

Invited session 18

Improving the Clinical Trial Ecosystem to Efficiently Generate Robust Research and Improve Care

Speakers

P.J. Devereaux

Dean Fergusson

Stuart G. Nicholls

Sameer Parpia

Program

- **Each speaker will present – 12 minutes + 3 minutes for any clarifications ONLY**
 - **P.J. Devereaux:** Clinical Trials and the Accelerating Clinical Trials (ACT) Canada Consortium
 - **Dean Fergusson:** Decreasing time & increasing efficiency of study initiation
 - **Stuart Nicholls:** Awareness, Engagement, and Access: getting the right trials to the right people
 - **Sameer Parpia:** Building Clinical Trials Capacity in Canada
- **Panel discussion – 30 minutes**

Clinical Trials and the Accelerating Clinical Trials (ACT) Canada Consortium

P.J. Devereaux, MD, PhD

Nominated Principal Applicant of ACT Consortium
CEO and Scientific Director of the World Health Research Trust
Deputy Director of the Population Health Research Institute

Disclosures

- Based on study questions I originated and grants I wrote
 - I have received grants from
 - Abbott Diagnostics, AOP, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Cloud DX, Covidien, Octapharma, Philips Healthcare, Roche Diagnostics, Roche, Siemens, Smith and Nephew, Stryker, Trimedica
- I have participated in
 - advisory boarding meeting GlaxoSmithKline, Bayer, Quidel Canada, Trimedica
 - expert panel meeting AstraZeneca, BI, Roche
 - International meetings AOP
- I have undertaken consultancy work for
 - Astra Zeneca
 - Abbott Diagnostics

A Child Identifies the Potential of RCTs and Highlights Canadian Challenges

- 2 yr old boy diagnosed with **metastatic brain cancer** in Ontario
- Family told he had **months to live** as there were **no** treatment options
- **Remortgaged house** brought son to NY and enrolled him in RCT
- Clinical trial **saved** his life; he is now 18 years of age

Key takeaways

- Everyday trials like this one **do not** come to Canada or limited numbers of participants are assigned to Canada
 - Because our **trials system is so inefficient**
- **Moral imperative** to improve ecosystem for doing RCTs in Canada
 - To bring more opportunities to Canadians to participate in trials

Accelerating Clinical Trials (ACT) Canada

**ACT is Funded by CIHR to improve ecosystem
for conducting RCTs in Canada**



Central Guiding Principle

Our activities will accelerate, optimize, and facilitate the conduct, implementation, and results translation from high-quality, high-impact RCTs to improve health in Canada and around the world.

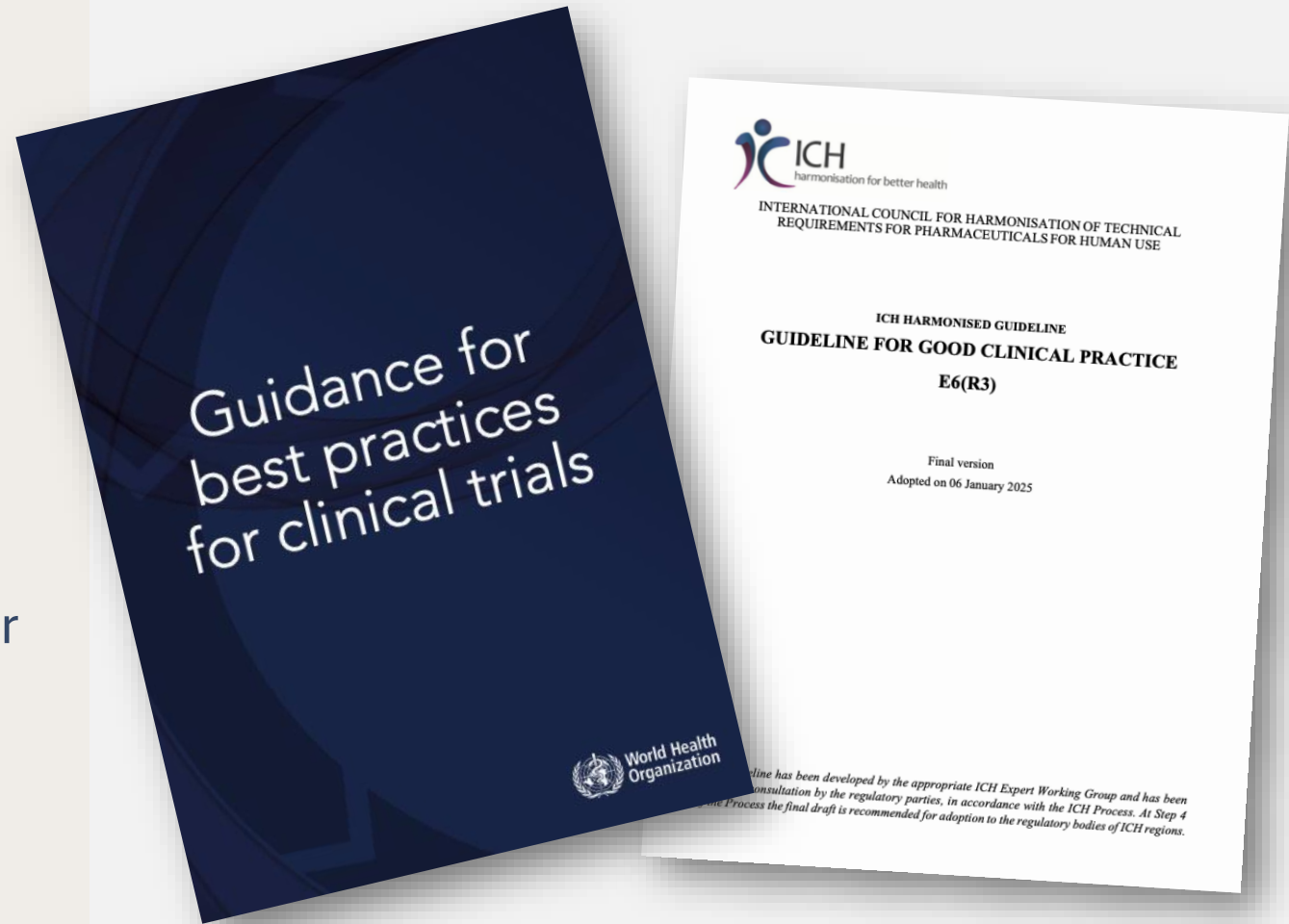
Creating Greater Democratization of Access to Participate in Clinical Trials

- Borrowing from successful **UK portfolio** system
- Activated **20** ACT Portfolio hospitals
 - imbedded study personnel in community hospitals to facilitate bringing clinical trials to more Canadians
- **Be The Cure** campaign

BETHECURE.CA

Regulatory

- ACT regulatory working group led submission to Health Canada recommending changes to the **draft ICH E6 (R3)**
- Contributed to **international** efforts
 - **WHO** guidance for best practices for clinical trial
 - **Trials of new drugs or devices** intended for a regulatory indication should follow ICH E6
 - **All other trials** should follow Guidance for Good Randomized Clinical Trials



Contracts

- Contracts are **major bottleneck** in conducting RCTs in Canada
- ACT has implemented Data and Samples Sharing Agreement in **53** Canadian centres
- Finalizing master clinical trial agreement for **CIHR funded trials**

Pan-Canadian, Distributive, Single REB Approval Process with Strict Timelines for Multi-Centre RCTs

- **Open** competition, objective selection process
- **CanReview** (<https://canreview.ca/>) selected
 - Leadership team consisting of experts from 10 Provinces and Territories
- Will utilize **digital platforms** for ethics approval which have already been audited and approved by both Health Canada and FDA

CanReview

Growing Funding Pie

- Too much **time wasted** among Canadian health researchers debating how to divide CIHR funding pie
- Lessons from the **EU**
 - Canadian trialists need to help support and grow Canadian biotechnology industry by evaluating their products in RCTs
 - Held 2 national meetings bringing >100 Canadian biotech companies and >300 researchers together to learn about Canadian biotechnologies
 - Held 2 granting opportunities that funded trials evaluating Canadian biotechnologies

Additional Grant Competitions

- Additional **granting competitions**
 - High-impact Canadian led clinical trials
 - Novel designs and trials evaluating methods to improve conduct of trials
 - Creation of new networks
 - Bring high-impact international RCTs to Canada
- Several of these trials have already been **published** in highest impact journals and impacted care globally
 - 5 NEJM
 - 1 Lancet

Reflections on ACT



- A lot has been **achieved** in first 2 yrs
- **Issue** is whether roots of system change are deep enough to be sustained with only 3 years of program funding

Introducing ACT-2.0

- Seek additional **3 years of funding** to solidify system changes
 - Ensure success of pan-Canadian, distributive, single REB review and approval process with strict timelines
 - Sustain and expand portfolio funding embedding study personnel in community hospitals across Canada
 - Ensure successful implementation of master clinical trial contracts
 - Continue to help grow Canadian biotech through granting opportunities for trials evaluating Canadian biotech

ACT-2.0

- New **Initiatives**
 - Creating change to ensure study personnel can **inform** all eligible patients about trials relevant to their health
 - Create network **contact process** to facilitate rapid determination of interested sites for pharma and investigator-initiated trials
 - Ensure **pregnant/lactating** women or women who could become pregnant are not automatically excluded or must prove they are not pregnant and require birth control

Conclusions

- RCTs provide **health opportunities** for Canadians and have **positive impacts** on our economy
- ACT will have **achieved** its goal if:
 - Canada becomes the **most efficient** country in the world for conducting RCTs
 - Permanent efficient systems are **implemented**, government implements **sustained** funding for RCTs, Canadian biotech grows, and **more** big pharma and device company trials come to Canada
 - then Canadian public benefits

SCT Invited Session: Improving the Clinical Trial Ecosystem to Efficiently Generate Robust Research and Improve Care

Decreasing time & increasing efficiency of study initiation

Dean Fergusson, MHA, PhD, FCAHS

Senior Scientist & Deputy Scientific Director, Ottawa Hospital Research Institute

Professor, Departments of Medicine, Surgery, and School of Epidemiology & Public Health, uOttawa

Endowed Chair in Clinical Epidemiology

Disclosures

- ACT Principal Applicant
- Co-Chair of ACT Systems Transformation Committee

Canadian System Challenges

- Slow study start up times
 - Affected by ethics approval, regulatory requirements, site approval processes, and contract negotiations
- Regulatory compliance
 - Understanding and navigating regulatory requirements
 - Complexity and requirements for monitoring, SAE reporting...
 - Health Canada audit requirements
- Insurance costs to conduct multinational trials
- Access to key core trial infrastructure (trial units and expertise) from design to execution to dissemination

How is ACT Addressing Slow Start-up Times?

- **ACT Working Groups for Ethics and Contracts**

- WG Mandates:
 - Pan-Canadian focus & representation to bring together thought leaders and decision-makers
 - Develop an action plan with either common or integrated provincial/regional solutions

- **ACT Systems Transformation Committee**

- Overarching aim is to support the ACT Consortium in delivering its strategic objectives around the following functions:
 - Optimizing pan-Canadian clinical trial processes
 - Improving the efficiency of RCTs

- **ACT Leadership (Central and Operations Committee)**

- To aggressively advocate for the streamlining of clinical trials to relevant invested parties from hospitals to federal and provincial authorities

ETHICS

Primary focus:

Funded by the Canadian government, the Accelerated Clinical Trials (ACT) Consortium has a national mandate and responsibility to establish a single Research Ethics Board (REB) review and approval process for multicentre RCTs.

ACT RFA for Single national REB process

Objective:

- Open competition to select a group to set up and run a sustainable Pan-Canadian, distributive, single Research Ethics Board (REB) review and approval process for the initiation and conduct of multicentre RCTs
- A distributive model will utilize qualified Canadian REBs and will distribute multicentre trial submissions to one qualified Canadian REB, which will act as the REB of record. If a qualified Canadian REB approves a trial, other Canadian centres should then accept this REB of record's approval of the ethics and methodology of the trial, without the need for re-evaluation.
- New system must set and achieve internationally competitive timelines regarding the review process.

Update on the RFA Process

- Development of RFA between March and May 2024
- RFA launched May 2024 and closed Aug 2024
- Established a robust independent external review process
 - External Review Committee (ERC) to score written submissions
 - Selection Committee (SC) to undertake interviews of successful submissions and make final selection
 - Co-Chairs of ERC and SC: Megan Singleton (Johns Hopkins) & Matt Westmore (UK Research Authority)
- CanReview was selected as the successful proposal in November 2024

CanReview system officially launched on May 20th!

CanReview

English

Français (French)

About

How it Works

CanReview Partners

Get Involved

News

Contact

Collaborating to build a Canada-wide research ethics review system that benefits all people in Canada

CanReview is a pan-Canadian collaboration supported by the [Accelerating Clinical Trials \(ACT\)](#) Consortium to enable a single research ethics review for multi-site clinical trials conducted across Canada, while ensuring the highest ethical standards.

[Learn more ↗](#)

Source: canreview.ca



CanReview: How it works

Powered by [CTO Stream](#), an adaptable, user-friendly web-based platform that facilitates a single research ethics review process for multi-site clinical trials. Leveraging this platform, CanReview will provide users with:

- A centralized entry point for sponsors and investigators to submit studies
- An assigned, CanReview Participating Research Ethics Board (REB) to review studies
- Proactive supports to effectively address provincial requirements when needed



Single REB Application

If you have a multi-site study, the ethics review will be done by one CanReview Qualified REB.



Standardized Forms

Sites will use the same ethics application forms and standardized consent form templates.



Fast & Efficient

Getting ethics approval for additional sites is quicker and more efficient.



Validated REB

Reviews are conducted CanReview Participating REBs, ensuring the highest ethical standards.

Sign up at canreview.ca!

Become a CanReview Partner

CanReview Partners play a vital role in demonstrating support for this important pan-Canadian initiative, sharing information about CanReview within their organizations.

Registering as a CanReview Partner will facilitate ongoing communication with your organization regarding CanReview's progress, as well as opportunities for engagement. Those who sign up to be CanReview Partners will be listed on the CanReview Partner webpage and subscribed to the CanReview newsletter.



Invite your organization to become a CanReview Partner

[Download Invitation](#)

[Download Template Letter for Institutional Support](#)

Is your organization ready to be a CanReview Partner? Sign up here.

Name

Organization *

Email *

CONTRACTS

Primary focus:

To address the significant delays in trial initiation due to extensive negotiations of trial contracts and agreements between institutions, sponsors, and funders by **developing inter-institutional templates and binding agreements across Canada**

Key Objectives of the Contracts Working Group:

- Reduce cycle times in the negotiation and execution of clinical trial agreements
- Develop master clinical trial agreement(s) and templates
- Create additional tools, templates, and resources to streamline clinical trial contracts in Canada
- Recruit and onboard institutions/organizations outside of the 11 ACT Clinical Trial Units to the Governing (Master) agreements and templates

Progress to date (gDSSA)

In February 2024, ACT launched the Governing Data and Biological Sample Transfers Agreement (gDSSA)

- Establishes a binding agreement with pre-negotiated terms and conditions
 - enables focused negotiations, leading to reduced execution timelines
 - features a transfer letter outlining specific study details and minimal changes, only if necessary
- The underlying principle is to uphold the pre-negotiated terms and conditions during utilization, maximizing efficiency in execution
- Signatories have grown from 29 parties at launch to 58 as of today

Progress to date (gDSSA Sub-site Template)

- Building on the gDSSA, the consortium integrated its language into a Sub-Site Template agreement for clinical trials.
- Template serves as a practical tool with flexibilities to account for various clinical trial scenarios (e.g. investigational products, indemnities) but the major terms and conditions largely do not require renegotiation
- As with the gDSSA, the intention is to uphold the pre-negotiate terms and conditions when appropriate
- Facilitates focused negotiations which decrease turnaround times in the execution of clinical trial agreements
- Launched in February 2025, has been distributed to over 50 institutions, affiliated hospitals, health authorities, and independent parties for use

Progress to date (Governing Agreements)

- Currently finalizing the development of a Governing (Master) Tri-Council Funded Participating Site Agreement (where the sponsor funding and obligations are known)
 - Serves as a master clinical trial agreement for CIHR-funded trials
- The binding agreement will be based on the terms negotiated during the development of the gDSSA and Sub-Site template agreements
- Anticipated finalization of this agreement is for June 2025
- Next priority is to establish Governing (Master) Agreements with industry sponsors

Conclusions

- ACT is making significant progress in addressing slow start-up times through master templates/agreements and establishing a single-entry REB system
- Requires Canadian institutions and authorities to join, support, and champion our initiatives
- Improving trial start-up times will lead to a greater number of Canadian trials and greater opportunities for Canadians to participate in trials
- In turn, this will bring improved health outcomes and economic benefits to Canadians

Awareness, Engagement, and Access: getting the right trials to the right people

Stuart Nicholls, PhD

Scientist , Methodological & Implementation Research (MIR) Program, Ottawa Hospital Research Institute

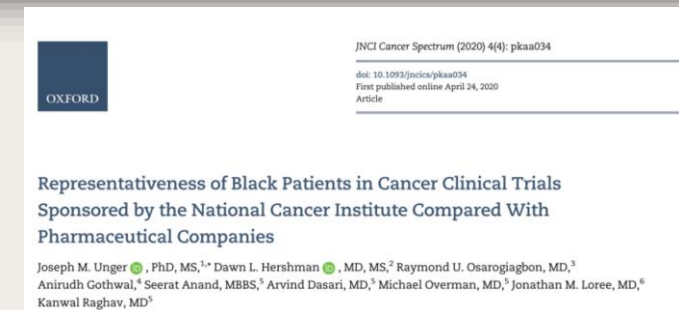
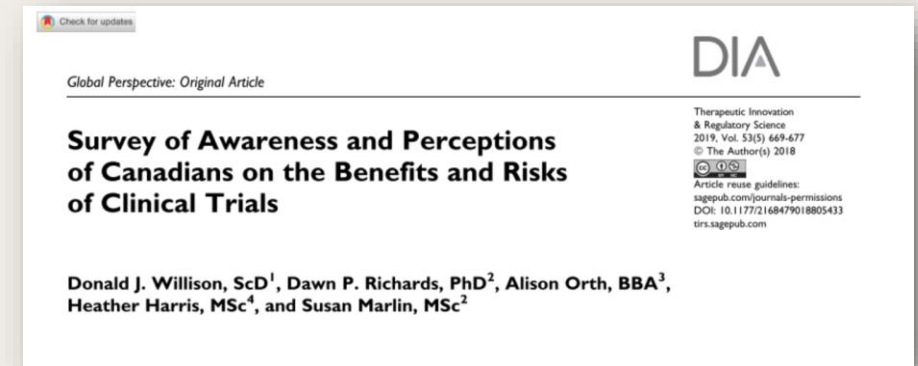
Lead, Office for Patient Engagement in Research Activities (OPERA), Ottawa Hospital Research Institute.

Disclosures

- ACT Co- Applicant
- Co-Chair of ACT Patient Engagement Committee
- Member, ACT Inclusion, Diversity, Equity & Accessibility Committee (IDEA)

Background

- Survey of 1602 adults in Ontario and British Columbia:
 - 11% had been invited to take part in a trial; 6% know someone close who had.
 - Yet between 63% and 87% would be very or somewhat willing to take part in a trial
- Research showing gaps in trial participants
 - In terms of availability of trials where people reside
 - For patients with complexities or where certain groups are excluded
 - Even when not excluded, underrepresentation



Increasing visibility of clinical trials: BeTheCure campaign

- Ran January 12 - July 1, 2024
 - 22M+ social media impressions, 22% growth + 33% newsletter growth
 - 2824 TV and radio slots
- 118,879 new website visits
- 26,341 new searches for trials
- Posts featuring personal stories of patients, had most engagement, showcasing the power of storytelling.

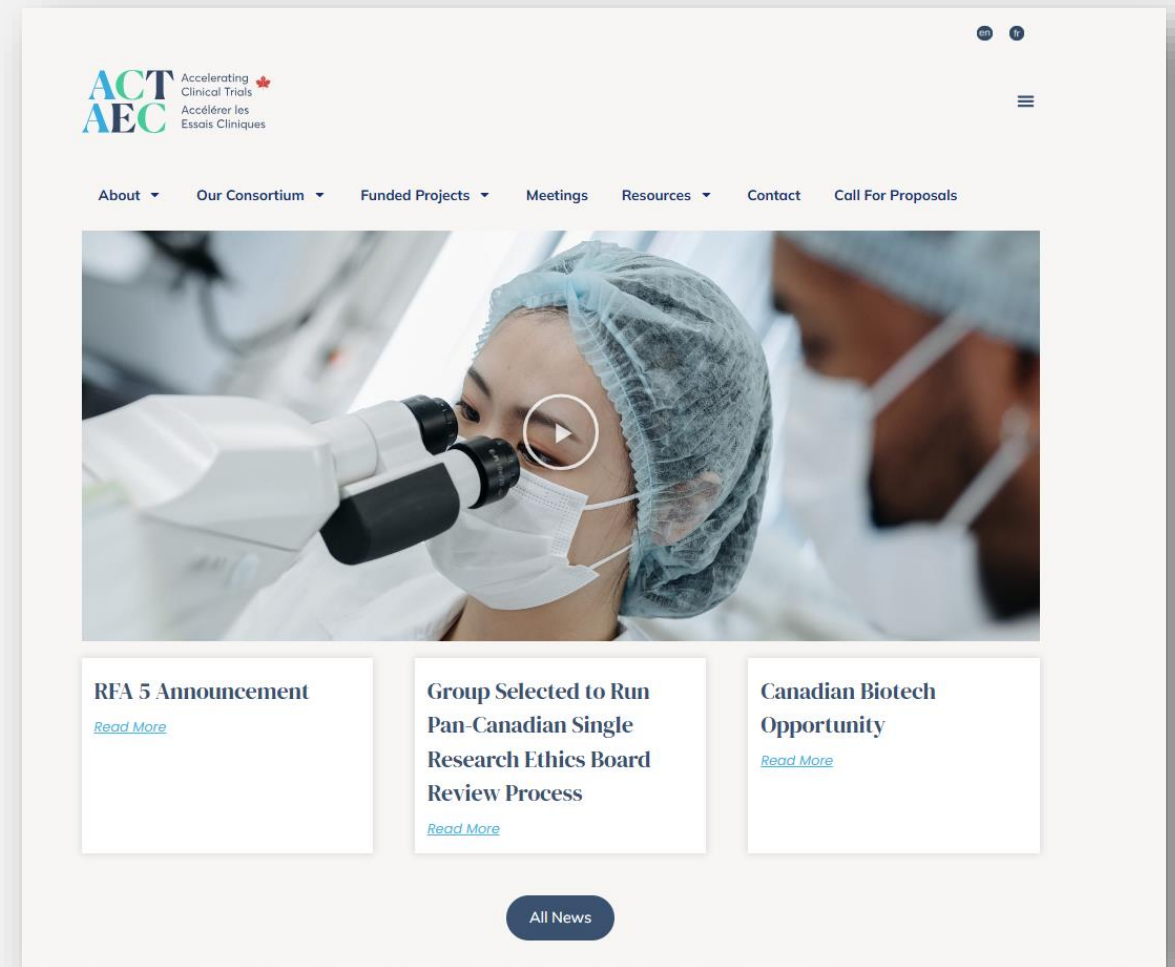
The image displays two overlapping screenshots. The top screenshot is a National Post article titled "Be the Cure is enhancing inclusivity in health-care research" by Julia Stratton, dated January 29, 2024. The article discusses how clinical trials help find treatments for Canadians. The bottom screenshot is the BeTheCure.ca website, featuring a "FACT SHEET" section. The website header includes "BETHECURE.CA" and navigation links for "STORIES" and "ABOUT". The "FACT SHEET" section is titled "Health Research in Canada" and contains several key points:

- Health Research in Canada:** Health research opportunities include taking part in working groups, councils, and steering committees as research partners. You can even take a more active role by co-leading research to make sure findings are meaningful to the public. Health research studies include clinical trials, observational studies, and other types of data-gathering studies where patients are subjects or participants. These studies explore questions and find answers to our most pressing diseases and health conditions.
- Canada captures 4% of global clinical trials, fourth in the number of clinical trials sites, and is the G7 leader in clinical trial productivity (number of trials/population).**
- There are around 40 research hospitals in Canada, who collectively house a \$2.8B research enterprises. Many research hospitals have multiple overseas collaborations.**
- Canada's extensive network of academic health institutions and research centres, which support clinical research includes 17 medical schools, approximately 40 groupings of academic healthcare organizations and about 15,000 researchers.**
- ACT will advance equitable access to trials for all Canadians – no matter where they live, inclusive of gender, ethnicity, and socioeconomic status – following the principles of equity, diversity, and inclusion in clinical trials such that the knowledge gained is applicable to all those affected.**
- ACT will maximize research impact and knowledge mobilization – following best practices in patient-oriented research and integrated knowledge translation, leveraging national and international contacts.**
- ACT will build clinical trial capacity – providing trial units with the knowledge, skills, and experience to conduct large-scale trials. We will streamline administrative processes (for example, ethics reviews, contracts, and protocols) to accelerate timelines and reduce costs.**

The website also features a banner with the text "YOU'RE THE MISSING PIECE." and a dropdown menu to "Select a Province or Territory". The Habit logo is visible in the bottom right corner of the website screenshot.

ACT website and outreach

- 15 social media campaigns.
 - The 60 posts have resulted in 27,950 impressions, total followers to 1002.
- Op-eds and public outreach
 - Saltwire, BioSpace, Globe & Mail
- ACT Educational Weekly newsletter
 - 47 newsletters, opened 67,000 times and 12,000 click throughs
- ACT Monthly updates
 - Opened over 10,000 times, 8,000 click throughs



Patient Engagement

- 12-member committee meeting monthly
 - Patient partners, community members, researchers (50% non-researcher)
- Feedback on all RFA calls
- Peer review of RFA applications
- Presentation at all ACT national meetings
- Webinars
 - Most viewed webinar on ACT YouTube channel: <https://www.youtube.com/@ACTAEC>
- Sharing of patient engagement resources for trial teams & consultations

<https://act-aec.ca/patient-engagement/>

Patient Engagement Research

- Three studies
 - Review of patient engagement in Canadian clinical trials*
 - Rapid scoping review of resources and competencies for trial teams
 - >120 resources identified
 - Qualitative study of barriers & facilitators to patient engagement in clinical trials

Patient and public involvement in Canadian randomized controlled trials: A scoping review

Motahareh Karimijashni , Amanda Doherty-Kirby , Annette Mainemer , Ada Tang , Maureen Smith , Yan Défossés², Cory Goldstein, Monica Taljaard , Dean Fergusson , Stuart Nicholls, on behalf of the Accelerating Clinical Trials (ACT) Consortium Patient Engagement Committee

The Ottawa Hospital | L'Hôpital d'Ottawa
Ottawa Methods Centre | Centre de méthodologie d'Ottawa

The Ottawa Hospital | L'Hôpital d'Ottawa
Research Institute | Institut de recherche

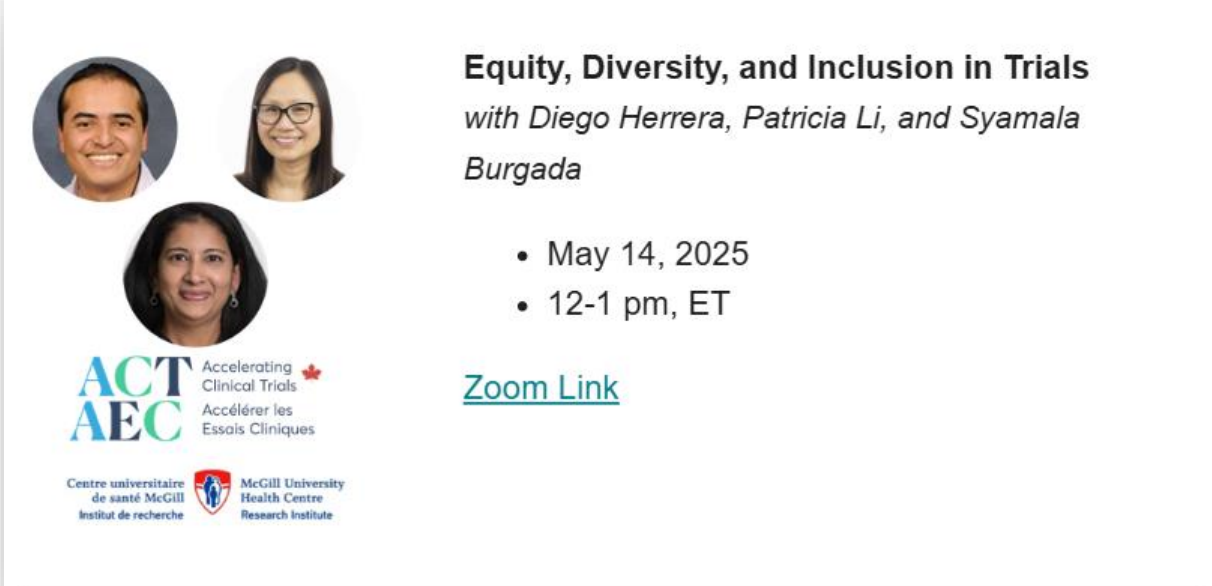
Inspired by research. Driven by compassion. | Inspiré par recherche. Guidé par la compassion.

Affiliated with / Affilié à
uOttawa

* Motahareh Karimijashni Oral presentation, Monday 19 May (9:30-10:15) Contributed session 11 “Patient and Public Involvement in Canadian Randomized Controlled Trials: A Scoping Review”

Inclusion, Diversity, Equity & Accessibility (IDEA)

- Development of a toolkit to support more inclusive clinical trials
 - Informed by scoping review of existing tools
 - Conducted focus groups (English & French)
 - Future collaboration and consultation with the Patient Engagement Committee and Indigenous Health Committee.
- Webinars



Equity, Diversity, and Inclusion in Trials
with Diego Herrera, Patricia Li, and Syamala Burgada

- May 14, 2025
- 12-1 pm, ET

[Zoom Link](#)

ACT AEC Accelerating Clinical Trials
Accélérer les Essais Cliniques

Centre universitaire de santé McGill Institut de recherche
McGill University Health Centre Research Institute

Supporting trial networks

- Ongoing support for 34 networks
- Funded 6 new networks through RFA 4 designed to meet areas of need
 - Canadian Network for Child and Youth Mental Health Trials - PI: Dr. Amanda Newton
 - The Canadian Home Mechanical Ventilation Research Network - PI: Dr. Reshma Amin
 - Canadian Collaborative on Urgent Care Surgery - PI: Dr. Kelly Vogt
 - Collaborative for Caring for Long-Term Care - PI: Dr. Paul Hebert
 - Canadian Medical Cannabis Clinical Trials Network - PI: Dr. Jason Busse, Dr. Hance Clarke
 - Canadian Paediatric Inpatient Research Network -PI: Dr. Peter J Gill

<https://act-aec.ca/new-networks/>

Building infrastructure

- Sites chosen from across Canada in a competitive process
- Each Portfolio Hospital site is funded with equivalent of 1.0 FTE x 3 years Research Coordinator
- Details: <https://act-aec.ca/portfolio-hospitals/>



Example: Niagara Health Knowledge Institute (NHKI)

- Lead: Dr Jennifer Tsang
- Funded in August 2023
- ACT Funding has supported
 - a new clinical trials research coordinator position
 - the establishment of a Hematology/Transfusion Medicine research program
- April 2024, involved in 2 new stroke trials: ENRICH-AF & LIBREXIA-STROKE

The screenshot displays the Niagara Health website with the following content:

- niagarahealth** logo with tagline "Extraordinary Caring. Every Person. Every Time." and navigation links: Home, About, Patients & Visitors, Sites & Services, Quality, Our Team, Research & Academics.
- Section: **News & Updates from Niagara Health** with social sharing options (SHARE THIS PAGE, f SHARE, TWEET).
- Article 1: **Grant funding supports new clinical research trials at Niagara Health**
 - Posted Aug 24th, 2023
 - Summary: Innovative and inspirational research at Niagara Health has received a boost thanks to more than \$300,000 in funding from the Accelerating Clinical Trials (ACT) Canada Consortium.
 - Text: Niagara Health was selected after the evaluation of 65 Canadian hospitals to become an ACT Portfolio Hospital, receiving three years of funding to support a Clinical Trials Research Co-ordinator position.
 - Quote: Dr. Jennifer LY Tsang, Niagara Health Knowledge Institute, "We'll be able to add more clinical trial programs in our community hospitals, which will allow us to deliver clinical trials without the need for those patients to travel to larger centres. But Dr. Tsang points out that more than 80% of hospitals in Canada are community hospitals in smaller or rural areas, which means they have a chance to be part of clinical trials."
- Article 2: **Niagara Health embarks on two new stroke trials**
 - Posted Jan 29th, 2024
 - Text: "The research we conduct at Niagara Health has a profound impact on the health and well-being of our patients and communities, and contributes to better understanding some of the most significant healthcare challenges of our time and have the potential to benefit patients in Niagara and across Canada."
 - Image: A group photo of the research team members.
 - Caption: Niagara Health's Neurology research team members are (from left): Elaine Orlando, Research Manager; Charmaine Martin, Nurse Practitioner; Dr. Donald Chew, Neurologist; Dr. Daniëlle De Sa Boasquevisque, Neurologist; Leanne Kent, Stroke Program Manager; Dr. Alicia Mattia, Neurologist; and Kallie Morrison, Research Co-ordinator.
- Text at bottom: Niagara Health (NH) is participating in two new clinical trials focused on stroke research, thanks to funding from the Accelerating Clinical Trials (ACT) Canada.

Conclusions

- ACT has increased awareness of clinical trials, is generating evidence regarding inclusion and engagement, and is building resources and infrastructure to improve access.
 - Our research indicates investments such as SPOR have had an impact, and we are beginning to see the impact of portfolio hospital investments
- Needs ongoing support – it is not ‘one and done’ – which requires multi-sectorial investments.
- We must maintain support for equitable access to clinical trials to ensure that new treatments arising from research reach the right people at the right time

Building Clinical Trials Capacity in Canada

Sameer Parpia, PhD

SCT Annual Meeting

21st May 2025

Outline

Clinical Trial Training Platforms

CANSTAT – Canadian Network for Statistical Training in Trials

Background

As part of the CIHR's goal to strengthen Canada's clinical trial ecosystem, it funded 7 clinical trial training platforms through the Clinical Trials Fund

Alongside investments infrastructure and research

Platforms

Pan-Canadian covering at least 5 provinces

Multi-institutional

Funding for three years

Platforms



Réseau de recherche sur les données de santé du Canada
Health Data Research Network Canada



Platforms

Modules

Webinars

Awards for graduate students and post-docs

Mentorship / Internship

Projects

Canadian Network
for Statistical Training
in Trials



Réseau Canadien de
Formation en Statistique
des Essais Cliniques



Background

Identified by CIHR in 2010 but is an issue today as well. This view is shared among the broader health research community.

"...the clinical research workforce has not grown since CIHR's creation in 2000, with obvious shortages of biostatisticians, health economists, clinical epidemiologists, social scientists, ..." and noted that "...most health science centres conducting clinical research report a critical shortage of biostatisticians and methodologists"

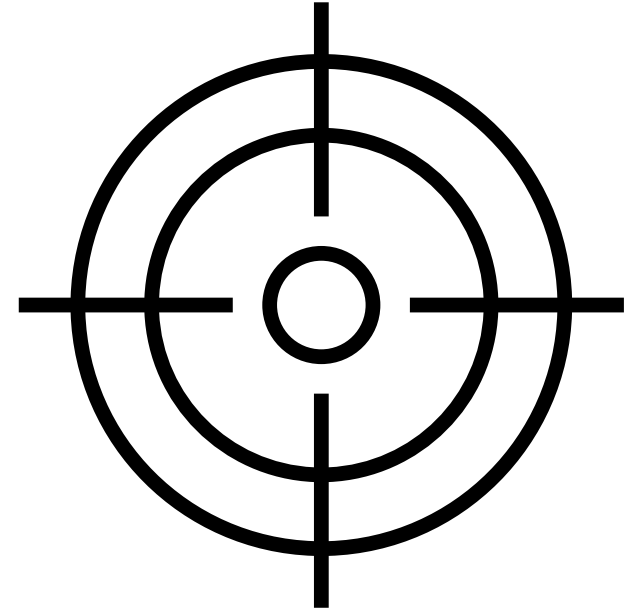
Background

Mathematics and (bio)statistics graduate programs provide graduates with a strong theoretical background in statistics, but the graduates have limited exposure to applied aspects of clinical trial design, conduct, monitoring, and analysis.

Limited offering for training and mentorships in important aspects of the clinical trials enterprise (e.g., data management, ethics, regulatory processes, etc.)

CANSTAT Objectives

The goal of the CANSTAT is to equip trainees with clinical trial knowledge, technical, and professional skills as well as the practical experience needed to develop into trial biostatisticians who can provide biostatistical leadership in clinical trials in Canada and globally.





7 provinces



16 clinical trial units or networks



Biostatisticians, clinicians, other health researchers, trainees (~75 members)



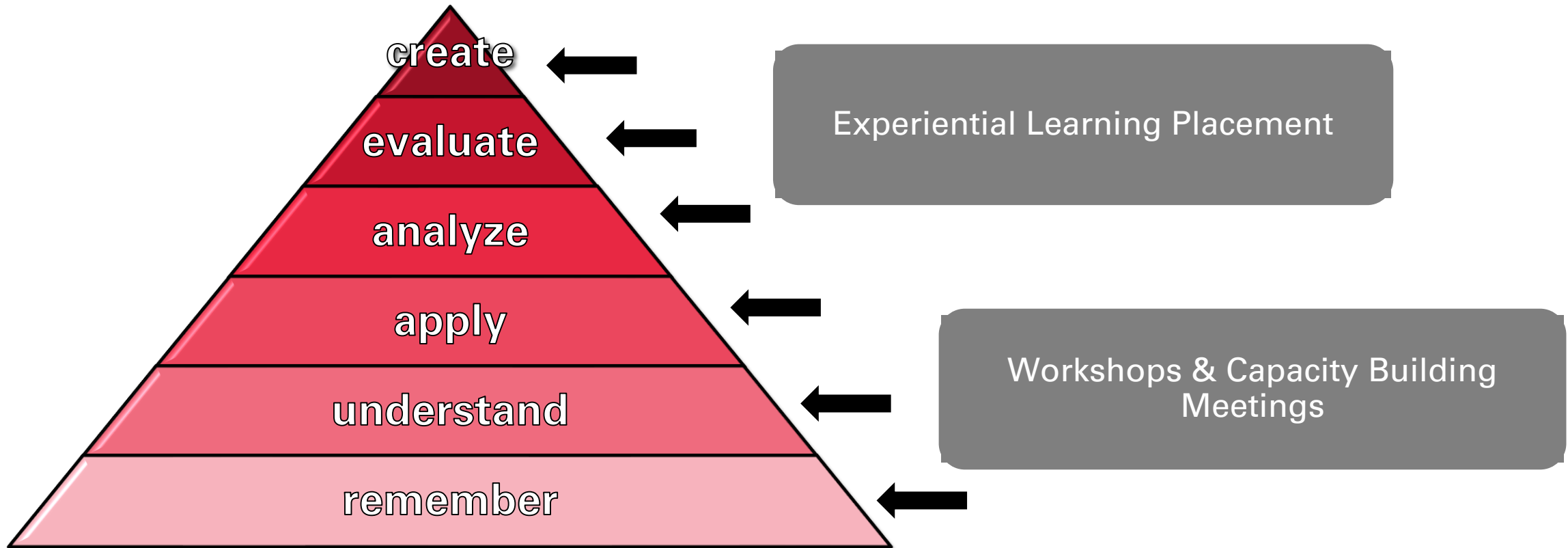
Collaborate with ACT and CTTPs

Network

Program Overview



Taxonomy of Educational Objectives & CANSTAT



CANSTAT Workshops



18 ONLINE WORKSHOPS AND
PRESENTATIONS



TOPICS INCLUDE
FUNDAMENTALS AND
SPECIALIST TOPICS



CANADIAN AND
INTERNATIONAL EXPERTS
FACILITATE

2023-24 Workshops

Working with Non-biostatisticians

Ethics & Regulatory Issues in Trials

Reproducible Research

Endpoint/Outcome Selection

Role of Biomarkers as Replacement

Randomisation

Sample Size and Power

Analysis Principles

Addressing Missing Data

Statistical Writing and Reporting

Economic Analysis

Safety Issues

Non-Inferiority Designs

Early-Stage Designs

Bayesian Design

Adaptive Designs

Design and Analysis of Vaccine Trials

Cluster and Stepped-Wedge



Experiential Learning

A foundational component of the training program is a one-year placement in an environment conducting clinical trials.

This placement will give trainees hands-on experience with actual clinical trials.

Each trainee will be co-mentored by a clinical trials biostatistician and a clinical investigator leading trials of their own.

Trainees will be exposed to statistical and non-statistical aspects of clinical trials

Experiential Learning Curriculum

1. Competencies
2. Experiential Learning Plan
3. Reflections



CANSTAT Competencies

Key Concepts	Mandatory Competencies
	Upon completion of the CANSTAT Program, Fellows will be able to...
Trial Design	Understand randomized trial design using necessary components of trial design.
Sample Size Estimation/Power Analysis	Estimate an appropriate sample size and power calculations for new clinical trials.
Randomization	Design randomization schemes for ongoing trials.
Statistical Analysis Plan (SAP)	Develop a Statistical Analysis Plan using best practice guidelines.
Data Management	Manage data for analysis as defined in a Statistical Analysis Plan using standardized software.
Data Analysis	Analyze and interpret trial data as described in the Statistical Analysis Plan.
Steering/Executive Committee	Understand the practical aspects of running clinical trials.
Data Safety Monitoring Boards	1) Understand how to prepare and present statistical reports to Data Safety Monitoring Boards. 2) Understand how interim trial analysis can lead to recommendations on studies.
Communication	Articulate concepts clearly through oral and written communication.
	Optional Competencies
Regulated Trials	Understand the requirements and complexities of obtaining regulatory approval for clinical trials.
Grant Preparation	Write a sample size description and an analysis plan for a grant application.
Case Report Form Design/Review	Review data collection instruments to ensure that study aims can be achieved.
Manuscript Review	Complete a peer review of a submitted manuscript.

Experiential Learning Plan

This individualized plan is created by mentors and trainees at the beginning of the fellowship to capture the trainees' competencies and outlines a plan of how the rest of the competencies will be achieved.

Templates provided

Updated quarterly

Experiential learning committee reviews

Reflections

Templates have been created for both trainees and mentors

Help them and us to analyze their experiences in the program and consider new ways to grow and develop.

Capacity Building Meeting

Bring together trainees and mentors and create a community within CANSTAT

Provide an opportunity for networking and collaboration

Train participants and mentors to undertake their roles within the CANSTAT program

Learn and discuss issues in clinical trials (e.g. pragmatic trials)

To date

9 trainees have completed the program

11 enrolled in the current cohort

7 to enrolled next year

Involved in varying aspects in over 75 trials

Overall, very positive feedback from trainees and mentors

Challenge: Sustainability

Currently exploring different options to fund the program after August 2025

Summary



Development a comprehensive training program



Program has been well received, with positive feedback from stakeholders



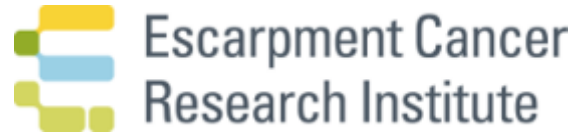
Funding for one more cohort thanks to partnerships

Conclusion



CANSTAT and other CTTs are working towards its objective of increasing clinical trial capacity in Canada

Funder and Partners



Panel discussion

Chair: P.J. Devereaux, MD, PhD