THE N2 EASTERN REGIONAL MEETING

Canada's Alliance for
Excellence in Clinical Research

NOVEMBER 27, 2019

Population Health Research Institute
& Hamilton Health Sciences
David Braley Research Institute-Auditorium
20 Copeland Avenue
Hamilton, Ontario

N2 NETWORK OF NETWORKS
RÉSEAU DES RÉSEAUX

Population Health Research Institute
HEALTH THROUGH KNOWLEDGE

Hamilton Health Sciences
RESEARCH

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AGENDA

9:00-9:20 AM	Welcome	Janette Panhuis (Chairperson) Jim Pankovich Katie Porter
9:20-9:50 AM	How to Overcome Inspection Phobia! 25 Year Journey to First Health Canada Audit	Dr. Anthony Chan
9:50-10:50 AM	ICH E17 Multi-Regional Clinical Trials: A Brief History of How and Why E17 was Developed • The Canadian perspective on implementation of E17 • The current situation and challenges relating to MRCTs from a regulatory perspective	Dr. Carole Légaré
10:50-11:05 AM	Networking Break	
11:05-11:35 AM	N2 Updates • Message from the N2 Board of Directors • N2 Strategic Objectives	Janette Panhuis
11:35-12:00 PM	N2 SOPs • How to Utilize N2 SOPs in Your Clinical Trials • Group discussion and questions	Keitha McMurray
12:00-1:00 PM	Networking Lunch	
1:00-2:00 PM	E6 Good Clinical Practice (R2) • Overview of the changes made to E6 • Implementation of E6 (R2) in Ontario • Available resources	Dr. Carole Légaré
2:00-2:15 PM	Networking Break	
2:15-3:00 PM	Plans to Modernize Clinical Trial Regulations	Dr. Carole Légaré
3:00-3:30 PM	Reflections and Q&A	Janette Panhuis
3:30-3:40 PM	Closing Remarks	Janette Panhuis

Note: A certificate for Continuing Education credits will be provided to attendees.

SPEAKERS

Dr. Anthony K. C. Chan

Professor, Pediatrics. Chair, McMaster Children's Hospital/Hamilton Health Sciences Foundation Pediatric Thrombosis and Hemostasis.

Dr. Anthony Chan graduated from medical school at the University of Hong Kong in 1987. After an internship and brief training in Nuclear Medicine, he began his pediatric career in 1989 at the University of Hong Kong and, subsequently, at the University of Saskatchewan. Dr. Chan completed his clinical training in pediatric hematology and oncology at the Hospital for Sick Children in 1995. He ran his first clinical trial in 1997. Dr. Chan joined McMaster University in 1993 as a research fellow and moved to The Hospital for Sick Children from 2000 - 2001. He rejoined McMaster University in July 2001 and has been a full professor in the Department of Pediatrics since 2005.

Dr. Chan's main research interest is in the study of the hemostatic system in the young and hemostatic mechanisms related to pediatric diseases. Currently, Dr. Chan is developing a family of novel serpin-glycosaminoglycan covalent complexes. The study of these compounds will further understanding of the mechanisms of action of glycosaminoglycans (eg. Heparin) with serpins (eg. Antithrombin). These compounds are potentially useful in the treatment and prevention of diseases. Potential uses of these compounds includes coating of biomaterials to render them less thrombogenic and, thus, prevent some thromboembolic diseases. In addition to treatment of thrombosis with these novel anticoagulants, Dr. Chan has co-invented a methodology for monitoring thrombin generation potential in the patient samples. He is an inventor with 13 patents (6 issued, 7 pending). Dr. Chan is very involved with clinical research/ clinical trials in pediatric thrombosis and hemophilia, and pediatric stroke.

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.

SPEAKERS

Keitha McMurray, BScN, RN (non-practicing), MSc

Executive Director, Research Integrity & Clinical Research Services Inclusive of the Human Research Protections Program Operations Director, Centre for Clinical Trial Support (CCTS) Sunnybrook Research Institute and Sunnybrook Health Sciences Centre

Keitha is the Executive Director, Research Integrity & Clinical Research Services at Sunnybrook Health Sciences Centre and Sunnybrook Research Institute and is responsible for the Human Research Protections Program including the administration and operations of the Sunnybrook Research Ethics Board (REB) and the clinical research Quality Assurance and Education program. Keitha works with both the REB and the research community to ensure the rights, safety and wellbeing of research participants through ethical oversight, sound research practice and regulatory compliance. Keitha is also the Operations Director of the Centre for Clinical Trial Support (CCTS) which operates in support of Sunnybrook investigators to facilitate the development, coordination and quality conduct of investigator driven clinical trials.

With undergraduate and graduate degrees from the University of Toronto, her previous roles include oncology nurse, clinical trials nurse, clinical trials manager, and both member and Vice-Chair of the Ontario Cancer Research Ethics Board. Keitha has served on multiple local, provincial and national committees paving the way through the complex ethics and regulatory environment. Keitha has also completed advanced leadership courses from both Schulich School of Business and Rotman School of Management and was awarded the Leo N. Steven Excellence in Leadership Award in recognition of exemplary leadership at Sunnybrook (2014).

Janette Panhuis, BScN, MBA

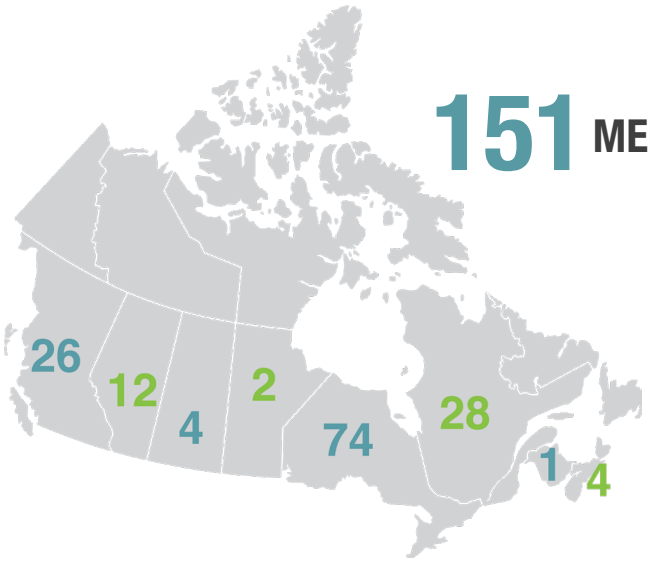
Chief Operating Officer of Population Health Research Institute

Janette is currently the Chief Operating Officer of Population Health Research Institute, a joint research institute with McMaster University and Hamilton Health Sciences Corp. in Hamilton, Ontario, Canada. She has held this position since 2011 and brings over 25 years of pharmaceutical industry experience in research operations and quality assurance. Janette is also a current board member of N2, a position she has held since 2013. Ms. Panhuis holds a Masters of Business Administration from York University and a Bachelor of Science in Nursing from the University of Western Ontario.

ABOUT N2

The Network of Networks (N2) is a not-for-profit alliance of Canadian research networks and organizations working to enhance national clinical research capability and capacity.

N2 provides a common national platform for sharing best practices, resources and research-related content to ensure efficient and high-quality research and integrity of clinical practices by bringing together trialists and clinical research professionals.



MEMBER INDUSTRIES

- provincial initiatives
- health authorities
- health centers
- academic centers
- research networks
- pharmaceutical & biotech companies

MEMBERSHIP TOOLS & RESOURCES

- Clinical research online training programs partnered with CITI
- Bilingual website and resources
- Permission-to-contact roll-out manual
- Preparation assistance for regulatory agency visits
- Toolkits to educate about clinical research
- SOPs as accepted by Health Canada
- Standard guidelines and regulations
- Community collaboration and support