Print Agenda

Day 1 Oct 30, 2023

1:00 PM — 4:30 PM

Tools and Methods to Evaluate the Effectiveness of Risk Minimization Measures

Session Chair(s)

Myriam Salem, MSc

Pharmacovigilance Manager
Health Canada, Canada

Myriam Salem is currently a pharmacovigilance manager in the Health Products and Food Branch (HPFB) at Health Canada. She previously led the Good Pharmacovigilance Practices inspection Program within the Regulatory Operations and Enforcement Branch (ROEB) and worked within HPFB as a senior scientific evaluator for several years. Prior to joining Health Canada, she held various positions in the pharmaceutical industry and academia at Merck Frosst Canada and McGill's Lady Davis Institute. She holds a master's degree in pharmacology from Université de Montréal and a master's degree in Pharmacovigilance and Pharmacoepidemiology from a consortium of European Universities under the EU2P program.

Nadiya Jirova, MSc

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

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

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Day 2 Nov 02, 2023

9:00 AM — 12:30 PM

Global Advertising and Promotion – Considerations for Compliance and Success

Day 3 Nov 07, 2023

7:30 AM — 6:00 PM Atrium, outside RM 106CD

Meeting Registration

7:30 AM — 8:30 AM Room 106CD

Networking Breakfast

8:30 AM — 8:55 AM Room 106CD

Welcome and Opening Remarks

8:55 AM — 10:00 AM Room 106CD

Session 1 Plenary: The Future of Therapeutic Products Development: Current Emerging Trends and Technologies

Artificial Intelligence (AI) and Machine Learning (ML) have great potential to enhance drug development in many ways, including to help bring safe and effective drugs to patients faster; provide broader access to drugs and thereby improve health equity; increase the quality of manufacturing; enhance drug safety; and develop novel drugs and drug classes, as

well as personalized treatment approaches. In this plenary session, representatives from industry, Health Canada and FDA will discuss impact of AI/ML on the development of therapeutic products and medical devices. This will be an interactive session, where participants will have an opportunity to ask questions on the latest regulatory requirements in this area.

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

- Describe challenges and opportunities presented by AI and ML
- Discuss areas of product development where AI and ML could be applied
- Explain Health Canada and FDA regulatory expectations for AI and ML

Track: General Session

Session Chair(s)

Yatika Kohli, PhD, MBA

Chief Regulatory 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.

Oxana Iliach, PhD

Senior Director Regulatory Strategy
Certara, Canada

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

Speaker(s)

FDA Approach to Artificial Intelligence/Machine Learning-Enabled Medical Devices

Sonja Fulmer, PhD

Deputy Director, Digital Health Center of Excellence, CDRH
FDA, United States

Sonja Fulmer is the Deputy Director for the Digital Health Center of Excellence in the Center for Devices and Radiological Health (CDRH). Dr. Fulmer works to advance and implement new policy approaches to medical device software and digital health technologies to better promote and protect public health. Dr. Fulmer joined the Center for Devices and Radiological Health (CDRH) in 2014 as an AIMBE Scholar to pursue her interest in science policy after earning her doctorate in Chemical and Physical Biology from Vanderbilt University. Dr. Fulmer has held several policy-focused positions in the Office of the Center Director and later as a Policy Advisor in the Office of Policy at CDRH, before joining the Digital Health Center of Excellence.

Health Canada’s Pre-Market Draft Guidance for Machine Learning-enabled Medical Devices

Tyler Dumouchel, PhD, MSc

Senior Scientific Evaluator
Health Canada, Canada

Tyler Dumouchel obtained his Ph.D. in Medical Physics from Carleton University in 2011, where his primary research was related to nuclear medicine imaging. After completing his studies, he joined an engineering consulting firm where he worked on projects related to nuclear safety and radiation protection. After spending five years in the nuclear industry, he joined Health Canada where he is currently a Senior Scientific Evaluator within the Digital Health Division of the Medical Devices Directorate. His current primary responsibilities are in regards to regulating radiation emitting medical devices and medical device software.

Can’t ChatGPT Do That? Practical Applications for AI in Life Sciences

Sean McGee, MS

Director of Product
Certara, United States

Sean McGee is currently the Director of Product for Certara's artificial intelligence (AI) division, Certara AI. Throughout his career, he has supported the strategy and go-to-market motions of various software technologies, including Benchling's laboratory informatics platform and the AI and molecular modeling and simulation offerings for Dassault Systèmes BIOVIA brand. In his role with Certara, Sean guides the development of new AI-focused use cases which maximize the benefits of the Certara AI and broader company portfolio. Sean completed his Master of Science at the University of Notre Dame exploring the scientific and commercial applications of medical devices designed to aid in the identification of child abuse.

Panelist

Rajeswari Devanathan, MSc

Senior Manager - Medical Devices
Amerisource Bergen, Tpireg, Innomar Strategies, Canada

Raje Devanathan is a Senior Manager Regulatory Affairs, Medical Devices at TPIreg a Division of Innomar Strategies with 22 years of professional/consulting experience and is a certified regulatory affairs and clinical research professional. She started her career in Biologics Drug research and regulatory, which then extended to medical device expertise. Her device experience covers medical devices, in vitro diagnostics, companion diagnostics, combination products, SaMD, wearables, medical app, AL/ML Devices. She is a certified ISO 13485 lead auditor. Prior to joining TPIreg, she headed the consulting and clinical team at Be-on-Quality- Germany and other consulting businesses in the UK, Ireland, and North America.

10:00 AM — 10:40 AM Room 106EFG

Refreshments, Exhibits, and Networking Break

10:40 AM — 12:10 PM Room 106CD

Session 2, Tracks A, B, C: Advancing Agile Regulations for Drugs: Updates from Health Canada

Between December 2022 and April 2023, Health Canada consulted on new regulatory proposals and guidance documents of the Agile Licensing for Drugs initiative. These are part of the department's Regulatory Innovation Agenda aimed at reducing regulatory irritants and modernizing its regulations based on agile tools tested through the COVID-19 response. In this session, speakers from Health Canada will situate the Agile Licensing for Drugs initiative within the modernization agenda and provide updates on the consultation feedback and planned next steps, in particular for the use of Terms and Conditions, Risk Management Plans, and Rolling Reviews.

Learning Objective :

- Contextualize the Agile Licensing for Drugs initiative within Health Canada's (HC's) Regulatory Innovation Agenda
- Identify key themes and feedback heard during HC's consultation, including the use of terms and conditions, risk management plans, and rolling reviews
- Gain insights on plans for next steps

Track: Track A, B, C

Session Chair(s)

Mandy Collier

Director, Health Products and Food Branch
Health Canada, Canada

Mandy Collier is the Director of the Office of Planning, Performance and Review Services in the Pharmaceutical Drugs Directorate (PDD) of Health Canada. She has worked in the Health Products and Food Branch (HPFB) for over 15 years in a variety of policy, advisory and management positions in the PDD, Biologic and Radiopharmaceutical Drugs Directorate, and the HPFB Assistant Deputy Minister's Office. She has a degree in pharmacology from McMaster University.

Melanie Cote, MS

Senior Manager, Regulatory Affairs
Otsuka , Canada

Melanie Cote, Senior Manager in Regulatory Affairs, has been with Otsuka Canada Pharmaceutical for 7 years working on regulatory filings in Canada. She studied biochemistry and worked for a few years in analytical development after graduating. She later completed a DESS (diplôme d'études supérieures spécialisées) in drug development, focusing on CMC, and has a Master of Pharmaceutical Sciences from the Université de Montréal. In 2010, Melanie fell in love with Regulatory Affairs and worked in European regulatory for 2 years at Mylan and AstraZeneca in the United Kingdom. Since 2013, Melanie has focused on Canadian regulatory. She is thrilled to be a committee member of the DIA Canada Annual Meeting for the first time this year.

Speaker(s)

Speaker

Saskia De Moree, JD, MA

Manager, Office of Legislative and Regulatory Modernization
Health Canada, Canada

Saskia de Morée is a manager of a regulatory policy team at the Office of Legislative and Regulatory Modernization at the Policy, Planning and International Affairs Directorate in Health Canada. She holds a B.A. and M.A. from Carleton University and an LL.B from Schulich School of Law and, after several years in the private and municipal sectors, joined the Government of Canada over 18 years ago with a focus on legislative and regulatory development.

Agile Licensing for Drugs: Terms and Conditions

Nadia Giancaspro

Senior Policy Analyst
Health Canada, Canada

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

Agile Licensing for Drugs: Risk Management Plans

Bruce Wozny, MA

Sr. Policy Officer, Health Products and Food Branch, Marketed Health Products
Health Canada, Canada

Bruce Wozny has been a senior policy officer with the Marketed Health Products Directorate of Health Canada since 2002. Before that he worked in compliance and enforcement of the Food and Drugs Act and Regulations. He is currently working on vigilance policy, including the development of regulations and guidelines for Risk Management Plans and other vigilance tools and activities.

Agile Licensing for Drugs: Rolling Reviews

Denis Arsenault, MBA

Manager, Policy Development, Health Products and Food Branch, Biologic and
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.

Panelist

Robyn Blom

Health Products and Food Branch, Pharmaceutical Drugs Directorate
Health Canada, Canada

Robyn Blom works within the Director General's Office of the Pharmaceutical Drugs Directorate and is leading the implementation of Terms and Conditions as part of Health Canada's Agile Licensing for Drugs initiative. She has over 17 years of experience within Health Canada and has held a number of regulatory, advisory and managerial positions within both the Health Products and Food Branch and the Controlled Substances and Cannabis Branch. Robyn holds a degree in Anatomy and Cell Biology from McGill University.

12:10 PM — 1:10 PM Room 106EFG

Luncheon, Exhibits, and Networking Break

1:10 PM — 2:10 PM Atrium, outside Room 106CD

Session 3, Tracks A, B, C: Integrating Equity, Diversity and Inclusion Across the Drug Product Lifecycle

Speakers in this session will provide an update on the efforts under way to promote diversity, equity and inclusion in clinical trials in Canada. Health Canada will outline its Sex and Gender Based Analysis Plus (SGBA Plus) Action Plan, including its regulatory proposal on disaggregated data. Attendees can expect to gain a better understanding of how government, industry and patients are supporting the creation of more equitable drug development and regulatory systems.

Learning Objective :

- Understand the importance of developing a more equitable drug development/ regulatory system, as well as the current challenges and barriers
- Describe current efforts to increase equitable drug development and regulatory systems
- Identify challenges and complexities in collecting and assessing disaggregated data

Track: Track A, B, C

Session Chair(s)

My Dang, MBA

Senior Manager, Regulatory Affairs
Knight Therapeutics , Canada

My is a Senior Manager of Regulatory Affairs at Knight Therapeutics Inc. She started out her career in health care 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, animal and cannabis health 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 on the Board of Directors. She had spearheaded the NOC and eNOC publications, assisted in CAPRA dinner coordination and presented CAPRA webinars.

Melanie Cote, MS

Senior Manager, Regulatory Affairs
Otsuka , Canada

Melanie Cote, Senior Manager in Regulatory Affairs, has been with Otsuka Canada Pharmaceutical for 7 years working on regulatory filings in Canada. She studied biochemistry and worked for a few years in analytical development after graduating. She later completed a DESS (diplôme d'études supérieures spécialisées) in drug development, focusing on CMC, and has a Master of Pharmaceutical Sciences from the Université de Montréal. In 2010, Melanie fell in love with Regulatory Affairs and worked in European regulatory for 2 years at Mylan and AstraZeneca in the United Kingdom. Since 2013, Melanie has focused on Canadian regulatory. She is thrilled to be a committee member of the DIA Canada Annual Meeting for the first time this year.

Speaker(s)

Speaker

Roberta Albany

Founder/CEO
Cancer In The Know, United States

Ms. Albany is the Founder/CEO of Cancer In The Know, focusing on the impact disparities have in the Black/African American community and is a contributing author of Bruised, Broken & Blessed. While receiving treatment for hormone receptor positive breast cancer in December 2013, Ms. Albany noticed there was a disconnect regarding the outcomes of underrepresented communities. To be part of the solution, Ms. Albany became a Young Women's Advocate via Living Beyond Breast Cancer in September 2015. Ms. Albany has and continues to work with numerous advocacy organizations, and serves as a patient advocate (research advocate-breast committee) for SWOG Cancer Research Network.

Speaker

Alysha Croker, PhD

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

Dr. Alysha Croker is the Director of the Centre for Policy, Pediatrics and International Collaboration, Health Products and Food Branch, Heath Canada. In this position, Dr. Croker is responsible for developing ways to increase access to safe and effective health products for pediatric populations in Canada, among other files. Previously, Dr. Croker managed the Canada Excellence Research Chair and the Canada First Research Excellence Fund programs for Canada's federal research funders. She also led the development of the CIHR's training and equity strategies where

she received the Innovation Award. Dr. Croker has a PhD from Western University where she studied the molecular mechanisms of breast cancer metastasis and therapy resistance.

Recent Clinical Trial Diversity Guidance in the United States

Vanessa Cahee

Clinical Operations & Clinical Trial Diversity Consultant
VCahee Consulting LLC, United States

Vanessa Cahee is a Clinical Operations and Clinical Trial Diversity Consultant with 20+ years of Clinical Operations experience in industry. Prior to consulting, Vanessa worked at SF Bay Area companies including Genentech, Amgen, Onyx, and Myovant; leading teams and contributing to the development of biologics and small molecules across many indications. Her work has led to approvals of several marketed products. She thrives on bringing new therapeutics to all patients and steering efforts in clinical trial diversity. An active and influential member of the DIA DEI community and a subject matter expert in clinical trial diversity, Vanessa works with clients to implement affordable solutions to enhance clinical trial populations.

Inclusive Clinical Studies – for Equitable Access to clinical reSearch in Europe (EASE)

Ambily Banerjee, PhD

Global Head of Clinical Development Equity
Novartis, United Kingdom

After a decade as an academic scientist, following a Ph.D. in Molecular Biology, Ambily moved to GSK Regulatory Affairs, where she held increasingly senior roles in Global Regulatory Affairs and Internal Audit. She also led the race and ethnicity Employee Resource Group, EMBRACE, as a volunteer, working in partnership with senior leaders to implement global changes to ensure equity for ethnic minorities. She moved to Novartis in Nov 2021 where her role is primarily focused on driving clinical trial diversity. Externally, Ambily is the Deputy Chair of The Network of Networks and on the Board of 'BBC Micro:bit Educational Foundation. She is passionate about DEI and ensuring the next generation have equal access to opportunities.

2:10 PM — 2:50 PM Room 106EFG

Refreshment and Networking Break

2:50 PM — 4:05 PM Room 106CD

Session 4, Track A: Innovation in Therapeutic Product and Device Development

Advances in both therapeutic products and devices pose technical as well as regulatory challenges that must be overcome to ensure safe and effective products. Innovations in Manufacturing also experience regulatory challenges that must be overcome for implementation. In this session we will identify regulatory frameworks, policies and industry experiences to support innovative advanced therapeutic products and devices, as well as new manufacturing technologies.

Learning Objective :

- Identify Canadian regulatory frameworks, challenges, and benefits for advanced therapeutics
- Explore decentralized manufacturing's advantages and regulatory hurdles for implementation
- Review the significant strides by jurisdictions in developing policies and how we can leverage the information for successful product development and review by regulatory authorities

Track: Regulatory

Session Chair(s)

Maria Anillo

Regulatory Affairs Project Manager
AstraZeneca Canada Inc., Canada

Maria Anillo is a Regulatory Affairs Project Manager at AstraZeneca Canada Inc. and holds a Master of Science degree in Molecular and Cellular Biology from the University of Guelph. She has over 4 years of experience in the brand name pharmaceutical industry working on both established and marketed products in various therapeutic areas. Prior to joining AstraZeneca, she was a Senior Associate, Established Products & Regulatory Operations at Boehringer Ingelheim (Canada) Ltd. and she completed the Pharmaceutical Regulatory Affairs and Quality Operations at Seneca College. Her current role allows her to expand her regulatory knowledge and maintain regulatory compliance of approved products.

My Dang, MBA

Senior Manager, Regulatory Affairs
Knight Therapeutics , Canada

My is a Senior Manager of Regulatory Affairs at Knight Therapeutics Inc. She started out her career in health care 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, animal and cannabis health 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 on the Board of Directors. She had spearheaded the NOC and eNOC publications, assisted in CAPRA dinner coordination and presented CAPRA webinars.

Speaker(s)

Canada's Regulatory Approach for Advanced Therapeutic Products

Kenneth Joly, MS

Senior Policy Analyst, Office of Advanced Therapeutic Products
Health Canada, Canada

Kenneth Joly is a Policy Analyst in the Office of Advanced Therapeutic Products at the Centre for Policy, Pediatrics and International Collaboration of the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) at Health Canada, and he has worked at BRDD since 2008. Ken is one of the policy leads working to bring the Advanced Therapeutic Products pathway to life. He has extensive experience in policy development and stakeholder engagement and enjoys finding creative solutions to complex policy and regulatory issues. Ken has a Bachelor of Social Sciences from the University of Ottawa and a Master of Science in Political Science from the University of Nebraska at Omaha.

Innovations in Manufacturing: Decentralized Manufacturing

Celeste Frankenfeld Lamm

Senior Director, Global Regulatory Affairs – CMC
Merck Sharpe & Dohme LLC , United States

Celeste Frankenfeld Lamm, Ph.D., is currently a Director of Global Regulatory Affairs – CMC at Merck & Co, Inc. with 16 years of industry experience. In this capacity she is responsible for regulatory strategy, engagement with regulatory authorities, and preparation of clinical CMC dossiers as well as marketing applications. In previous roles within the company, she led analytical development efforts to support both drug substance and formulation development, as well as a cross-functional team tasked with advancing a candidate from pre-clinical through clinical studies. Dr. Frankenfeld Lamm holds a B.A. in Chemistry and Biology from Greenville University, and a Ph.D. in Pharmaceutical Chemistry from the University of Kansas.

Regulatory Challenges and Opportunities in Decentralized Manufacturing: Canadian Perspective

Jennifer Wilhelm, MBA, MSc, RAC

Dir, Regulatory Affairs
Merck Canada Inc., Canada

Jennifer (JJ) Wilhelm is a regulatory affairs professional working as Director, Regulatory Affairs at Merck Canada Inc (Merck). She started in industry at a regulatory consulting firm, then worked for Canadian biotech companies, and has been with Merck since 2011. JJ holds an Honours BSc in Biomedical Sciences from the University of Guelph, an MSc in Pharmacology and Toxicology from McGill University, and an eMBA from JMSB at Concordia University, as well as the RAC (US) credential from RAPS. JJ is currently focused on CMC aspects of regulatory affairs in Canada, as well as related areas (DEL, drug shortages, etc). She is involved in policy activities, with Innovative Medicines Canada (Quality team) and BIOTECanada (BRAG), and Merck.

2:50 PM — 4:05 PM Room 118E

Session 4, Track B: Key Changes to the ICH E6 R3 Guidelines

ICH E6(R3) draft is now available but it has been completely reformatted. We will walk you through some of the key changes and point out some of the great things that have remained.

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

- Recognize the key changes in revision 3
- Identify how to utilize these changes in your day to day activities
- Summarize the key changes to your colleagues

Track: Clinical

Session Chair(s)

Vatche Bartekian, MSc

President
Vantage BioTrials, Canada

Mr. Bartekian is President of Vantage BioTrials, an award-winning Canadian CRO specializing in clinical trial management services. He's contributed his drug development knowledge to the pharma & device industry for over 24 years and has gained vast experience handling complicated trials across an array of therapeutic areas. He has also contributed his knowledge as an Advisor to Global Affairs Canada's Life Science division, and Colorectal Cancer Canada's Scientific Advisory Board for the establishment of a Patient Group Pathway Model to Accessing Cancer Clinical Trials. Vatche was also honored in 2021 by his alma mater, Concordia University, as a "Top 50 under 50 Who are Shaping Tomorrow" for his work in combatting Covid-19.

Marie-France Goyer, MSc

Director, Clinical Operations
Abcellera, Canada

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

Émilie Lévesque, MSc

Senior Clinical Quality Manager
Abcellera, Canada

Émilie has a Bachelor degree in Microbiology, a Master Degree in Molecular Biology and a Specialized Graduate Diploma in Drug Development. She has over 19 years experience in the clinical research industry including roles such as Clinical Research Associate (CRA), Clinical Project Manager and Country Clinical Quality Manager. Émilie is also a lecturer at the University of Montreal in the Drug Development Specialized Graduate Diploma.

Kim McDonald-Taylor, MS, MSc

Clinical Research Consultant
McDonald-Taylor Consulting, Canada

Kim McDonald-Taylor consults in project management, medical writing, training & teaching being in the clinical trials area for over 35 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 teaches QA & Critical Thinking in Post-Graduate Clinical Research Program at Seneca. 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.

Speaker(s)

Key Changes to the ICH E6 Guidelines: R2 to R3

Sabrina Ramkellawan

Chief Operating Officer
AxialBridge, Canada

Sabrina Ramkellawan started her career as a registered nurse with critical care speciality. She has 25 years of clinical research experience working for Pharma, CROs and Research sites. Sabrina has experience conducting clinical trials with novel therapeutics, vaccines, biologics, NHPs, cannabiniods and psychedelics. Sabrina is also the President of the Clinical Research Association of Canada and Board of Directors for MAPS Canada. She has been actively involved in education including building & teaching clinical research programs. She is currently the COO at AxialBridge with a focus on emerging therapeutics and helping biotech/life science companies navigate regulatory, and clinical operations to conduct clinical trials.

2:50 PM — 4:05 PM

Theatre Hall 201

Session 4, Track C: Creating a Safer Framework for Medicines Use in Pregnant and Breastfeeding People

Globally, >800 women and >12,000 newborns die daily due to complications of pregnancy. Drugs are required for pregnant women, but only two were developed for this purpose. In this session, the regulatory environment for drug safety in pregnancy, and proposed solutions for the use of medicines in pregnancy will be discussed.

Learning Objective :

- Recognize current global regulations and guidelines governing use of medicines in pregnancy and breastfeeding based on the Landscape Assessment of global guidelines and regulations
- Discuss tools (“Points-to -Consider”) for the use of medicines in pregnancy and when breastfeeding, particularly during clinical development
- Identify different initiatives ongoing for a safer use of medicines during pregnancy and breastfeeding

Track: Pharmacovigilance

Session Chair(s)

Marcia Bailey, BSN, MHS, RN

Safety Evaluation and Risk Management Scientific Director
GSK, Canada

Marcia is a registered nurse with many years of clinical and industry experience. In addition to her past role as a clinical research data management subject matter expert, more than a decade of pharmacovigilance duties has helped Marcia acquire much of the knowledge, skills, and abilities needed to help companies manage today’s evolving drug safety responsibilities and regulations. Marcia has been a DIA conference speaker and is currently a Safety Evaluation & Risk Management Scientific Director at GSK.

Vanessa Zapata

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

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

Speaker(s)

TransCelerate: Points to Consider for Pregnancy throughout the Product Lifecycle Based on the Regulatory Guidelines and Regulations Across the Globe

Keele Wurst, PhD, RPh

Senior Director and Head, Safety Science Epidemiology
GSK, United States

Dr. Wurst has spent 17 years at GlaxoSmithKline (GSK). As Head of Safety Science, Epidemiology, she provides strategic leadership and oversight of epidemiology into safety and risk management programs across GSK. She has

extensive experience in conducting safety studies, particularly in pregnancy. Keele is a member of GSK's Global Safety Board, and co-chair of GSK's Pregnancy Outcomes Advisory Panel. Externally, she is involved in the IMI Conception project and the TransCelerate project, Interpretation of PV Guidance & Regulations related to Pregnancy and Breastfeeding. Keele received a PhD in Epidemiology and a M. S in Pharmaceutical Policy from the University of North Carolina and a B.S. in Pharmacy from the University of Pittsburgh.

Canadian Mother-Child Initiative on Drug Safety in Pregnancy

Anick Berard, PhD, FISPE

Full Professor and Senior Researcher
University of Montreal, Canada

Dre Bérard has cross-training in epidemiology, pharmacoepidemiology, and genetics from McGill University, Harvard Medical School, and Stanford University. She is full professor of perinatal epidemiology at the University of Montreal, Faculty of Pharmacy, and CHU Ste-Justine in Montreal; and adjunct professor at the Faculty of Medicine of the Université Claude Bernard in Lyon, France. Dr Bérard holds a Canada Research Chair Tier 1 on Medications and Pregnancy; is a fellow of the Canadian Academy of Health Science; and the principal investigator of the CAMCCO initiative. She has published over 500 scientific papers, abstracts and patents, and has obtained over 37 million dollars in funding from CIHR, CFI, and FRQS as principal investigator.

Speaker

Marcy Powell, MD

Medical Director, Safety Evaluation and Risk Management
GSK, United States

I have been a safety physician in drug development at GSK since 2011. As a practicing, board certified OB/Gyn with a pharmacy degree, I have a particular interest in delivering benefit/risk knowledge on medication use in pregnancy to physicians and patients to guide evidence-based, informed decisions. I have been involved with collaborative initiatives to utilize current resources and build improved resources to support this effort. It is a privilege to share experience and ideas to drive progress in this important area of pharmacovigilance.

4:15 PM — 5:30 PM Room 106CD

Session 5, Track A: Accelerating Access to Medicines Through Collaboration

This session will focus on some international collaboration initiatives in place to support timely access to medicines in Canada. On behalf of the ACCESS (Australia, Canada, Singapore, Switzerland and United Kingdom) Consortium, Health Canada will provide updates on the ongoing work of Access New Active Substance Work group (NAS WG) including statistics, in addition to providing an update on the newly created Promise Pathway. At this session, representatives from

innovative Medicines Canada (IMC) will share the findings of its survey of members' experiences with submissions reviewed through this initiative as well as speak to the additional initiatives being taken by IMC to accelerate access to medicines for Canadians.

Learning Objective :

- Understand the key performance indicators and measures of the Access NAS WG from a regulator's perspective
- Gain awareness of the advantages, limitations and recommendations to enhance participation in the NAS WG from an industry perspective
- Explain additional IMC initiatives to accelerate access to medicines for Canadians

Track: Regulatory

Session Chair(s)

Yatika Kohli, PhD, MBA

Chief Regulatory 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.

Tharany Ganesh

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.

Amber McLeod, PhD

Lead, Regulatory Affairs
Abbvie Corporation, Canada

Amber McLeod has held the role of Lead, Regulatory Affairs at AbbVie Canada since May 1, 2020. She leads a team of Regulatory Affairs professionals focused primarily on the filing and approval with Health Canada of biopharmaceutical drug submissions for clinical development and commercial products in the areas of Immunology, Oncology, Virology, Neuroscience, Hormone Replacement Therapy, and Specialty Care. Amber joined Abbott in January 1999. Over her 24-year career with Abbott/AbbVie, she held various roles of increasing

responsibility where she led and managed countless regulatory filings, approvals and product launches in different therapeutic areas. Amber holds a Doctorate in Pharmacology and Therapeutics from McGill University.

Speaker(s)

Access: Feedback from 5 Country Survey and Update from Health Canada

Jeffrey Skene, MSc

Director, Bureau of Cardiology, Allergy and Neurological Science
Health Canada, Canada

Jeffrey Skene has been with Health Canada since 2003. He began his career at Health Canada in Regulatory Affairs and quickly joined the group responsible for the review of monoclonal antibodies as a CMC reviewer. He advanced to the position of Manager of the Monoclonal Antibodies Division, before becoming Associate Director in the Bureau of Gastroenterology, Infection and Viral Diseases. Mr. Skene moved to the role of Associate Director in the Bureau of Evaluation in the Medical Devices Directorate as part of the COVID-19 pandemic response before assuming his current role as Director of the Bureau of Cardiology, Allergy and Neurological Sciences in the Pharmaceutical Drugs Directorate.

Access: Feedback from 5 Country Survey and Update from Health Canada

Laura King, MBA

Vice Chair, Regulatory Operations Teams
Innovative Medicines Canada, Canada

Laura began her career in the pharmaceutical industry in Medical Information, but quickly developed an interest in regulatory affairs, and has spent more than 25 years in a variety of regulatory affairs roles including several large pharma companies, start-ups and consulting companies. She assumed her current role of Head of Regulatory Affairs for Novartis pharmaceuticals in 2013, and enjoys participating in both IMC an BioteCanada regulatory committees. Laura holds a B.Sc. in Cell and Molecular Biology and a MBA. She has a strong interest in the topics of worksharing/reliance and pediatric policy issues.

International Recognition Procedure (IRP)

Shirley Hopper, DrMed

Deputy Director, Innovative Medicines, HQA
Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

Dr Shirley Hopper is Deputy Director of Innovative Medicines at the UK Medicines and Healthcare products Regulatory Agency. Following a career in general practice, Shirley joined the MHRA as a medical assessor in 2008 and trained as a pharmaceutical physician. She developed special interests in oncology, rheumatology, vaccines, and pharmacogenomics. Shirley took up the Deputy Director role in 2022 and leads the teams who assess new active substances, both biological and chemical. Her teams also assess new indications and biosimilars, and provide

scientific and regulatory advice to developers. Shirley has played a leading role in the development of the UK's new International Recognition Procedure.

Enabling Patient Access via Policy Innovation

Jonathan Feairs

Director, Government Affairs & Public Policy
AstraZeneca Canada, Canada

Jon Feairs is the Director of Government Affairs and Public Policy at AstraZeneca Canada. He has over 15 years of experience in at the top levels of public policy discourse and decision making. He served as a senior political advisor to three Ontario Cabinet Ministers – including the Minister of Health – before joining AstraZeneca Canada in 2013. Since then, he's been a trusted advisor to the Executive Team at AZC in government affairs, policy, and market access roles. Jon obtained his degree in biochemistry from Queen's University in Kingston and has always been interested in the intersection of life sciences and politics. He lives in Toronto with his wife and two sons.

4:15 PM — 5:30 PM Room 118E

Session 5, Track B: Optimizing Clinical Trials Operationally in Canada

There is currently high interest by Canadian stakeholders, including government, to strengthen the clinical trials ecosystem in Canada. This presents a unique opportunity to further evolve and grow medical innovation as well as support patient care through clinical research. At the same time, there are new challenges in this sector. This session will provide an overview of ongoing initiatives as well as resources available for clinical research professionals and organizations to respond to opportunities and challenges as well as to maximize the success of their clinical research efforts.

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

- Identify challenges related to advancing clinical research in Canada
- Recognize the resources available to support various aspects of clinical research

Track: Clinical

Session Chair(s)

Marie-France Goyer, MSc

Director, Clinical Operations
Abcellera, Canada

As Director of Clinical Operations at AbCellera, I am passionate about and proud to be working on clinical trials because they help to improve and save the lives of patients in need. I have more than 20 years of experience in Clinical Research. Before joining AbCellera, I spent 5 years as a Director of Clinical

Operations at Merck, working in Oncology and General Medicine portfolios. Before moving to Merck, I worked as a Clinical / Sr. Clinical Project manager on the Asthma/Allergy, Cardiovascular, and HIV portfolios at Schering Canada. I completed a master's degree in Drug Development from Université de Montréal.

Émilie Lévesque, MSc

Senior Clinical Quality Manager
Abcellera, Canada

Émilie has a Bachelor degree in Microbiology, a Master Degree in Molecular Biology and a Specialized Graduate Diploma in Drug Development. She has over 19 years experience in the clinical research industry including roles such as Clinical Research Associate (CRA), Clinical Project Manager and Country Clinical Quality Manager. Émilie is also a lecturer at the University of Montreal in the Drug Development Specialized Graduate Diploma.

Lorella Garofalo, PhD

Head of Regulatory Sciences
Pfizer Canada, Canada

Lorella has been with Pfizer Canada since 2001 assuming roles of increasing responsibility in clinical research as well as medical affairs and is currently head of regulatory sciences for Pfizer Canada. She obtained a BSc (Honours) in Biochemistry and a PhD in Pharmacology & Therapeutics from McGill University. Prior to joining Pfizer, Lorella was a drug assessment officer at TPD, Health Canada and since 1999 has maintained an academic appointment with the department of Pharmacology & Therapeutics at McGill. She has served as a member of the board of directors/advisory councils for various research organizations and is a member of the regulatory affairs committees of Innovative Medicines Canada and BIOTECanada.

Speaker(s)

Supporting Canadian Clinical Research Excellence Through Collaboration

Rebecca Barnes, MS

Executive Director
Network of Networks (N2), Canada

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

Speaker

Bruno J Battistini, PhD, MS, MSc

National Executive Director and Chief Operating Officer
CANTRAIN, 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.

Introduction to Biopharmaceutical Manufacturing

Sven Ansorge, PhD

Associate Director of Technical Training
CASTL Canada, Canada

Sven has more than 15 years of experience in biopharmaceutical industry and R&D. He holds a PhD in Chemical Engineering from Polytechnique de Montréal and has led teams and projects within academic and industrial/GMP manufacturing environments. Since 2022, he works as Associate Director, Technical Training/Site Manager Montreal at the Canadian Alliance for Skills and Training in Life Sciences (CASTL). CASTL provides world-class technical skills development and training in life sciences specializing in biopharmaceutical manufacturing. It is a unique partnership between academia, industry, and government to address the future skills needs of the fast-growing bioscience sector.

4:15 PM — 5:30 PM

Theatre Hall 201

Session 5, Track C: Notification of Foreign Actions: Challenges and Best Practices

Health Canada first published the Notifying Health Canada of Foreign Actions guidance in November 2018. As industry has now had some time to become familiar with this requirement, this session will provide an update on Health Canada's experience with Notifications of Foreign Actions (NFA) process, provide practical feedback on the process and identify potential areas for improvement and collaboration with the industry. The session will also provide perspective from industry on best practices when dealing with actions from foreign regulators. Attendees will also be able to ask specific questions to Health Canada representatives.

Track: Pharmacovigilance

Session Chair(s)

Nadia Mian, MS

Pharmacovigilance Manager
Ipsen Biopharmaceuticals Canada Inc., Canada

Nadia Mian is currently working as local pharmacovigilance lead 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.

Nadiya Jirova, MSc

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

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

Agnes Jankowicz, MS

Vice President, Pharmacovigilance
Veristat, Canada

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

Speaker(s)

Notification of Foreign Actions: An Update by Health Canada

Bruce Wozny, MA

Sr. Policy Officer, Health Products and Food Branch, Marketed Health Products
Health Canada, Canada

Bruce Wozny has been a senior policy officer with the Marketed Health Products Directorate of Health Canada since 2002. Before that he worked in compliance and enforcement of the Food and Drugs Act and Regulations. He is

currently working on vigilance policy, including the development of regulations and guidelines for Risk Management Plans and other vigilance tools and activities.

Foreign Alerts: An Industry Perspective

Randy Levitt, PhD

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

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

Speaker

Koby Philip-Joseph

Regional Regulatory Compliance and Enforcement Officer
Health Canada, Canada

Regulatory experience within the Pharmaceutical industry for 5 years prior to joining Health Canada as an Inspector in 2018. Joined the GVP team within Health Canada in 2022. Responsible for performing regular GVP inspections and providing guidance to maintain and promote compliance with the Food and Drug Regulations.

Notification of Foreign Actions: An Update by Health Canada

Andrea Bell, PhD

Human Therapeutic Product Submission Assessment Evaluator
Health Canada, Canada

Andrea Bell is a senior scientific evaluator in the Marketed Pharmaceuticals Bureau (MPB) at the Marketed Health Products Directorate at Health Canada with over 16 years of experience at Health Canada. She is currently the chair of the Signal Identification from Foreign Agencies Signal Detection Working Group at MPB. She has a bachelor's degree in Biology with a concentration in Physiology (Cornell University) and a PhD in Biochemistry (University of Ottawa).

5:30 PM — 6:30 PM

Room 106EFG

Networking Reception

Day 4 Nov 08, 2023

7:30 AM — 4:00 PM | Atrium, outside Riin 106CD

Meeting Registration

7:30 AM — 8:30 AM | Room 106EFG

Networking Breakfast

8:30 AM — 9:45 AM | Room 106CD

Session 6, Track A: Nitrosamine Impurities – What's New and Where Do We Stand?

The evaluation and management of risks associated with N-nitrosamine impurities in medications is a global effort. Since the introduction of the calls for review and guidance relating to nitrosamine impurities in 2019, there have been further developments and experience gained by both regulators and industry globally. This session will provide Health Canada's and other regulator's current thinking on this subject with an overview of the requirements and approaches being taken to mitigate and manage risks. Industry perspectives on managing these requirements both globally and within Canada will be discussed. As close collaboration with international regulatory bodies has been an integral step taken by Health Canada and industry, information on international collaboration with global regulators and the Nitrosamines International Strategic and Technical Working Groups on the development and understanding of the issues associated with nitrosamine impurities will also be shared.

Learning Objective :

- Understand the global industry and regulator experiences and perspectives on managing these issues and the impact on local and global drug development and supply strategies
- Comprehend the quality and safety topics surrounding nitrosamine impurities
- Define specific attributes of HC's regulatory requirements on HC's Nitrosamines Impurities Guidance and utilization of international collaboration to inform regulatory requirements and decisions

Track: Regulatory

Session Chair(s)

Marcia Sam

Regulatory Affairs Strategy and Policy Manager
Hoffmann-La Roche Canada Limited, Canada

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

Tharany Ganesh

Head, Regulatory Affairs
AstraZeneca Canada Inc., Canada

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

Speaker(s)

Health Canada N-Nitrosamine Impurities Update

Gary Condran

Manager, Quality Risk Management and Operations Division, Bureau of Pharmaceutic
Health Canada, Canada

After obtaining his Chemistry degree from Acadia University in Nova Scotia, Gary Condran was employed for several years in the Regulatory Affairs Departments of two multi-national generic companies in the Toronto area. Gary joined Health Canada in 1995 and has since held several positions across the Department and is currently the Manager of the Quality Risk Management and Operations Division within BPS. He has been HC's rep. on several ICH working groups including the QDG, Q1, Q3A&Q3B and was the Regulatory Chair for the Q11 Q&A document. Gary coordinates actions and responses to Quality risk and drug shortage issues, including those associated with nitrosamines and is Co-Chair of the Nitrosamines International Technical Working Group.

Recommended Acceptable Intake Limits for Nitrosamine Drug-Substance Related Impurities (NDSRIs)

Jason Bunting, PharmD

Science Policy Analyst, Office of the Center Director, CDER

FDA, United States

Jason Bunting, PharmD, is a Science Policy Advisor in the Center for Drug Evaluation and Research (CDER), FDA. He is a member of the Drug Safety Operations (DSO) staff which is responsible for the management of significant and timely drug safety issues. DSO staff lead or serve as members of task forces and work groups providing direction in drug safety and developing regulatory and scientific policy and standards. In addition, Jason is the chair of the REMS Oversight Committee (ROC) and chair of the Emerging Impurities and Contaminants Committee (EICC). Prior to FDA, Jason received his Doctor of Pharmacy degree from the University of Maryland, School of Pharmacy, and worked as a pharmacist and pharmacy district manager for CVS Health.

The Nitrosamines Journey: Industry Quality Perspective

Gair Ford, PhD

Global Regulatory Affairs Director, CMC
AstraZeneca Global, United Kingdom

Gair studied chemistry at Strathclyde University before doing at PhD at the University of Sheffield. Following postdoctoral research at Boston College he returned to the UK and joined AstraZeneca as a process development chemist. After around 20 years in chemical development he moved to CMC Regulatory Affairs at AstraZeneca in 2019 and quickly became involved in the companies management of Nitrosamines risk assessments. He has been privileged to work with a number of external consortia and trade associations in the area including EFPIA and the IQ consortium and also interactions with a number of Regulatory Agencies, giving him a global overview of both the industry and Health Authority views on the risk of nitrosamines

Nitrosamines – What's Next

Joel Bercu, PhD, MPH

Executive Director
Gilead Sciences, United States

Dr. Joel Bercu PhD, MPH, DABT is an Exec. Director in the Nonclinical Safety and Pathobiology group at Gilead Sciences and has over 20 years of toxicology experience in pharmaceuticals. He leads the Environmental and Occupational Toxicology (EOT) group at Gilead. Dr. Bercu is an expert in the safety of impurities, especially mutagenic impurities. He manages the QSAR assessment, and mutagenicity testing of impurities. He also advises on the safety aspects of nitrosamine impurities within Gilead for nitrosamine risk assessments. Currently, he leads workgroups and actively involved with IQ, HESI, EFPIA and PhRMA.

Panelist

Alisa Vespa, PhD

Senior Scientific Evaluator/Safety Subject Matter Expert, Risk Management Divisi
Health Canada, Canada

Alisa Vespa is a senior drug evaluator for the Risk Management Division at Health Canada and has been involved in Health Canada's response to the risk of presence of nitrosamine impurities in pharmaceutical products. Alisa is co-leading the Nitrosamine International Technical Working Group (safety sub-team), a consortium of global regulators that share information on technical issues and approaches to (for example) establish Acceptable Intake limits for

nitrosamine impurities. Alisa is also an active participant in the Health and Environmental Sciences Institute (HESI) sub-teams that are working to address data gaps and improve risk assessments for nitrosamines.

8:30 AM — 9:45 AM Room 118E

Session 6, Track B: Decentralized Clinical Trials

Adoption of decentralized clinical trials (DCTs) has grown over the last few years spurred by the COVID-19 pandemic during which innovative trial operation strategies were needed to ensure that patients could continue to access new investigational treatments. DCTs have shown several advantages including improved patient engagement and outcomes as well as increased clinical trial diversity. While DCTs offer important opportunities to advance patient clinical trial experience and timely access to new therapies, challenges remain to ensure seamless trial execution with the right balance of traditional methods and technology in the best interest of patients. This session will review opportunities and challenges of DCTs from both an Industry and Regulator perspective.

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

- Recognize advantages and limitations of DCTs
- Discuss challenges in DCT implementation & possible solutions
- Define key GCP considerations for DCTs

Track: Clinical

Session Chair(s)

Lorella Garofalo, PhD

Head of Regulatory Sciences
Pfizer Canada, Canada

Lorella has been with Pfizer Canada since 2001 assuming roles of increasing responsibility in clinical research as well as medical affairs and is currently head of regulatory sciences for Pfizer Canada. She obtained a BSc (Honours) in Biochemistry and a PhD in Pharmacology & Therapeutics from McGill University. Prior to joining Pfizer, Lorella was a drug assessment officer at TPD, Health Canada and since 1999 has maintained an academic appointment with the department of Pharmacology & Therapeutics at McGill. She has served as a member of the board of directors/advisory councils for various research organizations and is a member of the regulatory affairs committees of Innovative Medicines Canada and BIOTECanada.

Speaker(s)

Innovation and Decentralized Clinical Trials at Pfizer

Laurie Berry, DrSc

Director of Strategic Partnerships
Pfizer, United States

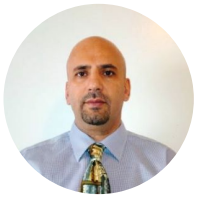
Laurie Berry, Ph D, PMP is Director, Clinical Innovation & Strategic Partnerships, in Pfizer's Global Product Development Operations Center of Excellence. She is responsible for leading Pfizer's Mobile Unit Initiative as well as the Direct to Patient and Clinical Trials Concierge which are part of the Pfizer's Decentralized Clinical Trials Community of Practice. My role is to develop and finding new innovative ways to improve clinical studies. In previous roles, Laurie led Clinical study teams and BLA and EMA submissions for Global Product Development and Research & Development. Prior to joining Pfizer in 1994, earned a BA/BS from St. Anslem College, and a PHD from the University of Vermont in Analytical Chemistry.

Health Canada's Clinical Trial Compliance Program

Kevin Chin

Compliance Specialist
Health Canada, Canada

Kevin Chin holds an Honors B.Sc. in Cell and Molecular Biology from the University of Toronto. He joined the Federal Public Service in 1997 and has been a Compliance Specialist since 2006. He helped in the development and implementation of the Medical Device Establishment Licence Inspection Program and was the Lead on the Pilot Inspection Project for Foreign Medical Device Establishment Licence holders prior to joining the Clinical Trial Compliance Program. In addition to inspections of Sponsors and Qualified Investigator sites, he was also responsible for the Medical Device Investigational Testing Pilot Project that concluded in 2023.



Health Canada's Clinical Trial Compliance Program

Hocine Abid, MD, MBA

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

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

8:30 AM — 9:45 AM

Theatre Hall 201

Session 6, Track C: Good Pharmacovigilance Practices Inspection Readiness

The Good Pharmacovigilance Practices (GVP) Inspection program at health Canada is intended to verify that health product manufacturers meet the requirements of the Food and Drug Regulations pertaining to adverse drug reaction (ADR) reporting. In this session, the Inspectorate representative will discuss the scope of the GVP inspections and

expectations from the regulator. In addition, a representative from the industry will describe best practices for pharmacovigilance inspections readiness requirements including but not limited to key QMS components. Common questions from the industry pertaining to GVP inspection preparation, conduct, and observations will be addressed.

Learning Objective :

- Describe Inspectorate's expectations during Health Canada GVP inspections
- Describe how to be inspection ready and how to navigate a successful PV inspection
- Apply the acquired information to successfully prepare for GVP inspections

Track: Pharmacovigilance

Session Chair(s)

Myriam Salem, MSc

Pharmacovigilance Manager
Health Canada, Canada

Myriam Salem is currently a pharmacovigilance manager in the Health Products and Food Branch (HPFB) at Health Canada. She previously led the Good Pharmacovigilance Practices inspection Program within the Regulatory Operations and Enforcement Branch (ROEB) and worked within HPFB as a senior scientific evaluator for several years. Prior to joining Health Canada, she held various positions in the pharmaceutical industry and academia at Merck Frosst Canada and McGill's Lady Davis Institute. She holds a master's degree in pharmacology from Université de Montréal and a master's degree in Pharmacovigilance and Pharmacoepidemiology from a consortium of European Universities under the EU2P program.

Agnes Jankowicz, MS

Vice President, Pharmacovigilance
Veristat, Canada

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

Nadiya Jirova, MSc

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

Nadiya Jirova is a manager for the Bureau of Biologics, Radiopharmaceuticals and Self-Care Products within the Marketed Health Products Directorate of Health Canada. Her section is responsible for post marketing surveillance of biotechnology products including blood, cells, tissues and organ products. She is also leading a team responsible for post market surveillance of Monoclonal Antibodies for COVID-19. She has over 15 years of experience in pharmacovigilance and risk management for biologic and pharmaceutical

drugs working within Health Canada. Nadiya holds a Bachelor's degree in Biochemistry from McGill University and a Master's degree in Pharmaceutical Sciences with specialization in Drug Development from the University of Montreal.

Speaker(s)

Speaker

Sandra Boulos, MSc

Senior Corporate Regulatory and Enforcement Advisor, Health Product Compliance a
Health Canada, Canada

Sandra Boulos is a microbiologist and immunologist by training, having completed her post-graduate studies in immunology-oncology research. She has experience in the pharmaceutical industry in manufacturing, packaging and QA/QC. She joined Health Canada in 2015 and has been involved in several roles, as a GMP Inspector and Specialist. She recently joined the GVP department as a GVP coordinator, working on updating guidance documents as well as taking part in the modernization of current regulations applicable to the Good Pharmacovigilance Practices.

Pharmacovigilance Inspection Readiness and Quality System

Bertha V Ferrer, MSc, RPh

Senior Director, Head of Quality Management and Inspections
Pfizer, United States

Bertha Ferrer ,Senior Director , Head of Quality Management and Inspections, Pfizer Inc- Based in Peapack, NJ, Bertha l leads a team that collaborates with the Pharmacovigilance Organization to create strategies for inspection readiness and support of inspections and audits globally. Bertha is also the business process owner for the Pharmacovigilance System Master File (PSMF) for multiple regions and countries. Bertha obtained a B.S in Pharmacy from Arnold and Marie College of Pharmacy of LIU and a Master of Science in Regulatory Affairs and Quality Assurance from Temple University and has more than 20 years experience in pharmacovigilance and quality.

Speaker

Paul Baillargeon

Regional Regulatory Compliance and Enforcement Specialist, Health Product
Health Canada, Canada

Chemist by training with 20 years experience in the pharma industry (innovators and generics) in such fields as QA/QC, manufacturing and clinical supplies. Started at Health Canada in 2019 and have been involved in GVP inspections ever since. As an Inspector-Specialist, responsible to not only perform the regular GVP inspections, but to participate in the writing of future guidance documents for the industry as well as taking part in the modernization of current regulations.

9:45 AM — 10:30 AM

Room 106EFG

Refreshments, Exhibits, and Networking Break

10:30 AM — 11:45 AM Room 106CD

Session 7, Track A: Advancements in Regulatory Data Transformation

With the ultimate goal of supporting faster access of therapies to patients globally, panel participants in this session will share their perspectives on considerations around global collaboration and reliance regarding digital advancements. Industry and Health Canada representatives will share their thoughts on current challenges and successes when it comes to collaborative approaches and technological solutions. Accumulus Synergywill present two use cases on how the cloud-based technology was used to enable real time transformative information and data exchange between sponsors and health authorities.

Learning Objective :

- Describe how a fit for purpose and highly secure platform can improve global collaboration
- Understand how a cloud-based data exchange can allow for governed flow of standardized information between life sciences organizations, health authorities and manufacturing sites
- Identify the opportunities for using cloud-based techology to streamline data exchange, analysis and interpretability

Track: Regulatory

Session Chair(s)

Yatika Kohli, PhD, MBA

Chief Regulatory 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.

Tharany Ganesh

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.

Ashley Jones-Mitchell

Director of Regulatory Innovation Strategy & Policy
Accumulus Synergy, United States

Ashley is Director of Regulatory Innovation Strategy & Policy for Accumulus Synergy. With nearly a decade of industry experience, Ashley is dedicated to leading and advocating for regulatory policies of importance. Ashley joined Accumulus Synergy in 2023 from the U.S. Food and Drug Administration, where she spent 17 years in project/program management roles in the Office of Regulatory Policy, Office of Management, Office of Generic Drug Policy, Office of New Drugs Executive Operations, and Office of New Drug Policy. Ashley has her BS of Science in Marketing from The Pennsylvania State University and is currently pursuing a Master of Public Health with a concentration in Public Health Practice and Policy from the University of Maryland.

Speaker(s)

Improving Joint Review Processes and Outcomes - Access Consortium Case Study

Marcin Boruk, MBA, MSc

Manager RMOD, HFPB
Health Canada, Canada

Marcin Boruk has been with Health Canada since 2005 and has worked in the areas review, legislation and business transformation. Currently he is a manager in the Information Sciences and Openness Division, Health Canada supporting the branch in projects related to data governance, stewardships and standards.

Regulatory Reliance: A CMC Post-approval Change Pilot

Cynthia Ban

Global Head, Regulatory CMC, Vaccines
Sanofi, Canada

Cynthia Ban is the Global Head Regulatory CMC & Devices for Vaccines at Sanofi. Senior Global Leader in the pharmaceutical industry specializing in Regulatory Affairs. Worked for small biotech and large multinational companies. Led and developed teams across multiple geographies and a wide range of therapeutic areas including, Vaccines, Oncology, HIV, Specialty Care, Rare diseases and established brands. Highly adaptable with extensive experience in new and rapidly changing environments such as pandemics. A strategic thinker who likes to disrupt the status quo.

10:30 AM — 11:45 AM Room 118E

Session 7, Track B: Clinical Trials: Focus on Patients, Innovation and Automation

This session will discuss how to develop and implement an effective supply chain management, ensure diversity of patients in the clinical trial and improve site and patients experience through implementation of digital protocol.

Learning Objective :

- Describe impact of the digital protocol automation on site and patient experience
- Identify key elements of effective clinical supply chain
- Discuss importance of patients diversity and inclusion

Track: Clinical

Session Chair(s)

Vatche Bartekian, MSc

President
Vantage BioTrials, Canada

Mr. Bartekian is President of Vantage BioTrials, an award-winning Canadian CRO specializing in clinical trial management services. He's contributed his drug development knowledge to the pharma & device industry for over 24 years and has gained vast experience handling complicated trials across an array of therapeutic areas. He has also contributed his knowledge as an Advisor to Global Affairs Canada's Life Science division, and Colorectal Cancer Canada's Scientific Advisory Board for the establishment of a Patient Group Pathway Model to Accessing Cancer Clinical Trials. Vatche was also honored in 2021 by his alma mater, Concordia University, as a "Top 50 under 50 Who are Shaping Tomorrow" for his work in combatting Covid-19.

Oxana Iliach, PhD

Senior Director Regulatory Strategy
Certara, Canada

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

Speaker(s)

Digital Protocol Automation: Eliminating Deviations and Improving the Site and Patient Experience

Joseph Kim, MBA

Chief Strategy Officer
ProofPilot, United States

Joseph Kim brings over 23 years of pharmaceutical expertise to ProofPilot, most recently in a senior leadership role as Senior Advisor in Lilly's Digital Health Office. He brings a wide array of pharmaceutical research industry knowledge and utilizes a unique approach that integrates his experiences working for other Sponsors such as Shire and Merck, CROs, and technology vendors. He has a robust combination of experience across all phases of clinical research, and a well-known history of innovation in the industry, recognized as one of the "Top 100 individuals on the 2015 MedicineMakers Power List," and "20 Innovators Changing the Face of the Clinical Trials Industry" by CenterWatch.

Clinical Trial Distribution in Canada: Patient Diversity and Inclusion

Negar Roofigari-Esfahani, MSc

Clinical Team Lead
Fortrea, Canada

Negar Roofigari-Esfahani, MSc, is a Clinical Trial Lead (CTL) at a large Contract Research Organization (CRO) with a background in Pharmaceutical Sciences. Previously, she worked as a Senior Clinical Research Associate (CRA) across Canada and as a Clinical Research Coordinator and Assistant at leading Montreal research centers, focusing on diverse clinical trials in various medical fields. In 2022, Negar was recognized as the PharmaTimes Clinical Researcher of the Year Bronze winner in the new CRA category. She is passionate about advancing Decentralized Clinical Trials, advocating for their transformative impact, and is committed to mentoring and nurturing aspiring clinical researchers.

Effective Clinical Supply Chain Management

Kaitlin Guarasci, MBA

Business Unit Director
Bay Area Research Logistics, Canada

As Business Unit Director for Bay Area Research Logistics (BARL), Kaitlin is responsible for planning, directing and managing operations, as well as future growth and strategic vision of the organization. She received her BA from Brock University, Pharmacy Technician Diploma at Niagara College, and studied Management with McMaster Continuing Education Center's Business Administration program before completing her MBA at Athabasca University. Kaitlin has developed expert knowledge of the business through experience as Director of Client Services, Business Development Manager, and Clinical Trial Coordinator at BARL and her prior experience as a Research Coordinator at Hamilton Health Science's Pharmacy Research Support Services.

Session 7, Track C: Artificial Intelligence (AI) in Pharmacovigilance

The use of Artificial Intelligence (AI) in pharmacovigilance has been increasing significantly. Companies have demonstrated how AI can be used for processing high volumes of Adverse Events to improve efficiencies without adding any ressources while reducing the risk of human errors.

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

- Recognize when AI can be used for a specific task
- Assess if a specific task would be performed more efficiently by AI than by a person
- Integrate AI to pharmacovigilance systems and workflows

Track: Pharmacovigilance

Session Chair(s)

Vanessa Zapata

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

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

Nadia Mian, MS

Pharmacovigilance Manager
Ipsen Biopharmaceuticals Canada Inc., Canada

Nadia Mian is currently working as local pharmacovigilance lead 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.

Agnes Jankowicz, MS

Vice President, Pharmacovigilance
Veristat, Canada

Agnes is an industry leader with over twenty years of experience in pharmacovigilance (PV) and medical information (MI) both in the pharmaceutical industry as well as in the consulting

environment. She is a Vice President of Pharmacovigilance at Veristat, a CRO whose team includes experienced and dedicated PV professionals. Agnes in an expert PV auditor and a recognized pharmacovigilance educator engaged in teaching pharmacovigilance courses and presenting on various PV topics. Agnes holds a graduate degree in Pharmacology & Toxicology and, prior to joining the pharmaceutical industry, was involved in academic research.

Speaker(s)

Use of Digital Platform to Report Aes

Suzanne Tracy, MBA

Head, Digital Innovation, PV Operations
Moderna, United States

Suzanne has spent a large portion of her career in large multinational pharma companies where she focused on the strategy and implementation of global Pharmacovigilance Systems encompassing Post-Marketed / Clinical Case Handling, Aggregate and Ad-hoc Reporting, and Surveillance activities. She has served as a lead to subject matter experts in the transformation of PV Systems while delivering alignment to industry standards and Health Authority regulations. Having joined Moderna in 2021, Suzanne is leading the integration of AI and ML techniques, data analytics and process automation to accelerate processes, drive quality and ensure compliance with worldwide regulations through innovative solutions.

Use of Digital Platform to Report Aes

Farheen Shaikh, MS

Director - Country Head, Pharmacovigilance, Canada
Moderna , Canada

Farheen heads the Pharmacovigilance team at Moderna Biopharma Canada since Aug 2021. With a Medical background, she was instantly drawn towards Patient Safety and chose Pharmacovigilance as her career path after a brief clinical practice. She has over 17 years of experience in the Pharmaceutical and Health Care industry across 3 different continents, last 11 + years of which have been spent in Canada. Farheen led the North America PV Operations and was the Canadian Local Safety Officer for Teva Canada until 2021 before she moved to Moderna to establish the local PV team at Moderna.

Predictive Modeling to Enhance Real-World Data for Safety Studies: Atopic Dermatitis as a Case Study

Heather Ward, PhD, MS

Director, Safety Surveillance Research
Pfizer, Canada

Dr. Heather Ward is an epidemiologist with over 15 years of experience, specializing in real-world pharmacoepidemiology studies focusing on safety and effectiveness. She completed a PhD in Epidemiology at the University of Cambridge (UK) and an MSc in Nutritional Sciences (Canada). Within the Safety Surveillance Research group at Pfizer, she is responsible for FDA- and EMA-committed post-authorization safety studies. Previously, Dr. Ward developed data collection methods for national cohort studies in Singapore and Qatar, and coordinated an

international cohort for studies of diabetes and cancer. She has published more than 50 peer reviewed publications and authored a chapter in the 2019 International Diabetes Federation Atlas.

11:45 AM — 12:45 PM Room 106EFG

Luncheon, Exhibits, and Networking Break

12:45 PM — 2:00 PM Room 106CD

Session 8, Track A: Do You Have a Handle on Data Transparency? Best Practices for Management and Public Release of Clinical Data and Confidential Business Information

Increased transparency requirements, with the need to protect personal information and confidential business information (CBI) have posed challenges. In this session, we will discuss obstacles faced by Sponsors to share best practices and key considerations for the public release of clinical data, which address feedback from Health Canada on data anonymization and redaction. We will also hear from an end user on use of data gathered from the platform.

Learning Objective :

- Define transparency requirements for sponsors and expectations from regulators
- Describe challenges faced by Sponsors when dealing with data anonymization/redaction
- Discuss best practices and key considerations for public release of clinical data, during dossier preparation and post-approval

Track: Regulatory

Session Chair(s)

Maria Anillo

Regulatory Affairs Project Manager
AstraZeneca Canada Inc., Canada

Maria Anillo is a Regulatory Affairs Project Manager at AstraZeneca Canada Inc. and holds a Master of Science degree in Molecular and Cellular Biology from the University of Guelph. She has over 4 years of experience in the brand name pharmaceutical industry working on both established and marketed products in various therapeutic areas. Prior to joining AstraZeneca, she was a Senior Associate, Established Products & Regulatory Operations at Boehringer Ingelheim (Canada) Ltd. and she completed the Pharmaceutical Regulatory Affairs and Quality Operations at Seneca College. Her current role allows her to expand her regulatory knowledge

and maintain regulatory compliance of approved products.

Brenda Gryfe, MSc

Director, Regulatory Affairs
TPIreg, Innomar Strategies, Canada

Brenda Gryfe has been Director of Regulatory Affairs at TPIreg, a Division of Innomar Strategies since 2014. She is a pharmacist with over 25 years' experience in the pharmaceutical industry. Ms. Gryfe has a business-focused understanding of Regulatory Affairs, gained from experience across several companies. Ms. Gryfe has guided Regulatory teams through a variety of strategically complex regulatory processes. She also provides support to promotional material development teams with regulatory advice and review services for the Canadian drug advertising environment. Since her research at U of Toronto in seniors' understanding of prescription drug labels, Ms. Gryfe retains a particular interest in labeling and patient education materials.

Speaker(s)

Public Release of Clinical Information Industry's Experience and Challenges

Lama Abi Khaled, JD, MBA

Executive Director, Ethics, Legal and Regulatory
Innovative Medicines Canada, Canada

Lama Abi Khaled joined Innovative Medicines Canada in April 2018. She is responsible for all matters related to the industry's ethical standards, regulatory and legal affairs. Lama holds a Biochemistry degree, a master's in business administration and a Juris Doctor from the University of Ottawa. Prior to becoming a lawyer, Lama worked for over 10 years in pharmaceutical pricing and market access both in the private and public sectors. Prior to joining IMC, Lama was In-House Legal Counsel and Compliance Officer at a weight loss company. She also worked at a national Intellectual Property firm in Ottawa and completed her clerkship at the Federal Court of Canada.

Best Practices in Protecting Personal and Confidential Business Information in Clinical Documents for Public Disclosure

Obaraboye Olude, MPH

Clinical Trial Transparency Manager
Privacy Analytics, Inc., Canada

Obaraboye Olude MBBS, MPH is a Clinical Trial Transparency Manager with Privacy Analytics. Obaraboye has an extensive background in medicine and public health, as well as over a decade of experience in clinical trials data analysis. In her 5+ years with Privacy Analytics, she has developed deep expertise in global clinical trial regulations and best practices for successful clinical document submissions. As well as performing, reviewing, and providing training on risk-based anonymization and redaction of personal and commercial information, she has led dozens of successful projects under EMA Policy 0070, HC PRCI, EU CTR and to other Health Authorities.

Proactive and Reactive Strategies for Protecting Personal and Confidential Business Information in Clinical Documents for Public Disclosure

Honz Slipka, MSc

Senior Transparency Specialist
Certara Synchrogenix, Canada

With a background in Neuroscience research, and experience working with several of PharmExec's Top 10 global pharmaceutical companies, I have an extensive understanding of clinical research, regulatory standards and best practices in the field of clinical data privacy, including the anonymization of patient data, as well as confidential business information. I'm using my experiences to lead the field of science, healthcare and research into the modern age of data transparency and digital privacy.

Speaker

Samantha Pollard, PhD, MS

Senior Methodologist
BC Cancer, Canada

Dr. Pollard is a Senior Methodologist within the Department of Cancer Control Research at BC Cancer. She holds a Bachelor of Arts in Philosophy from the University of British Columbia, a Master of Science in Health Research Methodology from McMaster University, and a PhD in Population and Public Health from the University of British Columbia. Dr. Pollard uses mixed methods approaches to evaluate precision oncology innovations from the perspectives of publicly funded health system payers, clinicians, patients, and members of the public. Her work endeavours to support the appropriate, timely, and values-informed integration of precision oncology across Canadian health systems.

12:45 PM — 2:00 PM Room 118E

Session 8, Track B: Clinical and Commercial Challenges of Emerging Therapies: Lessons Learned from Psychedelics and Cannabinoids

This session will discuss challenges and opportunities for psychedelic and cannabinoids clinical development, regulatory strategies, intellectual property and commercialization.

Learning Objective :

- Discuss the challenges and considerations for planning clinical trials with emerging therapies such as psychedelics and cannabinoids including how regulatory and clinical strategy impacts success of obtaining funding and early-stage

investments

- Identify challenges and review lessons learned from conducting clinical trials with psychedelics and cannabinoids
- Discuss Intellectual property and commercialization challenges for psychedelic and cannabinoid compounds

Track: Clinical

Session Chair(s)

Oxana Iliach, PhD

Senior Director Regulatory Strategy
Certara, Canada

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

Sabrina Ramkellawan

Chief Operating Officer
AxialBridge, Canada

Sabrina Ramkellawan started her career as a registered nurse with critical care speciality. She has 25 years of clinical research experience working for Pharma, CROs and Research sites. Sabrina has experience conducting clinical trials with novel therapeutics, vaccines, biologics, NHPs, cannabiniods and psychedelics. Sabrina is also the President of the Clinical Research Association of Canada and Board of Directors for MAPS Canada. She has been actively involved in education including building & teaching clinical research programs. She is currently the COO at AxialBridge with a focus on emerging therapeutics and helping biotech/life science companies navigate regulatory, and clinical operations to conduct clinical trials.

Speaker(s)

Clinical & Commercial Challenges of Emerging Therapies: Lessons Learned from Psychedelics and Cannabinoids

Kim McDonald-Taylor, MS, MSc

Clinical Research Consultant
McDonald-Taylor Consulting, Canada

Kim McDonald-Taylor consults in project management, medical writing, training & teaching being in the clinical trials area for over 35 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 teaches QA & Critical Thinking in Post-Graduate Clinical Research Program at Seneca. 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.

Regulatory Challenges and Considerations Including How to Design Effective Nonclinical and Clinical Program with Psychedelics and Cannabinoids

Ana Dukic, MPharm

RA/QA
Axialbridge, Canada

Ana serves as a quality and regulatory project manager in pharmaceutical and life sciences research. She has held regulatory compliance positions at various research organizations and supported many companies in bringing their products and devices to US, Canadian and European markets. Ana is passionate about improving clinical trials through science and providing validated data for novel therapies. Ana has strong academic background and experience in many therapeutic areas, from mental health and oncology studies to cardiovascular drugs and pulmonary device development. She also has previous experience with validating laboratory procedures and supporting regulatory submissions.

Commercial Challenges of Emerging Therapies: Intellectual property and Commercialization Challenges for Psychedelic and Cannabinoid Compounds

John Greiss, JD, RPh

Senior Associate
Norton Rose Fulbright Canada, Canada

John Greiss provides product regulation and strategic compliance advice to manufacturers, distributors and retailers of pharmaceuticals and medical devices, cosmetics, consumer products, hazardous or dangerous goods and other regulated products. John advises clients on a wide variety of intellectual property and regulatory issues, including licensing, packaging and labelling, product claims and advertising, recalls, facility inspections, product recalls and other product safety issues. He also provides advice on a wide range of contracts, including clinical trials, market research, promotions and sponsorships, manufacturing, supply and distribution, and licensing agreements. John is also a licensed pharmacist.

12:45 PM — 2:00 PM

Theatre Hall 201

Session 8, Track C: When Quantity Affects Quality: The Consequences of Overreporting

Safety reports are submitted to Health Authorities (HA) based on regulatory requirements. Some HAs however, have taken action to receive only Individual Case Safety Reports (ICSR) that will truly add value to assessing the benefit-risk or safety profile of a product. Receiving large amounts of poor-quality safety information impedes HAs from focusing on safety data that really matters. At what point does quantity affect quality?

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

- Identify what is considered as high-quality versus poor-quality safety information
- Recognize the impact of ICSR overreporting on the safety profile of a medication

Track: Pharmacovigilance

Session Chair(s)

Marcia Bailey, BSN, MHS, RN

Safety Evaluation and Risk Management Scientific Director
GSK, Canada

Marcia is a registered nurse with many years of clinical and industry experience. In addition to her past role as a clinical research data management subject matter expert, more than a decade of pharmacovigilance duties has helped Marcia acquire much of the knowledge, skills, and abilities needed to help companies manage today's evolving drug safety responsibilities and regulations. Marcia has been a DIA conference speaker and is currently a Safety Evaluation & Risk Management Scientific Director at GSK.

Vanessa Zapata

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

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

Caroline Croteau, PhD, RPh

Country Safety Lead
Pfizer Canada Inc, Canada

Caroline Croteau has been with Pfizer Canada since 1996 assuming roles of increasing responsibility in medical information as well as medical quality operations and is currently head of the Drug Safety Unit for Pfizer Canada, where she oversees local pharmacovigilance activities. She is a licensed pharmacist with previous experience in both hospital and community settings. Caroline is a graduate from Laval

University, School of Pharmacy and also holds a PhD in Medication and Population Health from University of Montreal, Faculty of Pharmacy.

Speaker(s)

A Systematic Leave In-Leave-out Analysis of the Effect of Solicited Adverse Event Reports on Signal Detection In A Spontaneous Reporting System Database

Manfred Hauben, MD, MPH

Senior Director Product Safety Surveillance and Reporting
Pfizer , United States

Manfred Hauben received his M.D. and M.P.H degrees from New York Medical College, and a Master of Applied Statistics from Pennsylvania State University. He is Senior Director, Risk Assessment and Management at Pfizer Inc. He has published extensively on data mining and artificial intelligence in pharmacovigilance. He was a member of the USFDA-PhRMA Safety Evaluation Tools (SET) Expert Working Group and an EMEA Eudravigilance expert working group on statistical methods for signal detection and team leader for the methodology subgroup of the CIOMSVIII Working Group on Signal Detection and Management in Pharmacovigilance. He is a member of the Drug Safety Research Unit International Working Group on New Developments in Pharmacovigilance.

Overview of the United States FDA IND Safety Reporting Requirements (The Final Rule) and its Impacts

Wendy Manko-Singer, DO

AVP, Global Clinical Safety & PV-Individual Case Medical Review, MRL
Merck Sharpe & Dohme, LLC, United States

Wendy Manko Singer, D.O., FACOOG, is a board-certified Obstetrician & Gynecologist who practiced 15 years of medicine prior to joining Merck Sharpe and Dohme, LLC nine years ago. She is currently the Associate Vice President, Global Clinical Safety and Pharmacovigilance - Individual Medical Review Organization, responsible for the end-to-end medical review aspects of individual case safety reports for regulatory reporting to global health authorities. Wendy received her BS at Ursinus College, followed by her medical degree at the University of New England College of Osteopathic Medicine; she completed an internship in Lancaster, PA, an OB/GYN residency at Ohio University, and then practiced medicine in the suburbs of Philadelphia, PA.

2:00 PM — 2:40 PM Room 106CD

Refreshments, Exhibits, and Networking Break

2:40 PM — 3:55 PM Room 106CD

Session 9 Plenary: How to Make Good Decisions Quickly

Hack the quality-time-cost paradigm. You and the team you lead can use Decision Science to make really good decisions, really fast, without having to pay for all the data you wish you had. Decision Science began in the late 1960's, and was adopted broadly by industry in the 90's, with a dozen of the top biopharmaceutical companies creating internal decision expertise teams to help on large, complex, strategic decisions. Learn their decision making secrets and a streamlined approach you can use on a weekly and daily basis.

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

- Describe 2 mindset shifts for improved decision making
- Use a simple technique broaden their thinking and unlock creativity
- Identify the 3 kinds of decisions most often faced in business and life
- Utilize proven, powerful questions to identify core values and key uncertainties
- Employ proven tactics to structure and make a decision quickly using an archetype

Track: General Session

Session Chair(s)

Tharany Ganesh

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.

Zohra Douida, MPharm, MS, MSc

Head, Regulatory Affairs Canada
Indivior Canada Inc., Canada

Zohra Douida is the Head of Regulatory Affairs for Indivior Canada Ltd.

Marcia Sam

Regulatory Affairs Strategy and Policy Manager
Hoffmann-La Roche Canada Limited, Canada

Marcia Sam is enjoying her role as a Regulatory Affairs Strategy and Policy Manager at Roche Canada. With over 16 years of experience in the Biotech/Pharmaceutical industry, she has a diverse

range of experiences with exposure to different areas of drug development, regulatory submissions in therapeutic areas as Hematology, Neuroscience, Oncology, Virology, Rare Diseases, etc., volunteered on the regulatory affairs committees of IMC, was a past guest speaker and instructor for regulatory courses at Seneca College of Applied Arts and Technology. She holds a BSc (Honours) degree in Neuroscience/Biology from the University of Toronto and a Post-graduate diploma in Pharmaceutical Regulatory Affairs and Quality Operations from Seneca College.

Speaker(s)

Speaker

Tyler Ludlow, MBA

Founder and Chief Decision Scientist
Decision Skills Institute, United States

As a decision scientist, Tyler helps people turn decision burdens into opportunities for growth. After earning a degree in applied math and an MBA, Tyler studied decision science at Stanford. He then spent a decade helping leaders at global 500 firms (including top pharma companies), make large, complex, and strategic decisions. Seeing the human benefits of decision science, he founded the Decision Skills Institute, whose mission is to make the world more deciderate by impacting 10 million decisions in 10 years. Professionally, he now helps employees, entrepreneurs, small business owners, patients, and caregivers learn better decision skills. Personally, he and his wife endeavor to do the same with their ten children.

3:55 PM — 4:10 PM Room 106CD

Closing Remarks

4:10 PM — 4:10 PM

Meeting Adjourns