SPEAKERS' BIOGRAPHIES

Karen Arts

Co-founder and Operation Support, N2 Board Member

Karen was the Executive Director for the Canadian Cancer Clinical Trial Network (3CTN) with its secretariat at the Ontario Institute for Cancer Research in Toronto, Canada. The Canadian Cancer Clinical Research Network (3CTN) is an extensive support network for cancer clinical research, aimed at addressing the impediments to academic clinical trial activities in Canada. The focus of Karen's work at 3CTN was to collaborate with stakeholders in clinical research to achieve enhancements and efficiencies in their infrastructure and processes to enhance the conduct of clinical trials.

Karen holds Masters and Bachelors of Science degrees in Nursing. She graduated with Honours and is a member of Sigma Theta Tau, the Honour Society of Nursing. Karen is certified in several areas, including Oncology, Clinical Research, Nursing Management and Administration, Palliative care, Obstetrics and Gynecology.

Karen has thirty-seven years of professional experience, in the Netherlands and in Canada, both in the pharmaceutical industry and in the public health system in a variety of positions, with a focus on Oncology and clinical research. In the pharmaceutical industry, Karen was employed in several positions in clinical development, operations, and medical communications areas. In the public health system her positions have ranged from staff nurse to educator, nurse-manager, research coordinator and manager; and director.

Karen is one of the founding members and part of the board of directors of the Network of Networks (N2), a not for profit organization, which aims to enhance Canada's clinical research capability and capacity, by providing clinical research professionals with the necessary tools and programs to conduct high quality research with integrity, efficiency and continuous quality improvement; acting as a national voice, advocating on behalf of membership for issues affecting or influencing clinical research in Canada; and serving as a national alliance, bridging regional and provincial initiatives. N2 fosters collaboration among stakeholder groups to strengthen Canada's research enterprise.

Dr. Cecilia Costiniuk

Associate Professor, Division of Infectious Diseases and Chronic Viral Illness Service, McGill University Health Centre

Dr. Costiniuk is an Associate Professor of Medicine in the Division of Infectious Diseases/Chronic Viral Illness Service of the McGill University Health Centre. A clinician investigator, she leads a research program funded by the CIHR and Fonds de recherche du Québec—Santé (FRQ-S) focused on pulmonary immunity and inflammation in the context of HIV infection. Dr Costiniuk also holds a Chercheur-boursier-clinicien Junior 1 salary award from the FRQ-S. Her interest lies in exploring the therapeutic potential of cannabinoids for various conditions affecting people living with HIV in the context of well-designed clinical studies. She is the lead investigator on an upcoming pilot study supported by the CIHR-CTN (PT028) which will investigate the safety, tolerability and effects on inflammation of cannabinoids in the context of HIV infection. Dr. Costiniuk also leads the CTN Cannabis Therapeutics Working group.

Dr. Daniel Keene

Senior Medical Officer and Manager, Office of Clinical Trials for Biological Agents, Health Canada

Dr. Daniel Keene is the senior medical officer and manager of the Office of Clinical Trials for biological agents within Biologics and Genetics Therapies Directorate of Health Canada.

After obtaining his medical degree from the University of Saskatchewan, he completed his post-graduate medical training in pediatrics at the Hospital for Sick Children in Toronto, and neurology at the Montreal Neurological Institute. He is a fellow of the Royal College of Physicians and Surgeons of Canada with speciality certification in both pediatrics and neurology. In addition, he has obtained a Master of Arts in Public Policy from Carleton University and a Graduate Certificate in Academic Excellence in Epidemiology form the School of Public Health, University of Michigan.

Prior to coming to Health Canada, he was an active member of the Medical Faculty at the University Ottawa in the Departments of Pediatrics and Medicine, and Senior Clinical Investigator at the Children's Hospital of Eastern Ontario. He has authored over a 100-peer reviewed scientific articles on variety of topics including identification of pediatric neurological disorders, neuro-oncology, epidemiology and health policy; as well as contributing to several sentinel medical textbooks in these areas.

Dr. Chitra Lalloo

Research Associate Child Health Evaluative Sciences, The Hospital for Sick Children

Dr. Chitra Lalloo is a digital health researcher at The Hospital for Sick Children and Assistant Professor at the Institute for Health Policy, Management, and Evaluation at the University of Toronto. Her work focuses on the use of mobile technologies to support disease self-management in young people with painful health conditions. Today she will be speaking about a new initiative to build and evaluate ResearchKit-enabled electronic consent within the pediatric research setting.

Dr. Carole Légaré, BSc, MD, CCFP, Cert PE & PV

Director, Office of Clinical Trials, Therapeutic Products Directorate, Health Canada

Dr. Carole Légaré completed her medical training at the University of Ottawa, and her postgraduate pharmacoepidemiology and pharmacovigilance training at the London School of Hygiene and Tropical Medicine in the UK. After gaining experience in clinical practice and public health, she joined Health Canada in 2002 where she initially worked in pharmacovigilance. She also worked as a senior medical advisor for the Centre for Biologics Evaluation during the H1N1 influenza pandemic. In 2013, she joined the Therapeutic Products Directorate as the Director of the Office of Clinical Trials, where she oversees all activities related to the approval and pharmacovigilance of clinical trials involving pharmaceuticals as well as Health Canada's Special Access Program. She is currently a member of the ICH E8 working group on General Considerations for Clinical Studies.

Martin Letendre

President, Veritas IRB Inc.

As President of the ethica Group of Companies (which includes ethica CRO Inc. and Veritas IRB Inc.), Martin is responsible for managing the business operations and for leading its Human Research Protection Program (HRPP). Martin is a member of the Quebec Bar and brings close to twenty years of experience in biotechnology law and research ethics. Martin was actively involved in the creation of an on-line tutorial for the institutional research ethics boards affiliated to the Quebec Ministry of Health. Martin also chaired the Research Integrity Committee of the Canadian Institutes of Health Research (CIHR) and was a member of Canada's federal research agencies' Panel on Responsible Conduct of Research (PRCR). Martin currently is a member of the Human Research Standards Organization (HRSO) board of directors and technical steering committee. His in-depth knowledge of the legal, regulatory and ethical complexities of clinical research has been instrumental to the development of innovative, effective and responsible product development strategies. Martin holds a Masters Degree in Law and Bioethics from McGill University, a LLB and a BA in philosophy from Université de Montréal.

Philippe Lucas

Vice President, Global Patient Research & Access, Tilray

Philippe Lucas PhD(c) is Vice President, Global Patient Research & Access at Tilray (www.tilray.ca), a federally authorized medical cannabis production, research and distribution company based in Nanaimo, BC; and a Graduate Researcher with the Canadian Institute for Substance Use Research. His scientific research includes the therapeutic use of cannabis in the treatment of pain, mental health conditions and addiction, and he has been invited to provide expert testimony before the Canadian House of Commons, the Canadian Senate, and the BC Supreme Court.

Philippe first became involved with medical cannabis as a patient, and founded the Vancouver Island Compassion Society in 1999 to serve the needs of patients who might benefit from the medical use of cannabis. He is extremely community involved, and served as a Victoria City Councillor and Regional Director from 2008-2011.

Philippe has received a number of accolades and awards for his work, including the Queen Elizabeth II Diamond Jubilee Medal (2013) for his work and research on medical cannabis, and a Lifetime Achievement Award from the Cannabis Canada Council (2018).

Dr. Tammy Mah-Fraser

Executive Director, Health Platforms, Alberta Innovates, N2 Board Member

Dr. Tammy Mah-Fraser received both her Doctorate in Public Health and Master in Genetic Counseling from the University of Pittsburgh, and undergraduate degree from the University of Alberta psychology and genetics. Tammy is currently the Executive Director, Health Platforms at Alberta Innovates with oversight and involvement on the Alberta Clinical Research Consortium, Alberta Research Ethics Community Consensus Initiative, Cannabis strategy, ethics of innovation, and Alberta SPOR SUPPORT Unit. With an interest in strategic planning on a systems-level, her area of focus is on provincial, multi-stakeholder initiatives and ecosystem transformations that will enhance Alberta's capability to attract and conduct clinical health research and innovation. She has over 15 years of experience in clinical research, regulatory affairs, and research and grant administration in both the United States and Canada specializing in ophthalmology, and pediatric and adult oncology. She has held diverse roles and represents Alberta on a number of national clinical trial initiatives including a Board Member of N2.

Enrico Mandarino

Chair of the Community Advisory Committee, CIHR Canadian HIV Trials Network

Enrico has over 25 years of experience as a healthcare professional within the hospital, educational and pharmaceutical industries. His breadth of experience in healthcare includes progressive positions in diagnostic and clinical research, health policy and quality assurance.

Enrico holds an associates degree in Medical Laboratory Science and a postgraduate certificate as a Clinical Research Associate from the Michener Institute of Applied Health Sciences. As a Regulated Health Professional, he maintains an active practicing registration with the College of Medical Laboratory Technologists of Ontario. Enrico has contributed to numerous public policy and clinical research initiatives and co-authored several published clinical and public policy papers.

Since the early 2000s, Enrico has been on the forefront of informing cannabis public policy and setting a research agenda. Enrico has been a both a participant in cannabis research and a community advisor/researcher on protocol development and knowledge translation.

In 2019, Enrico was appointed as the new Chair of the Community Advisory Committee of the CIHR Canadian HIV Trials Network (the CTN). The committee reviews all protocols and informed consents submitted to the Network and makes recommendations to the Steering Committee (SC).

Enrico is currently the Canadian Director of Training & Quality Assurance with MJardin Canada and is the Quality Assurance Person & Responsible Person for a License Holder. In 2012, Enrico was awarded the Queen Elizabeth Diamond Jubilee Medal, by the Governor General, for his significant contributions to Canada.

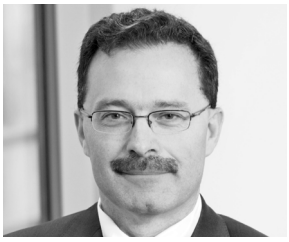
Dr. Frank Naus

Chief Operating Officer, Allphase Clinical Research Inc.

Dr. Frank Naus is the Chief Operating Officer of Allphase Clinical Research Inc., a Canadian CRO headquartered in Ottawa, Ontario. Frank earned his Doctorate in Business Administration from Walden University and has an MBA from Wilfrid Laurier University and MSc and BSc degrees in Applied Health Sciences from the University of Waterloo. Frank started his career in the pharmaceutical and clinical research industry. Prior to joining Allphase, he was Vice President Research at Hamilton Health Sciences.

Jim Pankovich

Vice President, Clinical Operations & Drug Development Qu-Biologics Inc., N2 Chair of the Board



Mr. Pankovich has more than 25 years of experience in the biopharmaceutical industry with extensive strategy development, clinical study management and operational experience. During his career, he has guided the development of novel compounds and biologics for the treatment of various cancers, inflammatory and infectious disease in all phases of clinical development from concept to NDA filing. Mr. Pankovich holds a M.Sc. (Experimental Medicine) from the University of Alberta and an MBA from Queen's University.

André Picard

Health Columnist, The Globe and Mail

André Picard is the health columnist at The Globe and Mail and the author of five books.

Shila Rastegar

GCP Compliance Specialist, Health Canada

Ms. Shila Rastegar has a Master's degree in Biochemistry from the University of Ottawa, and she has twenty-two years of experience working with Health Canada in different divisions. Ms. Rastegar is currently a Regulatory Compliance and Enforcement specialist in GCP Unit in Toronto, Regulatory Operations and Enforcement Branch. Since 2008 she is conducting regulatory inspections of the clinical trials for compliance with the Food and Drugs Act and Food and Drug Regulations, "Drugs for Clinical Trials Involving Human Subjects", at sponsors, Contract Research Organization and Investigator sites. She is also involved in compliance verifications/investigations in the area of clinical research. Furthermore, she is actively contributing to the development of the policies and guidance documents for the program. Prior to that, she was with the Medical Device Unit conducting regulatory inspections of manufacturers, importers and distributors of medical devices in Canada for compliance with the Food and Drugs Act and Medical Devices Regulations.

Dr. Rachel Syme

Assistant Director, Canadian Institutes of Health Research's Institute of Cancer Research, N2 Vice Chair of the Board

Dr. Syme is the Assistant Director with CIHR's Institute of Cancer Research. She received her BSc (Honours) at Queen's University, MSc (Medical Genetics) at the University of Calgary, and her PhD (Microbial Immunology) at the University of Calgary. She carried out post-doctoral work at the Tom Baker Cancer Centre focusing on dendritic cells and cellular based cancer vaccines. She spent a number of years as manager of the Clinical Trials Unit at the Tom Baker Cancer Centre prior to moving to a provincial position as Operations Leader of the Alberta Clinical Cancer Research Unit and then as Executive Director of Research Administration with Alberta Health Services. She currently holds an adjunct assistant professor position with the Department of Oncology at the University of Calgary. She also remains a coordinator and lecturer with the University's Master of Biomedical Technology Program. She is the Vice-Chair of N2's Board of Directors as well as a member of Mount Royal University's Research Ethics Board.

Adrian Thorogood (B.A &Sc., B.C.L.&LL.B., LL.M.)

Academic Associate, Centre of Genomics and Policy, McGill University

Adrian (B.A.&Sc., B.C.L.&LL.B., LL.M.) is a lawyer and Academic Associate at the Centre of Genomics and Policy (CGP) at McGill University. His legal research focuses on how genomic sequencing platforms, information and networking technologies, open science practices, and patient empowerment movements are disrupting biomedical research and health care. He has published numerous articles on health data governance and regulation, the duties and liabilities of health professionals, and the privacy of health information. He is also the Regulatory and Ethics Manager of the Global Alliance for Genomics and Health, a public-private consortium that develops standards for genomic data exchange. In this position, he coordinates the development of policy frameworks addressing consent, privacy and security, and research oversight enabling responsible data sharing between countries, institutions, and sectors.