Hilton Lac-Leamy

Oct 27, 2025 7:30 AM - Oct 28, 2025 3:40 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 22, 2025

10:00 AM — 2:00 PM

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

Day 2 Oct 27, 2025

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: 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.

- Advancing Regulatory Innovation: Canada's Role in Global Collaboration
  Kelly Robinson, Health Canada
- Enabling Faster Access and the Launch of Innovative Medicines and Vaccines
  Jenny Buckley, Innovative Medicines Canada
- Enhancing Patient Access to Therapies
  Jessy Ranger, Myeloma Canada
- What do the Metrics Tell Us
  Neil McAuslane, Centre for Innovation in Regulatory Science (CIRS)

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)

Advancing Regulatory Innovation: Canada's Role in Global Collaboration

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.

Enabling Faster Access and the Launch of Innovative Medicines and Vaccines

Jenny Buckley, MA, MSc

Director, Policy
Innovative Medicines Canada, Canada

Jenny Buckley has more than twenty years of health systems and policy experience across the continuum of health care at the provincial, national, and international level. At Innovative Medicines Canada, Jenny is responsible for the regulatory affairs portfolio, working closely with a team of regulatory experts from IMC member companies on the

Regulatory Advisory team. She also works closely with internal and external partners to explore ways to improve Canada's clinical research infrastructure to increase Canada's attractiveness for clinical trials and research investment. Jenny is a graduate of the University of Western Ontario (MA History) and the University of London (MSc Public Policy and Management).

What do the Metrics Tell Us

Neil McAuslane, PhD, MSc

Scientific Director
Centre for Innovation in Regulatory Science (CIRS), United Kingdom

Neil McAuslane PhD, Scientific Director of the Center for Innovation in Regulatory Science (CIRS) overseeing the scientific content of both CIRS regulatory and HTA programmes. Key research areas of work include regulatory strategy and strengthening, building quality into regulatory processes, the utilization of decision frameworks and the development of multistakeholder workshops which bring companies, patients, and agencies (Regulatory and HTA) together to discuss major areas of interest.He is currently involved in specific research on how best to measure the performance of agencies, risk-based approaches in the assessment of new medicines, building quality into the review process, decision making and HTA and regulatory alignment.

Enhancing Patient Access to Therapies

Jessy Ranger

Director, Patient Programs, Health Policy & Advocacy
Myeloma Canada, Canada

Jessy, a graduate in Political Science and Marketing Communications, brings over 18 years of experience in organizational and cross-sector communications, having worked across non-profits and within Quebec's healthcare system. In her current role, she leads the development of advocacy and educational initiatives for patients and caregivers. She also plays a key role in shaping strategies for new community services and advancing Myeloma Canada's mission to transform cancer care for all Canadians. Recently, Jessy co-authored research focused on improving access to top-tier care and treatment, including refining assessment processes and promoting informed consent through effective information dissemination.

10:00 AM — 10:45 AM

Refreshments, Exhibits, and Networking Break Sponsored by Bayshore Specialty Rx

10:45 AM — 12:00 PM Beethoven/Chopin

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 and policy initiatives, including agile licensing regulatory amendments, risk management plan requirements, and compliance and enforcement initiatives . Attendees will gain insights into upcoming changes in policies, emerging guidance documents and evolving standards impacting the regulated environment of health products in Canada. Health Canada speakers will provide updates and answer questions related to key HC regulatory modernization and policy initiatives related to: Advanced Therapeutic Products Framework and modernization of requirements for biologic drugs. Advancements made under the Pediatric Drug Action Plan will also be shared; Guidance related to implementation of Agile regulations for Terms and Conditions for drugs, Guidance document: Information and Submission Requirements for Biosimilar Biologic Drugs and; Management of Workload and mitigation measures to address the backlog of drug submissions.

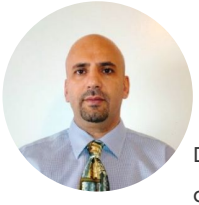
- Updates on Regulatory Modernization and the Pediatric Drug Action Plan
  Nicole van der Lee, Senior Policy Analyst, Health Canada
- Terms and Conditions (Drugs)
  Kristen Zorn, Health Canada
- Proposed Changes to Health Canada Guidance for Biosimilar Biologic Drugs Submissions
  Denis Arsenault, Biologic, Health Canada
- Health Canada's Management of Workload and Backlog
  Elana Cherry, Health Canada

Learning Objective :

- Identify strategies for involvement in the public consultation process related to the government regulatory initiatives in relation to Agile Regulations, Policies and Guidance documents
- Explain key changes proposed to the Guidance document: Information and submission requirements for Biosimilar Biologic Drugs (Biosimilars Guidance)
- Recognize the mitigation measures implemented by Health Canada for management of workload and backlog

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)

Updates on Pediatric Drug Action Plan and Regulatory Modernatization: Advanced Therapeutic Products

Nicole van der Lee

Associate Director
Health Canada, Canada

Nicole van der Lee is the Associate Director in the Centre for Policy, Pediatrics and International Collaboration (CPPIC) within Health Canada's Biologic and Radiopharmaceutical Drugs Directorate (BRDD). Nicole has been with CPPIC since 2020, where she began as a senior policy analyst, driving the development and implementation of the Advanced Therapeutic Products Pathway and contributing to pediatric policy, regulatory modernization, and international policy initiatives at CPPIC. With nearly 15 years of federal government experience—including roles at the Canadian Food Inspection Agency and Health Canada—Nicole brings expertise in biotechnology, program and policy development, project management, and drug and device regulation.

Terms and Conditions (Drugs)

Kristen Zorn

Manager, Policy Development, Pharmaceutical Drugs Directorate
Health Canada, Canada

Kristen Zorn joined Health Canada over 25 years ago after completing her degree in Biology at the University of Waterloo. She has spent her career in PDD and worked extensively in Regulatory Project Management with the Bureau of Gastroenterology, Infection and Viral Diseases and the Bureau of Metabolism, Oncology and Reproductive Sciences. Kristen was the Associate Director in the Bureau of Cardiology, Allergy and Neurological Sciences and then in the Bureau of Policy, Science and International Programs, where she currently works as a Manager of Policy Development.

Proposed Revisions of Guidance Document: Information and Submission Requirements for Biosimilar Biologic Drugs

Denis Arsenault, MBA

Manager, Policy Development, Biologic and Radiopharmaceutical Drugs Directorate,
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.

Health Canada's Management of Workload and Backlog

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.

10:45 AM — 12:00 PM Delfosse

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 and the use of AI are transforming both study conduct and participant engagement.

- "Fit-for-Purpose" Clinical Trials with Decentralized Elements
  Aneta Woroniecka-Osio, Independent
- An Inclusive Perspective About Clinical Research – From Patient to Clinical Research Professional
  Adriana Rodriguez Cruz, Global Health Equity Advocate
- An Agentic Approach to Patient-Centric Clinical Research
  Mark Baxter, RxPx Health

Learning Objective :

- Employ strategies to develop patient-centric approaches with a DEICT perspective
- Discuss the lived experiences of patients while exploring the patient and clinical research professional perspectives
- Contrast modern vs classical approaches in patient engagement and study conduct
- Identify modernization of clinical trials including the evolution of decentralized trials, use of AI digital applications, and fit for purpose study design

Track: Clinical

Session Chair(s)

Sabrina Ramkellawan

President and Board Director
Clinical Research Association of Canada, 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.

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

Manager, SCI
Bayer, 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. Aneta has led 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 Agentic Approach to Patient-Centric Clinical Research

Mark Baxter

Chief Product Officer
RxPx Health, Canada

Mark is Chief Product Officer at RxPx, an award-winning AI-powered SaaS platform for life sciences. He leads product vision and strategy to support patients, caregivers, researchers, and HCPs while helping customers deliver differentiated value. With 20+ years as an entrepreneur and product leader in health, education, AI/ML, and connected devices, his products have reached 30M+ users worldwide. He has guided companies from startup to acquisition, with expertise in fundraising, culture building, product development, marketing, and scaling growth. Mark believes technology can drive personal and collective improvement and is committed to making that potential real.

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

Adriana Rodriguez Cruz, PhD

Global Health Equity Advocate, 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.

10:45 AM — 12:00 PM Julien/Gagnon/Walker/Suzor-Cote

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.

- Multi-Stakeholder Collaboration to Modernize ICSR Management: A Model for Meaningful Discussion
  Clint Craun, TransCelerate BioPharma, Inc.
- From Duplication to Innovation: Modernizing ICSR Collaboration
  Laura Muranyi, Health Canada

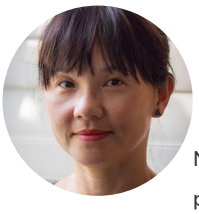
Learning Objective :

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)

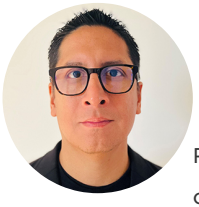


Mei Lam, BSN, RN

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)

From Duplication to Innovation: Modernizing ICSR Collaboration

Laura Muranyi

Manager, Health Products Surveillance and Epidemiology Bureau
Health Canada, Canada

Laura Muranyi is the Manager at Health Canada and leads the team responsible for the receipt, data entry and triage, quality assurance and maintenance and support of the Canada Vigilance Database. She has been working at Health Canada for over 18 years and has a vast knowledge of the complete health product lifecycle.

Multi-Stakeholder Collaboration to Modernize ICSR Management: A Model for 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.

12:00 PM — 1:00 PM Mozart

Luncheon, Exhibits, and Networking Break

12:15 PM — 12:45 PM

Roundtable Discussions

Each day's networking luncheon offers both open seating and focused roundtable discussions. Each topic listed below will be hosted at a designated table led by a moderator. If you're passionate about one of these subjects or would like to exchange ideas with peers who share similar interests, we invite you to join a designated table to enjoy both your meal and an engaging conversation.

T&C Implementation and Further Discussion hosted by Kristen Zorn, Health Canada
This fall, Health Canada will be consulting on two guidance documents that explain the new broad terms and conditions (T&C) authorities that will come into effect on April 1, 2027. The Roundtable session will be an opportunity to ask questions about how T&Cs will be implemented, including the processes and timing, and how T&Cs for submissions based on promising evidence of efficacy will replace the current Notice of Compliance with Conditions policy.

More on Health Canada's Management of Workload and Backlog hosted by Elana Cherry, Health Canada
At the DIA Canada Annual 2025 Meeting, Health Canada will present an overview of its current challenges and strategic responses related to the growing backlog in drug submissions. Since 2022, both the Pharmaceutical Drugs Directorate (PDD) and the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) have experienced significant increases in submission volume and complexity, compounded by staffing limitations and incomplete data packages. Despite internal efficiency measures, capacity constraints have persisted, prompting increased feedback from industry stakeholders requesting greater predictability and transparency, enhanced flexibility in the review process, stronger international collaboration, and timely updates to guidance and policy. Stakeholder workshops held in September led to a collaborative action plan focused on transparency, communication improvements, and increased flexibility. The roundtable discussion is an opportunity for more detailed discussion about shared responsibility, ongoing engagement, and balancing short-term actions with long-term sustainability. Health Canada looks forward to hearing your thoughts and ideas as part of this ongoing dialogue

What is your Regulatory Affairs Career Development Path? hosted by My Dang, Cencora, Marcia Sam, Regeneron and Melanie Cote, Otsuka Pharmaceutical Development & Commercialization Inc.
3 Regulatory Affairs professionals will be briefly sharing their experience in regulatory affairs and answering any question the attendees would have to give them ideas for their own career development.

Meet Your Health Canada Clinical Trial Reviewers: Collaborating Towards a Successful Clinical Trial Application hosted by Katherine Soltys,
Health Canada and Sophie Hamel, Health Canada To answer any questions you may have on Health Canada's clinical trial application (CTA) process, representatives from Health Canada's Office of clinical trials will host a roundtable on the preparation for a successful CTA

Canada on the International Stage hosted by Kelly Robinson, Health Canada
Kelly Robinson (Director General, PDD) would discuss topics related to Health Canada's participation in various international collaboration initiatives.

Session Chair(s)

Roundtable Discussion

United States

1:00 PM — 2:15 PM Beethoven/Chopin

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 e-labelling approaches and new risk-based methodology being applied for regulatory compliance. Furthermore, the session will provide insights on 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.

- Electronic Patient Medication Information (ePMIs) – Where are We Now?
  Neerja Goyal, GlaxoSmithKline, Inc.
- Words Matter: Adopting Gender Inclusive Language in Product Labelling
  Adesola Adeyemi, BAYER INC.
- Pharmaceutical Drug Directorate Paper Package Insert Waiver Assessment Process
  Amanda Starr, Health Canada

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)

Pharmaceutical Drug Directorate Paper Package Insert Waiver Assessment Process

Amanda Starr, PhD

Scientific Evaluator - Pharmaceutical Drugs Directorate
Health Canada, Canada

Amanda Starr holds a BSc and MSc from the University of Guelph, and a PhD in Biochemistry from the University of British Columbia. She is currently a clinical Scientific Evaluator in the Metabolic and Musculoskeletal Drugs Division of the Pharmaceutical Drugs Directorate at Health Canada. With over 15 years of professional experience in academia and government, she has held progressively senior roles in leading research projects, clinical trial review, and design and implementation of internal workflows to improve review efficiency.

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 Delfosse

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

This session will delve into three critical pillars of clinical trial operations. We will explore how sponsors manage Canada's competitiveness in placing trials globally, contrast expectations versus reality in site selection and operations, and examine how AI is transforming participant recruitment by enhancing outreach, precision, and efficiency. You will hear the perspectives of the sponsor, site, and vendor, and learn how their collaboration is essential to ensure Canada's attractiveness in clinical trials.

- Jean-Francois Leger, Sanofi
- Suzie Talbot, Diex Research
- Bruno J Battistini, University of Ottawa

Learning Objective :

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

- Describe Canada's current competitive standing in global clinical trials
- Identify challenges in evaluating trial feasibility and site operational impact
- Recognize the potential of AI and technology in enhancing trial efficiency

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)

Speaker

Jean-Francois Leger, MSc

Site Engagement Lead
Sanofi, Canada

Jean-François Léger, Site Engagement Lead, Clinical Study Unit, Canada at Sanofi. Mr. Léger brings more than three decades of clinical research expertise to his current role as Site Engagement Lead within Sanofi's Clinical Study Unit. With a master's degree in microbiology and immunology, he has dedicated 20 years of his career at Sanofi, where he continues to leverage his extensive experience in pharmaceutical clinical development.

Optimizing Clinical Trial Operations: Strategy, Sites, and Smart Recruitment

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.

Speaker

Bruno J Battistini, PhD, MSc

Adjunct-Professor & Lecturer, Faculty of Health Sciences
University of Ottawa, Canada

Dr B. started as a Health Res. Scholar and Asst-Prof. (Medicine) at Université Laval, Scientist at Hôpital Laval-QC Heart & Lung Inst. He occupied positions in the private sector (CSO, VP, Dir.), served as President/CEO/Sc. Dir. of NBHRF, Co-Chaired NAPHRO and CIHR-led Forum of Health Res. Funders. Over 30 years, he fostered strategic planning, new programs/value demonstration initiatives, alliances with charities, federal/national agencies, fostering health/medical Rx&D/Innovation in the public/private sector, and investment in the Health Res. Enterprise. He serves on advisory/peer-review committees/boards, chairs oversight cttees and lectures at uSherbrooke and is an Adjunct-Prof. at uOttawa.

1:00 PM — 2:15 PM

Julien/Gagnon/Walker/Suzor-Cote

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.

- Introducing a Framework to Improve Access to Canadian Digital Medical Information
  Joanna Rizos, Eli Lilly Canada Inc.
- RWE through Medical Information Automation using Controlled AI Chatbots
  Manar Hammood, Zenith PV
- Medical Information Matters: Partnering with Purpose in Pharma
  Josee Brisebois, JJB Pharma Consulting

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, Medical Information and Patient Support
Knight Therapeutics Inc., Canada

Randy Levitt is the Director, Pharmacovigilance, Medical Information and Patient Support at Knight Therapeutics Canada. He recently joined Knight from Paladin Pharma, where he worked for 13 years, most recently as Director, Pharmacovigilance and Medical Affairs. He is currently a Board Member of the Pharmacovigilance and Medical Information Network (PVN-MI) – Canada and Ethics Advisory Team Member at Innovative Medicines Canada. Randy completed his undergraduate and graduate degrees at McGill University, graduating with his PhD in Experimental Medicine.

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)

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

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.

2:15 PM — 3:00 PM Mozart

Refreshments, Exhibits, and Networking Break Sponsored by Bayshore Specialty Rx

3:00 PM — 4:15 PM Beethoven/Chopin

Session 4, Track A: Health Canada, the Industry, 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. Industry experts will provide their experience into the impact of Project Orbis on accelerating global oncology approvals across multiple countries as well as sharing data-driven perspectives on its effectiveness in streamlining access to innovative treatments.

- Project Orbis at Health Canada: The Regulator's Perspective
  Melissa Hunt, MSc, Health Canada
- Analysis of Project Orbis Participation by Health Canada on New and Supplemental Drug Submissions: An Industry Perspective
  Jonathan Zaslavsky, AstraZeneca Canada
- Project Orbis: An Industry Perspective
  Sabrina Moers, Merck Canada Inc.

Learning Objective :

- Examine the concurrent partnership between Health Canada, the industry, and other Health Agencies around the world 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, 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. My 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 third year.

Speaker(s)

Project Orbis at Health Canada: The Regulator's Perspective

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.

Project Orbis: An Industry Perspective

Sabrina Moers, MSc

Director Regulatory Affairs
Merck Canada Inc., Canada

Sabrina is currently a Director in Regulatory Affairs at Merck Canada and has been with the company for over 20 years. Prior to joining the Pharmaceutical Industry, she was at Health Canada for 2 years as a Regulatory Project Manager. Sabrina holds a Bachelor's degree in Medical Biology and a Masters in Pharmaceutical Sciences.

3:00 PM — 4:15 PM

Delfosse

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 rebuild trust and reshape the narrative surrounding clinical research. Attendees will gain insights from National trends on public perception and learn about patient centric initiatives that promote transparency and the importance of sharing clinical trial results.

- Rebuilding Public Trust: Changing the Narrative Around Clinical Trials
  Fraser Gibson, Advantage Clinical
- Rebuilding Public Trust: Changing the Narrative Around Clinical Trials
  Alison Orth, Michal Smith Health Research BC

Learning Objective :

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

- Summarize strategies to rebuild trust and increase public engagement in clinical trials
- Identify misconceptions and past ethical failures that drive public distrust, amplified by media
- Recognize strategies like transparency, education and patient-centricity can rebuild trust

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

Fraser Gibson is a clinical research professional with extensive experience spanning global drug development, clinical operations, and regulatory compliance. Drawing on over a decade in the industry, he has led complex, multi-therapeutic studies and worked closely with sponsors, CROs, and investigators to improve trial delivery and patient engagement. Fraser has explored the theme of public trust in the pharmaceutical and clinical research sectors in depth in his forthcoming book, Bench to Bedside: The Business of Clinical Research and Drug Development, which examines how transparency, communication, and patient involvement can rebuild confidence in the industry.

Rebuilding Public Trust: Changing the Narrative Around Clinical Trials

Alison Orth

Director
Clinical Trials British Columbia, Canada

Alison Orth is the Director of Clinical Trials British Columbia, part of Michael Smith Health Research BC. With over 25 years of leadership experience in both the private and public sectors, she has guided major system change initiatives to strengthen BC's clinical trials ecosystem. Alison has played a key role in developing a collective vision for clinical trials in BC, advancing a provincial single ethics review service, and contributing to a national clinical research workforce strategy. She is passionate about strengthening clinical trial ecosystems, making trials more accessible, and improving the clinical trial experience for patients and communities across British Columbia and Canada.

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

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.

- Patient Supports Programs and Drug Safety
  Riti Singh, Bayshore Healthcare (Bayshore Specialty Rx Ltd.)
- Good Pharmacovigilance Practices Audits Of Patients Support Programs
  Agnes Jankowicz, Claropv Services Inc.

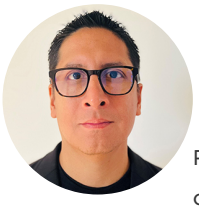
- Patient Support Programs and Safety Reporting: An Industry Perspective
  Nadia Latif, Ipsen Biopharmaceuticals Canada Inc

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
Bayshore Healthcare (Bayshore Specialty Rx Ltd.), Canada

Riti Singh is a dynamic and strategic, transformational leader, accomplished in building departments from inception and transforming them into high performing, value-added, revenue generating functions. With over 20 years of broad therapeutic experience in the life sciences and healthcare sector, she has expertise in setting up pharmacovigilance, medical information, medical affairs, and quality operations for local and global organizations. Riti holds a PharmD degree from Leslie Dan Faculty of Pharmacy at University of Toronto and

an MBA from California State University. Currently at Bayshore, Riti is the National Director overseeing Clinical Trials, RWE, Pharmacovigilance, Medical Information, Quality and Regulatory DEL/MDEL activities.

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.

Good Pharmacovigilance Practices Audits Of Patients Support Programs

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 ClaroPV whose team includes experienced and dedicated PV & MI 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.

4:25 PM — 5:40 PM Beethoven/Chopin

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

Explore the Submissions Relying on Third Party Data (SRTD) 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 foreign regulatory packages for Canadian filings. Attendees will gain essential knowledge to optimize their future SRTD submissions.

- SRTD Regulatory Pathway: Challenges, Strategic Insights, and Case Study Findings
  Vishal Oza, Cencora, Innomar Strategies Inc.
- SLR 4 SRTD NDS - HUH?
  Brenda Gryfe, Brenda Gryfe Regulatory Consulting
- The Third-Party Tightrope: Managing Third-Party Evidence in Regulatory Submissions
  Torrey Parker, Health Canada

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)

The Third-Party Tightrope: Managing Third-Party: Evidence in Regulatory Submissions

Torrey Parker, DrMed, MD, MA, FRCP

Acting Director, Bureau of Medical Sciences, Pharmaceutical Drugs Directorate
Health Canada, Canada

Dr. Torrey M. Parker earned her medical degree from the University of Ottawa in 2009 and completed her Pediatrics residency at CHEO in 2015. Her clinical work has spanned both community and hospital settings, and she continues as a part-time consulting pediatrician. In 2020, she joined Health Canada's Health Products and Food Branch, Pharmaceutical Drugs Directorate as a Medical Evaluator in the Bureau of Medical Sciences (BMS). She is currently Acting Director of BMS, leading teams in pre-market drug evaluation and risk management. Dr. Parker also holds a cross-appointment as Assistant Professor at the University of Ottawa Faculty of Medicine.

SRTD Regulatory Pathway: Challenges, Strategic Insights, and Case Study Findings

Vishal Oza, MPharm

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

Vishal Oza is the Manager of Regulatory Affairs at Cencora, Innomar Strategies Inc., Canada, with over 15 years of experience in the global pharmaceutical industry and consulting, including 14 years specializing in regulatory affairs. His expertise lies in successfully managing a broad spectrum of U.S. regulatory submissions for both innovative and generic pharmaceuticals across diverse therapeutic areas. In addition, he has acquired substantial experience in managing Canadian regulatory submissions relying on third-party data and conducting Cochrane-style literature reviews. Vishal has a Master of Pharmacy degree in Pharmaceutical Analysis from Nirma University, India.

SLR 4 SRTD NDS - HUH?

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 & Cochrane-style literature reviews. 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 Delfosse

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

This session is geared toward clinical trial sponsors, investigators, and study coordinators to promote Good Clinical Practices (GCP) as per the new ICH E6 R3. Speakers will provide helpful guidance on ensuring compliance with the regulatory requirements to initiate a clinical trial in Canada. The session will conclude with a Q&A period which will give participants the opportunity to ask the Health Canada representative for additional clarification.

- Navigating Good Clinical Practice Inspections with Health Canada
  Kevin Donato, Health Canada
- ICH E6(R3) Foundational Concepts and Overview of Selected Highlights
  Katherine Soltys, Health Canada
- Good Clinical Practices in the Context of the Clinical Trial Application Process
  Sophie Hamel, Health Canada
- Navigating Good Clinical Practice Inspections with Health Canada: Clinical Trial Compliance Program Overview
  Alex Basiji, Health Canada

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

- Identify the key changes with ICH E6(R3), and how this will impact Health Canada and Canadians
- How to prepare a successful clinical trial application
- How to prepare for a successful regulatory GCP inspection under the GCP standard (ICH E6R3)
- Understand the key elements for a proportionate risk-based approach to inspection

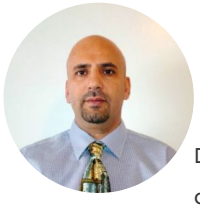
Track: Clinical

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)

Good Clinical Practices in the Context of the Clinical Trial Application Process

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.

ICH E6(R3) Foundational Concepts and Overview of Selected Highlights

Katherine M. Soltys, MD

Director, Office of Clinical Trials, Pharmaceutical Drug Directorate
Health Canada, Canada

Dr. Soltys is the Executive Director of the Office of Clinical Trials in the Pharmaceutical Drugs Directorate of the Health Products and Food Branch at Health Canada. In this role, she oversees all activities related to the approval and pharmacovigilance of clinical trials involving pharmaceuticals in Canada, as well as Health Canada's Special Access Program. She also represents Health Canada internationally as a member of ICH and the ACCESS Consortium. In addition to her regulatory work, Dr. Soltys maintains part time clinical practice at The Ottawa Hospital Cancer Centre where she participates in the care of patients with lung cancer and gastrointestinal cancer.

Navigating Good Clinical Practice Inspections with Health Canada: Clinical Trial Compliance Program Overview

Alex Basiji

National Director of Clinical Compliance and Border Operations
Health Canada, Canada

Alex has been a federal public servant for 26 years. He has been Health Canada's National Director of Clinical and Border Compliance Programs for the last 7 years. In his current capacity he has been responsible for providing executive leadership in supporting, influencing regulatory program priorities including the delivery of large and complex national operations, namely clinical trial and biological products compliance as well as importation of health products at the Canadian border ports of entry. In addition, in this leadership role and along with his team he has focused efforts on modernizing the activities of his national programs, ensuring that the transformation of Programs is based on adoption of a ri

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.

4:25 PM — 5:40 PM

Julien/Gagnon/Walker/Suzor-Cote

Session 5, Track C: Health Canada Pharmacovigilance Updates

This session will highlight key initiatives transforming post-market safety evaluation in Canada. We will begin with the Health Canada's Operation Glasswing, an activity aimed at exploring a long-standing concern raised by industry with obtaining meaningful AR data from the Canada Vigilance Program. Health Canada will also provide an overview of the WHO pharmacovigilance tools such as VigiLyze database, the global platform from the Uppsala Monitoring Centre, which enables review of aggregated AR reports across countries, and providing valuable international context for Health Canada's pharmacovigilance activities.

- Operation Glasswing: Understanding Barriers to Adverse Reaction Data Access for Industry
  Laura Muranyi, Health Canada
- Health Canada's Overview and Use of WHO/UMC Pharmacovigilance Tools
  Da Graça, Health Canada

Learning Objective :

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

- Describe industry barriers to accessing the Canada Vigilance adverse reaction (AR) data
- • Explain how continued collaboration with the World Health Organization (WHO) supports Health Canada pharmacovigilance activities

Track: Safety and Pharmacovigilance

Session Chair(s)

Yulia Vasianovich, PhD, RAC

Scientific Evaluator, Marketed Health Products Directorate
Health Canada, Canada

Yulia is a Scientific Evaluator at the Marketed Pharmaceuticals Bureau (MPB), Health Canada, where she focuses on drug safety. Prior to this role, she conducted research in genome stability and cell signaling at Université de Sherbrooke and McGill University, and later supported global clinical and regulatory strategies at Allucent. With over 15 years of experience in academia, industry, and government sectors, spanning fundamental and biomedical research, clinical trials and regulatory affairs, she brings a broad expertise across the drug development life cycle. Yulia holds a PhD degree in Cell and Molecular Biology from the University of Edinburgh, UK and RAPS Regulatory Affairs Certification (RAC-Drugs).

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)

Health Canada's Overview and Use of WHO/UMC Pharmacovigilance Tools

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.

Operation Glasswing: Understanding Barriers to Adverse Reaction Data Access for Industry

Laura Muranyi

Manager, Health Products Surveillance and Epidemiology Bureau
Health Canada, Canada

Laura Muranyi is the Manager at Health Canada and leads the team responsible for the receipt, data entry and triage, quality assurance and maintenance and support of the Canada Vigilance Database. She has been working at Health Canada for over 18 years and has a vast knowledge of the complete health product lifecycle.

5:40 PM — 6:40 PM — Mozart

Networking Reception

Day 3 Oct 28, 2025

7:30 AM — 8:30 AM — Mozart

Networking Breakfast

7:30 AM — 3:40 PM — Ballroom Foyer

Registration

8:30 AM — 9:45 AM — Beethoven/Chopin

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 preparedness and collaboration of industry and regulators across domains to transition to data and content-based exchanges that are seamless, secure and efficient. Presentations will cover content standardization, the modernization of the CMC data lifecycle with Fast Healthcare Interoperability Resources (FHIR)- a Health Level Seven International (HL7®) standards and the vision of building a shared semantic layer for exchanging clinical, manufacturing and regulatory information.

- Enabling Digital Filings: Moving from Documents to Data
  Todd Georgieff, RWS
- Digital Submissions: Path to Real-time Regulatory Workflows and Personalization
  Craig Anderson, Pfizer, Canada
- Bridging Worlds: Aligning Clinical, Regulatory, and Manufacturing Data
  Heiko Waldmuller, ACCURIDs

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
- To describe how structured and semantically linked data can unlock automation

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.

Digital Submissions: Path to Real-time Regulatory Workflows and Personalization

Craig Anderson

Director, Data Standards & Continuous Improvement
Pfizer Inc , Canada

Craig Anderson, Director of Data Standards & Continuous Improvement at Pfizer, oversees global Labeling projects, focusing on electronic labeling, drug product details, AI, digital health, and data standards. With industry experience and a regulatory background from Health Canada, he led projects on Structured Product Labeling, IDMP, and AE reporting. Craig also co-leads HL7 FHIR initiatives, including ePI, PQI, Structured Regulatory Correspondence, and API Exchange of Medicinal Product Information.

Bridging Worlds: Aligning Clinical, Regulatory, and Manufacturing Data

Heiko Waldmueller, DrMed, MD

Senior Consultant: Pharma & Digital Health Solutions
ACCURIDS GmbH, Canada

Dr. Heiko Waldmüller, MD is a medical informatics specialist and physician with deep expertise in digital health transformation and interoperability. He has played a pivotal role in shaping Germany's national eHealth landscape—advising on large-scale initiatives like the ePA für Alle (Personal Health Record for all citizens) and the European Health Data Space. Combining medical insight with technical acumen, Heiko bridges the gap between healthcare practice and IT innovation. His projects span from AI-driven hospital workflows to data standardization with HL7 FHIR and SNOMED CT. Passionate about connecting medicine, data, and people, he brings strategic clarity to complex health IT ecosystems.

8:30 AM — 9:45 AM Delfosse

Session 6, Track B: Canada Now – Together

Manitoba reviewed its clinical trials system using human-centered design and lean methods to make it more predictable, efficient, and aligned with provincial strengths. A working group of researchers, industry, government, and academia identified that trial activity remains below pre-COVID levels. The review focused on time to conduct, patient engagement, infrastructure, and partnerships, leading to key recommendations. Outcomes include streamlined processes, rural engagement strategies, infrastructure needs, and new partnership opportunities to support a stronger research environment.

- Advancing Clinical Trials in Manitoba: Towards a Pan-Canadian Approach
  Andrea Ladouceur, Bioscience Association of Manitoba

- Canada Now Together
  Suzie Talbot, Diex Research
- Patient Voice: Enhancing Clinical Trial Impact
  Ursula Mann, Patient Voice Partners

Learning Objective :

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

- Increase understanding of clinical trials from the perspectives of: patients; industry access and economic development; and health innovation
- Identify the value of clinical trials from these perspectives and how a pan-Canadian approach can support advancement in trials and possibly adoption (rooted in the recent Manitoba experience)

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

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.

Advancing Clinical Trials in Manitoba: Towards a Pan-Canadian Approach

Ursula Mann, BSN

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

Ursula Mann is the Principal & Chief Patient Officer at Patient Voice Partners, a life sciences team dedicated to integrating multi-partner perspectives into innovation development, research, and healthcare services. She also supports matchmaking patients and caregivers with initiatives to inform healthcare initiative as Global Patient Engagement Officer for Patient Voice Connect, an affiliate of Patient Voice Partners and is the Co-Founder of the EvidaHealth Foundation, a non-profit data registry organization. Her personal journey as a caregiver ignites her passion for advocacy and drive the work she leads today.

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 Julien/Gagnon/Walker/Suzor-Cote

Session 6, Track C: Advancing Pharmacovigilance Through Artificial Intelligence: From Real-World Data to Practical Applications

This session explores how artificial intelligence (AI) is transforming pharmacovigilance practice. It will showcase practical applications of AI that can enhance day-to-day routine activities in patient safety. The session will also highlight a use-case for patient identification. Attendees will gain insights into how AI can be applied to identify patient populations in real-world data and enhance post-market safety studies, using atopic dermatitis as a case study.

- Use of AI for Patient Identification in Safety Studies: Spotlight on Atopic Dermatitis Patient Prediction
  Heather Ward, Pfizer
- Practical Uses of AI
  Indy Ahluwalia, ELIQUENT Life Sciences

Learning Objective :

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

- Identify practical, routine applications of AI that can enhance efficiency and decision-making in day-to-day patient safety activities
- Gain insights and knowledge of AI use in patient populations in real-world data and enhancing post-market safety studies
- 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)

Practical Uses of AI

Indy Ahluwalia

Senior Managing Consultant
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 Eliquent Life Sciences.

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

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.

9:45 AM — 10:30 AM Mozart

Refreshments, Exhibits, and Networking Break Sponsored by Bayshore Specialty Rx

10:30 AM — 11:45 AM Beethoven/Chopin

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.

- When Every Patient Counts: Regulatory Challenges in Rare Diseases: A Sponsor's Perspective
  Annie Bergevin, Novartis Pharmaceuticals Canada
- Health Canada's Approach for Rare Disease Drug Review
  Bassam Haidar, Health Canada
- Challenges in Rare Disease Treatment in Canada: Development and Access
  Mauricio Ede, Incyte Corporation

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, 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. My 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)

Health Canada's Approach for Rare Disease Drug Review

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.

When Every Patient Counts: Regulatory Challenges in Rare Diseases: A Sponsor's Perspective

Annie Bergevin, MSc

Regulatory Affairs Franchise Lead
Novartis Pharmaceuticals Canada Inc., Canada

Annie Bergevin is a Regulatory Affairs Franchise Lead at Novartis Pharmaceuticals Canada Inc. With more than 20 years of experience in the pharmaceutical industry, she has held progressively senior roles in Regulatory Affairs and has led a wide range of regulatory activities across the product development life cycle. Her experience spans multiple therapeutic areas, including neuroscience, ophthalmology, and oncology, as well as innovative platforms such as gene therapy and radioligands. Annie holds a Master's in Pharmacology, a Master's in Pharmaceutical Sciences, and a Bachelor's in Biology from the Université de Montréal.

Challenges in Rare Disease Treatment in Canada: Development and Access

Mauricio Ede, MD, PhD

Head of Medical Affairs
Incyte Biosciences Canada, Canada

Mauricio is a senior professional with more than 20 years' experience in Clinical Development and Medical Affairs and an established track-record of leading diverse teams through pre- and post-launch activities, clinical development, regulatory approvals, and Medical Affairs at Country, Regional and Global levels across multiple therapeutic areas, including rare diseases, immuno-oncology, immunology, cardiovascular and metabolic, women's health and infectious diseases. Mauricio earned his MD degree in Brazil; his PhD at University of Manitoba in Canada and has post-doctoral training in Cardiac surgery from University of Ottawa; he completed his fellowship at Hôpital Européen de Paris, in Paris, France.

10:30 AM — 11:45 AM Delfosse

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.

- Elevating the Clinical Research Workforce: Canada's Competitive Edge in a Changing World
  Rob Henderson, BioTalent Canada
- JTF Core Competency Framework Adoption – A Network Approach
  Stephen Sundquist, Canadian Cancer Clinical Trials Network (3CTN)
- Canada's Clinical Research Workforce Strategy
  Munaza Jamil, McMaster University/N2 [canada]

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)

Elevating the Clinical Research Workforce: Canada's Competitive Edge in a Changing World

Rob Henderson

President & CEO
BioTalent Canada, Canada

Rob Henderson is President and CEO of BioTalent Canada, where he's led the organization's growth into a national leader in bioscience talent development. With over 30 years of executive experience, Rob has helped connect thousands of Canadians to careers, championed workplace diversity, and advised governments on HR strategy. He's a bilingual Quebec native, a biology graduate, and a passionate advocate for inclusion and the life sciences.

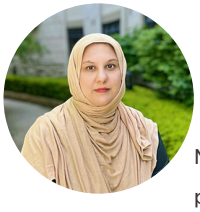
JTF Core Competency Framework Adoption – A Network Approach

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.

Canada's Clinical Research Workforce Strategy



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.

10:30 AM — 11:45 AM Julien/Gagnon/Walker/Suzor-Cote

Session 7, Track C: Post-Market Drug Evaluation in Canada: The Role of Canada's Drug Agency PMDE Program

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 for post-market evidence in regulatory decision-making, an overview of CDA's PMDE Program and its impact, and examples of the work of one of CoLab's core network partners, the Canadian Network for Observational Drug Effect Studies (CNODES).

- Health Canada's Key Collaborations in Real-World Evidence (RWE) Use for Post-market Drug Safety Evaluation
  Celline Brasil, Health Canada
- The Role of the PMDE Program and its National Collaborative Network
  Tarry Ahuja, Canada Drug Agency
- Canadian Network for Observational Drug Effect Studies (CNODES)
  Michael Paterson, Institute for Clinical Evaluative Sciences

Learning Objective : <

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

- Identify Health Canada domestic and international collaborations and key initiatives in harmonizing and using real-world data (RWD) for post-market drug evaluation
- Understand the structure, goals and the impact of CDA's 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

Yulia is a Scientific Evaluator at the Marketed Pharmaceuticals Bureau (MPB), Health Canada, where she focuses on drug safety. Prior to this role, she conducted research in genome stability and cell signaling at Université de Sherbrooke and McGill University, and later supported global clinical and

regulatory strategies at Allucent. With over 15 years of experience in academia, industry, and government sectors, spanning fundamental and biomedical research, clinical trials and regulatory affairs, she brings a broad expertise across the drug development life cycle. Yulia holds a PhD degree in Cell and Molecular Biology from the University of Edinburgh, UK and RAPS Regulatory Affairs Certification (RAC-Drugs).

Randy Levitt, PhD

Director, Pharmacovigilance, Medical Information and Patient Support
Knight Therapeutics Inc., Canada

Randy Levitt is the Director, Pharmacovigilance, Medical Information and Patient Support at Knight Therapeutics Canada. He recently joined Knight from Paladin Pharma, where he worked for 13 years, most recently as Director, Pharmacovigilance and Medical Affairs. He is currently a Board Member of the Pharmacovigilance and Medical Information Network (PVN-MI) – Canada and Ethics Advisory Team Member at Innovative Medicines Canada. Randy completed his undergraduate and graduate degrees at McGill University, graduating with his PhD in Experimental Medicine.

Speaker(s)

Health Canada's Key Collaborations in Real-World Evidence (RWE) Use for Post-market Drug Safety Evaluation

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.

The Role of the PMDE Program and its National Collaborative Network

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.

Canadian Network for Observational Drug Effect Studies (CNODES)

Michael Paterson, MSc

Scientist and Research Program Lead
Institute For Clinical Evaluative Sciences (ICES), Canada

Michael joined ICES (formerly Institute for Clinical Evaluative Sciences) as an Epidemiologist in 1992 and became an ICES Scientist and Research Program Lead in 2008. He is an Assistant Professor in the Department of Family Medicine at McMaster University and the Institute of Health Policy, Management and Evaluation at the University of Toronto. He holds a Bachelor's degree in Human Biology from the University of Guelph and a Master's degree in Physiology from the University of Toronto. In addition to his work with ICES, Michael is a core member of the Ontario Drug Policy Research Network (ODPRN, odprn.ca) and Ontario Site Lead and Steering Committee member for the Canadian Network for Observational Drug Effect Studies (CNODES, cnodes.ca).

11:45 AM — 12:45 PM Mozart

Luncheon, Exhibits, and Networking Break

12:00 PM — 12:30 PM

Roundtable Discussions

Each day's networking luncheon offers both open seating and focused roundtable discussions. Each topic listed below will be hosted at a designated table led by a moderator. If you're passionate about one of these subjects or would like to exchange ideas with peers who share similar interests, we invite you to join a designated table to enjoy both your meal and an engaging conversation.

Uncovering the Bottleneck in the Canadian Clinical Trials Ecosystem by Suzie Talbot, Diex Research, Jean-Francois Leger, Sanofi and Bruno Battistini, University of Ottawa

The panelists from Session 3B will continue the discussion around the challenges and opportunities related site feasibility, selection, and recruitment using AI.

Meet Your Health Canada Clinical Trial Inspectors: Collaborating Towards a Successful GCP Inspection hosted by Kevin Donato, Health Canada and Hocine Abid, Health Canada

To continue on the topic of a proportionate risk-based inspection approach, Health Canada's clinical trial Inspectors will host a roundtable on the inspection process and preparation for a successful clinical trial inspection.

Documents to Data, Advancing Digitization - Current Status and Future Vision hosted by Todd Georgieff, RWS

Join us to continue a discussion about enabling real-time, data- and content-based submissions based on interoperability standards including HL7 FHIR, CDISC, OMOP and others.

A Closer Look at Canada's Post-Market Drug Evaluation Program hosted by Michael Paterson, Institute for Clinical Evaluative Sciences and Tarry Ahuja, Canada Drug Agency

Join us for a roundtable discussion that offers a deeper exploration of Canada's Drug Agency Post-Market Drug Evaluation (PMDE) Program, its key stakeholders, and its role in supporting evidence-based decision-making. The session will also highlight CoLab — a national expert network — including its structure and collaborative contributions to post-market drug evaluation.

Meet Your Health Canada Clinical Trial Reviewers: Collaborating Towards a Successful Clinical Trial Application hosted by Katherine Soltys, Health Canada and Sophie Hamel, Health Canada

To answer any questions you may have on Health Canada's clinical trial application (CTA) process, representatives from Health Canada's Office of clinical trials will host a roundtable on the preparation for a successful CTA.

Session Chair(s)

Roundtable Discussion

United States

12:45 PM — 2:00 PM Beethoven/Chopin

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.

- Regulatory Intelligence to Drive Regulatory Strategy
  Meena Muthiah, Astrazeneca
- The Submission Isn't Over: Strategically Leveraging Post-Agency Feedback to Future-Proof Submissions
  Anaya Rehman, Certara
- Building Regulatory Strategies Using Regulatory Intelligence in Canada's Evolving Healthcare Environment
  Pooja Sharma, Allucent Inc.

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 third year.

Speaker(s)

Regulatory Intelligence to Drive Regulatory Strategy

Meena N. Muthiah, MPH, MS, RAC

Director, Regulatory Intelligence & Policy
Astrazeneca, United States

Meena N. Muthiah is the Director of Regulatory Intelligence and Policy at AstraZeneca and has been part of the pharmaceutical/biotech industry since 2009. Her expertise has been in regulatory strategy that focuses on spearheading strategies that accelerate drug approvals. Strategic thinker, and an effective communicator with expertise in regulatory intelligence tools development, driving collaboration across cross-functional teams, developing regulatory landscapes, solving complex regulatory strategic questions and proactive regulatory policy development. Pharmacist by training, with a Public Health degree in Health Policy and Clinical practice from Dartmouth.

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

Pooja has more than 13 years' professional experience in the pharmaceutical and biopharmaceutical industry, spanning regulatory strategy, clinical research, medical writing, health authority engagement, and lifecycle management across Canada, US, EU and other semi-regulated markets. As a Senior Scientist, Regulatory Affairs at Allucent, she is responsible for writing, evaluating, and reviewing technical documents, managing health authority interactions, preparing and leading regulatory submissions, and advising internal teams and clients on complex regulatory pathways.

12:45 PM — 2:00 PM Delfosse

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.

- Clinical Trials 2035: Innovations that will Transform the Future of Research
  Allison Cuff Shimooka, TransCelerate Biopharma Inc
- Perry Poole, F. Hoffmann-La Roche Ltd.
- Clinical Trials Innovation and Modernization: Canadian Perspective
  Hocine Abid, Health Canada
- Ivy Salter, Ottawa Hospital Research Institute

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.

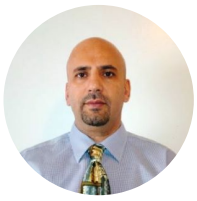
Speaker(s)

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.



Clinical Trials Innovation and Modernization: Canadian Perspective

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

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.

Speaker

Ivy Salter, MA

Manager, Regulatory and Quality Assurance
Ottawa Hospital Research Institute, Canada

Ivy Salter has been with the Ottawa Hospital Research Institute (OHRI) for over 11 years, contributing to a wide range of clinical trials across multiple therapeutic areas. In 2021, she transitioned from study coordination to Research Administration as a Clinical Research Facilitator, and since 2024, has served as Manager of Regulatory and Quality Assurance. In this role, Ivy oversees institutional compliance and quality assurance initiatives, and leads ongoing education and training programs to ensure adherence to all applicable principles, regulations, and guidance governing clinical research.

12:45 PM — 2:00 PM Julien/Gagnon/Walker/Suzor-Cote

Session 8, Track C: From Self-Care to Surveillance: Emerging Tools for Detecting Safety Signals

Discover how Health Canada manages safety signals for self-care products and the challenges of post-market surveillance. Learn how advanced technologies, including AI-enabled devices, are transforming safety monitoring. These tools help detect signals earlier across a range of product types. Explore how timely interventions driven by smart technologies can lead to better patient outcomes.

- Challenges in the Post-market Vigilance of Health Products Available for Self-selection
  Jasmine Bhathena, Health Canada

- Devices, Detection, and AI (oh my!)
  Anand Sudhakar Tamilarasan, ATJP Consulting Services

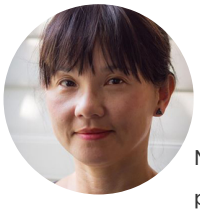
Learning Objective :

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

- Describe the process used by Health Canada for safety signal management and identify key challenges in the post-market surveillance of non-prescription drugs and natural health products
- Understand how advanced technologies, including AI-enabled devices, are being integrated to proactively detect safety signals and enhance patient safety along with the associated challenges and risks

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)

Challenges in the Post-market Vigilance of Health Products Available for Self-selection

Jasmine Bhathena, PhD, MS, MSc

Senior Scientific Evaluator, BBRS, MHPD
Health Canada, Canada

Jasmine Bhathena is the Acting Manager of the Self-care Products section at the Marketed Health Products Directorate, Health Canada. With over 16 years of combined academic and regulatory experience, she has held diverse roles in health product assessment and vigilance, regulatory management, and policy support across multiple product lines. Jasmine holds a Bachelor's degree and two Master's degrees in Microbiology, as well as a Ph.D. in Biomedical Engineering from McGill University.

Devices, Detection, and AI (oh my!)

Anand Sudhakar Tamilarasan

VP, Digital Transformation Leader
ATJP Consulting Services, United States

Anand Tamilarasan is a life sciences technology leader with over 25 years of experience aligning IT strategy with business goals to drive digital transformation. He delivers ROI through cloud platforms, data integration, and AI adoption, enabling operational efficiency and regulatory compliance. Anand has led enterprise initiatives across Regulatory, Quality, and Safety domains for global pharma and biotech organizations. He holds a Bachelor of Engineering in Electronics and Communication from Bharathiar University, India.

2:10 PM — 3:25 PM Beethoven/Chopin

Session 9 Plenary: Embracing AI: Practical Approaches to Transforming Clinical, Regulatory Affairs, and Post-Approval Activities

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.

- Leveraging AI in Clinical Development: Accelerating Study Design and Simplification
  Katrina Mateo, Regeneron
- AI Powered Translation for Global Pharma
  Anand Sudhakar Tamilarasan, ATJP Consulting Services
- AI in Action: Transforming Clinical Data Disclosure and Transparency
  Anaya Rehman, Certara

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

- Identify how AI can enhance clinical trial design and accelerate drug development timelines
- Recognize AI tools and how they are being used in the pharmaceutical industry and future trends
- Mitigate some of the common risks associated with AI and AI tools

Track: General Session

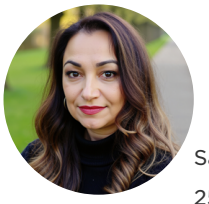
Session Chair(s)

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

President and Board Director
Clinical Research Association of Canada, 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.

Speaker(s)

Leveraging AI in Clinical Development: Accelerating Study Design and Simplification

Katrina Mateo, PhD, MPH

Associate Director, Development Innovation
Regeneron, United States

Katrina F. Mateo, PhD MPH, is a public health researcher, interventionist, and strategist bringing evidence-based, human-centered solutions to complex challenges. She leverages qualitative/mixed-method research methodology, human-centered design thinking, systems-thinking, behavioral science, and implementation science to drive meaningful impact in clinical trials, digital health, and public health initiatives. At Regeneron, she identifies & leads innovation opportunities to optimize clinical trial speed, efficiency, and quality. Her educational journey includes a BA from Vassar College, MPH from Columbia School of Public Health, PhD from CUNY School of Public Health, and MBA (in progress) at Boston University's Questrom School of Business.

AI Powered Translation for Global Pharma

Anand Sudhakar Tamilarasan

VP, Digital Transformation Leader
ATJP Consulting Services, United States

Anand Tamilarasan is a life sciences technology leader with over 25 years of experience aligning IT strategy with business goals to drive digital transformation. He delivers ROI through cloud platforms, data integration, and AI adoption, enabling operational efficiency and regulatory compliance. Anand has led enterprise initiatives across Regulatory, Quality, and Safety domains for global pharma and biotech organizations. He holds a Bachelor of Engineering in Electronics and Communication from Bharathiar University, India.

AI in Action: Transforming Clinical Data Disclosure and Transparency

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.

3:25 PM — 3:40 PM Beethoven/Chopin

Closing Remarks