Hilton Lac-Leamy

Oct 27, 2025 7:30 AM - Oct 28, 2025 4:00 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 Oct 16, 2025

10:00 AM — 1:15 PM

## Short Course: ICH E6(R3) in Practice: Canadian Perspective from Health Canada GCP Inspectors

### Day 2 Oct 22, 2025

10:00 AM — 2:00 PM

## Short Course: Tools and Methods to Evaluate the Effectiveness of Risk Minimization Measures

### Day 3 Oct 27, 2025

7:30 AM — 8:30 AM

## Networking Breakfast

7:30 AM — 6:30 PM

## Registration

8:30 AM — 8:45 AM

## Welcome and Opening Remarks

8:45 AM — 10:00 AM

## Session 1 Plenary: Advancing Regulatory Innovation: Canada’s Role in Global Collaboration

This session will provide an in-depth exploration of Health Canada’s current and future priorities including key regulatory initiatives. Attendees will gain insights into Health Canada engagement with international partners to advance regulatory collaboration on a global scale. The discussion will include diverse perspectives from industry representatives and patient groups, highlighting the collective impact of collaborative efforts on public health outcomes and regulatory innovation.

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

- Describe Health Canada's current and future regulatory priorities and international collaboration pathways
- Understand key regulatory metrics stemming from international collaboration pathways and opportunities
- Gain insights on industry and patient group perspectives on collaboration pathways and future considerations

Track: General Session

## 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.

### 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)

### Speaker

### Kelly Robinson, MSc

Director General, Pharmaceutical Drugs Directorate
Health Canada, Canada

Kelly Robinson is the Director General of the Pharmaceutical Drugs Directorate at Health Canada. In this role she leads a multidisciplinary team responsible for the authorization of innovative and generic pharmaceuticals, clinical trial evaluation, and the Special Access Program. Kelly has held various leadership positions in drug authorization and post-market surveillance at HC. She has played a pivotal role in advancing national and international regulatory initiatives including fostering alignment between HC and HTAs, enhancing international collaboration through

platforms such as Access and ORBIS, and co-chairing the International Coalition of Medicines Regulatory Authorities (ICMRA) Working Group on Real-World Evidence.

Speaker

Jenny Buckley, MA, MSc

Director, Policy
Innovative Medicines Canada, Canada

10:00 AM — 10:45 AM

## Refreshments, Exhibits, and Networking Break

10:45 AM — 12:00 PM

## Session 2, Track A: Evolving Regulatory Landscapes: Key Updates in Health Canada's Regulations, Policies, Guidance and Compliance Framework

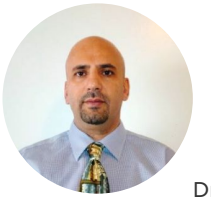
This session provides an overview of Health Canada's latest updates on regulatory, policy and Red-Tape Reduction initiatives, including advancements in clinical trial regulatory modernization, agile licensing amendments, risk management plan requirements, compliance and enforcement initiatives, and the integration of Sex- and Gender-Based Analysis Plus (SGBA+) into policy frameworks. Attendees will gain insights into upcoming changes in regulations, policies, emerging guidance documents and evolving standards impacting the regulated environment of health products in Canada.

Learning Objective :

- Identify key changes in proposed clinical trial regulations in Canada, focusing on Canada Gazette 1 consultations and key implementation timelines
- Outline strategies to overcome regulatory barriers and implement clinical trial systems that ensure quality and regulatory compliance
- Share successful approaches to engage in public consultations on Agile Regulations, guidance, and Red-Tape Reduction initiatives

Track: Regulatory

### Session Chair(s)



## Hocine Abid, MD, MBA

National Manager, Regulatory Operations and Enforcement Branch
Health Canada, Canada

Dr Hocine Abid is an international medical doctor graduate. Hocine also holds an MBA from École des Hautes Études Commerciales (École des HEC Montréal) and a Graduate Diploma in public administration from École Nationale d'Administration Publique. Hocine is the national manager for Health Canada's Clinical Trial Compliance Program that oversees the inspections of clinical trials since 2018. Before this, he occupied different roles in various positions within Health Canada such as manager of the GMP inspection program, and Head of the medical cannabis program overseeing the evaluation and the delivery of authorizations to possess and produce cannabis for medical purposes.

## Yatika Kohli, PhD, MBA

Chief Compliance and Strategy Officer
NoNO Inc, Canada

Dr. Yatika Kohli is an accomplished Senior Regulatory Professional with strong leadership skills, strategic foresight and business acumen. At NoNO Inc, Dr. Kohli is leading all strategic and global regulatory initiatives for NoNO's products. With more than 20 years of experience in Biotech/Pharmaceutical industry, Dr. Kohli has expertise in developing global regulatory and clinical strategy with project and product management across multiple modalities and jurisdictions. She led the regulatory activities for the registration and launch of two blockbuster vaccines for Sanofi Pasteur in the USA and Apotex's first biosimilar product in Europe.

# Speaker(s)

## Speaker

## Representative Invited

Health Canada, Canada

## Instructor

## Representative Invited

Health Canada, Canada

Denis Arsenault is a manager in the Office of Policy and International Collaboration within Health Canada's Biologic and Radiopharmaceutical Drugs Directorate (BRDD). In this capacity, Mr. Arsenault leads policy development initiatives for BRDD on a number files including regulatory modernization and biosimilar biologic drugs.

## Speaker

## Elana Cherry, PhD

Director, Center for Blood, Blood Products, and Biotherapeutics
Health Canada, Canada

Dr. Elana Cherry is the Director of the Centre for Blood, Blood Products and Biotherapeutics at Health Canada's Biologics and Radiopharmaceuticals Drugs Directorate. She has a wealth of regulatory, operational, and policy experience with almost 20 years at Health Canada and the Public Health Agency of Canada. After obtaining a Ph.D. in Microbiology and Immunology (HIV/AIDS) from McGill University and working in biotech and academia, Dr. Cherry joined Health Canada and has been working in roles of increasing responsibility in health product regulation (medical devices, pharmaceuticals, biologics, and COVID-19 vaccines) as well as in interdepartmental COVID-19 Border Measures and modernizing Canada's biosecurity oversight framework.

### Speaker

### Representative Invited

Health Canada, Canada

Nadia Giancaspro has been with Health Canada since 2001. She is a Senior Policy Analyst within the Therapeutics Directorate of the Health Products and Food Branch. Her latest work has been focused on the development of regulations, policies and guidance on issues related to special access to drugs in Canada, the opioid crisis, H1N1, and other emergency-related issues.

10:45 AM — 12:00 PM

## Session 2, Track B: Re-Defining Patient-Centric Clinical Research

This session explores the evolving landscape of clinical trials through the patient perspective and modern trial approaches. Attendees will gain insights into patient-centric, fit-for-purpose trial designs and the lived experiences shaping Diversity, Equity, and Inclusion in Clinical Trials (DEICT). Real-world case studies and personal narratives will highlight how modern approaches are transforming both study conduct and participant engagement.

Learning Objective :

- Employ strategies to develop patient-centric approaches with a Diversity, Equity, and inclusion in clinical trial (DEICT) perspective
- Discuss the lived experiences of patients while exploring both the patient and clinical research professional perspectives
- Understand different approaches in the modernization of clinical trials including the evolution of decentralized trials and fit for purpose study design

Track: Clinical

### Session Chair(s)

### 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.

## 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)

## Evolution in Decentralized Clinical Trials - Patient-centric, Fit for Purpose Approach to Modernize Study Conduct

### Aneta Woroniecka-Osio, MD

Ex-Bayer, Independant, 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.

## An Inclusive Perspective About Clinical Research – From Patient to Clinical Research Professional

### Adriana Rodriguez Cruz, PhD

Global Health Equity Advocate

N/A, Canada

Adriana Rodriguez-Cruz, PhD in Biomedical Sciences, finished her academic pathway with two postdoctoral fellowships, one at McGill University and the second at Université de Montréal. Her field of research is in Infectious Diseases, primarily HIV, focusing on Epidemiology and patient-oriented research in Clinical Trials. She has 6+ years of combined experience both, in biomedical laboratory and clinical research. Having worked in the public healthcare system and Clinical Research Organizations broadens her understanding of Clinical Research. She advocates for Global Health Equity and promotes Patient-Centric Clinical Research by strengthening the role of medical service dogs and contributing to scientific knowledge and global health.

Speaker

Representative Invited

RxPx Health, United States

10:45 AM — 12:00 PM

# Session 2, Track C: From Duplication to Innovation: Modernizing ICSR Collaboration

This session presents a forward-looking conceptual model aimed at transforming how Individual Case Safety Reports (ICSRs) are managed across the pharmacovigilance ecosystem. It tackles the critical challenges of data duplication and inefficiency, proposing a collaborative, multi-stakeholder approach involving regulators, marketing authorization holders, and global experts. Attendees will explore how this model can enhance data quality, streamline safety surveillance, and support the launch of a scalable pilot initiative.

Learning Objective :

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

- Understand and summarize the proposed ICSR model and its implications for global regulatory harmonization
- Identify the technical or regulatory barriers to implementing reduced ICSR replication
- Evaluate the potential of the proposed model to improve data quality, streamline safety surveillance processes, and support the development of a scalable pilot initiative

Track: Safety and Pharmacovigilance

## Session Chair(s)

### Mei Lam, BSN, RN

Associate Director Consumer Safety Regions Americas
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.

## Ricardo Pasquel Cook, MD

Safety Team Lead
Pfizer Inc., 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 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.

## Speaker(s)

## The First Step to a Multi-Stakeholder Collaboration to Modernize ICSR Management: A Model to Stimulate Meaningful Discussion

## Clint Craun, MA

Program Director
TransCelerate BioPharma, Inc., United States

Clint is Associate Program Director at TransCelerate BioPharma Inc., a nonprofit advancing biopharma collaboration. He has led and supported patient safety initiatives, including ICSR automation and modernization. Previously, he held senior roles at ICON plc and PRA Health Sciences, managing late-phase and RWE protocols and progressing through Clinical Research Associate and Project Management roles. He has contributed to 20+ peer-reviewed publications in patient safety and health sciences through writing support or co-authorship. Clint holds an MA in Experimental Psychology from Middle Tennessee State University and completed undergraduate studies at Lipscomb University.

## Speaker

## Representative Invited

Health Canada, Canada

12:00 PM — 1:00 PM

# Luncheon, Exhibits, and Networking Break

1:00 PM — 2:15 PM

# Session 3, Track A: Evolution of Labelling

This session will focus on the latest trends and challenges in product labeling, with an emphasis on technological advancements, regulatory compliance, and inclusive communication practices. Attendees will explore the evolving landscape of digital medication information dissemination and gain insights into XML standards required for regulatory compliance, ensuring market access and managing associated risks. Furthermore, the session will highlight the necessity of adopting gender-inclusive language in labeling to promote equitable and respectful consumer communication. This discussion aims to provide participants with the knowledge and tools needed to effectively navigate and adapt to current and future labeling practices.

Learning Objective :

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

- Describe the current developments in product labelling as a result of changing technology and regulatory compliance
- Explain how patients and industry will benefit from utilizing technology
- Identify how to incorporate gender-inclusive language into labelling to enhance patient communication

Track: 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 a Senior Manager, Regulatory Affairs at Regeneron Canada Company. 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)

## Electronic Patient Medication Information (ePMIs) – Where are We Now?

### 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 ePILs.

## Words Matter: Adopting Gender Inclusive Language in Product Labelling

### Adesola Adeyemi, MSc

Senior Associate, Regulatory Affairs, Bayer Inc. Canada
Bayer Inc., Canada

Adesola Adeyemi has been with Bayer Inc. since 2019 with the Regulatory Affairs team. Adesola has worked on various regulatory submissions for human and animal drug products during her career at Bayer Inc. Adesola has a Master of Science degree in Drug Design, a Bachelor of Science in Chemistry/Industrial Chemistry and a Post-graduate diploma in Regulatory Affairs.

1:00 PM — 2:15 PM

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# Session 3, Track B: Optimizing Clinical Trial Operations: Strategy, Sites, and Smart Recruitment

This session delves into three critical pillars of clinical trial operations. A strategic framework for effective vendor selection and management to ensure quality and alignment throughout the trial lifecycle. Then, we'll contrast expectations versus reality in site selection, followed by a look at how AI is transforming participant recruitment by enhancing outreach, precision, and efficiency.

Learning Objective :

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

- Identify the critical elements for a successful study feasibility – A site perspective
- Describe the power of AI for recruitment in clinical trials

Track: Clinical

## Session Chair(s)

### Marie-France Goyer, MSc

Senior Director, Clinical Operations
Abcellera, Canada

As the Head 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.

### Kim McDonald-Taylor, MS, MSc

Clinical Research Consultant
Clinical Research Association of Canada Inc., Canada

Kim McDonald-Taylor consults in project management, medical writing, training & teaching being in the clinical trials area for over 37 years, including 12 years with Endpoint Research. Her therapeutic experience includes most diseases & therapies. Kim has volunteered with CRAC since 1997. She is a member of Human Research Accreditation Canada Council since 2018. Kim earned her MSc from Ontario Veterinary College at Guelph University. She has presented & co-chaired sessions at DIA, ACRP and others. Kim was awarded the Excellence in Clinical Research award 2018 at the CTP conference & 2016 Volunteer of the Year for her work with Brain Injury Canada. In her spare time, Kim enjoys photography, birding, genealogy, music and downhill skiing.

## Speaker(s)

### Site Selection in Clinical Trials: Expectations vs. Reality

### Suzie Talbot, MBA, RN

President
Diex Research, Canada

Suzie Talbot is the President and Founder of DIEX Recherche, a Canadian private clinical research organization with 6 sites across Quebec. With nearly 30 years of experience in clinical research, she brings deep operational expertise and a strong site perspective to trial execution. Suzie is a passionate advocate for early, meaningful site engagement and for impactful research that improves patient health. She is also a founding member of the Canadian Clinical Research Coalition, which promotes Canada as a premier destination for clinical trials. Her leadership is driven by a

commitment to operational excellence, strong collaboration between stakeholders, and research that truly makes a difference in people's lives.

### Health Equity Meets Machine Learning: AI in Canadian Clinical Trials


Paolo Melgarejo

Chief Executive Officer
Trialshub, Canada


1:00 PM — 2:15 PM

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## Session 3, Track C: Advancing Access and Automation for Canadian Medical Information

This session explores cutting-edge approaches to improving access to Canadian digital medical information and advancing Real-World Evidence (RWE) through AI-driven automation. Attendees will discover innovative frameworks designed to streamline medical information sharing while ensuring accuracy and accessibility. Join us to learn how technology is transforming medical information management.

Learning Objective :

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

- Explain the current challenges in accessing Canadian digital medical information and the role of Real-World Evidence (RWE)
- Analyze innovative frameworks designed to streamline the sharing of medical information
- Understand the role and value of the medical information department within the company

Track: Safety and Pharmacovigilance

### Session Chair(s)

### Randy Levitt, PhD


Director, Pharmacovigilance and Medical Affairs, Canada
Knight Therapeutics 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.

## Anna Bussel, MPharm

Vice President Pharmacovigilance and Medical Information
ClaroPV Services Inc, Canada

Anna Bussel is a pharmaceutical professional with 15+ years of experience in pharmacovigilance (PV), regulatory affairs (RA), and quality assurance (QA). Her career spans both the pharmaceutical industry—holding PV, RA, and QA roles at Eli Lilly and Company—and consulting, where she headed the PV & MI Department at Veristat, Science-First™ CRO, providing strategic PV & MI advice to multiple clients. She has led numerous GVP and GMP audits on behalf of Marketing Authorisation Holders and liaised with Health Authorities on market access and drug policy improvements. Anna holds a Master's in Pharmacy and is an active member of the DIA.

## Speaker(s)

### Introducing a Framework to Improve Access to Canadian Digital Medical Information

### Joanna Rizos, MBA, RPh

Director, Medical Information
Eli Lilly Canada Inc., Canada

In her current role, she provides strategic leadership and oversight for activities related to Medical Information and Medical Information Digital solutions. She began her career as a community pharmacist, before joining the Pharmaceutical Advertising Advisory Board (PAAB) as an Assistant Commissioner. She joined Lilly, 25 years ago, first supporting Medical Information before holding various roles in Legal, Sales, Compliance and Medical Affairs. Joanna obtained her B.Sc. in pharmacy from the University of Toronto and her MBA from the Schulich School of Business. Joanna is also a board member of the Pharmacovigilance and Medical Information Network (PVN-MI) Canada.

### RWE through Medical Information Automation using Controlled AI Chatbots

### Manar Hammood, MSc

Founder and Director of PV Operations
Zenith PV, 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.

## Medical Information Matters: Partnering with Purpose in Pharma


### Josee Brisebois, PhD

Senior Biopharma and Life Sciences Advisor
JB Pharma Consulting, Canada


Josée Brisebois, PhD is a senior biopharma and life sciences consultant with over 30 years of experience driving innovation to improve patient outcomes. She has held leadership roles in Medical Affairs, Medical Information, Clinical and Regulatory at Incyte, Gilead/Kite, and Merck in Canada, spanning diverse therapeutic areas including oncology, cell therapy, infectious diseases, HIV, inflammation, dermatology, vaccines, and rare diseases. Josée has helped launch transformative therapies and brings deep expertise across the pharmaceutical ecosystem—from discovery to commercialization. She collaborates with stakeholders across academia, industry, public health, and patient advocacy, serves on the Board of BioCanRx, and has lectured at McGill

2:15 PM — 3:00 PM

## Refreshments, Exhibits, and Networking Break

3:00 PM — 4:15 PM

## Session 4, Track A: Bridging Borders: Health Canada, the FDA, and the Future of Oncology Approvals

International collaboration is reshaping the regulatory landscape. This session will explore Health Canada's evolving relationship with the FDA, examining key milestones, as well as current and future initiatives. Insights from the FDA on the strengths and challenges of this collaborative framework will be shared. Industry experts will provide an in-depth analysis into the impact of Project Orbis on accelerating global oncology approvals as well as sharing data-driven perspectives on its effectiveness in streamlining access to innovative treatments.

Learning Objective :

- Examine the concurrent partnership between Health Canada, the FDA and other jurisdictions on Project Orbis and future plans aimed at enhancing regulatory cooperation
- Share data-driven perspectives on the effectiveness of international collaboration in streamlining access to innovative treatments
- Hear from industry experts how these collaborations influence the development and approval of new treatments in oncology

Track: 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.

### Melanie Cote, MS

Senior Manager, Global Regulatory Affairs
Otsuka Pharmaceutical Development & Commercialization 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 and Global regulatory. She is thrilled to be part of DIA Canada Annual Meeting program committee for her second year.

## Speaker(s)

### Speaker

### Representative Invited

FDA, United States

Dr. de Claro is the Division Director for Division of Hematologic Malignancies I with Office of Oncologic Diseases. He provides leadership and scientific direction to staff engaged in the review and evaluation of applications for investigational new drugs and drug approvals. Dr. de Claro is also the Associate Director (Acting) for Global Clinical Sciences with US FDA Oncology Center of Excellence (OCE). In this role, he leads OCE efforts to advance cancer drug development and regulatory science across the globe, including direction of Project Orbis, a global collaborative review program started in 2019. He is board certified in Internal Medicine, Hematology, and Medical Oncology.

### Speaker

### 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.

### Analysis of Project Orbis Participation by Health Canada on New and Supplemental Drug Submissions: An Industry Perspective

Jonathan Zaslavsky, MSc

Regulatory Affairs Associate
AstraZeneca Canada, Canada

Jonathan Zaslavsky works in Regulatory Affairs at AstraZeneca for the Canadian business, focusing on oncology. He holds an MSc in Pharmaceutical Sciences from the University of Toronto, where he explored data-driven approaches, an interest he brings to regulatory strategy and innovation.

3:00 PM — 4:15 PM

## Session 4, Track B: Rebuilding Trust and Awareness in Clinical Trials

This session explores the shifting landscape of public engagement with clinical trials. It begins with strategies to re-build trust and reshape the narrative surrounding clinical research. Attendees will also gain insights from Research Canada's data on public perception trends since 2015 and learn about a public education initiative in British Columbia that promotes transparency and the importance of sharing clinical trial results.

Learning Objective :

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

- Develop strategies to increase public engagement in clinical trials
- Recognize the importance of transparency initiatives

Track: Clinical

### Session Chair(s)

## Marie-France Goyer, MSc

Senior Director, Clinical Operations
Abcellera, Canada

As the Head 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.

## 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)

### Rebuilding Public Trust: Changing the Narrative Around Clinical Trials

### Fraser Gibson, MBA

Founder
Advantage Clinical, Canada

### Initiative in British Columbia for Public Education on Clinical Trials

### Alison Orth

Director
Clinical Trials BC, Canada

Alison Orth is a portfolio director, research programs at Michael Smith Health Research BC. She has over 25 years of experience leading organizations, programs and multi-disciplinary teams in both the private and public sectors. In her role as portfolio director Alison provides leadership for the Clinical Trials BC, Research Ethics BC and REACH BC teams along with provincial system change initiatives. More recently Alison led the development of a vision for clinical trials in British Columbia. She serves on several provincial and national committees dedicated to advancing clinical trials and improving the clinical trial experience for participants.

3:00 PM — 4:15 PM

# Session 4, Track C: Patient Support Programs and Drug Safety: Compliance, Reporting, and Optimization

As Patient Support Programs (PSPs) become increasingly integral to patient care - especially with the rise of injectable therapies - ensuring pharmacovigilance (PV) compliance and data quality is more critical than ever. This session explores the evolving PSP landscape in Canada and the U.S., highlighting key differences, challenges, and opportunities. Experts will share proactive strategies for designing compliant post-market surveillance workflows, optimizing AE reporting, and improving collaboration between PV and commercial teams. Attendees will gain practical insights into monitoring PSP-provider compliance, enhancing data quality, and aligning workflows with regulatory expectations to safeguard patient safety.

Learning Objective :

- Compare Canadian vs. U.S. regulatory expectations for Patient Support Programs (PSPs), using regional examples to highlight major differences
- Outline effective strategies to design and monitor PSP workflows that improve adverse event (AE) reporting quality and ensure compliance
- Apply KPIs to evaluate PSP effectiveness in pharmacovigilance and suggest enhancements for organizational processes

Track: Safety and Pharmacovigilance

## Session Chair(s)

### Ricardo Pasquel Cook, MD

Safety Team Lead
Pfizer Inc., 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 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.

### Anna Bussel, MPharm

Vice President Pharmacovigilance and Medical Information
ClaroPV Services Inc, Canada

Anna Bussel is a pharmaceutical professional with 15+ years of experience in pharmacovigilance (PV), regulatory affairs (RA), and quality assurance (QA). Her career spans both the pharmaceutical industry—holding PV, RA, and QA roles at Eli Lilly and Company—and consulting, where she headed the PV & MI

Department at Veristat, Science-First™ CRO, providing strategic PV & MI advice to multiple clients. She has led numerous GVP and GMP audits on behalf of Marketing Authorisation Holders and liaised with Health Authorities on market access and drug policy improvements. Anna holds a Master's in Pharmacy and is an active member of the DIA.

## Speaker(s)

### Patient Supports Programs and Drug Safety

### Riti Singh, PharmD, MBA

National Director, Scientific Affairs, Quality, Ethics and Compliance Offi
Bayshore Healthcare (Bayshore Specialty Rx Ltd.), Canada

### Speaker

### Agnes Jankowicz, MS

Vice President, Pharmacovigilance
ClaroPV Services Inc, Canada

Agnes is an industry leader with over twenty years of experience in pharmacovigilance (PV) and medical information (MI) both in the pharmaceutical industry as well as in the consulting environment. She is a Vice President of Pharmacovigilance at Veristat, a CRO whose team includes experienced and dedicated PV professionals. Agnes in an expert PV auditor and a recognized pharmacovigilance educator engaged in teaching pharmacovigilance courses and presenting on various PV topics. Agnes holds a graduate degree in Pharmacology & Toxicology and, prior to joining the pharmaceutical industry, was involved in academic research.

### Speaker

### Nadia Latif, MS

Senior Manager, Pharmacovigilance
Ipsen Biopharmaceuticals Canada Inc., Canada

Nadia Latif 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.

4:25 PM — 5:40 PM

# Session 5, Track A: Navigating Submissions Relying on Third Party Data (SRTDs)

Explore the SRTDs pathway for drug registration in Canada. This session will cover Health Canada's requirements, the critical role of Systematic Literature Reviews (SLRs), and strategies for adapting global regulatory packages for Canadian filings. Attendees will gain essential knowledge to optimize their future SRTD submissions.

Learning Objective :

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

- Identify the essential elements required for successful Submissions Relying on Third Party Data (SRTDs)
- Acquire approaches to implement effective methodologies for conducting Systematic Literature Reviews (SLRs)
- Gain insights into developing strategic approaches for leveraging global regulatory packages in Canadian SRTD submissions

Track: Regulatory

## Session Chair(s)

### Louise Blythe, MSc

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)

## Dual Market Access: Adapting U.S. 505(b)(2) for Canadian SRTD Success with Case Study Insights


Vishal Oza, MPharm

Manager, Regulatory Affairs
Cencora, Innomar Strategies Inc. , Canada


## SLR 4 SRTD NDS - WTF?


Brenda Gryfe, MSc

Regulatory Consultant
Brenda Gryfe Regulatory Consulting, 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.

4:25 PM — 5:40 PM

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# Session 5, Track B: Navigating the Quality by Design and Inspection Process for Enhanced Safety and Result Reliability of Clinical Trials

This session will identify and discuss key elements to implement a proportionate risk-based approach to enable quality by design and leverage publicly available tools to help navigate the implementation of ICH E6(R3). Health Canada representatives will discuss how to work with inspectors to plan and prepare for a successful regulatory GCP inspection.

Track: Clinical

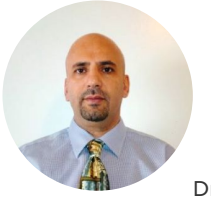
### Session Chair(s)


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.



### Hocine Abid, MD, MBA

National Manager, Regulatory Operations and Enforcement Branch
Health Canada, Canada

Dr Hocine Abid is an international medical doctor graduate. Hocine also holds an MBA from École des Hautes Études Commerciales (École des HEC Montréal) and a Graduate Diploma in public administration from École Nationale d'Administration Publique. Hocine is the national manager for Health Canada's Clinical Trial Compliance Program that oversees the inspections of clinical trials since 2018. Before this, he occupied different roles in various positions within Health Canada such as manager of the GMP inspection program, and Head of the medical cannabis program overseeing the evaluation and the delivery of authorizations to possess and produce cannabis for medical purposes.

## Speaker(s)

### Navigating Good Clinical Practice Inspections with Health Canada

### Kevin Donato, PhD

Senior Compliance & Enforcement Advisor
Health Canada, Canada

Kevin completed his PhD in the Dept. of Laboratory Medicine and Pathobiology, University of Toronto. His research described how bacteria interact with the gut to contribute to health or illness. At Health Canada he served as a pharmacovigilance evaluator and later became a scientific advisor that involved communicating about these evaluations and contributing to the department's transparency initiatives. Currently, he serves as an advisor that works closely with inspectors and industry to navigate GCP compliance & enforcement processes as well as risk management.

### Speaker

### Representative Invited

Health Canada, Canada

Dr. Soltys received her MD degree and completed her post-graduate training at the University of Saskatchewan. In addition to her regulatory work, Dr. Soltys maintains part time clinical practice at The Ottawa Hospital Cancer Centre where she is involved in the care of patients with lung cancer.

### Speaker

## Sophie Hamel, PhD, MSc

Senior Clinical Reviewer, PDD OCT
Health Canada, Canada

Dr. Sophie Hamel is a Senior Clinical Evaluator at Health Canada's Office of Clinical Trial (OCT). She joined the Public Service under the Management Training Program, gaining experience in risk management, emergency drug access, and health crisis management. She previously was the New Drug Officer at the Special Access Program and acting manager of the OCT Medical Group during the COVID pandemic. She holds a Master in Experimental Medicine from McGill University, a PhD in Cellular & Molecular Medicine from the University of Ottawa, and completed a postgraduate pharmacovigilance externship at Harvard University. She is an Action Canada alumni, having completed a national policy internship focused on public leadership and policy development.

## Speaker

## Representative Invited

Health Canada, Canada

4:25 PM — 5:40 PM

# Session 5, Track C: From Policy to Practice: Health Canada's 2025 Pharmacovigilance Guidance Update

This session will introduce Health Canada's new guidance document on the Management of Post-Market Vigilance Submissions. It will also provide a comprehensive overview of recent updates to two existing guidances: Notification of Foreign Actions and Summary Reporting. Attendees will gain insights into key changes, regulatory expectations, and practical implications for compliance in the evolving pharmacovigilance landscape.

Learning Objective :

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

- Review the upcoming updates to Health Canada's guidance on Notification of Foreign Actions and Annual Summary Reports
- Understand how these changes would impact pharmacovigilance practices and regulatory compliance in Canada
- Learn about Health Canada's planned initiatives aimed at streamlining post-market pharmacovigilance submissions

Track: Safety and Pharmacovigilance

### Session Chair(s)

## Yulia Vasianovich, PhD, RAC

Scientific Evaluator, Marketed Health Products Directorate

Health Canada, Canada

## Daniel Greco, PharmD, MS, 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)

## Speaker

## Representative Invited

Health Canada, Canada

5:40 PM — 6:40 PM

# Networking Reception

## Day 4 Oct 28, 2025

7:30 AM — 8:30 AM

# Networking Breakfast

7:30 AM — 3:40 PM

# Registration

8:30 AM — 9:45 AM

# Session 6, Track A: Advancing Digital Submissions: Transforming Documents into Data in Regulatory Affairs

This session explores the shift from traditional document-based submissions to data-driven and content-based approaches in regulatory affairs. Attendees will gain insights into industry and regulatory efforts, including Health Canada's transition to XML-based Product Monographs. Presentations will cover content standardization, Health Canada's XML-PM initiative, and the modernization of the CMC data lifecycle with FHIR standards.

Learning Objective :

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

- To provide an overview of industry and regulatory efforts to move from document-based to data and content-based submissions
- To describe the problem statement and opportunity that content management, content governance and digital submissions provide, particularly in the ePI and FHIR-PQ domains
- Provide an update on Health Canada's recent move to XML-based Product Monographs

Track: Regulatory

## Session Chair(s)

### Yatika Kohli, PhD, MBA

Chief Compliance and Strategy Officer
NoNO Inc, Canada

Dr. Yatika Kohli is an accomplished Senior Regulatory Professional with strong leadership skills, strategic foresight and business acumen. At NoNO Inc, Dr. Kohli is leading all strategic and global regulatory initiatives for NoNO's products. With more than 20 years of experience in Biotech/Pharmaceutical industry, Dr. Kohli has expertise in developing global regulatory and clinical strategy with project and product management across multiple modalities and jurisdictions. She led the regulatory activities for the registration and launch of two blockbuster vaccines for Sanofi Pasteur in the USA and Apotex's first biosimilar product in Europe.

## Speaker(s)

## Enabling Digital Filings: Moving from Documents to Data

### Todd Georgieff, MBA, RPh

Fonto IAP lead
RWS, Canada

Todd has been working in Drug Development for more than 30 years. He has extensive experience in clinical operations and also participated in and led many large-scale change and process improvement initiatives. Todd is currently Product Owner for implementation of a new Protocol authoring. Prior to his current role, he was Roche's Program Lead for TransCelerate.

## Speaker

### Craig Anderson

Director, R&D Labeling Lead, International Labeling Group
Pfizer Inc , Canada

As Director, R&D Lead at Pfizer, Craig Anderson is responsible for research, development, business and process-related functions across the International Labeling organisation. This includes topics such as electronic labelling, medicinal product information, digital health, and data standards. Craig is also Co-lead of HL7's Vulcan accelerator project for electronic Product Information (ePI) and co-lead for HL7's Pharmaceutical Quality (Industry) project.

8:30 AM — 9:45 AM

# Session 6, Track B: Canada Now – Together

Inequitable access to clinical trials is a long-standing issue and it is well documented that patients and clinical trials participants want more accessibility. Learn from this panel about what is being done by different clinical trial community members to help bring more trials to a diversity of people in Canada.

Track: Clinical

## Session Chair(s)

### Rebecca Barnes, MS

Executive Director
Network of Networks (N2), Canada

Rebecca began her career as a cancer researcher and, over the past 15 years, has held a range of leadership roles dedicated to strengthening health research capacity within Canada. She specializes in building sustainable systems that enhance research excellence, while fostering meaningful engagement. Prior to joining N2 Canada, Rebecca played a key role in leading in leading the Canadian Tissue

Repository Network and advancing research engagement by managing the CIHR SPOR initiative for the Vancouver Island region. Most recently, she served as Director of the Office of the Vice-President Research and Innovation at the University of Victoria. Rebecca holds a BSc in Biology and a Master's in Environmental Toxicology/Carcinogenesis.

### Speaker(s)

Canada Now - Together

Andrea Ladouceur

President and CEO
Bioscience Association of Manitoba, Canada

Andrea is an innate leader that designs, delivers and realigns strategic and transformation plans in multiple, complex arenas including finance, technology, energy and climate, and health and the economy. She consistently achieves desired outcomes by maximizing partnerships and true collaborations, understanding risks, and unleashing the power and talent of the BAM team to support and elevate the Bioscience industry.

8:30 AM — 9:45 AM

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## Session 6, Track C: Advancing Drug Safety with Artificial Intelligence: From Innovation to Oversight

This session explores how artificial intelligence (AI) is transforming pharmacovigilance. Attendees will gain insights into AI implementation in identifying patient populations in real-world data to enhancing post-market safety studies. We will showcase recent advances in machine learning for patient identification using atopic dermatitis as a case study. The session will also examine emerging regulatory expectations for AI in safety systems, focusing on efficiency, transparency, validation, and risk mitigation. Join us to learn how innovation and oversight are converging to shape the future of drug safety.

Learning Objective :

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

- Gain insights and knowledge of AI use in patient populations in real-world data and enhancing post-market safety studies
- Have knowledge of regulatory expectations for AI in safety systems
- Identify risks associated with the use of AI

Track: Safety and Pharmacovigilance

### Session Chair(s)

Daniel Greco, PharmD, MS, 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 Latif, MS

Senior Manager, Pharmacovigilance
Ipsen Biopharmaceuticals Canada Inc., Canada

Nadia Latif 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)

## Use of AI for Patient Identification in Safety Studies: Spotlight on Atopic Dermatitis Patient Prediction in Secondary Data

## 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.

## Speaker

## Representative Invited

ELIQUENT Life Sciences, United States

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.

9:45 AM — 10:30 AM

## Refreshments, Exhibits, and Networking Break

10:30 AM — 11:45 AM

## Session 7, Track A: Navigating the Novel: Multi-faceted Challenges in Rare Disease Treatment in Canada

This session will explore regulatory challenges in developing treatments for rare diseases, emphasizing pathways and expert advice to navigate these hurdles. Attendees will recognize diverse challenges associated with first-in-class treatments, analyze the impacts of small patient populations and novel manufacturing on submission strategies, and evaluate the benefits of early scientific engagement and interagency collaboration. Panelists will address unique challenges, share case studies, discuss evidence generation for approval, and highlight the importance of characterization and scientific exchange.

Learning Objective :

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

- Identify and explore the unique challenges in developing rare disease drugs where guidelines may not fully apply
- Evaluate innovative evidence generation and approval strategies for rare drug therapies
- Appreciate the role of collaboration in regulatory processes to harmonize expectations for advanced therapies

Track: 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.

## 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)

### Navigating the Novel: Multi-faceted Regulatory Challenges in Rare Disease

### Representative Invited

Novartis Pharmaceuticals Canada, Canada

### Speaker

### Bassam Haidar, PhD

Manager, Metabolic and Musculoskeletal Drugs Division, Pharmaceutical Drugs Dire
Health Canada, Canada

Bassam Haidar is the Manager of the Metabolic and Musculoskeletal Drugs Division in the Pharmaceutical Drugs Directorate at Health Canada. With more than 20 years of experience in pharmaceutical evaluation and regulatory affairs, he leads the evaluation of therapies for metabolic and musculoskeletal diseases, including treatments for rare conditions. Bassam's expertise spans endocrinology, cardiovascular diseases, venous disorders, dyslipidemia, diabetes, obesity, and autoimmune conditions. He holds a PhD in Biomedical Science from Université de Montréal and completed postdoctoral training at the University of Ottawa Heart Institute.

### Speaker

### Representative Invited

Incyte Corporation, Canada

10:30 AM — 11:45 AM

# Session 7, Track B: Building the Backbone: Clinical Research Workforce Development in Canada

Clinical Research Professionals (CRPs) form the operational backbone of the clinical trials ecosystem, playing a critical role in executing ethically sound, regulatory-compliant research that improves patient outcomes. Despite their essential contributions, Canada's CRP workforce faces a crisis marked by high turnover, job instability, limited career pathways, and lack of formal recognition. This session will provide an overview of some initiatives underway that aim to standardize, professionalize, and sustain the CRP workforce. By strengthening workforce infrastructure, this initiative aligns with national efforts to build our national clinical research capacity and position Canada as a global leader in clinical research.

Learning Objective :

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

- Understand the critical challenges facing Canada's clinical research workforce and their impact on trial continuity and quality
- Explore the objectives and outcomes of initiatives underway that aim to standardize and professionalize Clinical Research Professional (CRP) roles
- Summarize the impact of a strengthened CRP workforce on Canada's clinical trials capacity

Track: Clinical

## Session Chair(s)

### Kim McDonald-Taylor, MS, MSc

Clinical Research Consultant
Clinical Research Association of Canada Inc., Canada

Kim McDonald-Taylor consults in project management, medical writing, training & teaching being in the clinical trials area for over 37 years, including 12 years with Endpoint Research. Her therapeutic experience includes most diseases & therapies. Kim has volunteered with CRAC since 1997. She is a member of Human Research Accreditation Canada Council since 2018. Kim earned her MSc from Ontario Veterinary College at Guelph University. She has presented & co-chaired sessions at DIA, ACRP and others. Kim was awarded the Excellence in Clinical Research award 2018 at the CTP conference & 2016 Volunteer of the Year for her work with Brain Injury Canada. In her spare time, Kim enjoys photography, birding, genealogy, music and downhill skiing.

### Rebecca Barnes, MS

Executive Director
Network of Networks (N2), Canada

Rebecca began her career as a cancer researcher and, over the past 15 years, has held a range of leadership roles dedicated to strengthening health research capacity within Canada. She specializes in building sustainable systems that enhance research excellence, while fostering meaningful

engagement. Prior to joining N2 Canada, Rebecca played a key role in leading in leading the Canadian Tissue Repository Network and advancing research engagement by managing the CIHR SPOR initiative for the Vancouver Island region. Most recently, she served as Director of the Office of the Vice-President Research and Innovation at the University of Victoria. Rebecca holds a BSc in Biology and a Master's in Environmental Toxicology/Carcinogenesis.

## Speaker(s)

### Speaker

### Representative Invited

BioTalent Canada, Canada

### Building the Backbone: Clinical Research Workforce Development in Canada

### Munaza Jamil

Faculty, Applied Clin Research Program
McMaster University, 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.

### Speaker

### Stephen Sundquist, BSN

Executive Director
Canadian Cancer Clinical Trials Network (3CTN), Canada

Stephen has over 25 years of experience in clinical trial operations and health programs' leadership. His clinical research expertise includes roles in pharma, CRO and academic settings involving the conduct of drug, biologic, and device trials across a wide range of therapeutic areas. 3CTN, the Canadian Cancer Clinical Trials Network, maintains a Portfolio of 850 multi-centre academic cancer clinical trials and mobilizes and supports a pan-Canadian community of investigators, clinical research professionals and patient partners across its 53 pediatric- and adult-member Cancer Centres in improving shared aims for equitable access, accrual and the efficient, high-quality conduct of trials.

10:30 AM — 11:45 AM

# Session 7, Track C: Post-Market Drug Evaluation in Canada: The Role of the Canada's Drug Agency PMDE Program and a National Collaborative Network

The Post-Market Drug Evaluation (PMDE) Program, launched by Canada's Drug Agency (CDA) in 2022, provides timely, evidence-based responses to questions from federal, provincial, and territorial decision-makers about the safety and effectiveness of approved drugs. Supported by a national expert network known as CoLab, the program delivers real-world insights about post-market drug safety and effectiveness. This session will feature Health Canada on the need of post-market evidence in regulatory decision-making, CDA providing an overview of the PMDE Program and its impact, and a case study from a CoLab team lead illustrating how evidence is generated and applied.

Learning Objective :

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

- Identify the Health Canada and CDA domestic and international partnerships and key initiatives in harmonizing RWD use for post-market drug evaluation
- Understand the structure, goals and the impact of the CDA PMDE Program and the CoLab Network
- Recognize the role of stakeholder input—patients, clinicians, and industry—in shaping PMDE activities

Track: Safety and Pharmacovigilance

## Session Chair(s)

### Yulia Vasianovich, PhD, RAC

Scientific Evaluator, Marketed Health Products Directorate
Health Canada, Canada

### Randy Levitt, PhD

Director, Pharmacovigilance and Medical Affairs, Canada
Knight Therapeutics 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)

Speaker

### Celline Brasil, PhD, MPH

Senior Epidemiologist
Health Canada, Canada

Celline Brasil is a pharmacist by training, with an MPH in Epidemiology and a PhD in Drug Utilization and Pharmaceutical Policy. As a pharmacist and researcher in Brazil, she contributed to advancing pharmaceutical policy and equitable access to high-cost medications for chronic and rare diseases within the public health system. As a postdoctoral fellow at McGill University, she conducted real-world comparative safety and effectiveness research to improve outcomes for vulnerable populations. Since 2021, Celline is a Senior Epidemiologist at Health Canada's Marketed Health Products Directorate, where she assesses real-world evidence and provides expert advice on drug safety for regulatory decision-making.

Speaker

### Tarry Ahuja, DrSc, MSc

Director, Post Market Drug Evaluation (PMDE)
Canada's Drug Agency, Canada

TARRY AHUJA, PhD is currently the Director of the new Post-Market Drug Evaluation Program at CADTH, the leading HTA agency for Canada. Prior to this he was a senior medical real-world evidence scientist for Eli Lilly for Europe and Canada. He has worked for over 10 years in the hospital setting in the area of sleep disorders and he has over 10 years of clinical research in the areas of otolaryngology, Alzheimer's, stroke and ischemia with the National Research Council of Canada. He holds a PhD in Neuroscience with a specialty in electrophysiology and pharmacology, and has been a lecturer at Carleton University teaching "Biological Foundations of Addictions" and "Health Psychology" for over 15 years.

Speaker

### Michael Paterson

Scientist and Research Program Lead
Institute for Clinical Evaluative Sciences, Canada

11:45 AM — 12:45 PM

## Luncheon, Exhibits, and Networking Break

12:45 PM — 2:00 PM

# Session 8, Track A: Devise Effective Regulatory Strategy: Using the Lens of Regulatory Intelligence

Join us for a professional development session that explores how to leverage Regulatory Intelligence to drive regulatory strategy and improve submission outcomes. Presenters will share insights on various approaches to manage regulatory intelligence (e.g., health authority advice/feedback, regulatory precedents), the significance of post-approval insights, and techniques that translate intelligence into actionable strategies aligning with Health Authorities evolving frameworks, including Health Canada. Attendees will enhance their skills in navigating the evolving regulatory environment, ultimately improving their professional expertise and impact.

Learning Objective :

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

- Gain a comprehensive understanding of how regulatory intelligence can enhance decision-making and shape regulatory strategies
- Acquire various approaches and practical techniques for constructing robust frameworks that translate regulatory intelligence into actionable strategies
- Improve their ability to navigate the dynamic regulatory environment and enhance their professional impact

Track: Regulatory

## Session Chair(s)

### Louise Blythe, MSc

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 Pharmaceutical Development & Commercialization 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 and Global regulatory. She is thrilled to be part of DIA Canada Annual Meeting program committee for her second year.

Speaker(s)

### Regulatory Intelligence to Drive Regulatory Strategy


Meena Muthiah, MPH, MS, RAC

Director, Regulatory Intelligence & Policy
Astrazeneca, United States


### The Submission Isn't Over: Strategically Leveraging Post-Agency Feedback to Future-Proof Submissions


Anaya Rehman, MD, MS

Senior Transparency Specialist
Certara, Canada


Anaya Rehman is a Senior Transparency Specialist at Certara, with over a decade of experience in healthcare, academic research, and the pharma industry. She provides technical leadership and expertise for clinical trial disclosure, helping sponsors navigate stringent regulations such as Health Canada's PRCI, EMA Policy 0070 and EU Clinical Trial Regulation 536/2014. Anaya is a regular speaker at conferences on this subject, captivating audiences as she champions compliance and safeguards sensitive information in clinical documentation. She also serves on the Ontario Chapter leadership team at the Regulatory Affairs Professionals Society (RAPS), further solidifying her influence in the field.

### Building Regulatory Strategies Using Regulatory Intelligence in Canada's Evolving Healthcare Environment


Pooja Sharma, MPharm

Regulatory Affairs, Senior Scientist
Allucent Inc., Canada


12:45 PM — 2:00 PM

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## Session 8, Track B: Clinical Trial Innovation and Modernization: The Future of Clinical Trials

In this session, we will explore how in the future, integrating clinical research into a patient's healthcare journey can enhance personalized medicine and data sharing. We will explore strategies to normalize clinical trial participation, improve patient and caregiver experiences, and the technology needed to support these advancements. This comprehensive approach aims to create a future state where clinical research is seamlessly integrated into healthcare.

Learning Objective :

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

- Integrating clinical research into a patient's healthcare journey
- Opportunities for global stakeholders to collaborate, influence, and implement change
- How to normalize clinical trial participation
- Improving patient & caregiver experiences
- The technology needed to create this future state

Track: Clinical

## 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.

### 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)

### Clinical Trials 2035: Innovations That will Transform the Future of Research

### Allison Cuff Shimooka, MBA

Chief Operating Officer
TransCelerate Biopharma Inc, United States

Allison is Chief Operating Officer of TransCelerate BioPharma Inc. In this role, Allison is responsible for shaping and delivering on TransCelerate's strategic vision: to advance collaboration in driving efficient, effective and high-quality delivery of new medicines through the convergence of clinical care and clinical research. Before joining TransCelerate, Allison was Senior Vice President of Strategy and Product Innovation for Optum Life Sciences, held a variety of leadership roles at the Advisory Board Company, and provided strategic guidance to biotechnology, medical device and health services companies. Allison has an MBA in healthcare management from the Wharton School and received her undergraduate degree from Dartmouth College.

### Speaker

### Perry Poole, RN

Senior Director, Clinical Operations, Global Compliance and Process
F. Hoffmann-La Roche Limited, Canada

Perry is the late-stage Global Head of Compliance, Process, and Vendor Oversight at Hoffmann-La Roche Limited, with over 30 years of experience in Clinical Research and Pharma Technical domains. She leads a global team ensuring process efficiency, compliance, and effective vendor oversight across Roche. She started her career as as a nurse, fueling her ongoing passion for innovative study delivery and creating a patient-centric culture, dedicated to simplifying the patient journey and access. She is excited about the future of Clinical Research and how technology will advance innovation. She currently serves as Roche/Genentech's Industry Lead for TransCelerate in the Good Clinical Practice (GCP) space.

12:45 PM — 2:00 PM

## Session 8, Track C: Signal Management Without Boundaries: Navigating Rx and OTC Safety Challenges

Session 8, Track C: Signal Management Without Boundaries: Navigating Rx and OTC Safety Challenges

Track: Safety and Pharmacovigilance

### Session Chair(s)

### Mei Lam, BSN, RN

Associate Director Consumer Safety Regions Americas
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.

### Nadia Latif, MS

Senior Manager, Pharmacovigilance
Ipsen Biopharmaceuticals Canada Inc., Canada

Nadia Latif 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

### Representative Invited

Health Canada, Canada

2:10 PM — 3:25 PM

# Session 9 Plenary: Embracing AI: Practical Approaches to Transforming Clinical, Regulatory Affairs, Safety, and Medical Affairs

Artificial Intelligence (AI) is a tool that is becoming more prominent in the pharmaceutical industry. As pharmaceutical professionals, it is important for us to understand AI and how it can help us across our different roles. This session will investigate how adopting and embracing AI in our respective fields of expertise in clinical, regulatory affairs, safety and medical affairs will transform our work. Through sharing real experiences in AI use, participants will learn how AI can be beneficial to our respective roles.

Track: General Session

## Session Chair(s)

### Marcia Sam

Senior Manager, Regulatory Affairs
Regeneron Canada Company, Canada

Marcia Sam is a Senior Manager, Regulatory Affairs at Regeneron Canada Company. 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.

### 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.

## Speaker(s)

### Embracing AI: Practical Approaches to Transforming Clinical, Regulatory, Safety, and Medical Affairs

Representative Invited

Regeneron, United States

Jim Brown has over 25 years of technical implementation expertise in the Life Sciences sector. He specializes in designing and delivering solutions that enable data management, operational efficiency, and strategic insights, particularly in highly regulated environments like Clinical and Pharmacovigilance. With deep knowledge of both drug development process and the clinical, regulatory and safety systems that support it, Jim has led global teams through complex projects, including system migrations and disaster recovery implementations. His experience bridges IT, regulatory compliance, and business strategy, offering actionable solutions for innovation in regulated industries.

3:25 PM — 3:40 PM

## Closing Remarks