



CAPT ACTP

**The Canadian Association for Population Therapeutics/
Association Canadienne pour la Thérapeutiques des Populations
Presents:**

Taking Action on Real World Evidence: From Analysis to Impact

PROGRAM

**October 22nd – 23rd, 2018
MaRS Discovery District
101 College Street
Toronto, Ontario**

CAPT-ACTP MISSION & VISION

The CAPT-ACTP Mission is to advance population-based research of therapeutic interventions to improve the health outcomes of Canadians by:

- Bringing together diverse perspectives
- Facilitating open exchange of ideas and collaboration, and
- Influencing policy and practice

The CAPT-ACTP Vision is to become the recognized Canadian leader for linking population-based therapeutic research, policy and practice to optimize health outcomes.

www.capt-actp.com

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Message from the President

It is my very great pleasure to welcome all of you to the 2018 Canadian Association for Population Therapeutics (CAPT)-Association Canadienne pour la Thérapeutique des Populations (ACTP) annual conference! Our theme this year is “Taking Action on Real World Evidence: From Analysis to Impact.” Early on in the planning of the conference, it became very clear we had picked a topic that was top of mind for our members, and partners, as evidenced by our pre-conference workshop, co-sponsored by the Canadian Agency for Drugs and Technology in Health (CADTH), Health Canada and the Institute for Health Economics (IHE).

The CAPT-ACTP Scientific Program Committee has put together an outstanding agenda, with the goal of bringing together perspectives from academia, industry, government, and health system leaders for a thoughtful and collaborative exchange of ideas.

This year CAPT-ACTP achieved an important milestone, hiring our first ever Executive Director, Marjorie Morrison. We welcomed Marjorie to CAPT-ACTP on August 1, 2018, and, already, she's made important contributions to our organization, not the least of which is a much enhanced CAPT-ACTP presence on Twitter. With Marjorie's help, we plan to expand offerings to our membership beyond the annual Conference over the coming year, and into the future. Marjorie joins Peggy Kee as CAPT-ACTP staff. Peggy provides secretariat support for our organization, and is also responsible for organizing logistics for the conference. There would be no CAPT-ACTP conferences without Peggy, and I want to thank her on behalf of the Board and membership for her incredible commitment to our organization.

On behalf of the CAPT-ACTP Board and Membership, I want to sincerely thank all the people and organizations who have made this event possible. The CAPT-ACTP Scientific Program Committee (SPC), Local Organizing Committee, and Partnership Committee, and the CAPT-ACTP Secretariat have all worked extremely hard for the better part of a year to bring this conference together, and I am personally grateful to them, and inspired by their efforts. In addition to hard work and dedication, an event like this requires sufficient funding. Our funding comes from sponsors, many of whom have supported CAPT-ACTP consistently for years. We would not be here if not for their contributions. Finally, I want to recognize the speakers who volunteer their time to provide the content for the conference, and also the participants joining us for these two days.

I hope to speak with many of you personally during the conference, and I hope you will join us at our Monday evening poster presentation session, to ask questions of presenters, and mingle with CAPT-ACTP Board members and fellow Conference participants.

Please take the time to complete our daily surveys. We need your input to ensure we are providing you with relevant and timely information. We're particularly interested in your ideas for a theme for the 2019 CAPT-ACTP Conference. Your volunteer Board members will start planning for 2019 as you're leaving us at the end of what promises to be a very successful, informative and thought-provoking 2018 Conference.

Make sure to follow us on Twitter at @CAPT_ACTP and please tweet your conference observations over the next two days with the hashtag #CAPT-ACTP2018.

Kimberly Robinson
CAPT-ACTP President

Conference Overview

The theme for this year's CAPT-ACTP conference is timely – Taking Action on Real World Evidence (RWE): From Analysis to Impact. As regulatory agencies approve more technologies with the requirement for subsequent data (e.g. NOC/c approvals) and health technology assessment (HTA) agencies move towards appraising products throughout their lifecycle, now more than ever, is the time to review the current status of RWE in Canada and what the future holds.

The CAPT-ACTP Scientific Program Committee (SPC) has worked diligently with our panelists and sponsors to create a program that touches as many relevant questions related to RWE, with as high a quality and diverse a group of speakers, from academia, government, industry, and patient representatives, as possible.

We begin with the pre-conference workshop that has been organized through partnership between CAPT-ACTP, CADTH, Health Canada and IHE. This interactive workshop is aimed to inform ongoing work to develop regulatory and HTA guidance.

The conference itself will address the “5 W’s” of RWE, starting with an introductory session addressing where RWE is at in Canada and where is it going, followed by who needs to be involved, from a stakeholder perspective, and when do we need to start planning for RWE. The first day’s agenda will also include oral presentations of the 8 top-ranked posters and will finish with a key note speaker, Professor Torill Tveito, who will provide insight into RWE in Norway, and a poster presentation session.

Our second day opens with a breakfast workshop examining methodological issues relating to RWE, followed by RWE case studies that demonstrate what the experience has been to date making health care decisions based on RWE, capped with two final sessions looking at why it’s important we try to get it right with RWE in Canada and how we can move forward together.

Thank you again to the members of the SPC and our speakers for contributing to what is bound to be an interesting, interactive conference and I look forward to hearing from our members about your experience.

Lois Mitchell
CAPT-ACTP Scientific Program Committee Chair

Pre-Conference Workshop

As part of its mission to advance population-based research of therapeutic interventions to improve the health outcomes of Canadians, CAPT-ACTP in conjunction with CADTH, Health Canada, and IHE is pleased to host a pre-conference workshop on:

Defining “Decision-Grade” RWE and its Role in the Canadian Context: A Design Sprint

While active participation in the workshop is limited to invited attendees, CAPT-ACTP has secured access to the workshop for its conference attendees to observe and provide comments for potential inclusion in the report. CAPT-ACTP observers will also have an opportunity to see the final report.

Unfortunately due to space and other constraints, participation of CAPT-ACTP members may be limited. As a result, expressing an interest in attending does not ensure that you will be able to attend. CAPT-ACTP will do its best to provide out of town members with as much lead time as possible to facilitate travel and other arrangements.

8:30AM – 12:00PM Registration

Location: Rossetti Room, Third Floor, Chelsea Hotel

9:00AM – 5:00PM CAPT-ACTP, CADTH, Health Canada and IHE Present: Defining “Decision-Grade” RWE and its Role in the Canadian Context: A Design Sprint

Location: Rossetti Room, Third Floor, Chelsea Hotel

Workshop Overview: The intent of this full day meeting is to engage stakeholders and identify the appropriate use of RWE to support decision-making, both from a regulatory and HTA/payer perspective. This includes a shared understanding of the type of decisions RWE can most usefully support, as well as conditions upon which RWE will be considered of sufficient quality to support decision-making. The workshop will employ a Design Sprint approach, in order to develop a prototypical or example oncology therapeutic *Lifecycle Evidence Development Plan*, defining where RWE can be useful and the quality standards, as well as next steps/questions to answer in order to implement the plan (e.g., data access).

Workshop 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.

Monday, October 22, 2018

7:00AM – 8:45AM Registration / Breakfast (Sponsor: Allergan)
Location: Lower Concourse Auditorium Foyer

8:45AM – 9:00AM Welcome to Day 1
Location: Lower Concourse Auditorium
Speaker: Kimberly Robinson, CAPT-ACTP President

9:00AM – 10:15AM Session 1: Where is RWE at in Canada & Where is it Going?
Moderator: Bernie Boxill (STI Technologies)
Speakers: Dr. Winson Cheung (Cancer Control Alberta), Dr. Tammy Clifford (CADTH), Martine Elias (Myeloma Canada), Rhonda Kropp (Health Canada), Brad Millson (IQVIA)

Session Overview: In this introductory session, we will examine when and where RWE has been used in Canada to date, and what the future looks like for collecting, analyzing and interpreting real world data. The panelists will focus on examples from their perspective and experience, that will demonstrate the opportunities and limitations/stumbling blocks of the implementation of RWE in this country, with an emphasis on where we are going.

10:15AM – 10:45AM Break (Sponsor: Astellas)

10:45AM – 12:00PM Session 2: Stakeholder Engagement in RWE Oncology (Sponsor: Merck)
Moderator: Virginie Giroux (Merck)
Speakers: Alexandra Chambers (CADTH), Carole Chambers (Alberta Health Services), Sujitha Ratnasingham (ICES), Barry Stein (Colorectal Cancer Canada)

Session Overview: As interest in utilizing RWE to inform HTA and reimbursement decisions continues to expand, multiple stakeholders are examining the potential impact and opportunities of this new approach. Recently, an initiative involving public payers, representatives of CADTH and health policy experts was launched to develop a RWE framework to support cancer drug funding decisions. This framework will be used to facilitate reassessment and validation of currently reimbursed cancer therapies. This panel will discuss the role of RWE throughout the patient access pathway, especially in the context of HTA and funding decisions, as well as provide examples and opportunities for various stakeholders to collaborate with payers on RWE initiatives.

12:00PM – 12:25PM Session 3A: Oral Presentations of Top-Ranked Posters
Moderator: Lois Mitchell, CAPT-ACTP President Elect

1. Patient characteristics, treatment patterns and survival for unresectable stage III non-small cell lung cancer in Ontario, Canada (**Soo Jin Seung**)
2. Influence of opioid prescribing standards on drug utilization among patients with chronic opioid use: a retrospective cohort study (**Richard Morrow**)

3. Estimating the Impact of Treatment Evolution in Non-Small Cell Lung Cancer (NSCLC): the iTEN model (**Manjusha Hurry**)

12:25PM – 1:15PM **Lunch** (*Sponsors: AstraZeneca Canada Ltd. & Biogen*)

Location: Lower Concourse Auditorium Foyer

Student Networking

Location: Lower Concourse Auditorium

Organizer: Jennifer Donnan (Memorial University of Newfoundland)

1:15PM – 2:30PM **Session 4: Leveraging CADTH's Scientific Advice Program for Early Feedback: From Phase 2 to RWE** (*Sponsor: Takeda*)

Moderator: Ross Selby (Takeda Oncology)

Speakers: Dr. Megan Bettle (Health Canada), Dr. Muhammad Mamdani (St.Michael's Hospital), Suzanne McGurn (Ontario Public Drug Program), Dr. Amy Sood (CADTH)

Session Overview: This panel will consider the following questions with respect to CADTH's Scientific Advice Program: How does CADTH's Scientific Advice program improve overall trial design? In the absence of an RCT, can the program be used to provide guidance on RWE to help support earlier access of innovative medicines for patients? What outcomes can be expected from the program? What does the future of CADTH's Scientific Advice Program look like? From each panelists' perspective, what are practical next steps for CADTH's Scientific Advice program to continue to support earlier access of innovative medicines for patients?

2:30PM – 3:00PM **Break** (*Sponsor: Boehringer-Ingelheim Canada*)

3:00PM – 3:45PM **Session 3B: Oral Presentations of Top-Ranked Posters**

Moderator: Lois Mitchell, CAPT-ACTP President Elect

1. Real-world safety of second-generation direct-acting antivirals in Hepatitis C (**Marina Machado**)
2. Interrupted time series analysis of long-acting injectable antipsychotic use (**Donica Janzen**)
3. Outcomes of metastasectomy in metastatic renal cell carcinoma patients: The Canadian Kidney Cancer information system experience (**Sara Nazha**)
4. A non-opioid alternative to intravenous (IV) opioids in emergency departments (ED) would significantly reduce the economic burden on the healthcare system. A societal perspective cost-consequence analysis (**Sebastien Dao**)
5. Time trends among new users of osteoporosis drugs over 20 years: considerations for pharmacoepidemiologic study design (**Kaley Hayes**)

3:45PM – 4:30PM **Global Best Practices: Lessons from Norway**

Speaker: Professor Torill H. Tveito, (University of South-Eastern Norway)

Session Overview: Norway consistently scores very high on different rankings in health care performances worldwide and can potentially provide some lessons into how real world data can be collected and utilized to improve health outcomes in Canada. RWE successes and challenges, and a look at the future of RWE in Norway will be discussed.

4:30PM – 4:45PM Day 1 Summary

Speaker: Kimberly Robinson, CAPT-ACTP President

4:45PM – 6:00PM Poster Presentation Session (Sponsors: Amgen Canada Inc. & Novartis)

Location: Lower Concourse Auditorium Foyer

Drinks, Food Stations and Hors D'oeuvres

Location: Lower Concourse Auditorium Foyer

Tuesday, October 23, 2018

7:00AM – 8:45AM **Registration / Breakfast** (Sponsors: Celgene & CIHR)
Location: Lower Concourse Auditorium Foyer

7:30AM – 8:30AM **Breakfast Workshop: Advancing the RWE Methodological Toolbox**

Location: Lower Concourse Auditorium
Presented by: CAN-AIM, CNODES, MAGIC
Moderator: JM Gamble (University of Waterloo)

Speaker 1: Dr. Robert Platt (CNODES)
Topic: Creative use of study design in distributed networks: examples from CNODES.

Speaker 2: Dr. Michal Abrahamowicz (CAN-AIM)
Topic: Application of competing risk analysis

Speaker 3: Dr. Andrea Tricco (MAGIC)
Topic: Integration of individual level patient data into network meta-analysis

Session Overview: The objective of this session is to learn about the application of advanced methods that further advance the science of using real-world evidence to answer questions regarding drug safety and effectiveness. Researchers from three DSEN teams will provide examples of how their team uses novel methods in addressing a drug safety or effectiveness question.

8:45AM – 9:00AM **Welcome to Day 2**

Location: Lower Concourse Auditorium
Speaker: Kimberly Robinson, CAPT-ACTP President

9:00AM – 10:15AM **Session 5: How RWE Can Inform Reimbursement Questions: A Case**

Study Approach (Sponsor: Bristol-Myers Squibb)

Moderator: William Dempster (3Sixty)
Speakers: Donald Allard (Bristol-Myers Squibb), Bob Bick (Kidney Cancer Canada), Sylvie Bouchard (INESSS), Dr. Bill Evans (McMaster), Dr. Michael Jewett (Princess Margaret Hospital), Angie Wong (Ontario Public Drug Program)

Session Overview: Real world data are being collected on more wide ranging platforms, by more diverse communities, especially as the time between the approval of a drug and its reimbursement on public drug plans lengthens in Canada. How these data (e.g. from patient registries, patient support programs) can be effectively used to assist in reimbursement, and other clinical decisions, will be examined, as well as the role the research community can play in compiling and distributing the results.

10:15AM – 10:45AM **Break** (Sponsor: Eisai Ltd.)

10:45AM – 12:00PM Session 6: Are We Ready for RWE: What do We Need to Create RWE from a Technical Perspective?

Moderator: Wanrudee Isaranuwatchai (St. Michael's Hospital)

Speakers: Dr. Kelvin Chan (Sunnybrook Odette Cancer Centre), Claire de Oliveira (CAMH), Professor Jeffrey Hoch (University of California), Charles Victor (Institute for Clinical Evaluative Sciences)

Session Overview: This session will present the readiness around system, data, and methods for real world analysis. The panelists will discuss their work in real world evidence including challenges and potential solutions from their experiences and perspectives (system, data, methods, and clinical). The discussion will help us assess our readiness for RWE (and what we need to make it happen) from a technical perspective.

12:00PM – 1:00PM Lunch (Sponsors: IQVIA and Leo Pharma)

Annual General Meeting

Location: Lower Concourse Auditorium

Speaker: Kimberly Robinson on behalf of the CAPT-ACTP Board

1:00PM – 2:15PM Session 7: Use of RWE in Decision Making: Now & in the Future

(Sponsor: Janssen Canada Inc.)

Moderator: Don Husereau (University of Ottawa)

Speakers: Dr. Tarry Ahuja (CADTH), Dr. Kelvin Chan (Sunnybrook Odette Cancer Centre), Janey Shin (Janssen Canada Inc.), Dr. Mina Tadrous (Ontario Drug Policy Research Network)

Session Overview: This session will draw on the diverse perspectives of the accomplished panel (from academic to HTA to industry and beyond) to build on the Part 1 discussion of challenges and delve deeper into how various stakeholders can practically move forward. Using a pertinent and timely case study, the panel will: apply learnings from navigating RWE challenges in the *past*; discuss current acceptance of RWE and efforts to implement guidelines at *present*; and develop a shared vision for use of RWE in health care decision making in the *future*.

2:15PM – 2:45PM CAPT-ACTP Awards Ceremony (Kris Schindel Award), Closing Remarks

Location: Lower Concourse Auditorium

Speaker: Lois Mitchell, CAPT-ACTP President 2019

For any inquiries (abstracts, hotel, registration, etc.), please contact Ms. Peggy Kee (peggy.kee@sunnybrook.ca), or visit the CAPT-ACTP website at: (www.capt-actp.com).

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