CAPT Conference Workshop
October 21, 2018
Chelsea Hotel, Rossetti Room
33 Gerrard St W, Toronto

Workshop Title

Defining "Decision-Grade" Real World Evidence (RWE) and its Role in the Canadian Context: A Design Sprint

Objectives

1. To identify the value and applications of RWE in supporting pharmaceutical regulatory and reimbursement decision-making.
2. To identify the conditions upon which RWE will be considered of sufficient quality to inform decision-making.

Agenda

Timing	Topic	Presenter/ Facilitator
9:00 – 9:15	Welcome and Design Sprint Overview	Allan Gillman
9:15 – 10:15	Lightning Talks	Tammy Clifford, Rhonda Kropp, Kelvin Chan, Michael Duong
10:15 – 10:30	Break	
10:30 – 10:45	Design Challenge Statement and Case Study Presentation	Dan Palfrey
10:45 – 12:45	Identification of Applications of RWE (Breakout Rooms – Sprint 1)	Kimberly Robinson, Peter Dryda
12:45 – 1:30	Lunch	
1:30 –2:30	Identification of "Decision-Grade" Quality Standards (Breakout Rooms – Sprint 2)	Kimberly Robinson, Peter Dryda
2:30 - 2:45	Break	
2:45 – 3:45	Identification of Implementation Considerations	Dan Palfrey
3:45 – 4:00	Wrap-Up & Adjourn	Tammy Clifford and Rhonda Kropp

Speaker Biographies

Dr. Tammy Clifford

Dr. Tammy Clifford is presently CADTH's Chief Scientist and Vice President, Evidence Standards. Over the past dozen years, she has held a number of senior leadership roles at CADTH. She is actively engaged in many national and international HTA activities, including serving as a deputy editor with the *International Journal of Technology Assessment in Health Care*, and was the co-chair of the International Scientific Programme Committee for HTAi 2018, that was held in Vancouver in June 2018. Tammy holds a PhD in Epidemiology & Biostatistics, and is on faculty with the University of Ottawa's School of Epidemiology and Public Health. At the end of October, Tammy will become the Vice President, Research Programs at CIHR.

Rhonda Kropp

Rhonda Kropp is currently the Director General for the Marketed Health Products Directorate in the Health Products and Food Branch of Health Canada. She is responsible for the oversight of the vigilance of marketed health products in Canada, including ensuring Canadians and health professionals are informed of important issues impacting the safety and effectiveness of health products in a timely fashion.

Rhonda has been working in health policy, programs and surveillance for over 20 years as a nurse, microbiologist, researcher and infectious disease epidemiologist. She undertook her graduate training in public health at the University of California, Berkeley. After a few years directing public health research projects in California for the state government, Stanford University and the University of California, San Francisco, Rhonda joined the Government of Canada in 2003.

During her fifteen years with the Government of Canada, Rhonda has taken on a diversity of roles in the federal health portfolio in the areas of sexual health, travel health and infectious disease prevention and control before joining the regulatory environment. Rhonda was the proud recipient of the Chief Public Health Officer of Canada medal in 2017.

Dr. Kelvin Chan

Dr. Kelvin Chan is a medical oncologist at the Sunnybrook Odette Cancer Centre, an associate professor at the University of Toronto, and an associate scientist at the Sunnybrook Research Institute. He specializes in GI oncology and head and neck oncology. As a clinical epidemiologist and biostatistician, Dr. Chan's research interests include health services research, health technology assessment, meta-analysis including network meta-analysis, cost-effectiveness analyses, and statistical methods research in health economics. He is co-director at the Canadian Centre for Applied Research in Cancer

Control, funded by the Canadian Cancer Society. Professionally, Dr. Chan has an interest in cancer drug reimbursement related issues. He is a member of multiple provincial and national committees related to cancer drug assessments and recommendations including the Committee to Evaluate Drug, and the Ontario Steering Committee of Cancer Drugs, which he currently chairs. He is also the clinical lead for the Provincial Drug Reimbursement Programs at Cancer Care Ontario.

Dr. Michael Duong

Dr. Michael Duong is the Director for Personalized Healthcare and Evidence Generation in Medical Affairs for Hoffmann-La Roche Limited. In this role, Michael manages a team responsible for medical research in Canada, including clinical trials, real world data sciences, health outcomes research, and biostatistics. In addition, Michael is responsible for Roche's strategy to advance the personalization of healthcare in Canada. Prior to that, Michael led Health Economics at Roche in the Reimbursement and Health Economics Department. In that role, Michael provided expertise and guidance over the health economic and outcomes research activities conducted at Roche Canada. Prior to that Michael spent three years in health care consulting, specializing in health economics and outcomes research, and medical communications. Michael received his undergraduate degree in Biology and Pharmacology and a Ph.D. in Medical Sciences with a specialization in Neuroscience, both from McMaster University.