Canadian Cancer Clinical Trials Network

Canadian Remote Access Framework for Clinical Trials (CRAFT) 2.0 Workshop

DoubleTree by Hilton Hotel Toronto Downtown
Toronto Ballroom
March 7, 2025
9:00 am – 4:00 pm

Workshop Objectives:

- To provide an update on the current decentralized clinical trials (DCT) landscape and CRAFT implementation success
- To address CRAFT implementation challenges and areas identified for further refinement:
  - Feasible and cost-effective options for establishing trial clusters
  - Professional liability and indemnity with investigators, healthcare providers, insurers and sponsors
  - Consult with Health Canada to ensure regulations support trial conduct at satellites
  - Inter-provincial barriers

Key questions to address:

- What has changed in the Canadian DCT landscape since 2019?
- What can we learn from CRAFT implementation case examples?
- Does the Framework/Toolkit need to be updated? Expanded?
- What system changes will enable successful implementation and sustainability of CRAFT?

Anticipated Outcomes:

- “What We Heard” document
- Additional CRAFT tools or resources (e.g., toolkit needs)

Production of this CRAFT Workshop has been made possible through collaboration and financial support from the Canadian Partnership Against Cancer Corporation and Health Canada.

WORKSHOP AGENDA

Facilitator: Ross Wallace, Principal, Santis Health

Q&A on Slido: https://app.sli.do/event/jMdfk8JZCfxbXEMnaxzPWB (event code: CRAFT)
Questions can be submitted in advance or in real-time throughout the Workshop.

Time	Topic
8:30 am	Breakfast & Registration
9:00 – 11:45 am	***Setting the Stage: Decentralized Clinical Trials & CRAFT Implementation***
9:00 am	**Welcome & Opening Remarks** Janet Dancey, *Scientific Director, 3CTN*
9:10 am	**Achieving Health Equity in Clinical Trials Through a Teletrial Model** *(prerecorded)* Sabe Sabesan, *Senior Medical Oncologist, Townsville Cancer Centre*
9:25 am	**Advances in Decentralized Clinical Trials in Canada & CRAFT Implementation Barriers and Challenges, Opportunities and Resources** Stephen Sundquist, *Executive Director, 3CTN* Kathy Brodeur-Robb, *Executive Director, C17 Council*
10:05 am	**Geography Should Not Determine Survival: A Patient Perspective on CRAFT** Carla Bossart-Pletzer, *Patient Partner, OICR Patient and Family Advisory Council*
10:15 am	Networking Break
10:35 am	**Panel Discussion: Key Successes and Learnings for DCT and CRAFT** **Panelists:** • **Carla Bossart-Pletzer**, *Patient Partner, OICR Patient and Family Advisory Council* • **Carol Digout**, *Executive Director, APPHON* • **Lauren Gogo**, *Manager of Research Contracts, Hamilton Health Sciences* • **Gillyan Gravelle**, *Manager, Clinical Research – Oncology, Health Sciences North Research Institute* • **Linda Hershon**, *Clinical Research Nurse, CHU Sainte-Justine* • **Patti O'Brien**, *Innovation Lead, Canadian Cancer Trials Group* • **Suzan O'Donnell**, *Clinical Operations Lead, Hoffmann-La Roche Limited*
11:45 – 12:30 pm	Lunch
12:30 – 3:45 pm	***Breakout Discussions***
12:30 pm	**Orientation**
12:40 pm	**Discussion 1:** *Challenges Impeding DCTs (including CRAFT) Today* • Discuss the significance of each challenge. • Beyond supportive resources and systems/processes currently available, what is needed to address each challenge?

1:30 pm	**Discussion 2:** *Solutions for Enabling CRAFT Going Forward*
	• Provide recommendations for addressing each challenge:
	  • Consider how to overcome anticipated hurdles.
	  • Who needs to be involved in the solution (i.e., role of champions and others)
	• What does success look like in 6 months? 3 years?

2:15 pm	Networking Break
2:45 pm	**Report Back**
3:45 pm	**Closing Remarks**
4:00 pm	Adjourn

Speaker Bios

Ross Wallace, *Principal, Santis Health*

Joining Santis in 2014, Ross brings more than 15 years of experience in public affairs, corporate strategy and journalism. In his role, Ross helps organizations working at the intersection of healthcare, life sciences and innovation overcome strategy and policy challenges. Most recently, Ross was the Director of Government Affairs and Corporate Responsibility at AstraZeneca Canada (AZC).
Prior to joining AZC, Ross spent nearly four years as the Director of Strategic Partnerships at the MaRS Discovery District. Ross' experience also includes five years working in Washington, DC – first at the Embassy of Canada and then at the G7 Group, a political and economic consulting company.
Beyond his work at Santis, Ross spent 8 years as an Innovation Fellow at Women's College Hospital, where he advised the Institute for Health System Solutions and Virtual Care (known as "WIHV") on public policy, strategy and stakeholder relations. He has an MPA from Queen's University and an MBA from the University of Toronto, where he delivers regular guest lectures in the Executive MBA program.

***Sabe Sabesan**, Senior Medical Oncologist, Townsville Cancer Centre*

Professor Sabe Sabesan is a senior Medical Oncologist at the Townsville Cancer Centre and James Cook University in North Queensland, Australia and the Clinical Director of the Australian Teletrial Program, Office of Research and Innovation, Queensland Health. He is currently the president of the Clinical Oncology Society of Australia. Leveraging this role, he plans to advocate for creating equitable health systems in Australia and healthy workplace culture as the foundation for human wellbeing.

Stephen Sundquist, *Executive Director, 3CTN*

Stephen has over 25 years of experience in clinical trials and health programs' leadership. His clinical research expertise includes roles in pharma, CRO and academic settings involving the conduct of Phase 1-3b drug, biologic and device trials across a wide range of therapeutic areas. In his role as Executive Director for the Canadian Cancer Clinical Trials Network (3CTN), Stephen is responsible for leading initiatives designed to improve equitable trial access, patient accrual, as well as the efficient, high-quality conduct of academic cancer clinical trials led by the nearly 60 Network Cancer Centers across Canada.

Kathy Brodeur-Robb, *Executive Director, C17 Council*

Kathy is an Executive Director with 20 years of experience with C17 Council, a national non-profit research network linking all pediatric oncology/hematology/BMT programs across Canada. She is knowledgeable and involved in the current regulatory, ethics, legal and political landscape of clinical research in Canada and a contributing member of numerous national committees.

Carla Bossart-Pletzer*, Patient Partner, OICR Patient and Family Advisory Council*

A mother of two small children and a freelance designer and illustrator, Carla was diagnosed with stage-III, triple negative, inflammatory breast cancer at age 34. She is focused on communicating the challenges of early adult cancer and the long-term health consequences of both lifesaving and prophylactic treatments as a carrier of BRCA1, MSH-6, ATM and MUYTH genetic mutations. Located in Sudbury, Ontario, she advocates for expedient and socially equitable cancer diagnoses and treatment for patients of Northeastern Ontario. She is a member of OICR's PFAC, Vice Chair of her hospital PFAC, and co-founded the HSNRI Patient Partners in Research Program.

Carol Digout, *Executive Director, Atlantic Provinces Pediatric Hematology/Oncology Network (APPHON)*

Carol is the Executive Director of APPHON. APPHON has developed and implemented a shared Levels of Care framework that has been in use since 1995. Carol is the Vice Chair of the IWK Research Ethics Board, past Chair of the Psychosocial Quality/Site team for both pediatric/adults in NS, member of the Scientific Review Committee at the IWK, member of the NSH Cancer Quality Council, and member of the iPOG Network steering committee.

Lauren Gogo, *Manager of Research Contracts, Hamilton Health Sciences*

Lauren Gogo is an accomplished research management professional and the Manager of Research Contracts at Hamilton Health Sciences, one of Canada's leading research hospitals. A strong leader in the academic and health sectors, Lauren has extensive knowledge of clinical research agreements and various health policies related to clinical trials and other research, both in Canada and internationally. With over 14 years of experience working in non-profit, university, and hospital settings, Lauren has reviewed contracts, drafted and reviewed granting applications, negotiated commercialization terms and intellectual property agreements, and provided expert advice on clinical trial regulations and privacy considerations in accordance with PHIPA. Her wealth of experience ensures that research agreements and processes are managed efficiently and in compliance with relevant policies. In her current role, Lauren oversees a dedicated team of contracts and grants professionals, managing the review, negotiation, and execution of research-related agreements. She also actively contributes to the development of research policies and plays a key role in strategic projects aimed at enhancing research capabilities. Lauren's collaborative approach extends to participating in working groups to further strengthen research contracts and foster key partnerships. In addition to her managerial duties, Lauren has delivered numerous internal and external presentations on topics including the clinical trials process, clinical trial registration, privacy in research, and contracts & ethics, sharing her expertise with a wider audience to advance knowledge in these critical areas. With her strong leadership and commitment to healthcare research, Lauren continues to make a significant impact on the research landscape at Hamilton Health Sciences. Lauren has a Master in Biomedical Technology (MBT) from the University of Calgary and is a member of the Board of Directors of the Canadian Association of Research Administrators (CARA).

Gillyan Gravelle, *Manager, Clinical Research – Oncology, Health Sciences North Research Institute*

Gillyan Gravelle, RN, is an accomplished Oncology Clinical Research Manager with a comprehensive background in nursing, healthcare leadership, and clinical research. Currently serving at Health Sciences North Research Institute, Gillyan oversees the management of oncology clinical trials, ensuring seamless cross-functional collaboration, regulatory compliance, and financial oversight. With a commitment to innovation and patient-centered care, Gillyan leverages advanced training in Change Management, Leadership Development, and Lean Methodologies to optimize clinical research processes and drive continuous improvement in oncology research and patient outcomes.

Linda Hershon, *Clinical Research Nurse, CHU Sainte-Justine*

Linda Hershon is an experienced pediatric oncology clinical research nurse working at CHU Sainte-Justine. She is the Children's Oncology Group lead Clinical Research Associate for her institution and enjoys mentoring team members. She is Vice President of the Quebec Association for Nurses in Oncology and Medical Director of the Tip of the Toes Foundation that brings teens and young adults living with cancer to wilderness expeditions.

Patti O'Brien, *Innovation Lead, Canadian Cancer Trials Group*

Patti O'Brien has a Bachelor of Science in Occupational Therapy from Queen's University and a Master of Science in Rehabilitation from the University of British Columbia, as well as her Project Management Professional (PMP) Certification. After working clinically as an Occupational Therapist for 10 years, Patti has been working in research at Queen's University for 23 years and at the Canadian Cancer Trials Group (CCTG) for 19 years. She has worked as Study Coordinator for multiple large international registrational and non-registrational trials throughout the entirety of this period, as well as being a team leader in the Office of Clinical Trials Management for 10 years and then as the Innovation Lead at CCTG for the past 5 years. In her position as Innovation Lead, Patti has helped lead several cross-portfolio initiatives, including the Patient Sharing or Decentralized Clinical Trials activities at CCTG.

Suzan O'Donnell, *Clinical Operations Lead, Hoffmann-La Roche Limited*

Suzan O'Donnell is a Clinical Operations Lead at Roche in Mississauga. She has been with Roche for 9 years, working in both country and global clinical operations in oncology. Prior to her work at Roche, she was a Research Manager at Sick Kids working in inflammatory bowel disease, a Research Coordinator at Population Health Research Institute working in cardiology and a Study Site Coordinator at St. Michael's Hospital working in electrophysiology for almost a decade. She is passionate about helping patients get access to treatments and is grateful for the opportunity to contribute to the CRAFT 2.0 discussions today.