CAPT ACTP

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

Presents:

Driving Health Innovation: Harnessing the Power and Value of Real-World Evidence

PROGRAM

**October 21st – 22nd, 2019
MaRS Discovery District
101 College Street
Toronto, Ontario**

CAPT-ACTP MISSION & VISION

The CAPT-ACTP Mission is to advance epidemiologic research of therapeutic and other health interventions in Canada by:

- Bringing together diverse perspectives in a neutral forum
- Facilitating open exchange of ideas and collaboration
- Influencing policy and practice

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

www.capt-actp.ca

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Message from the President

Welcome to the 2019 Canadian Association for Population Therapeutics (CAPT) / Association Canadienne pour la Thérapeutique des Populations (ACTP) annual conference, as CAPT-ACTP continues its mission to advance population-based research of therapeutic interventions to improve the health outcomes of Canadians by:

- Bringing together diverse perspectives in a neutral forum
- Facilitating open exchange of ideas and collaboration
- Influencing policy and practice

We aim to continue to pursue our mission at this conference, as we delve deeper into real-world evidence with this year's theme **"Driving Health Innovation: Harnessing the Power and Value of Real-World Evidence"**

Firstly, I would like to thank you for attending this conference and for all our sponsors and presenters, who have supported us today and over the years - without you, there would be no conference.

Secondly, I would like to thank the CAPT-ACTP Board and the various committees that have worked throughout this past year, to not only bring together this conference, but also the other CAPT-ACTP offerings, such as the four webinars we held, the member's survey and the strategic planning session we conducted earlier this year. We're planning more outreach, more engagement for our members, so stay tuned to your inbox and your Twitter & LinkedIn accounts to find out about our future plans.

For this year's conference, on behalf of the CAPT-ACTP Board and Membership, I want to thank, in particular, the Scientific Program Committee and the Local Organizing and Partnership Committees, who have all worked hard to bring this conference together.

Besides the conference sessions, we will be holding our Monday evening poster presentation session showcasing the research accomplishments of CAPT-ACTP members and we look forward to seeing everyone there. On Tuesday, please plan on joining us at the Annual General Meeting, over the lunch hour.

For the students, there will be a mentoring session during the lunch hour on Monday, as well as a reception, following the poster session, later that day.

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 2020 CAPT-ACTP conference.

And, 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_ACTP2019.

Lois Mitchell
CAPT-ACTP President

Conference Overview

The 2019 CAPT-ACPT Scientific Program Committee (SPC) is excited to bring you a diverse set of speakers for this year's theme, Driving Health Innovation: Harnessing the Power and Value of Real-World Evidence (RWE). In the era of personalized medicine, the scope of what is considered real-world evidence is expanding, as is the range of analytic methods being applied to those data. We have therefore brought together leaders in population health, artificial intelligence, big data analytics and machine learning to discuss the latest trends in how these techniques are driving the next wave of RWE.

Our conference will start with a keynote address by Nancy Dreyer of IQVIA, who will discuss RWE in the context of global regulatory activities. The sub-theme for day one of the conference is enabling the potential of real-world data, where we will hear about valuable pan-Canadian sources of data, innovative new methods that extract unique insights, and a new approach to support Canadians with rare diseases. Closing off day one will be oral presentations from researchers submitting top ranked abstracts followed by a poster session.

On day two, our sub-theme is RWE in action and driving innovation. We will hear about how RWE is used to support decisions at both the clinical and policy levels, how the application of machine learning techniques to real-world data is optimizing care, and how RWE is being leveraged to support outcomes-based agreements with payers. Our conference will close with an update from CADTH's Core Action Team on the current state of RWE in Canada.

The CAPT-ACTP SPC has worked closely with each of our partners and speakers to create a program that is intellectually stimulating and engaging, and introduces topics that are of prescient importance in population therapeutics.

We wish to thank you for being a member of CAPT-ACPT, and hope you enjoy the conference.

Luca F. Pisterzi & J.M. Gamble
CAPT-ACTP Scientific Program Committee Co-Chairs

7:00AM – 8:30AM   **Registration / Breakfast** *(Sponsor: Astellas Pharma Canada)*
        Location: Lower Concourse Auditorium Foyer

8:15AM – 8:30AM   **Welcome to Day 1**
        Location: Lower Concourse Auditorium
        Speaker: Lois Mitchell, CAPT-ACTP President

8:30AM – 9:30AM   **Keynote Address**: Beyond the 1%: Knowing when and how to use RWD to
        support medical product approvals and use *(Sponsor: IQVIA)*
        Introduction: Neil Corner, IQVIA
        Speaker: Nancy Dreyer, Chief Scientific Officer, IQVIA

Session Overview: Growing interest in using real-world evidence (RWE) for regulating medical products necessitates the creation of agreed-on processes and factors to determine when RWE is sufficiently reliable for a given purpose. This presentation will discuss recent regulatory activities related to RWE outside of Canada and current efforts to establish guidelines for RWE quality, with attention to establishing big data networks as "research-ready" and key considerations for research methods. Examples of innovative studies using RWE that have been used for product label expansions will also be discussed, along with a vision for the future use of RWE.

9:30AM –10:45AM   **Session 1**: Privacy, data sharing, and access
               (Sponsor: Canadian Partnership Against Cancer (CPAC))
        Moderator: Craig Earle (CPAC)
        Speakers: Eric Sutherland, Canadian Institute for Health Information (CIHI)
               Isabel Fortier, McGill University
               Ma'n Zawati, McGill University

Session Overview: In the era of big data analytics, population health researchers often design an approach that collects as vast a dataset as possible to address a more diverse array of questions. These datasets are often enriched through linkages to health utilization data, or broadened by harmonizing individual variables with those collected by other local, national or international cohorts created to address similar questions. Both approaches create larger more informative cohorts, and support a trend toward greater investment in the analysis of those data, rather than the collection of new data that could duplicate efforts. Data custodians are supporting this trend by creating policies that make data available to the broader research community in a manner that preserves privacy. In this session, examples of pan-Canadian data-sharing initiatives will be discussed, highlighting the challenges encountered and progress celebrated thus far.

10:45AM – 11:15AM Break *(Sponsor: Biogen)*

11:15AM – 12:30PM Session 2: Rare drug reimbursement: Policy solutions to patient access
(Sponsor: Takeda Canada Inc.)
Moderator: Adam Haynes, Takeda Canada Inc.
Speakers: Sang Mi Lee, pCPA
Nicole Mittmann, CADTH
Whitney Goulstone, Canadian Immunodeficient Patient Organization (CIPO)
Jeff Round, Institute of Health Economics (IHE)

Session Overview: It is estimated that approximately three million Canadians – 1 in 12 – suffer from a rare disease. Although the population sizes for individual rare diseases are small, collectively, rare diseases can impose a substantial societal and economic burden. From a pharmaceutical manufacturer perspective, investments in R&D must be recovered from a lower number of patient beneficiaries within a single rare disease area. This, in turn, creates challenges for HTA agencies and payers when applying traditional reimbursement measures of cost-efficiency and budget impact. The overall impact is that patients with rare diseases remain underserved with limited access to treatments. This panel convenes experts to discuss policy frameworks addressing the challenges faced in the reimbursement of rare disease drugs.

12:30PM – 1:30PM Lunch *(Sponsor: AstraZeneca Canada Inc.)*
Location: Lower Concourse Auditorium Foyer

Student Networking
Location: Lower Concourse Auditorium
Organizer: Shanna Trenaman, CAPT-ACTP Student Representative, Dalhousie University

1:30PM – 2:45PM Session 3: UNTAPPED: Innovative ways to use big data in healthcare
(Sponsor: Amgen Canada Inc.)
Moderator: Gerry Jeffcott, 3Sixty Public Affairs
Speakers: Winson Cheung, University of Calgary
Tara Cowling, Medlior Health Outcomes Research
Aaron Leibtag, Pentavere

Session Overview: There is a massive amount of health data generated by researchers and clinicians each year. Due to the sheer volume and variety, the data complexities are also increasing. Thus, there is a need to identify new ways to uncover the 'value' in the data. This requires transformation of static information into smart, actionable data. This 75-min session will discuss untapped data available in Canada, challenges associated with the analyses, and why there is need for continued investment.

2:45PM – 3:15PM Break *(Sponsor: Boehringer-Ingelheim Canada)*

3:15PM – 4:30PM Session 4: A method to the madness: Innovative RWE methods that are changing the game *(Sponsor: Janssen)*
Moderator: John-Michael Gamble, University of Waterloo
Speakers: Khaled El-Emam, Children's Hospital Of Eastern Ontario
Chris Cameron, Cornerstone Research
Suzanne Cadarette, University of Toronto

Session Overview: This session will take a *practical* view of current/emerging RWE methods, through expert panelists presenting a clear picture of the method itself and how it can be applied. Participants will also learn about the potential impacts of these methods within the context of real world evidence generation and application in Canada.

4:30PM – 5:10PM **Session 5:** Oral presentations of top-ranked research abstracts
                    Moderator: Luca Pisterzi, CAPT-ACTP President Elect

• The economic burden of CLL in Canada associated with the adoption of oral targeted therapy - Jean Lachaine

• Impact of patient-target financial incentives on healthcare costs: A systematic review of randomized controlled trials – Brittany Humphries

• HIV treatment response among female sex workers participating in a treatment as prevention demonstration project in Cotonou, Benin - Mamadou Diallo

• Systemic sclerosis (SSc) with interstitial lung disease (SSc-ILD) in Canada's largest province: An estimate of the prevalence and survival of SSc and SSc-ILD in Ontario -Kobina Quansah

5:00PM – 5:15PM **Day 1 Summary**
                    Speaker: Lois Mitchell, CAPT-ACTP President

5:15PM – 6:30PM **Poster Presentation Session** *(Sponsors: Hoffmann-La Roche & Novartis)*
                    Location: Lower Concourse Auditorium Foyer

                    Drinks and Hors D'oeuvres
                    Location: Lower Concourse Auditorium Foyer

7:00AM – 8:45AM **Registration / Breakfast** *(Sponsor: Celgene Inc.)*
Location: Lower Concourse Auditorium Foyer

8:30AM – 8:45AM **Welcome to Day 2**
Location: Lower Concourse Auditorium
Speaker: Lois Mitchell, CAPT-ACTP President

8:45AM – 10:00AM **Session 6:** Where Real World Evidence (RWE) can be used to support suboptimal evidence across all clinical development phases. *(Sponsor: Eisai)*
Moderator: Mona Sabharwal, Rexall Pharmacy Group
Speakers: Don Husereau, University of Ottawa
Tarry Ahuja, CADTH

Session Overview: The role of Real World Evidence (RWE) to support decision-making is gaining prominence, and decision-makers are examining how RWE can be used to inform or revisit health system decisions. An area of emerging interest is the increasing trend of new (oncology or orphan) drugs being granted marketing authorization on the basis of phase II data or surrogate outcomes rather than phase III RCT data. In Canada, the pan-Canadian Oncology Drug Review's Expert Review Committee (pERC) often, in their (negative) recommendations on drug submissions made with Phase II evidence, suggest that the next step for manufacturers is to conduct a Phase III RCT. However there are many settings where a Phase III trial may not be feasible, either for ethical or pragmatic reasons. In this panel we will review the opportunities along all phases of clinical development to: (1) support areas where there is suboptimal evidence using real world evidence, (2) review how other jurisdictions are adapting their HTA pathways to address the growing trend of drugs being granted marketing authorization on the basis of Phase II data, (3) and examine factors that should be considered for determining when RWE is viable in scenarios where Phase III trials are not viable.

10:00AM – 10:30AM **Break** *(Sponsor: Leo Pharma)*

10:30AM – 12:00PM **Session 7:** How Canada's health and pharmacare programs can leverage real-world data and strategic partnerships to address the challenges and opportunities of an aging population and new health technologies *(Sponsor: Merck Canada Inc.)*
Moderator: Fred Horne, Principal, Horne & Associates, senior advisor with 3Sixty Public Affairs
Speakers: Jennifer Chan, Merck Canada
Scott Gavura, Cancer Care Ontario
Michael Nicin, National Institute on Ageing (NIA)
Annette Cyr, Melanoma Network of Canada

Session Overview: The pharmaceutical industry's pipeline is burgeoning with new medicines for many diseases that were previously considered untreatable, including cancer. Many of these therapies involve complex compounding and delivery systems, are administered in combination with other medicines and/or involve companion diagnostics. At the same time, Canada's population is aging, driving a growing incidence of cancer and chronic diseases. In light of these trends, this panel will

consider how Canada can be positioned to manage the integration of new pharmaceuticals in a manner that contributes to the triple aim of accessibility, affordability and appropriate use.

12:00PM – 1:00PM   **Lunch** *(Sponsor: PDCI)*

Annual General Meeting & Awards Presentations
Location: Lower Concourse Auditorium
Speaker: Lois Mitchell on behalf of the CAPT-ACTP Board

1:00PM – 2:15PM   **Session 8:**   The era of artificial intelligence in healthcare
Moderator: Luca Pisterzi, CAPT-ACTP
Speakers: Marwan Sati, IBM/Watson Health
                       Francis Jeanson, Datadex Inc.
                       Muhammad Mamdani, St Michael's Hospital

Session Overview: The emergence and continual refinement of artificial intelligence (AI) holds great promise to advance the delivery of care and discovery of medicines, and improve how we understand our patients. In this session, our speakers will outline three examples of how AI is being applied to tackle some of the toughest challenges in healthcare. Our first speaker from IBM/Watson Health will outline his work leading the development of medical imaging AI solutions designed to help detect diseases such as liver cancer, lung cancer and a variety of other diseases. Our next speaker from Datadex Inc, a Toronto-based startup, will describe a platform that will allow us to get more out of our data by using AI to discover new relationships with other datasets, to securely link to those data, and ultimately generate new insights, faster. Our final speaker from St. Michael's Hospital will describe the application of AI to the hospital setting, unlocking the predictive power of health administration data to generate accurate projections that range from the detection of patients at imminent risk of mortality through to volume of patients expected in the emergency department on any given day

2:00PM – 3:00PM   **Session 9:**   RWE to support outcomes-based agreements in Canada: A case study using patient support program data**.**
Moderator: Allison Wills, 20Sense Specialty Pharmaceutical Consulting
Speakers: Sang Mi Lee, pCPA
                       Janey Shin, Janssen
                       Chris Dalseg, BioScript Solutions

Session Overview: This session will draw on the research conducted in 2019 by the *Real-World Evidence and Outcomes-Based Agreements Working Group* (OBA) on the opportunity to leverage RWE to inform outcomes-based payer agreements. Findings on OBA benefits, appropriateness, challenges, and a 7-step process for monitoring and reporting on health outcomes data will be presented. This will include an overview of a case study on launching a drug with the intent of establishing an OBA using health outcomes data collected within a patient support program. Panelists will provide input on the process and case study from their perspectives, and a discussion will be facilitated on opportunities to further advance the application of outcomes-based agreements in Canada.

3:00PM – 3:15PM   **Break** *(Sponsor: Patient Access Solutions)*

3:15PM – 4:15PM   **Session 10:**   The path to the future: updates from the CADTH Core Action
                                          Team (CAT) on the progress of RWE in Canada.
                      Moderator: Lois Mitchell, CAPT-ACTP President
                      Speakers: Tarry Ahuja, CADTH
                                          Virginie Giroux, Merck Canada Inc.
                                          Mina Tadrous, Women's College Hospital
                                          Sylvie Bouchard, INESSS

Session Overview: Since the establishment of the multidisciplinary RWE CAT last year, the team has been working on sharing initiatives, supporting the development of a pan-Canadian approach to the use of RWE and identifying where RWE can add value to regulatory and reimbursement decision-makers. Members of the RWE CAT will present an update on their activities and provide some insights into what the future might hold.

4:15PM – 4:30PM   **Closing Remarks**
                      Location: Lower Concourse Auditorium
                      Speaker: Luca Pisterzi, CAPT-ACTP President 2020

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.ca).

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