the Innovation Award. Dr. Croker has a PhD from Western University where she studied the molecular mechanisms of breast cancer metastasis and therapy resistance.

Speaker(s)

Introduction to RareKids-CAN Pediatric Rare Disease Clinical Trials and Treatment Network

Thierry Lacaze-Masmonteil, MD, PhD, FRCPC

Scientific Director
Maternal Infant Child and Youth Research Network (MICYRN), Canada

Dr. Thierry Lacaze received his medical degree from the University Paris 5 in 1993 and a PhD in biological sciences from the University Paris 7 in 1995. He was appointed professor of Pediatrics at the University Paris Saclay in 1997. He moved to Alberta in 2003 to become the inaugural Scientific Director of the Women and Children Health Research Institute in 2006. He is currently Clinical Professor of Pediatrics at the University of Calgary. He became the Scientific Director of MICYRN in 2018. Since March 2024, he is the Principal Investigator of the Pediatric Rare Disease Clinical Trial and Treatment Network, an initiative funded by the CIHR Institute of Genetics, as part of the Rare Disease Drug Strategy of the Government of Canada.

Introduction to The Critical Path Institute and its Rare Disease Cures Accelerator -Data Analytics Program (RDCA-DAP)

Collin Hovinga, PharmD, MS

Vice President Rare, Orphan Pediatric Diseases Programs
Critical Path Institute, United States

Dr. Collin Hovinga is Vice President of the Rare, Orphan and Pediatric Disease Programs at the Critical Path Institute multiple public-private partnerships. He completed his PharmD from Creighton University. After which he pursued a Residency and Fellowship in Pediatric Pharmacotherapy with emphasis in Pediatric Neuroscience at the University of Tennessee, Memphis, LeBonheur Children's Medical Center. He has a Masters of Epidemiology from the University of Tennessee Health Science Center. Dr. Hovinga has been active in studying factors that influence the efficacy and safety of medications in children and in rare/orphan diseases. Dr. Hovinga is recognized as an expert in neuropharmacology and has served as an advisor to NIH, FDA and PCORI.

Speaker

Breanne Stewart, BSN, RN

Network Director, RareKids-CAN
Maternal Infant Child and Youth Research Network, Canada

Breanne Stewart is the Network Director for RareKids-CAN: Pediatric Rare Disease Clinical Trials and Treatment Network, where she provides strategic leadership, oversees operations, and fosters collaboration within the network. With a background as a registered nurse, Breanne has dedicated 10 years to the clinical trial field, supporting both investigator-initiated and industry-sponsored trials. For the past 6 years, she has served with the Maternal Infant Child and Youth Research Network as the inaugural Associate Director of Clinical Trials, where she played a key role in developing an Academic Research Organization.

8:30 AM — 9:45 AM

Julien/Gagnon/Walker/Suzor-Cote

Session 6, Track C: Advancements in Patient Safety and Centricity

This session will explore Patient safety initiatives and effective patient safety engagement strategies as it applies to pharmacovigilance and drug safety. Attendees will have an overview of different safety initiatives both within Canada and Globally. Various patient advocacy groups will share their work and ideas for these initiatives to create a patient centricity culture.

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

- Have knowledge of different patient safety awareness initiatives and dates they occur every year
- Gain insights and knowledge to educate colleagues / company employees about these patient safety awareness initiatives
- Recognize different patient advocacy groups in Canada and their purpose/strategy

Track: Track C: Safety/Pharm

Session Chair(s)

Randy Levitt, PhD

Director, Pharmacovigilance and Medical Affairs
Paladin Pharma Inc., Canada

Randy Levitt is the Director of Pharmacovigilance and Medical Affairs at Paladin. He is also the local compliance champion and works closely with the legal and compliance teams at Endo, the parent company of Paladin. He joined Paladin in 2011 as Manager, Scientific Communications and Publications after Paladin's acquisition of Labopharm, where he had worked in the medical department since 2008. Randy completed his undergraduate and graduate degrees at McGill University, graduating with his PhD in Experimental Medicine in 2006.

Nadia Mian, MS

Senior Manager, Pharmacovigilance
Ipsen Biopharmaceuticals Canada Inc., Canada

Nadia Mian is currently working as the head of local pharmacovigilance for the affiliate office at Ipsen Biopharmaceuticals Canada. With over 20 years of successful experience in the Biotech/Pharmaceutical industry and expertise in Pharmacovigilance and Clinical research, she has a diverse range of experiences in different therapeutic areas: Neuroscience, Oncology, Hematology, Immunology, Renal disease and Rare diseases. She holds a Master's degree in Pharmaceutical Science, Biopharmacy from King's College, University of London, UK.

Speaker(s)

Speaker

Carolyn Hoffman, BSN, RN

Chief Executive Officer
Institute For Safe Medication Practices Canada (ISMP Canada), Canada

Carolyn Hoffman RN BScN MN has senior leadership experience in hospital operations, nursing regulation and quality improvement in healthcare. She became CEO of ISMP Canada in 2018. Carolyn is a co-author of the Tool for the Concise Analysis of Patient Safety Incidents (2016), Canadian Incident Analysis Framework (2012); and co-author of the Canadian Patient Safety Dictionary (2003).

Empowering Pharmacovigilance: The Critical Role of Patient Engagement

Ursula Mann, BSN

Principal and Chief Patient Officer (CPO)
Patient Voice Partners, Canada

As Principal & Chief Patient Officer at Patient Voice Partners, Ursula leads stakeholder engagement conversations within healthcare to develop innovative solutions and advance service care delivery/evaluation across every aspect of disease management and treatment. In the role of Global Patient Engagement Officer for Patient Voice Connect by Patient Voice Partners, Ursula supports matching patients and caregivers to patient voice activities of interest. She also holds the position of Board Member & Executive Managing Director with the TOWWERS Institute, a not-for-profit that advances value-based healthcare for faster access to innovative therapies by centering on the patient, value, and affordability with multi-stakeholder engagements.

Patient Centricity and Partnership

Melissa Sheldrick, MEd

Patient and Family Advisor
ISMP Canada, Canada

Melissa is a trained educator and has been working with families for more than 20 years. She began advocating for improved safety after the loss of her 8-year-old son, Andrew, from a community pharmacy medication error in 2016.

Since that time, Melissa has been working with organizations to advance continuous quality improvement programs in community pharmacy, including error reporting. She is an active member of Patients for Patient Safety Canada and continues to advocate for patient safety, and more specifically medication safety, across the country and internationally. Melissa has delivered presentations on medication safety to local, provincial, national and international audiences.

9:45 AM — 10:30 AM Mozart

Refreshments, Exhibits, and Networking Break

10:30 AM — 11:45 AM Beethoven/Chopin

Session 7, Track A: Opportunities and Challenges of Electronic Labelling Implementation

Companies and regulatory agencies are implementing new processes to enable patients to have electronic access to the most current patient information. There are many benefits but also challenges in this approach to patients, manufacturers and supply chain partners. This session will explore the benefits and challenges of moving to electronic labelling, summarize global and Canadian efforts in adopting this new patient-centric approach and learnings from pilots conducted to date.

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

- Describe the benefits and challenges of implementing electronic patient medication information (ePMIs)
- Understand the status of implementation of ePMIs in Canada and globally

Track: Track A: Regulatory

Level: Intermediate

Session Chair(s)

Tharany Ganesh, MSc

Head, Regulatory Affairs
AstraZeneca Canada Inc., Canada

Tharany Ganesh has been with AstraZeneca since 2006, holding progressive roles in Regulatory Affairs, Quality Assurance and Patient Safety. She has worked in several different therapy areas including Oncology, Cardiovascular, Respiratory, Vaccines and Infectious Diseases, Gastrointestinal and Neuroscience during her career at AstraZeneca and is the current Head of Regulatory Affairs for the Canadian business. Tharany holds a Master of Biotechnology degree from the University of Toronto, and an Honours Bachelor of Science degree from the University of Waterloo.

Neerja Goyal, MS

Director, Regulatory Strategy and Policy
GlaxoSmithKline, Inc., Canada

Neerja is the Director of Regulatory Strategy and Policy at GSK Canada. She currently oversees a number of functions including Regulatory policy and intelligence, compliance, training and operations. She has been in Regulatory for over 30 years with experiences in all aspects of Canadian regulatory. Neerja is also a long standing member of the Regulatory Affairs Operational Team at Innovative Medicines Canada, and is the IMC lead for ePMI.

Speaker(s)

Stakeholder Supported ePMI Proposal for Canada

Kristin Willemsen, MS

Vice President, Scientific and Regulatory Affairs
Canadian Generic Pharmaceutical Association, Canada

Kristin Willemsen is the Vice President of Scientific & Regulatory Affairs for CGPA. She works with CGPA members advocating for the implementation of regulatory, policy and guidance changes to increase access to safe, effective, and affordable generic medicines for Canadians. A key part of her role as an industry association professional over the past 15 years has been developing productive, collaborative relationships with governments and stakeholders to drive impactful regulatory outcomes. Kristin is also a Certified Association Executive and has earned a MSc from University of Ottawa.

Going Digital: Transitioning to Electronic Product Information

Dag Jordbru, MPharm

Strategic Director, Regulatory Affairs and Better Use of Medicines
NOMA, Norway

Dag R. Jordbru, MRPharmS is Strategic Director for Better use of Medicines at the Norwegian Medicines Agency with responsibility for regulatory activities related to marketing authorisations, pharmacovigilance, product information and distribution of structured product data to support e-prescription in Norway. Working with the Norwegian Federation of Organisations of Disabled People (FFO), the Norwegian Pharmaceutical Product Compendium, the Association of the Pharmaceutical Industry in Norway (LMI) and the Norwegian Pharmacy Association, Dag is currently building a stakeholder coalition to facilitate the transition to digital as the preferred source of product information by healthcare professionals and patients.

Planetary Health, Pharmacy and Paper-Less Monographs

Ariane Blanc, PharmD, MBA, MS, RPh

Director of Pharmacy, Chief Clinical Pharmacist
The Children's Hospital of Eastern Ontario - Ottawa Children's Treatment Centre, Canada

Ariane is a Canadian bilingual hospital pharmacy leader with more than 20 years of extensive academic, professional, research and mentorship experience in adult and pediatric hospitals in Ottawa, Montreal and Paris (France). She is the Director of Pharmacy at the Children's Hospital of Eastern Ontario, CHEO Research Institute research investigator and uOttawa adjunct professor. She volunteers as the Canadian Society of Hospital Pharmacists (CSHP) Ontario Branch President Elect, the CSHP sustainability task force member and the Canadian Association of Pharmacy for the Environment (CAPhE) Director of Research and Quality Improvement. She is the founder and chair of the Canadian Pediatric Hospital Pharmacy Leadership group (CPHPL).

10:30 AM — 11:45 AM Delfosse

Session 7, Track B: The State of ICH GCP: Moving towards Innovative Approaches in Clinical Trial Operations

As we quickly approach the launch of the official ICH GCP E6 Revision 3 guidelines, the clinical trial industry and its stakeholders are making every effort to understand how the changes in R3 impact the way we work on a day-to-day basis, from the perspective of Sites, Sponsors and CROs. In this session we'll be exploring the challenges of patient recruitment, how to be inspection-ready in light of the changes to ICH E6, and how best to utilize the principles of Quality by Design to meet the requirements of the updated guidelines.

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

- Tackle the challenges of participant recruitment using effective solutions
- Apply best practices on how to prepare for and undergo a regulatory inspection within the context of ICH GCP E6 (R3)
- Demonstrate how Quality by Design principles add immense value to a clinical program through actionable steps

Track: Track B: Clinical

Session Chair(s)

Vatche Bartekian, MSc

President
Vantage BioTrials, Canada

Mr. Bartekian is President of Vantage BioTrials, an award-winning Canadian CRO specializing in clinical trial management services. He's contributed his drug development knowledge to the pharma & device industry for over 26 years and has gained vast experience handling complicated trials across an array of therapeutic areas. He has also contributed his knowledge as an Advisor to Global Affairs Canada's Life Science division, and Colorectal Cancer Canada's Scientific Advisory Board for the establishment of a Patient Group Pathway Model to Accessing Cancer Clinical Trials. Vatche was also honored in 2021 by his alma mater, Concordia University, as a "Top 50 under 50 Who are Shaping Tomorrow" for his work in combatting Covid-19.

Speaker(s)

Enrollment is Not a Priority in Clinical Trials

Ted Trafford

Director of Business Development
Probity Medical Research Inc., Canada

With 29 years of experience in clinical research, Ted Trafford leads Feasibility, Business Development, and Site Relationship teams as Director of Business Development at Probity Medical Research, a clinical trial site administrative support company with a consortium of 70 sites across four countries. As a writer and speaker, Ted contributes to thought leadership and strategic initiatives in the clinical trials industry, leveraging his extensive experience and creative approach to drive meaningful discussion and progress for Sponsors, CROs, Sites and Technology Vendors. Ted recently launched a podcast called Innovating Clinical Trials for clinical research professionals eager to deepen their understanding of clinical trials.

Preparing for a Clinical Trial Inspection or Audit

Flora Noitsis

Senior Associate, Compliance & Regulatory
BioAcuity Consulting Inc., Canada

Flora began her pharmaceutical career working as a bench microbiologist. In 1991 she Health Canada's drug inspection unit where she inspected companies manufacturing importing, testing and wholesaling drugs for human and veterinary use for GMP compliance. In 2008 she joined the Clinical Trial Compliance Program where she planned and conducted inspections of sponsors, investigators and CRO establishments. She represented Health Canada on a PIC/s GCP joint inspection group. As part of Health Canada's project to modernize the Health Canada GCP Program, Flora was assigned to conducting clinical trial inspections of bioequivalence studies. In May 2022 Flora joined BioAcuity Consulting Inc. providing quality, compliance and regulatory services

Speaker

Kerstin Koenig, PhD, MSc

Vice President, Global Quality Assurance
GSK, United States

Kerstin is a global Quality Executive with in-depth knowledge of current GxPs recognized for shaping and leading quality assurance strategies and audit processes. Known as a visionary leader, her current focus is on the "Future of Quality", including the digitalization of quality processes, data analytics and Quality by Design. Kerstin is the VP, Global Quality Assurance at GSK. In this role, she is responsible for the development and oversight of the world-wide quality assurance activities in the areas of GLP, GCP and GVP. Kerstin has been the EFPIA topic lead for ICH E8 (R1) renovation and was a member of the CTTI QbD adoption initiative.

10:30 AM — 11:45 AM

Julien/Gagnon/Walker/Suzor-Cote

Session 7, Track C: Signal or Noise? Decoding the Pharmacovigilance Symphony

In the ever-evolving landscape of pharmacovigilance, distinguishing meaningful safety signals from background noise is crucial. This session, "Signal or Noise? Decoding the Pharmacovigilance Symphony," delves into the intricacies of assessing safety signals, emphasizing Health Canada's oversight approach. Participants will gain insights into practical tools and frameworks for identifying potential safety signals and explore future applications in signal detection and management.

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

- Understand Health Canada's approach to oversight in signal management
- To apply tools/framework to identify a potential safety signal
- To understand future applications to signal detection and management (TBD)

Track: Track C: Safety/Pharm

Session Chair(s)

Mei Lam, BSN, RN

Canada PV Manager/Safety Regional Country Contact
Haleon, Canada

Mei Lam is the Pharmacovigilance Manager for Haleon Canada. She has over 15 years in industry, primarily in Pharmacovigilance (PV). In addition to PV, Mei has experience in medical information, medical affairs, and global deviation management. Mei is a registered Nurse in Ontario who volunteers for the Region of Peel Public Health Unit.

Daniel Greco, PharmD, RPh

Associate Director of Patient Safety
Bristol-Myers Squibb Company, Canada

Daniel Greco is the Associate Director of Patient Safety at Bristol Myers Squibb, with a specialization in Risk Management. In this capacity, Daniel has led substantial changes to the risk management program responsible for overseeing the risks associated with thalidomide and its derivatives in Canada. He earned his H.BSc. and PharmD from the University of Toronto, and is presently pursuing a Masters in Pharmacovigilance and Pharmacoepidemiology through the Eu2P program. Moreover, Daniel is practicing as a licensed Pharmacist in the province of Ontario, where he has gained invaluable firsthand experience in direct patient care.

Speaker(s)

Aspects to Consider in Causality Assessment of Safety Signals: Broadening the Thought Process

Salman Afsar, MD, MHA

Senior Director and Signal Management Team Chair
Bristol-Myers Squibb Company, United States

Dr. Salman Afsar, Senior Director and Signal Management Team Chair at Bristol Myer Squibb, is a distinguished physician specializing in Medical Safety Assessment. With a strong background in the pharmaceutical industry including notable positions at Sanofi and Astellas, Dr. Afsar brings extensive expertise to his role. Before transitioning to industry he made significant contributions in academia and clinical practice, earning him prestigious awards for his exceptional work.

Speaker

David Duguay, PhD

Pharmacovigilance Scientific Manager, Marketed Pharmaceuticals Bureau at MHPD
Health Canada , Canada

David Duguay is a scientific manager at the Marketed Pharmaceuticals Bureau, Marketed Health Product Directorate, in the Health Products and Food Branch, at Health Canada. He has over 10 years of regulatory drug safety experience with Health Canada. His work involves the post-market surveillance of prescription drugs including Risk Management Plans (RMPs), safety assessments, benefit-risk assessments, and signal detection involving the review of adverse event reports. David graduated from the Université de Montréal (Ph.D. Pharmacology) in 2007 with a focus on cardiovascular pharmacology, and he completed a postdoctoral fellowship in neurosciences at McGill University in 2010.

Speaker

Heather Ward, PhD, MS

Director, Safety Surveillance Research
Pfizer, Canada

Dr. Heather Ward is an epidemiologist with over 15 years of experience, specializing in real-world pharmacoepidemiology studies focusing on safety and effectiveness. She completed a PhD in Epidemiology at the University of Cambridge (UK) and an MSc in Nutritional Sciences (Canada). Within the Safety Surveillance Research group at Pfizer, she is responsible for FDA- and EMA-committed post-authorization safety studies. Previously, Dr. Ward developed data collection methods for national cohort studies in Singapore and Qatar, and coordinated an international cohort for studies of diabetes and cancer. She has published more than 50 peer reviewed publications and authored a chapter in the 2019 International Diabetes Federation Atlas.

11:45 AM — 12:45 PM Mozart

Luncheon, Exhibits, and Networking Break

12:45 PM — 2:00 PM Beethoven/Chopin

Session 8, Track A: Fostering Transparency: Health Canada, Industry, and Patient Perspectives on PRCI's Role

Increased transparency requirements, with the need to protect personal information and confidential business information (CBI) have posed challenges for both Sponsors and Regulators. In this session, we will discuss feedback from Health Canada on data anonymization and/or redaction and obstacles faced by Sponsors, share best practices and key considerations for the public release of clinical data (PRCI). We will also hear from an end user on how the data gathered from PRCI is used by patient associations/groups and the value that it brings.

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

- Explain transparency requirements for Sponsors and what Regulators expect from PRCI submissions
- Discuss data anonymization/redaction challenges faced by both Sponsors and Regulators
- Share best practices and key considerations for public release of clinical data, during dossier preparation and post-approval
- Recognize the value of PRCI to relevant stakeholders

Track: Track A: Regulatory

Session Chair(s)

Amber McLeod, PhD

Immunology, Virology, and Specialty Head, Regulatory Affairs
Abbvie Corporation, Canada

Amber McLeod has held the role of Head of Immunology, Virology, and Specialty at AbbVie since May 2020. In this role, she leads a team of Regulatory Affairs professionals focused on filing and obtaining approval for biopharmaceutical drug submissions with Health Canada, spanning clinical development and commercial products in the fields of Immunology, Virology, Neuroscience, and Specialty Care. Amber joined Abbott in January 1999. Over her 25-year tenure with Abbott/AbbVie, she has held various roles of increasing responsibility, leading and managing numerous regulatory filings, approvals, and product launches across diverse therapeutic areas. Amber holds a Doctorate in Pharmacology and Therapeutics from McGill University.

Marcia Sam

Senior Manager, Regulatory Affairs
Regeneron Canada Company, Canada

Marcia Sam is enjoying her role as a Regulatory Affairs Strategy and Policy Manager at Roche Canada. With over 16 years of experience in the Biotech/Pharmaceutical industry, she has a diverse range of experiences with exposure to different areas of drug development, regulatory submissions in therapeutic areas as Hematology, Neuroscience, Oncology, Virology, Rare Diseases, etc., volunteered on the regulatory affairs committees of IMC, was a past guest speaker and instructor for regulatory courses at Seneca College of Applied Arts and Technology. She holds a BSc (Honours) degree in Neuroscience/Biology from the University of Toronto and a Post-graduate diploma in Pharmaceutical Regulatory Affairs and Quality Operations from Seneca College.

Speaker(s)

Speaker

Etienne Thomas, MSc

Regulatory Affairs Specialist
Health Canada, Canada

Etienne has been with Health Canada since 2016 and with Public Release of Clinical Information team since 2020. Prior to joining PRCI, Etienne acquired experience reviewing clinical trial applications in Health Canada's Biologics and Radiopharmaceuticals Drugs Directorate, as well regulatory assessment and review in the Controlled Substances and Cannabis Branch. He has an MSc in Pharmaceutical Sciences: Drug Development from the University of Montreal.

Speaker

Representative Invited

Regeneron, United Kingdom

Cathal Gallagher is the Associate Director of Clinical Transparency & Trial Disclosure at Regeneron, with over a decade of experience in clinical trial data technology. Specialising in data and document transparency, Cathal develops and implements technical solutions to ensure compliance with EMA Policy 0070 and Health Canada's PRCI. Known for his strategic approach and dedication to regulatory compliance, he advocates for transparency as a cornerstone of ethical research. Cathal's interests include blockchain technology, fitness, and continuous self-improvement.

Speaker

Julie Holtzople

President
Holtzople Consulting, United States

Julie Holtzople is a seasoned Clinical Trial Transparency professional. She spent 10 years building Clinical Transparency and Data Sharing at AstraZeneca, becoming an expert in Plain Language Summaries, Clinical Document Anonymization and Clinical Data Sharing. She also led the implementation and readiness for EU CTR Transparency requirements. Julie has been an active member of numerous CTT working groups and organizations contributing to CTT standards and best practices. Prior to AstraZeneca, she started her career as a management consultant working at Ernst & Young and then Booz Allen. Julie has recently returned to consulting as an independent. She specializes in Clinical Trial Transparency, process optimization and program delivery.

12:45 PM — 2:00 PM Delfosse

Session 8, Track B: Statistical, Modeling and Dose Optimization Considerations for Trial Design

This session will provide an overview of current approaches to optimization of doses with focus on oncology studies, statistical consideration for the studies with the small population and latest updates in this area from Health Canada.

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

- Describe project Optimus objectives and current status
- Discuss statistical considerations for the design of the study with the small population
- Explain latest Health Canada advancement and requirements for the statistical approaches in the clinical studies

Track: Track B: Clinical

Session Chair(s)

Oxana Iliach, PhD

Senior Director Regulatory Strategy
Certara, Canada

Oxana Iliach, PhD is a Sr. Director, Regulatory Strategy and Policy at Certara/Synchrogenix. She has more than 15 years of experience in the healthcare industry including the last 10+ years in regulatory affairs. Her specialty is developing and executing regulatory strategies for drugs for rare diseases, pediatrics, advanced therapy products and biosimilars, with a focus on Chemistry, Manufacturing and Control (CMC). Oxana has experience with the FDA, EMA, Health Canada, and other smaller agencies. She is also a part-time lecturer at Northeastern University, Toronto campus and professor at Seneca College of Applied Arts and Technology. Oxana is a member of CAPRA, RAPS, CORD and IRDiRC.

Katalin Bertenyi, MSc

Manager, Centre for Blood, Blood Products and Biotherapeutics
Health Canada, Canada

Katalin Bertenyi is the manager of the Clinical Evaluation Division - Endocrine and Metabolic Diseases, situated in CBBB in the Biologic and Radiopharmaceutical Drugs Directorate of Health Canada. Her team is responsible for the evaluation of biologics for endocrine and metabolic diseases, including rare diseases. She has over 20 years of experience with Health Canada, in the clinical evaluation of biologic and pharmaceutical drugs in the areas of reproduction, urology, oncology, endocrinology and metabolism, as well as experience in regulatory affairs, and clinical trials for medical devices and pharmaceutical drugs. Katalin holds a B.Sc. (Honours) in Biotechnology/Biology and a M.SC in Biology, both from Carleton University in Ottawa.

Speaker(s)

FDA’s Project Optimus: An Overview

Jade Huguet, PhD

Associate Director Clinical Pharmacology Clinical Pharmacology/Translational Med
Certara, Canada

Statistical Considerations for Trial Design in Rare Diseases: Examples from Duchenne and Becker Muscular Dystrophy

Utkarsh Dang, PhD

Associate Professor
Carleton University, Canada

Utkarsh is an Associate Professor in the Department of Health Sciences at Carleton University. He is a biostatistician and data scientist who works in health outcomes, clinical trials, biomarkers, and statistical/machine learning. Utkarsh's work in health outcomes is on understanding phenotypic, genotypic, and treatment response variability in two progressive diseases: Duchenne and Becker muscular dystrophy.

Statistical Regulatory Challenges: Health Canada Perspective

Alex Bliu, PhD

Senior Biostatistician
Health Canada, Canada

Dr. Bliu, a senior biostatistician at Health Canada, has over 22 years of expertise in statistics, pharmaceutical development, and regulations. With a Ph.D. in Biostatistics from McGill University, he has made significant contributions to oncology, vaccines, autoimmune diseases, pediatrics, and rare disorders therapeutic areas. His research interests include advanced study designs and methodologies, Bayesian approaches, causal inference methods, and real-world data applications. He has collaborated internationally on studies, forums, and policy guidance documents such as ICH. As a dedicated educator, he lectures at McGill University and contributes to workshops and conferences on statistical methodologies and clinical study design.

12:45 PM — 2:00 PM

Julien/Gagnon/Walker/Suzor-Cote

Session 8, Track C: Unveiling the Power and Value of Pharmacovigilance Teams: Pioneering Safety Guardians of the Pharmaceutical World

Unveiling the Power and Value of Pharmacovigilance Teams explores the indispensable role pharmacovigilance has as guardians of patient safety, delving into the trends, challenges, and opportunities shaping this ever-evolving landscape. Renowned experts shed light on cutting-edge strategies and best practices, empowering attendees to navigate complexities with unparalleled expertise. This captivating discourse unveils the invaluable impact of pharmacovigilance teams, fostering a profound appreciation for their pivotal responsibilities in safeguarding public health and ensuring the integrity of pharmaceutical products.

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

- Analyze the evolving trends, challenges, and opportunities shaping the pharmacovigilance landscape
- Evaluate the invaluable impact of pharmacovigilance teams in safeguarding public health and ensuring regulatory compliance
- Formulate an action plan to elevate the recognition and value of pharmacovigilance departments within organizations

Track: Track C: Safety/Pharm

Session Chair(s)

Vanessa Zapata

Associate Director, Regional Pharmacovigilance Officer
Merck Canada Inc., Canada

Vanessa Zapata started her career in the pharmaceutical industry in 1998. For 12 years, she fulfilled different roles in the Clinical research field. In 2011, she moved to Pharmacovigilance where she has held various roles of increasing responsibility. She currently fulfills a position of Associate Director, Regional Pharmacovigilance at Merck Canada Inc. She also is the business owner of the company's Global Pharmacovigilance training that gets assigned annually to more that 115 000 employees and external partners around the world.

Myriam Salem, MSc

Good Pharmacovigilance Practices National Coordinator
Health Canada, Canada

Myriam Salem is currently coordinating the Good Pharmacovigilance Practices inspection Program at Health Canada. She previously worked as a pharmacovigilance scientific manager and a senior scientific evaluator for several years. She was involved in the implementation of several policies leading to a strengthened post market oversight of opioid products in Canada. Prior to joining Health Canada, she held various positions in the pharmaceutical industry and academia. She is a biochemist by training and holds a master's degree in pharmacology from Université de Montréal and a master's degree in Pharmacovigilance and Pharmacoepidemiology. She is the chair of the PIC/S GVP international working group on Artificial Intelligence-Machine learning.

Randy Levitt, PhD

Director, Pharmacovigilance and Medical Affairs
Paladin Pharma Inc., Canada

Randy Levitt is the Director of Pharmacovigilance and Medical Affairs at Paladin. He is also the local compliance champion and works closely with the legal and compliance teams at Endo, the

parent company of Paladin. He joined Paladin in 2011 as Manager, Scientific Communications and Publications after Paladin's acquisition of Labopharm, where he had worked in the medical department since 2008. Randy completed his undergraduate and graduate degrees at McGill University, graduating with his PhD in Experimental Medicine in 2006.

Speaker(s)

Pharmacovigilance - Trends, Challenges and Opportunities

Gurpreet Singh

Vice President, Managing Director Integrated Safety
IQVIA, United Kingdom

Gurpreet Singh is Vice President, Managing Director Integrated Safety at IQVIA. Based in UK, he has 18 years' experience in Pharma Industry of which 16+ years have been in Global Drug Development. He has had the opportunity to work with some top global companies like Cognizant, Tata Consultancy, Novartis and Parexel. At Novartis he was the Global Head of PV Operations managing all Global PV activities. At Parexel he was the Senior Director PV Operations responsible for managing PV projects of top Global Pharma and Biotech companies. Gurpreet is a certified Six Sigma and Project Management Professional. He has interest in Digital Transformation and Organization Culture and has led various projects during his tenure in the Pharma Industry.

Speaker

Christopher Gravel, PhD

Assistant Professor
University of Ottawa (School of Epidemiology and Public Health), Canada

Dr. Christopher Gravel is an assistant professor of biostatistics in the School of Epidemiology and Public Health at the University of Ottawa. He obtained a PhD in Probability and Statistics from Carleton University and a post-doctoral fellowship from McGill University. His research is on the development and improvement of methods for drug and vaccine safety studies focused on measurement error, disproportionality analysis and causal inference. Dr. Gravel is an investigator with networks on post-market drug safety evaluation (PMDE), pediatric rare disease (RareKids-CAN) and perinatal pharmacoepidemiology (CAMCCO-L). Prior to joining the University of Ottawa Dr. Gravel worked for Health Canada in both pre and post market regulatory settings.

2:00 PM — 2:30 PM Mozart

Refreshments, Exhibits, and Networking Break

2:30 PM — 3:45 PM Beethoven/Chopin

Session 9 Plenary: AI: Investments and Future Outcomes

This session will provide an overview of Health Canada current view on use of AI and potential future outcomes.

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

- Describe potential use of AI
- Discuss investments in AI development
- Explain latest Health Canada expectations for AI outcomes

Track: General Session

Session Chair(s)

Oxana Iliach, PhD

Senior Director Regulatory Strategy
Certara, Canada

Oxana Iliach, PhD is a Sr. Director, Regulatory Strategy and Policy at Certara/Synchrogenix. She has more than 15 years of experience in the healthcare industry including the last 10+ years in regulatory affairs. Her specialty is developing and executing regulatory strategies for drugs for rare diseases, pediatrics, advanced therapy products and biosimilars, with a focus on Chemistry, Manufacturing and Control (CMC). Oxana has experience with the FDA, EMA, Health Canada, and other smaller agencies. She is also a part-time lecturer at Northeastern University, Toronto campus and professor at Seneca College of Applied Arts and Technology. Oxana is a member of CAPRA, RAPS, CORD and IRDiRC.

Marcia Sam

Senior Manager, Regulatory Affairs
Regeneron Canada Company, Canada

Marcia Sam is enjoying her role as a Regulatory Affairs Strategy and Policy Manager at Roche Canada. With over 16 years of experience in the Biotech/Pharmaceutical industry, she has a diverse range of experiences with exposure to different areas of drug development, regulatory submissions in therapeutic areas as Hematology, Neuroscience, Oncology, Virology, Rare Diseases, etc., volunteered on the regulatory affairs committees of IMC, was a past guest speaker and instructor for regulatory courses at Seneca College of Applied Arts and Technology. She holds a BSc (Honours) degree in Neuroscience/Biology from the University of Toronto and a Post-graduate diploma in Pharmaceutical Regulatory Affairs and Quality Operations from Seneca College.

Speaker(s)

Speaker

Kelly Robinson, MSc

Director General, Marketed Health Products Directorate
Health Canada, Canada

Kelly is the Director General of Health Canada's Marketed Health Products Directorate. She leads a team on a range of health product regulatory activities including surveillance, assessment, and risk management; risk communications; health product advertising; use of real-world data/evidence; administration of drug related intellectual property regimes; and domestic and international stakeholder engagement. She has worked to align reviews between Health Canada and Health Technology Assessment organizations, in establishing and advancing collaboration with foreign regulatory authorities through various platforms such as Access and ORBIS, and co-chairing the ICMRA Working Group on Real-World Evidence for Public Health Emergencies.

Speaker

Myriam Salem, MSc

Good Pharmacovigilance Practices National Coordinator
Health Canada, Canada

Myriam Salem is currently coordinating the Good Pharmacovigilance Practices inspection Program at Health Canada. She previously worked as a pharmacovigilance scientific manager and a senior scientific evaluator for several years. She was involved in the implementation of several policies leading to a strengthened post market oversight of opioid products in Canada. Prior to joining Health Canada, she held various positions in the pharmaceutical industry and academia. She is a biochemist by training and holds a master's degree in pharmacology from Université de Montréal and a master's degree in Pharmacovigilance and Pharmacoepidemiology. She is the chair of the PIC/S GVP international working group on Artificial Intelligence-Machine learning.

3:45 PM — 4:00 PM Beethoven/Chopin

Closing Remarks