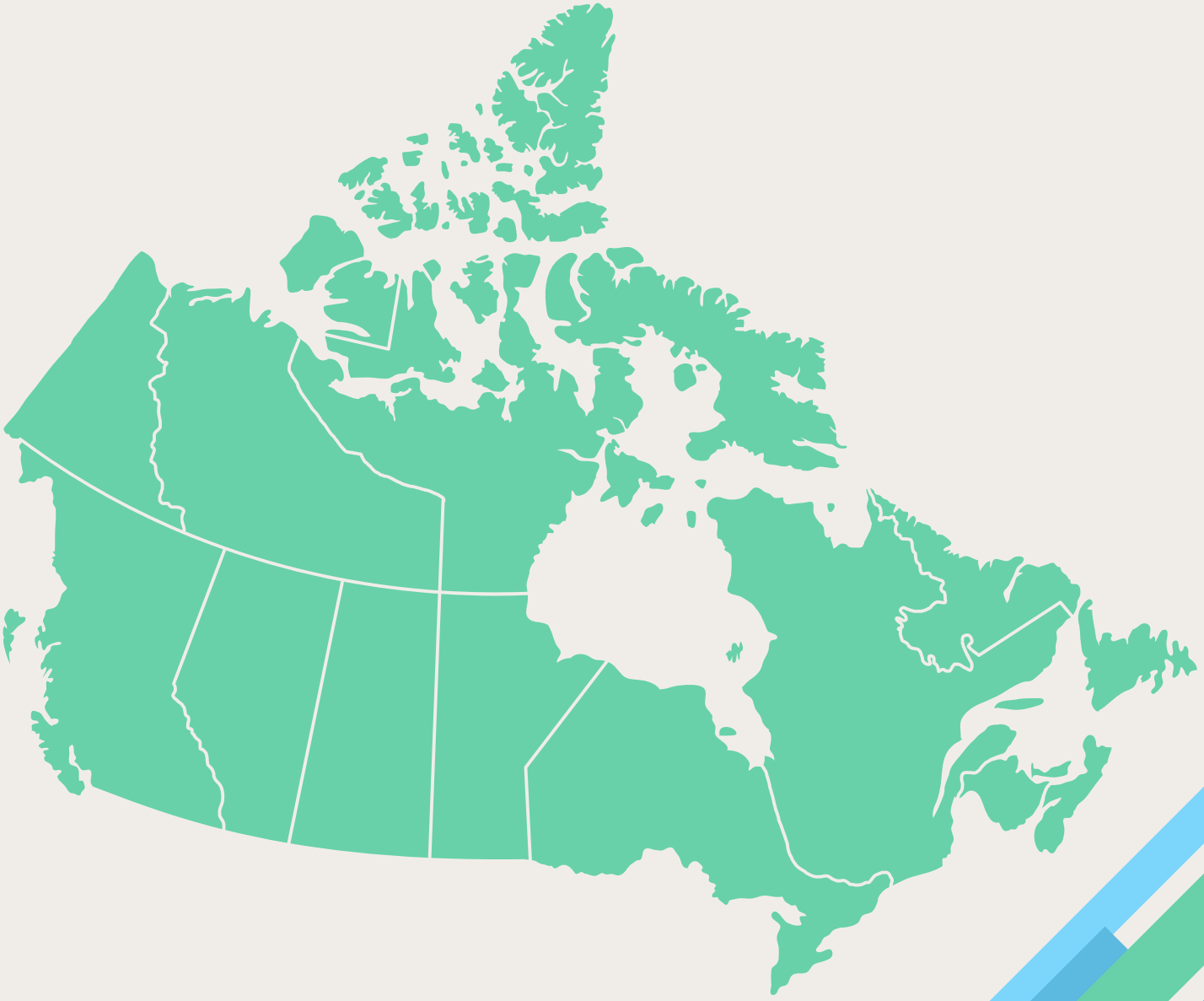
2023-2026

ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

Accelerating Clinical Trials Consortium

Impact Report



Letter from the ACT PIs

We are grateful to the Canadian Government and the Canadian Institutes of Health Research (CIHR) for funding a 3-year grant supporting the Accelerated Clinical Trials (ACT) Canada Consortium.

Over the past three years, the ACT Consortium has delivered transformative, system-level advances to Canada's clinical trials ecosystem. ACT successfully convened and integrated 11 clinical trial units, 34 national clinical trial networks, 20 community portfolio hospitals, regulators, patients, Indigenous partners, and industry around a shared mandate to improve the speed, efficiency, equity, and global impact of randomized controlled trials (RCTs) conducted in Canada.

ACT measurably strengthened trial efficiency by developing and implementing nationally adopted contracting and ethics solutions, including the governing Data and Biological Sample Transfer Agreement, master clinical trial agreement, and the launch of CanReview, Canada's first single national research ethics board review process with defined timelines. Early adoption of these tools has led to substantial reductions in contract cycle times at participating institutions and is laying the foundation for faster, more predictable trial start-up across the country.

ACT also expanded Canada's capacity to conduct trials at scale and closer to patients, notably through the Portfolio Hospital Program. Over 230 ACT-affiliated RCTs have been activated in these community hospitals across eight provinces, resulting in >8500 patients randomized – many from regions that previously had limited or no access to clinical trials. This program has embedded sustainable research infrastructure in community settings and increased trial diversity and generalizability.

Internationally, ACT elevated Canada's visibility and influence by providing funding to bring 10 international trials to Canada, establishing a high-level International Advisory Board, contributing to World Health Organization (WHO) clinical trials guidance, and becoming a member of the Global Clinical Trials Forum. These activities have positioned Canada as a credible, reliable partner in global trials.

Critically, ACT embedded equity, diversity, inclusion, patient engagement, and Indigenous leadership across its activities. Through dedicated committees, funded demonstration projects, and national toolkits, ACT advanced inclusive trial design, patient-led engagement, and distinctions-based Indigenous clinical trials – addressing longstanding structural barriers in Canadian research.

ACT-1 funded 46 high-quality RCTs (including trials evaluating Canadian biotechnologies) and 3 Indigenous-led trials, generated high-impact publications in leading journals, mobilized knowledge nationally, impacted care globally, and secured substantial partner co-investment. These accomplishments demonstrate that coordinated national action can meaningfully modernize Canada's clinical trials system – providing a strong foundation for consolidation, scale-up, and sustained impact.

We want to thank all the individuals who made ACT possible and are responsible for its success including all the ACT investigators, highly qualified personnel, committee and working group members, the coordination team at the Population Health Research Institute, and the individuals who participated in ACT supported trials. We hope you will enjoy the ACT IMPACT REPORT.

Sincerely
PJ Devereaux & Guy Rouleau

Table of Contents

>8,800
Patients randomized in trials at Portfolio Hospitals

Led the international initiative to find a group to run a pan-Canadian distributive REB process

CanReview

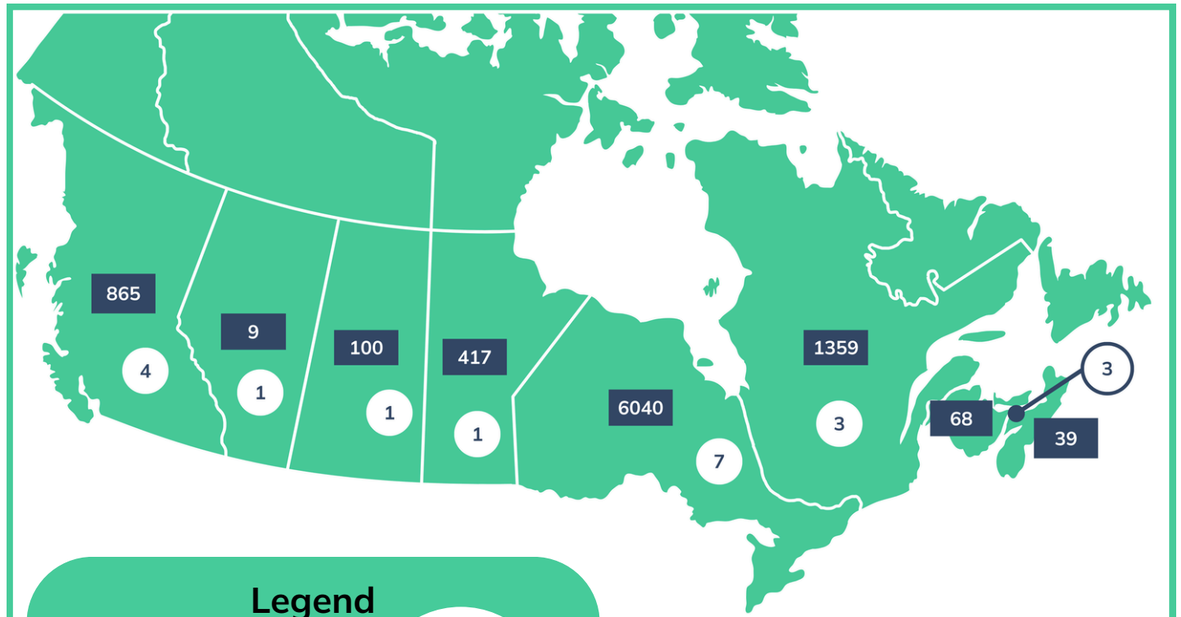
Up to **77%**
Reduction in agreement negotiation time

ACT Portfolio Hospitals

A key priority for the ACT Consortium is to create greater democratization of access to participate in clinical trials for Canadians. The implementation of the **Portfolio Hospital program** addresses the reality that most people living in Canada are treated at community hospitals with limited access to clinical research opportunities. Over the past three years, ACT has activated 20 ACT community portfolio hospitals across 8 provinces with an aim to expand clinical trial recruitment beyond research hospitals in large urban centres that have established research programs, making trials more accessible to people living across Canada. The expansion funding provided to these community hospitals went towards embedding study personnel in these hospitals to facilitate bringing clinical trials to more Canadians – a model based off the UK's Portfolio Hospital program.

Over the past two years, the ACT Consortium has facilitated partnerships and collaborations between research networks, industry, and portfolio hospitals, including at the most recent ACT Consortium Meeting where a targeted networking session was held to connect industry representatives with portfolio hospitals. As a result, all ACT portfolio hospitals have collaborated with at least one ACT network and are involved in at least one ACT committee and/or working group.

As of March 2026, ACT portfolio hospitals have participated in over **220 trials** and have randomized over **8,800 patients** into these trials over the last 3 years. This represents greater access for patients in communities where trials either had not previously occurred or were very infrequent.



In the 3 years of ACT, over 8800 patients have been randomized in ACT Portfolio Hospitals across Canada.

220 +

Trials conducted at portfolio hospitals

1.66

Average new research personnel per site

4.1

Average new researchers per site

ACT Portfolio Hospitals

Visit our website for more details.

Cambridge Memorial Centre
Dr. Shekhar Pandey
Cambridge, ON

Cape Breton Regional Hospital (CBRH)
Dr. Paul McDonald
Sydney, NS

Centre Hospitalier Affilié Universitaire Régional (CHAUR) de Trois-Rivières
Dr. Jean-François Naud
Trois-Rivières, QC

Dr. Georges-L.-Dumont University Hospital Centre (DGLDUHC)
Dr. Rémi LeBlanc
Moncton, NB

East Kootenay Regional Hospital (EKRH)
Dr. Denise Jaworsky
Cranbrook, BC

Grace Hospital
Dr. Gloria Vazquez-Grande
Winnipeg, MB

Health Sciences North (HSN)
Drs. Robert Ohle & Ravinder Jeet Singh
Sudbury, ON

Hôpital Cité-de-la-Santé
Drs. Marios Roussos & Marco Bergevin
Laval, QC

Hôtel-Dieu de Lévis (HDL)
Drs. Patrick Archambault & Martin Crête
Lévis, QC

Humber River Health (HRH)
Dr. Gihad Nesrallah
North York, ON

"Participating in ACT strengthened our site's capacity to support clinical research within a community setting. We increased study start-up processes, increased staff knowledge of clinical trial requirements and enhanced collaboration across departments."
- Humber River Health

"Participation in ACT has allowed us to grow and improve as a research organization. We have been able to engage with medical programs and departments in the hospital that we have not previously worked with and be involved with trials that we may not have had access to previously or may not have been considered for. This opportunity has the potential to greatly benefit the patients in our region by bridging the gap between appointments and placing access to care directly into their hands."
- Health Sciences North

Kelowna General Hospital (KGH)
Drs. Matthew Boyko & Aleksander Tkach
Kelowna, BC

Mackenzie Health
Drs. Kimia Honarmand & Tess Fitzpatrick
Richmond Hill, ON

Medicine Hat Regional Hospital (MHRH)
Dr. Alejandro Manosalva
Medicine Hat, AB

Nanaimo Regional General Hospital (NRGH)
Dr. David Forrest
Nanaimo, BC

Niagara Health
Dr. Jennifer Tsang
St. Catharine's, ON

Oak Valley Health
Drs. Dipayan Chaudhuri, Paul Lee, & Anthony La Delfa
Markham, ON

Penticton Regional Hospital (PRH)
Dr. Michelle Scheepers
Penticton, BC

Queen Elizabeth Hospital (QEH)
Dr. Heather Williams
Charlottetown, PE

Regina General Hospital (RGH)
Dr. Payam Dehghani
Regina, SK

Windsor Regional Hospital (WRH)
Drs. Wassim Saad & Caroline Hamm
Windsor, ON

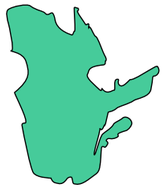
ACT Portfolio Hospitals - Case Studies

Cape Breton Regional Hospital

Prior to ACT, there were a limited number of RCTs occurring at Cape Breton Regional Hospital. As a direct result of the ACT investment, the **number of site PIs** expanded to **4** from **1**, and there are currently **15 clinical trials** at various stages of execution. Cape Breton University continues to expand access to clinical trials to identify and pursue collaborations on RCTs.

15	39	4x
Current clinical trials	Patients randomized	More researchers since joining ACT

Centre Hospitalier Affilié Universitaire Régional (CHAUR) de Trois-Rivières



Participation in the ACT Portfolio Hospital program has strengthened CHAUR de Trois-Rivières' capacity to conduct high quality randomized controlled trials, particularly in complex and high acuity settings such as the intensive care unit. One of the most notable gains has been the expansion and diversification of their ACT-affiliated research portfolio. As a result of ACT, the number of trials has increased from 10 (excluding oncology) studies primarily focused on cardiology to a **total of 23 RCTs** across a broad range of therapeutic areas, including cardiology, critical care, gastroenterology, psychiatry, and infectious disease. This represents a remarkable transformation that has entrenched research into an accessible and integrated component of care.

23	450	3x
Current clinical trials	Patients randomized	More researchers since joining ACT

Mackenzie Health

Before ACT, Mackenzie Health had no formal research office, no dedicated research personnel, limited research governance, and minimal participation in active clinical trials. Research activity was fragmented, externally driven, and operationally unsupported, with no sustainable infrastructure to support trial initiation, execution, or growth.

ACT participation enabled a fundamental shift from ad hoc research activity to the creation of a structured, institutionally embedded clinical research program. Mackenzie Health began participating in its first clinical trial in December 2024 and is **currently participating in 6 trials**, with an additional **4 in start-up**, while supporting **17 locally-led studies**.

In December 2025, they **enrolled their 100th patient**. Collectively, this progress reflects the rapid development and expansion of a research program and growing capacity to support high-quality clinical trials within a community hospital setting.

10	227	3x
Current clinical trials	Patients randomized	More researchers since joining ACT

"As a result of ACT, Mackenzie Health now has: A formal Office of Clinical Research with dedicated research personnel & defined institutional research governance; Active participation in multiple investigator-initiated multicentre clinical trials across diverse specialties, including critical care, nephrology, endocrinology, cardiology, & stroke rehabilitation; and Broad physician enthusiasm & engagement, with multiple clinicians now serving as site co-principal investigators.

- Regina General Hospital

ACT Portfolio Hospitals - Case Studies

Regina General Hospital

The impact of the portfolio hospital program goes beyond number of trials, patients enrolment, and infrastructure/capacity building. In many cases, portfolio hospitals have been able to establish and deepen partnerships and collaborations with networks and industry.

This was most evident with Regina General Hospital, where, in addition to **doubling the number of active trials**, increasing clinical trial volume and diversity, there has also been a significant increase in the level of **interest from industry**, as evidenced by invitations from Novo Nordisk, Novartis, and AstraZeneca to partner on RCTs. As a direct result being a part of ACT, **Regina General has joined an additional 9 networks** (CAIC, CCCTH, CHF Alliance, ACHDI, CTRC, CAnet, PACT-V, PCPCRC, Perioperative Care Network), which has led to the launch or engagement in **5 different trials** (BRAVE, ASPIRE, Detect, PHosphate, LAAOS IV).

17	100	2x
Current clinical trials	Patients randomized	More researchers since joining ACT

"Participation in clinical trials provided patients with access to novel therapies, closer clinical monitoring, and enhanced follow-up. Patients frequently reported feeling more informed, supported, and engaged in their care as a result of research participation."

- Regina General Hospital

Niagara Health Knowledge Institute

Since launching in May 2023, the Niagara Health Knowledge Institute (NHKI) has grown to include eight clinical research programs with funding from the ACT Consortium. The NHKI currently conducts **38 ACT-affiliated and non-ACT-affiliated RCTs** in cardiology, critical care, emergency medicine, hematology/transfusion medicine, infectious diseases, oncology, neurology and thrombosis. Researchers have **enrolled more than 1800** over the last 3 years, creating equity in healthcare by providing access to novel treatments that, historically, have been reserved for patients in larger centres. Recently, researchers with Niagara Health's neurology research program received awards for their efforts, including launching the program in September 2023 with help from ACT and ambitiously growing it to six clinical trials.

"Our hematology/transfusion medicine research program which was started using the ACT funding for an RC, is participating in the EPCAT 3 clinical trial. This study has created a new internal partnership for us, with Dr. Refaei building a collaboration with our orthopaedic surgery team at Niagara Health which is their first foray into research and will hopefully translate to future engagement in research. This team has also recruited 322 patients into the trial between March and December 2025, making it consistently the second highest recruiting site across Canada each month since joining the study - an impressive feat for a nascent program in a community hospital!"

- Niagara Health Knowledge Institute

38	1,812	1.5x
Current clinical trials	Patients randomized	More researchers since joining ACT

ACT Networks

ACT was launched with an initial **28 Canadian clinical trial networks** as identified in the 2022 grant application. In 2023, ACT engaged with provincial/territorial and federal government stakeholders, as well as researchers to identify areas that were not adequately covered by existing research networks. After a robust open request for applications (RFA) and review process, **6 additional Canadian trial networks were funded**, including one in mental health – a priority area identified by government.

Engagement and involvement among the ACT-1 networks has been exceptionally high and steadily increased over the past 3 years – 100% of networks have shared their international investigator contact lists and 97% of networks attended both the last annual virtual all-networks meeting, as well as the 4th Annual ACT Consortium meeting in Cape Breton (85 network representatives). Further, 25 of the original 28 networks nominated trials in at least one or more RFA processes, and 21 of the 28 networks had trials, they nominated, funded through one of the seven RFA processes.

34
Research Networks

1,500+
Canadian researchers in ACT Networks

Cardiovascular

- Canadian Association of Interventional Cardiology Clinical Trials Network (CAIC)
- Canadian Heart Function Alliance (CHF Alliance)
- Canadian Research Network for Adult Congenital Heart Disease Interventions (CRN-ACHDi)
- Cardiovascular Network of Canada (CANet)
- Pan-Canadian Trial Network in Valvular Heart Disease (PACT-V)

Chronic Disease and Cancer Care

- Canadian Chronic Airway Disease Network (CCADN)
- Canadian Donation and Transplantation Research Program (CDTRP)
- Canadian Nephrology Trials Network (CNTN)
- The Canadian Home Mechanical Ventilation Research Network (CanHMVr)
- Cardiometabolic Health, Diabetes, and Obesity Research Network (CMDO)
- Collaborative for Caring for Long-Term Care (CCARE-LTC)
- Diabetes Clinical Trials Network (DCTN)
- IMAGINE Network (*chronic disease*)
- Ontario Clinical Oncology Group (OCOG)

Pediatrics and Child Health

- Canadian Network for Child and Youth Mental Health Trials (CYMH)
- Canadian Paediatric Inpatient Research Network (PIRN)
- INFORM RARE Network (*children with rare genetic diseases*)
- Maternal Infant Child and Youth Research Network (MICYRN)

Infectious Disease

- Canadian COVID-19 Emergency Department Rapid Response Network (CEDRRN)
- Canadian Immunization Research Network (CIRN)
- Infectious Disease Network

Operative and Critical Care

- Canadian Critical Care Trials Group (CCCTG)
- Canadian Collaborative on Urgent Care Surgery (CANUCS)
- Orthopaedic Trauma Surgery Research Network
- Perioperative Care Network

Stroke and Traumatic Brain Injury

- Canadian Stroke Consortium (CSC)
- Canadian Stroke Prevention Intervention Network (CSPIN)
- Canadian Traumatic Brain Injury Research Consortium (CTRC)
- CanStroke Recovery Trials Platform
- Research in Non-Invasive Brain Stimulation (CANStim)

Prescribing, Deprescribing, Pain and Palliative Care

- Canadian Medication Appropriateness and Deprescribing Network (CaDeN)
- Canadian Medical Cannabis Clinical Trials Network (CMCN)
- Chronic Pain Network (CPN)
- Pan-Canadian Palliative Care Research Collaborative (PCPCRC)

New Networks

ACT held an open competition to fund the development of new or existing trial networks in areas of need. A total of $900,000 was awarded to fund 6 new networks, including one network focused on mental health - a government identified priority area.

Canada Supporting Partnerships, Advancing caRe and Knowledge in Long-Term Care (CanSPARK LTC)

CanSpark LTC is a research network focused on conducting RCTs in long-term care, across Canada. Interventional trials in this area have been minimal due to barriers such as limited infrastructure and a shortage of researchers with interest and experience in long-term care RCTs.

CanSpark LTC's vision is for Canada to become a world leader in providing evidence informed, person-centered care and wellbeing for those who live and work in LTC.

Studies Being Designed

Workforce Wellbeing & Quality Of Life

Understanding the relationship between workforce policies and quality of care

Quality Of Life & Person-Centred Care

What is the best approach to promoting sleep in LTC?

Canadian Network for Child and Youth Mental Health Trials (CYMH Trials Network)

ACT sought input from federal, provincial, and territorial Ministries of Health to identify areas they find challenging to obtain research data in. The Ministries identified mental health as one of these areas, resulting in applications requested for the creation of a network focused on mental health RCTs.

The Canadian Network for Child and Youth Mental Health Trials was the awardee selected to fulfill this need for mental health data. The CYMH Trials Network specifically focuses on mental disorders in childhood, which are often complex and multimorbid.

Initial RCTs

Specialty Care for Youth Wellness Trial

Multidisciplinary, transdiagnostic interventions for youth with complex and impairing disorders

Digital Health Technology Trial

Personalized behavioural sleep treatment using digital health technology

Canadian Medical Cannabis Clinical Trials Network (CMCN)

CMCN was created to help close the knowledge gap related to the use of cannabis for medical purposes, such as chronic pain and mental illness, by supporting high-quality, rigorous trials of medical cannabis products.

Initial RCT

Cannabidiol (CBD) vs. placebo to reduce persistent pain after TKA

40-patient, parallel, feasibility RCT

Canadian Paediatric Inpatient Research Network (PIRN)

PIRN was created with the aim of increasing research capacity to conduct high-quality RCTs in pediatric inpatient units.

Initial RCTs

DEX2 Pilot Study

Feasibility of conducting an RCT comparing oral dexamethasone to placebo for children hospitalized with croup following ED corticosteroid treatment

DOC Pilot Study

Feasibility of conducting an RCT comparing IV dexamethasone to placebo for children and youth hospitalized with orbital cellulitis

The Canadian Home Mechanical Ventilation Research Network (CanHMVr)

CanHMVr was created to address the lack of large-scale studies focused on the Home Mechanical Ventilation population. There is currently a need for this research due to intense healthcare utilization of patients and associated costs of HMV. The network's aim is to develop, evaluate and implement innovative treatment strategies and healthcare system delivery models to improve the health and healthcare experience of the HMV population.

Initial RCT

PSG vs home initiation of non-invasive ventilation (NIV) in pediatric neuromuscular disease and NIV vs CPAP for COPD

Canadian Collaborative on Urgent Care Surgery (CANUCS)

CANUCS focuses on trials involving Emergency General Surgery (EGS). Although EGS makes up >10% of hospital admissions, there is a limited evidence base in this area and no other EGS networks in Canada.

Initial RCT

Fast track pathway to accelerated cholecystectomy vs. standard of care for acute cholecystitis trial (FAST)

For patients with acute calculous cholecystitis, is accelerated care superior to standard care?

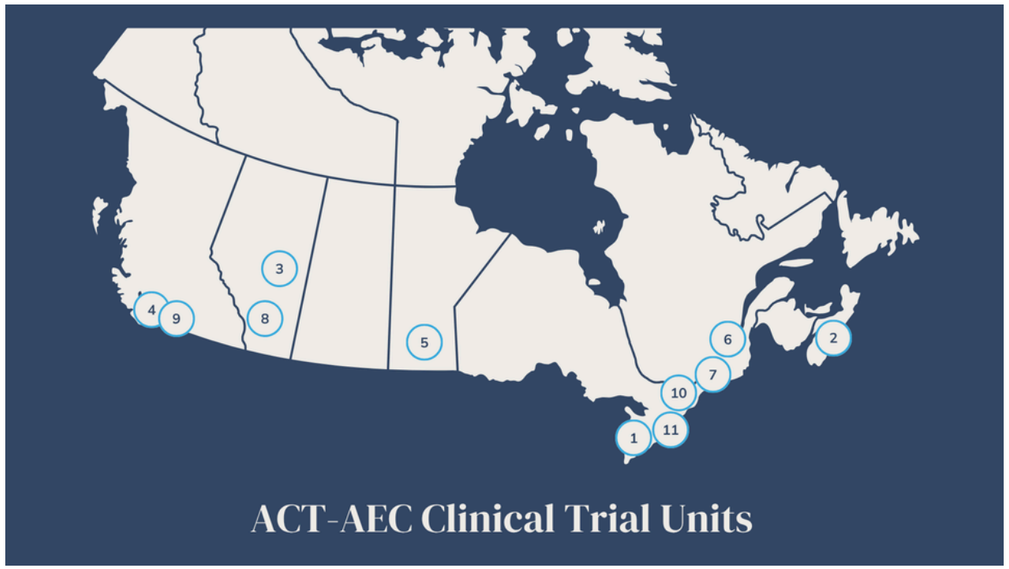
ACT CTUs

Over the past 3 years, ACT has provided funding to **11 Clinical Trial Units (CTUs)** to support resources focused on innovation, coordination, data acquisition and linkage, privacy, quality assurance, implementation of standard operating procedures (SOPs), and trial unit management of ACT initiatives. These 11 CTUs are strategically positioned across the country to provide specialized support for a wide range of trials, from conventional to innovative designs and offer tailored expertise for investigators and industry partners seeking optimal trial design and execution. Further, these CTUs are dedicated to advancing clinical research, fostering collaborations, and ensuring excellence in trial design and execution

50+
Jobs supported

100+
New organizational collaborations

150+
New trials due to ACT



ACT-AEC Clinical Trial Units

Schulich MEDICINE & DENTISTRY

Accelerating Randomized Trials (ART) Platform

Schulich School of Medicine & Dentistry, Western University

Location

London, ON

Areas of Specialization

Gastrointestinal trials
The use of admin data and streamlined processes to execute trials

Website

www.schulich.uwo.ca/pragmatictrialservice/

"We feel that Manitoba is punching well above it's weight for clinical trials leadership because of ACT funding. We've scaled and now lead international trials in over **60 sites** and **7 countries.** The CTU has received almost $10M in funding for trials they lead. The CTU has been recognized as a trusted partner in the development and conduct of novel trial designs."
- AURORA Clinical Research

"Capacity building efforts and standardization within the CTU have allowed us to develop a replicable educational and services program that supports **33 trials**, and **more than 75 learners** across **10 provinces**. The rapid growth of our CTU would not have been possible without the ACT funding."
- Accelerating Randomized Trials Platform

AURORA Clinical Research

AURORA Clinical Research

Rady Faculty of Health Sciences, University of Manitoba

Location

Winnipeg, MB

Areas of Specialization

Sepsis
Anticoagulation
Platform trials

ACT CTUs

Canadian Center for Vaccinology (CCfV)

Faculty of Medicine, Dalhousie University

Location

Halifax, NS

Areas of Specialization

Infectious disease and vaccines

Website

centerforvaccinology.ca

Canadian VIGOUR Centre (CVC)

Faculty of Medicine, University of Alberta

Location

Edmonton, AB

Areas of Specialization

Cardiovascular disease
Trials with patient populations at risk for CVD (diabetes, renal, PH)

Website

thecvc.ca/

"Over the past three years, ACT infrastructure funding has been instrumental in advancing CCfV's capacity as a Clinical Trials Unit (CTU). This sustained support has enabled the addition of dedicated staff and operational resources that have strengthened core trial functions, including study start-up, regulatory coordination, and clinical trial execution. The availability of ACT-supported personnel has improved responsiveness to partners, reduced start-up timelines, and increased CCfV's ability to manage multiple complex studies in parallel. "
- Canadian Center for Vaccinology

Centre for Cardiovascular Innovation (CCI-CIC)

Vancouver Coastal Health / Faculty of Medicine, University of British Columbia

Location

Vancouver, BC

Areas of Specialization

Acute coronary syndromes (ACS)
Interventional and structural cardiology
Cardiovascular surgery
Arrhythmia and heart failure
Cardiovascular disease (CVD) prevention
Women's heart health
Adult congenital
Cardiology-oncology
Sports cardiology
Urology
Neurology
Pharmaceutical sciences

Website

cci-cic.org/

"Through ACT meetings, working groups, and national networking opportunities, our CTU has been able to connect with investigators, CTUs, industry, and other clinical trial stakeholders across Canada. "
- Centre for Cardiovascular Innovation

CHU de Québec

Université Laval Research Center

Location

Québec City, QC

Areas of Specialization

Trauma
Critical care medicine
ICU
Neurology
Neurosurgery

Website

www.crchudequebec.ulaval.ca/en/

Health Policy Trials Unit

Cumming School of Medicine, University of Calgary

Location

Calgary, AB

Areas of Specialization

Populations with low incomes and chronic diseases

Website

obrieniph.ucalgary.ca/centre/health-policy/what-centre-health-policy/health-policy-trials-unit

ACT CTUs

Maternal Infant Child & Youth Research Network (MICYRN)

Location

Vancouver, BC

Areas of Specialization

Maternal and perinatal health
Neonatology
Pediatrics

Website

www.micyrn.ca/

Ottawa Hospital Research Institute (OHRI)

Affiliated University: University of Ottawa

Location

Ottawa, ON

Areas of Specialization

Thrombosis
Transfusion medicine
Oncology
Nephrology
Respirology
Novel trials design

Website

ohri.ca/ottawamethodscentre/

Population Health Research Institute (PHRI)

McMaster University & Hamilton Health Sciences

Location

Hamilton, ON

Areas of Specialization

Arrhythmia and thrombosis prevention
Renal
Diabetes
Perioperative medicine
Global and population health
Acute coronary syndrome
Cardio-oncology
Brain health

Website

www.phri.ca/

"ACT funding has successfully brought together key decision-makers—those with the authority to implement necessary changes—to push initiatives that needed to progress beyond any individual CTU, on a national level"
- Ottawa Hospital Research Institute

Research Institute McGill University Health Centre (RI-MUHC)

McGill University Health Centre

Location

Montreal, QC

Areas of Specialization

Prescribing
Oncology
Cardiology
Respirology
Infectious diseases
Pediatric gene therapy

Website

rimuhc.ca/

"ACT funding also enabled the transformation of a previously fragmented clinical trial landscape into a cohesive, collaborative Clinical Trial Unit. Our CTU is successfully breaking down silos in which investigators conduct trials independently, fostering a more inclusive and integrated environment where expertise, infrastructure, and resources are shared to accelerate trial development and execution across disciplines"
- Research Institute McGill University Health Centre

One initiative ACT CTUs were focused on was the assessment, evaluation, and selection of a preferred electronic trial master file (eTMF) vendor for ACT-affiliated trial units. Led by operations managers across 7 CTUs, a robust engagement and evaluation process was completed, resulting in the selection of RAN BioLinks as the preferred vendor from a short list of 11 vendors based on technical, functional, and regulatory criteria, as well as implementation feasibility and cost/budget considerations. This offering is currently being rolled out to interested CTUs and will support and complement existing trials' infrastructure across the country in a cost-effective manner. Long-term cost savings will be realized by participating CTUs, and the offering is scalable depending on uptake.

CanReview

ACT held an open competition to select a group to set up and run a sustainable pan-Canadian, distributive, single REB review and approval process with strict timelines for the initiation and conduct of multicentre RCTs in Canada.

Selection Process

A panel of reviewers were selected to independently evaluate the proposals, those that achieved a mean score of 70 or more on the written application moved forward to the interview stage. The selection committee, comprised of individuals from across Canada and the globe with expertise in the REB process, led the interview and selection process. After reviewing the anonymized scores and comments, the Selection Committee unanimously named **CanReview** the successful candidate.

CanReview

CanReview Partners

125 *Partner organizations*

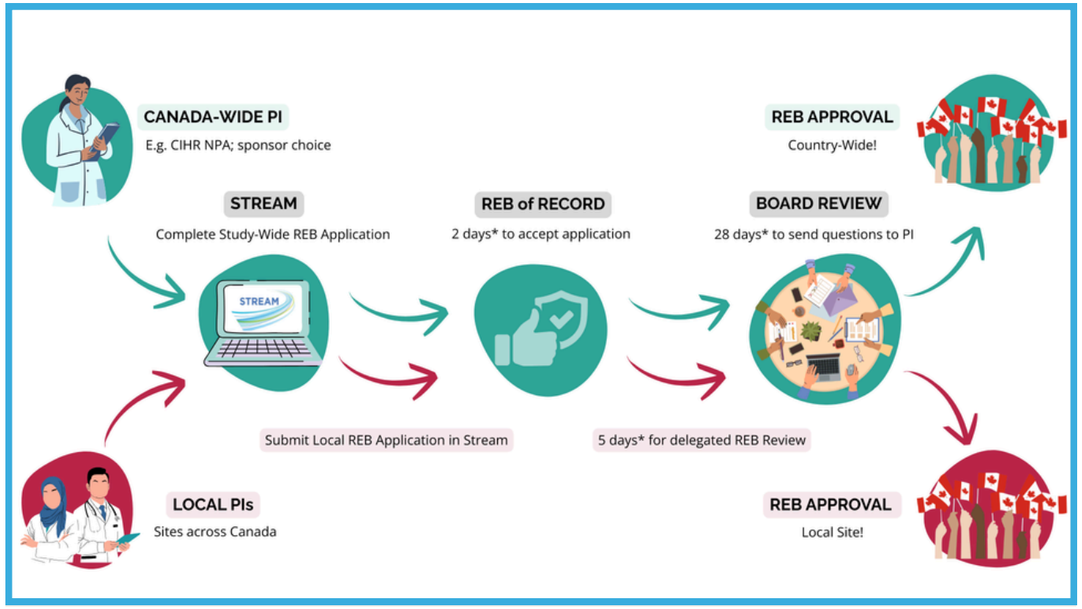
Over 125 organizations across Canada have become CanReview partners and are collaborating on this new initiative.

The following institutions have officially registered or declared their intent to become a participating site.

- Bruyère Health Research Institute
- Cape Breton University
- Health Sciences North
- Health Sciences North Research Institute
- Holland Bloorview
- Lawson Research Insitute
- Lakeridge Health
- London Health Sciences Centre Research Institute
- Research Institute of the McGill University Health Centre
- Sinai Health
- Sunnybrook Research Institute
- Thunder Bay Regional Health Sciences Centre
- University of Ottawa Heart Institute
- University of Waterloo
- Vitalité Health Network
- Western University

About the CanReview Process

CanReview optimizes the REB review and approval process for pan-Canadian multicentre RCTs through a single, centralized online platform. The system ensures rapid turnaround times through the CanReview Process illustrated in the diagram below:



2 *Days* — **For study-wide application acceptance**

28 *Days* — **For study-wide application decision**

5 *Days* — **For local site application decision**

"The planned single national ethics review proposal for clinical trials in Canada represents a huge opportunity for the people of Canada to access innovative therapies. Streamlined, excellent ethics oversight of clinical trials will position Canada as a world leader in medical research. Clinical research studies will be done according the highest ethical and scientific standards. The diversity of the Canadian population, the quality of Canadian researchers and the strengths of the healthcare system will translate into an economic benefit for us all."

- Raphael Saginur, Associate Professor, University of Ottawa / Ottawa Health Sciences Network Research Ethics Board Chair

ACT Contracts

The ACT Consortium Contracts Working Group has developed several agreements, including the Governing Data and Biological Sample Transfers Agreement (gDSSA), Sub-Site Template Agreement and the Participating Site Agreement Template, to enable focused negotiations and meaningfully reduce review timelines.

Early insights into efficiency gains from the **gDSSA** suggest an important reduction in the number of days it takes for an agreement to be finalized, with % reduction rates as high as 77% at some institutions. In one example, cycle times for the gDSSA at Ottawa Hospital Research Institute (OHRI) fell from 75 days to 22 days (a 53-day reduction) post implementation. The gDSSA has now been adopted by 72 organizations including universities, research institutes, hospitals and health authorities.

The Contracts Working Group developed two governing Participating Site Agreements (**gPSA**) or master clinical trial agreements - one for Tri-Council funded studies that are regulated by Health Canada (48 signatories as of March 19, 2026 covering over 60 sites), and one that is for studies that are not Health Canada-regulated (30 signatories). To ensure these agreements are implemented and shared effectively across the Canadian landscape, the Contracts working group is implementing a dissemination plan – this has included translated guidance documents, and a webinar.

72+
gDSSA Signatories

up to **77%**
reduction in agreement negotiation time

50+
gPSA Signatories

Governing Data and Biological Sample Transfers Agreement (gDSSA)

The ACT Consortium Contracts Working Group has developed the Governing Data and Biological Sample Transfers Agreement (gDSSA)—a streamlined approach to facilitating research collaborations. This agreement establishes a binding framework with pre-negotiated terms and conditions, significantly reducing execution timelines by enabling focused negotiations.

A key feature of the gDSSA is the transfer letter, which outlines study-specific details while maintaining the integrity of the pre-established terms. Changes are kept to a minimum, ensuring efficiency and consistency in the execution process.

Executed in February 2024, the gDSSA initially included 29 Canadian signatories from universities, research institutes, hospitals, and health authorities. Since then, the agreement has expanded to include over 70 adoptees, demonstrating its value in fostering research collaborations.

The gDSSA is ideal for research involving:

- Secondary use research
- Retrospective chart reviews
- Prospective chart reviews

The gDSSA is beneficial for:

- Academic institutions and research organizations
- Hospitals and health authorities
- Affiliated institutions involved in data and biological sample transfers

Governing Participating Site Agreement (gPSA)

The Accelerating Clinical Trials (ACT) Consortium Contract Working Group has developed the Governing Participating Site Agreement for Tri-Council Funded Studies: Interventional and Regulated (gPSA Regulated).

This agreement is designed to streamline contract negotiations for inter-institutional, Health Canada–regulated clinical trials funded by the Tri-Council Agencies (CIHR, NSERC, SSHRC). By establishing a pre-negotiated, legally binding framework, it aims to improve efficiency and accelerate study start-up timelines for academic and affiliated healthcare institutions/health authorities participating in these studies.

The agreement includes two key components:

1) Agreement: A pre-negotiated, legally binding contract that outlines standard clauses and conditions. Parties agree to the terms in full unless specific changes are outlined in the accompanying Study Letter.

2) Study Letter: A project-specific document for each trial conducted under the agreement, which includes:

- Study-specific details and identifiers
- Optional clauses tailored to trial characteristics

A section for any permitted modifications to the Governing Agreement

Key benefits of the gPSA include:

- Reducing the need for full re-negotiation of terms for every new study
- Enabling focused review of only study-specific details
- Promoting consistency in legal and governance terms across academic organizations and health authorities nationwide

Current number of adoptees:

51

Canadian Biotech

ACT firmly believes that a thriving biotechnology industry is key to a strong economy and strengthened research capacity across Canada. Over the past 3 years, ACT has invested in growing the Canadian biotechnology industry by: holding 2 national meetings that brought over 100 Canadian biotechnology companies and over 300 ACT-affiliated researchers together to learn about Canadian biotechnologies, facilitated networking, partnership, and collaboration between industry, biotechnology companies, and ACT networks and trial units at subsequent meetings, and funding RCTs that evaluate Canadian biotechnology.

Through the RFA 3 and RFA 6 processes, funding was provided to eleven successful trials to evaluate biotechnologies from Canadian-controlled private corporations in partnership with Canadian clinical trialists from ACT networks

100+
Biotech companies at ACT Meetings

50+
RFA Applications

11
Funded studies

Funded Studies - Apr 2023

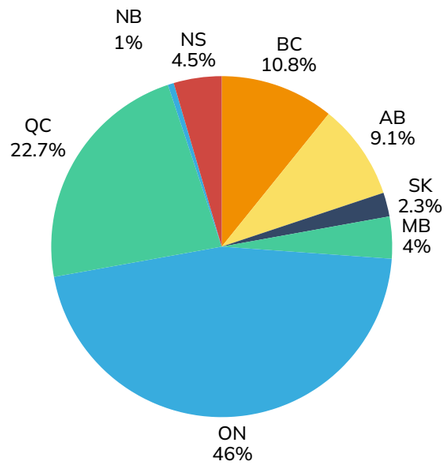
This funding opportunity supported ACT Network members in the completion of high-quality RCTs, with a high potential to create meaningful impact.

Of special note, numerous ACT-funded high-impact RCTs have now been published in peer-review journals:

New England Journal of Medicine (NEJM): REVISE, ARTESIA, HEMOTION, CLEAR Spironolactone, CLEAR Colchicine
The Lancet: ACHIEVE, COP-AF

Knowledge Mobilization Stats	
Peer-reviewed journal publications	58
Plain-text publications	71
Citations	1493
Conference/Symposia presentations	18

Provincial Site Locations



"ACT funding allowed completion of this landmark global critical care trial, which is the largest single patient parallel group randomized trial ever led by Canada. Operating in 68 centers in 8 countries, it showed that proton pump inhibitors are not only highly effective but also cost effective - beneficial for patients and the healthcare system. We are extremely grateful."
- REVISE Study Team

53,000+ patients supported

ACHIEVE
Aldosterone bloCkade for Health Improvement EValuation in End-stage renal disease
Dr. Michael Walsh, Canadian Nephrology Trials Network

ARTESiA
Apixaban for the Reduction of Thrombo-Embolism in Patients with Device-Detected Sub-Clinical Atrial Fibrillation
Dr, Jeff Healey, Canadian Stroke Prevention Intervention Network

BFREE
Benzodiazepine-free cardiac anesthesia for reduction of postoperative delirium
Dr. Jessica Spence, Perioperative Care Network

CYCLE
Critical Care Cycling to Improve Lower Extremity Strength
Dr. Michelle Kho, Canadian Critical Care Trials Group

COP-AF
Colchicine For The Prevention Of Perioperative Atrial Fibrillation In Patients Undergoing Thoracic Surgery
Dr. David Conen, Perioperative Care Network

RAFF4
A Randomized Trial of Anti-Arrhythmic Agents to Improve Management of Emergency Department Patients with Acute Atrial Fibrillation
Dr. Ian Stiell, Cardiac Arrhythmia Network of Canada

CLEAR SYNERGY
A 2×2 factorial placebo-controlled trial of colchicine and spironolactone in patients with acute myocardial infarction (MI)
Dr. Sanjit Jolly, Canadian Association of Interventional Cardiology

EnAKT LKD
Effect of a Multi-Component Quality Improvement Intervention on Patient Access to Kidney Transplantation and Living Kidney Donation
Dr. Amit Garg, Canadian Nephrology Trials Network

HEMOTION TRIAL
HEMOglobin transfusion threshold in Traumatic brain Injury OptimizatioN
Dr. Alexis Turgeon, Canadian Traumatic Brain Injury Research Consortium

REVISE
REVISE: Re-Evaluating the Inhibition of Stress Erosions in the ICU Trial
Dr. Deborah Cook, Canadian Critical Care Trials Group

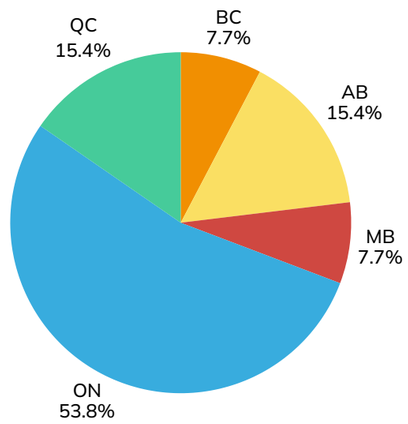
REFINE ICD
REFINE-ICD: Risk Estimation Following Infarction Non-invasive Evaluation – ICD Efficacy
Dr. Derek Exner, Cardiac Arrhythmia Network of Canada

Funded Studies - June 2023

This funding opportunity was dedicated to supporting ACT Networks in conducting trials with a novel design.

Knowledge Mobilization Stats	
Peer-reviewed journal publications	11
Plain-text publications	8
Citations	12
Conference/Symposia presentations	15

Provincial Site Locations



"The most valuable aspect of ACT funding was its support for developing and integrating the project's exceptionally complex suite of resources, including study documentation, consent materials, outreach scripts, workflow tools, and QA/privacy processes, with the privacy-compliant, multi-stage recruitment and enrollment pathway standing as the clearest example of this comprehensive effort."
- KidneyCareOutreach Study Team

ALICE
Anxiolysis for Laceration Repair in Children: An Open-Label Multicentre Adaptive Trial
Dr. Naveen Poonai, Maternal Infant Child and Youth Research Network

CRAVE
Canadian Right ventricular AdatiVE platform
Dr. Jason Weatherald & Dr. Lisa Mielniczuk, Canadian Heart Function Alliance

Dial-Bicarb
Lower vs. higher dialysate bicarbonate in patients receiving hemodialysis
Dr. Samuel Silver & Dr. Amber Molnar, Canadian Nephrology Trials Network

KidneyCareOutreach
Vanguard phase of a population-based randomized clinical trial to strengthen kidney care delivery for patients at high risk of kidney failure
Dr. Ann Young, Canadian Nephrology Trials Network

NAPTEM-C
Developing a National Adaptive Platform Trial in Emergency Medicine to Evaluate COVID-19 Therapies
Dr. Corinne Hohl, Canadian COVID-19 Emergency Department Rapid Response Network

TheRAPy
The effect of retrograde autologous priming on transfusion requirements after cardiac surgery: A multi-centre, multi-period, vanguard randomized cluster crossover trial
Dr. Jessica Spence & Dr. Deborah Siegal, Perioperative Care Network

OK TRANSPLANT
Obesity management for kidney TRANSPLANTation: a vanguard study for an innovative randomized controlled trial, embedded in routine care
Dr. Kristin K Clemens & Dr. Louise Moist, Diabetes Clinical Trials Network

SAFE
Surgical Ablation of Atrial Fibrillation Trial
Dr. Emilie Belley-Côté & Dr. Richard Whitlock, Cardiac Arrythmia Network of Canada

VICTORY
Virtual, Innovative, postsurgical Care To Optimize Return home for older people with frailty
Dr. Sylvie Aucoin, Perioperative Care Network

Funded Studies - June 2023

This opportunity focused on Studies Within a Trial (SWATs) that generate evidence on interventions that streamline processes and elevate participant engagement and data quality of RCTs.

Knowledge Mobilization Stats	
Peer-reviewed journal publications	1
Plain-text publications	2
Citations	6

SWIFT

Recruitment Intervention for BRAVE SWIFT
Prof. Shrikant Bangdiwala & Prof. Susan Jac, Cardiometabolic Health, Diabetes & Obesity Research Network

CAPTIVATE
The Chronic kidney disease Adaptive Platform Trial Investigating Various Agents for Therapeutic Effect

Consent for Adaptive Platform TrIals using abbreViATEd, patient-centered, modular audiovisual methods: A trial within multiple platform trials of ATTACCCAP, PRACTICAL and REMAP-CAP
Dr. Sylvain Lother, Canadian Critical Care Trials Group

WHEAT-SWAT

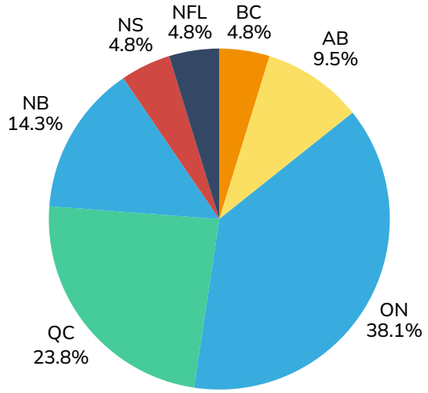
Examining the efficacy of a parent-targeted co-designed digital media intervention to increase recruitment rates across a multi-site randomized clinical trial in Canadian NICU's
Dr. Balpreet Singh, Maternal Infant Child and Youth Research Network

PROMs

Interventions to Optimize Response Rates for Online, Patient-Reported Outcomes Measures
Dr. Paul Karanicolas, Perioperative Care Network

SIMPLY-SNAP

Evaluating the impact of a SIMPlified LaYered consent process versus a conventional informed consent form on recruitment of potential participants to a large platform clinical trial: a pragmatic nested randomized controlled trial
Dr. Nick Daneman, Infectious Disease Network



Provincial Site Locations

"The ACT funds enabled us to do the SWAT; without this financial support, it would not have been possible to build this important methods study into the trial. In other words, the most valuable element was to support an area of research (i.e., methodological research questions) where traditionally, there are very limited funding opportunities"
- PROMs Study Team

Funded Studies - July 2023

1,190+
patients supported

The objective of this opportunity was to fund partnerships with Canadian-controlled biotechnology companies and clinical trialists within ACT networks.

"The most valuable aspect of ACT funding for the trial was it supported the essential infrastructure needed to conduct a complex perioperative, investigator-initiated trial with integrated translational endpoints, while ensuring patient safety and data integrity"
- PEROP-06 Study Team

Knowledge Mobilization Stats	
Peer-reviewed journal publications	1
Plain-text publications	2
Citations	1
Conference/Symposia presentations	8

Liberation from ventilation through Extubation Advisor Decision Support
Dr. Karen EA Burns & Dr. Andrew Seely, Canadian Critical Care Trials Group

EQUAL Dialysis

Evaluation of Qidni Urea And metabolite cLearance in maintenance Dialysis
Dr. Michael Walsh, Dr. Peter Margetts & Dr. Pavel Roshanov, Canadian Nephrology Trials Network

AMT-143

A Phase 1 Randomized Controlled Trial Evaluating AMT-143 in Healthy Volunteers to Assess Sustained Analgesic nRelease for Non-Opioid Pain Treatments
Dr. Hance Clarke & Dr. Paul Karanicolas, Perioperative Care Network

PERIOP-06

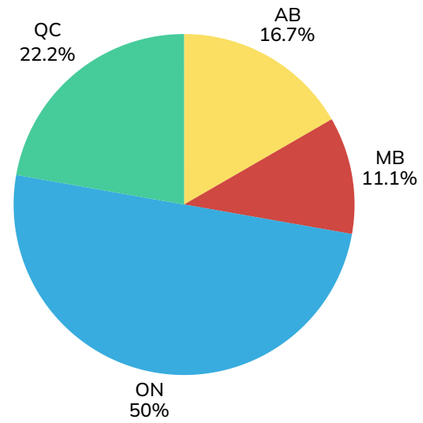
A Phase II Study of Perioperative QBECO Site Specific Immunomodulator in Patients with Metastatic Colorectal Adenocarcinoma Within the Liver Undergoing Resectio
Dr. Rebecca Auer & Dr. Paul Karanicolas, Perioperative Care Network

PONTIAC

Prevention of Nephrotoxin-induced AKI with Cilastatin Trial
Dr. Matthew James, Dr. Neesh Pannu & Dr. Daniel Muruve, Canadian Nephrology Trials Network

pVC-RAM-2

Post discharge after surgery Virtual Care with Remote Automated Monitoring technology-2 Trial
Dr. Sandra Ofori & Dr. Michael McGillion, Perioperative Care Network



Provincial Site Locations

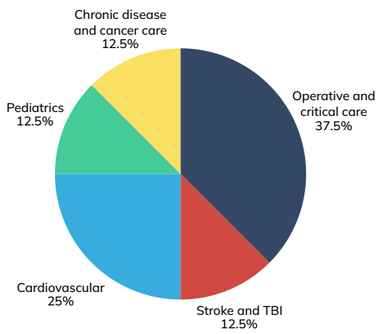
Funded Studies - Sept 2024

The goal of this opportunity was to encourage new collaborations between Canadian researchers and international, high-impact RCTs.

1,000+
patients supported in Canada

"The most valuable aspect of ACT funding was support for a dedicated Canadian trial research coordinator, which enabled efficient coordination across Canadian sites and seamless integration with the international lead site. This centralized coordination improved communication, regulatory alignment, data quality, and trial efficiency, and was essential for Canada's successful participation in a complex international randomized controlled trial"
- SURFS-UP Study Team

Studies by research area:



"The ACT funding was instrumental in bringing this trial to Canada. The CRAAFT study will be completed faster with the addition of the Canadian sites. Once the ACT funding is depleted, the UK investigators are exploring ways in which to continue funding the Canadian sites, thereby increasing research funding in Canada"
- CRAAFT-HF Study Team

Avoiding Risks of Thrombosis and Bleeding in Surgery
Dr. Phillippe Violette, Dr. Arnav Agarwal & Dr. Kali Tikkinen, Perioperative Care Network

Better Evidence And Translation for Calciphylaxis
Dr, David Collister & Dr. Meg Jardine, Canadian Stroke Consortium

BELIEVERS: Imaging Substudy of Bicuspid aortic valve replacement: EvaLuatIon of transcathetEr Versus surgERy-PILOT
Dr. *Maral Ouzounian, Dr. David Wood, Dr. Philippe Pibarot & Dr. Raj Makkar, Pan-Canadian Trial Network in Valvular Heart Disease*

CRAAFT-HF

Cryoballoon/Radiofrequency Ablation of Atrial Fibrillation versus Medical Treatment for heart failure
Dr. Ratika Parkash & Dr. Pier Lambiase, Cardiovascular Network of Canada

Early atrial fibrillation ablation for stroke prevention in patients with high comorbidity burden
Dr, Jason Andrade & Dr. Paulus Kirchhof, Cardiovascular Network of Canada

IMPRoving Outcomes in Vascular diseasE - Aortic Dissection
Dr. Laura Marie Drudi & Dr. Manesh R Patel, Perioperative Care Network

MAC-HF

My Anesthesia Choice: Implementing an evidence-based approach to increase shared decision-making in anesthesia care for patients undergoing hip fracture surgery
Dr. Derek Dillane & Dr. Mark Neuman, Perioperative Care Network

SURFactant Administration by SUPraglottic Airway
Dr. *Georg Schmölzer & Dr. Calum Roberts, Maternal Infant Child and Youth Research Network*

The 3LTA Study

A Randomized Controlled Trial of Polysomnographic Titration of Non-invasive Ventilation in Amyotrophic Lateral Sclerosis
Dr. Reshma Amin & Dr. David Berlowitz, The Canadian Home Mechanical Ventilation Research Network

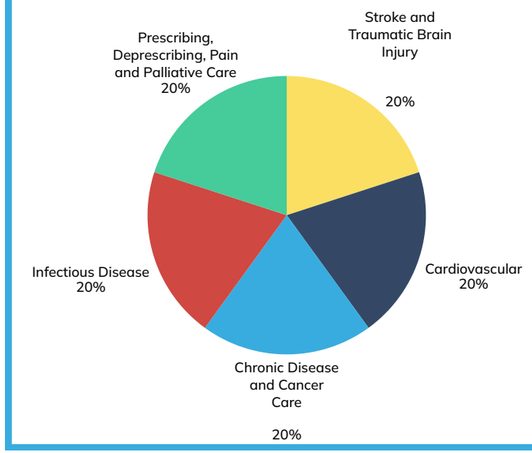
Threshold for Platelets

A prospective randomised trial to define the platelet count below which critically ill patients should receive a platelet transfusion prior to an invasive procedure
Dr. François Lamontagne, Dr. Neill Adhikari, Dr. Donald Arnold & Dr. Peter Watkinson, Canadian Critical Care Trials Group

Funded Studies - Jan 2025

This funding opportunity supported partnerships between Canadian-controlled biotechnology companies and clinical trialists within ACT networks.

Studies by research area:



"The trial has broader system-level impact by demonstrating a collaborative, pan-Canadian model for conducting complex vaccine trials that integrates academic leadership, industry partnership, community engagement, and national infrastructure support through ACT. Lessons learned from the trial will inform future study."
- HiaVaccine Study Team

"ACT funding was instrumental in getting this trial started and executed, and thus will have been instrumental in informing regulatory decision-making about the use of microdose psilocybin in palliative care. In particular, the Special Access Program has told us directly that they need a phase 3 trial demonstrating the benefit (if any) of this intervention before they could offer this treatment to patients at the end-of-life. This ACT-funded study will be the first of its kind and directly provide this evidence to Health Canada"
- PSYCHED-PAL Study Team

ANIMATOR
brAin coNtrolled robotic arM rehabilitation fOr stRoke
Dr. Sean Dukelow, Dr. Janice Eng & Dr. Mark Bayley, CanStroke Recovery Trials

DONATION ADVISOR
Improving deceased organ donation and transplantation: a multicenter feasibility implementation randomized controlled trial of the Donation Advisor tool
Dr. Sonny Dhanani & Dr. Andrew Seely, Canadian Donation and Transplantation Research Program

HiaVaccinePhase2
A phase 2 randomized controlled trial of a Haemophilus influenzae type a vaccine in healthy Indigenous and non-Indigenous adults
Dr. Scott Halperin, Dr. Brian Ward & Dr. Joanne Langley, Canadian Immunization Research Network

PROTECT PGD
Prospective Reduction Of Transplant complications through EnhanCed Preservation Therapy to prevent Primary Graft Dysfunction Pilot Randomized Trial
Dr. Yasbanoo Moayedi, Dr. Vivek Rao & Dr. Phyllis Billia, Canadian Donation and Transplantation Research Program

PSYCHED-PAL
Psilocybin microdose for psychological distress in patients with advanced illness: A phase 3 double-blind, placebo-controlled, parallel-arm clinical trial
Dr. James Downar, Pan-Canadian Palliative Care Research Collaborative

"The most valuable aspect of ACT funding was its role in enabling early-stage feasibility and infrastructure development for the PROTECT-PGD trial. ACT support provided protected resources at a critical inflection point, allowing the project to transition from concept to execution by supporting study start-up, dedicated research personnel, and regulatory readiness."
- PROTECT-PGD Study Team

Funding Opportunities

The ACT Consortium conducted 6 funding opportunities (RFAs) to support studies being done by ACT networks. These opportunities targeted specific research priorities as listed below, and supported over 45 studies.

55,000+
patients supported

Apr 2023

RFA 1
Supporting the Completion of High-Impact Randomized Controlled Trials

RFA 1 was established to support the completion of high-quality RCTs, with a high potential to create meaningful impact. 43 applications from across Canada were submitted, and 11 awardees received up to $200,000 in funding, totalling to approximately $2 million.

June 2023

RFA 2
Advances in the Conduct of Randomized Controlled Trials

RFA 2 was divided into two streams and both sought to catalyze innovative research.

Stream 1 was dedicated to novel trial designs. 33 applications were recieved, $1.7 million of funding was awarded across 9 projects.

Stream 2 focused on Studies Within a Trial (SWATs) that generate evidence on interventions that streamline processes and elevate participant engagement and data quality of RCTs. 8 applications were recieved, $400,000 was awarded across 5 projects.

July 2023

RFA 3
Evaluating Canadian Biotechnologies with Randomized Controlled Trials (RCTs)

The objective of RFA 3 was to fund partnerships with Canadian-controlled biotechnology companies and clinical trialists within ACT networks. 30 applications were received, of which 6 were awarded a portion of $2 million of funding to support Canadian biotechnology clinical trials.

Sept 2024

RFA 5
Bringing High-Impact Randomized Controlled Trials to Canada that Were Initiated and Are Led by a Non-Canadian Country

The objective RFA 5 was to encourage new collaborations between Canadian researchers and international, high-impact RCTs. 19 applications were received, with 10 applications being funded $200,000 each. This RFA resulted in collaborations across 5 countries – Australia, Finland, Germany, United Kingdom, and the United States.

Jan 2025

RFA 6
Evaluating Canadian Biotechnologies with Randomized Controlled Trials (RCTs)

The objective of RFA 6 was to fund partnerships with Canadian-controlled biotechnology companies and clinical trialists within ACT networks. 25 applications were received, of which 5 were awarded a portion of $2 million of funding to support Canadian biotechnology clinical trials.

***note: RFA 4 was completed in January 2024 and focused on the development of new networks**

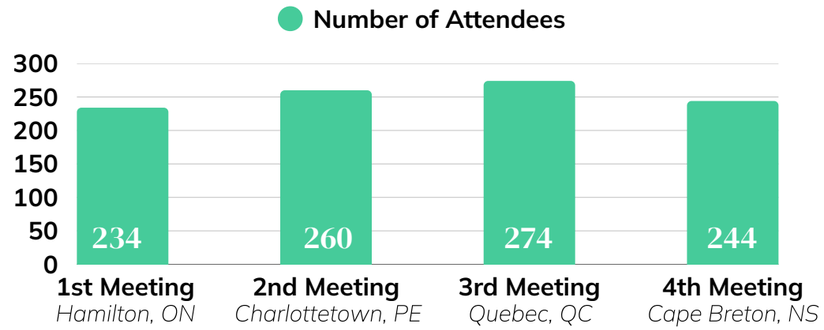
ACT Consortium Meetings

Over the past 3 years, ACT has been successful in building partnerships and collaborations and convening stakeholders to support increased efficiency and impact of research, particularly through the annual ACT Consortium Meetings. Meetings have generated meaningful outputs including: net new collaborations between Canadian biotechnology companies and trialists, facilitated connections between investigators, industry, and portfolio hospitals, consolidated feedback from ACT members that culminated in a submission to Health Canada recommending changes to the draft ICH E6 (R3), visioning on requirements for a pan-Canadian single national research ethics board review and approval process, and focus groups that informed the Inclusion, Diversity, Equity, and Accessibility toolkit.





The most recent ACT Consortium Meeting in Cape Breton had 258 attendees, as well as 51 attendees who attended a half-day Health Canada workshop focused on regulations and inspections, directly engaging with Health Canada inspectors and compliance staff. Attendees comprised of a cross section of stakeholders including trialists, trainees, research administrators, patient partners, and Indigenous representatives, spanning our 34 research networks, 11 clinical trial units, 20 portfolio hospitals, industry, government, regulators, venture capitalists, and academic/research institutions. In an effort to advance the efficiency and impact of research, attendees engaged in discussions exploring proportionate consent models, permission to approach, and inclusion of pregnant and lactating women and women of childbearing potential, and those with renal impairment in clinical trials.



Indigenous Demonstration Projects

Across the Indigenous Health Committee portfolio, these demonstration projects show how ACT funding catalyzed transformative models of research that move beyond participation toward Indigenous authority, innovation, and systems change. Collectively, they represent First Nations, Métis, and Inuit leadership in reshaping how clinical trials are conceived, governed, and implemented in Canada.

Spanning mental health, addictions, medical education, artificial intelligence, food sovereignty, and culturally grounded care, these initiatives demonstrate that distinctions-based approaches are not parallel to scientific excellence, they are essential to it.

Key Themes Across the Portfolio

Indigenous Governance and Self-Determination	Communities determine priorities, research methods, data stewardship, and definitions of success, ensuring projects are accountable to the Peoples they are intended to serve.
Capacity Building and Workforce Development	Projects prepare the next generation of Indigenous and allied clinicians, researchers, and health leaders through culturally grounded education, mentorship, and innovative training models.
Health Equity Innovation	From AI-assisted assessments to land-based wellness interventions and emerging therapeutic models, these projects apply innovation responsibly while centering ethics, relationality, and community benefit.
Clinical Trials Transformation	The portfolio demonstrates that rigorous randomized trial designs can be successfully integrated with Indigenous knowledge systems, community protocols, and rights-based governance.
Distinctions-Based Solutions	By advancing First Nations-, Métis-, and Inuit-specific approaches, these projects recognize that equitable research requires responses grounded in the unique histories, rights, cultures, and priorities of each Peoples.
National Significance	Together, these projects position Canada as a global leader in community-led, distinctions-based clinical trials and Indigenous health research innovation. They offer scalable models for universities, health systems, funders, and governments seeking to advance reconciliation through action, evidence, and Indigenous leadership.

Building Capacity and Healing:
A First Nations-Led Educational Pathway for Psychedelic-Assisted Therapy

Lead Institution: *First Nations Health and Social Secretariat of Manitoba (FNHSSM)*
Partners: *Indigenous Clinical Trials Unit (ICTU), Sacred Circle Wellness*

This innovative randomized controlled feasibility trial responds directly to the opioid and substance use crisis disproportionately affecting First Nations communities. The project develops and tests a First Nations-led training pathway for health practitioners that combines mainstream psychedelic-assisted therapy education with Indigenous teachings, ceremony, land-based learning, and ethical protocols.

The initiative is grounded in the principle that knowledge is the first medicine, ensuring that healing practices involving psilocybin are approached with cultural integrity, community oversight, and relational accountability.

Early Outcomes / Anticipated Impact

- Creation of the first culturally grounded curriculum for psychedelic-assisted therapy in First Nations contexts
- Increased practitioner readiness to provide culturally safe and trauma-informed care
- Strengthened Indigenous governance over emerging therapeutic research areas
- A scalable model for future Indigenous-led clinical trials in mental health and addictions

Communities Served

- First Nations communities across Manitoba
- Indigenous health practitioners, healers, and wellness workers
- Populations affected by trauma, addictions, PTSD, and systemic oppression

Indigenous Demonstration Projects

Mawiiyahk Nakatikasho: No One Left Behind

Assessing and Improving Competence in Caring for Two-Spirit Métis Patients through an AI-Assisted OSCE

Lead Institutions: *University of Alberta, University of Manitoba, University of Saskatchewan*

This multisite randomized feasibility trial addresses a critical gap in postgraduate medical education by improving physician competency in caring for Two-Spirit Métis patients, particularly in reproductive, perinatal, and gender-affirming care settings.

The project uses an innovative AI-assisted Objective Structured Clinical Examination (OSCE) to simulate culturally grounded patient encounters while reducing burden on community members who would otherwise repeatedly portray patients in training exercises. AI tools are co-developed under Métis governance to ensure authenticity, sovereignty, and respectful representation.

Early Outcomes / Anticipated Impact

- First Indigenous-governed AI clinical education tool in Canada
- Improved resident competency in trauma-informed and affirming care
- Reduced harm and emotional labour for community standardized patients
- Replicable model for AI innovation grounded in Indigenous data sovereignty and reconciliation

Communities Served

- Two-Spirit Métis patients and communities
- Obstetrics & Gynecology residents across three Canadian universities
- Future healthcare systems seeking inclusive and affirming care models

Niqittiavak and Resilience:

Integrating IQ Principles in Multi-Level Mental Health Clinical Trials

Lead Institutions: *University of Alberta, Aqqiumavvik Wellness Centre, Nunavut community partners*

This groundbreaking Inuit-led clinical trial explores how country foods, Inuit knowledge systems, and community wellness practices can improve mental health outcomes in Arviat, Nunavut.

Designed as a 97-day randomized mixed-methods trial, the study evaluates whether increased access to traditional foods such as caribou and Arctic char, combined with Elder-led cultural programming and system-level healthcare improvements, can reduce depression and strengthen resilience.

The project is rooted in Inuit Qaujimajatuqangit (IQ) principles, emphasizing relationality, collective wellness, cultural continuity, and self-determination. It represents a significant shift from conventional mental health interventions by recognizing that food sovereignty, land connection, and Inuit knowledge are essential determinants of wellness.

Early Outcomes / Anticipated Impact

- Demonstrates the feasibility of Inuit-designed randomized clinical trials in northern settings
- Evaluates country foods as a culturally relevant protective factor for depression and anxiety
- Strengthens intergenerational knowledge transfer through Elder-led programming
- Generates policy recommendations to address structural barriers to food sovereignty and culturally safe care
- Creates a scalable model for integrating Indigenous knowledge systems into mental health clinical trials across Inuit Nunangat

Communities Served

- Inuit adults in Arviat, Nunavut
- Families experiencing food insecurity and mental health challenges
- Local health and wellness organizations
- Healthcare providers serving northern communities

Be The Cure

The Be The Cure campaign was executed by ACT in collaboration with the University of Alberta and ran from January 12 - July 1, 2024. The purpose of this campaign was to generate awareness of and increase participation in clinical trials across Canada.

Some assets of the campaign, in both English and French, included the following:

- Website
- Newsletter Graphics
- Social Media Graphics
- Banners
- Fact Sheet
- and More

The campaign was designed to make participation simple, utilizing multiple marketing streams such as:

- Be The Cure Website
- Social Media Platforms
- The ACT Newsletter
- Radio and TV Advertising
- Digital Publications

Visit the campaign website

Website & Social Media Snapshot Numbers

118, 879 Website Visits

26, 341 Searches for a Study

22M+ Impressions Across Channels

Social Media Impressions:

6M+

Overall Engagement Rate*:

5.22%

*Average engagement for healthcare social media is 1.0% - 3.7%

Radio

2, 824 TV and Radio Slots

1, 977 Radio Ad Slots

17 Radio Stations

Shared in **6** Provinces Across Canada

Digital Out of Home

800+ Digital Screens

500+ Locations

10M+ Estimated Impressions

Digital Publications

300k+ Impressions

3, 058 Unique Visitors

20k+ Link Clicks

Other ACT Initiatives

ACT Training Committee

ACT maintains a strong connection with the seven CIHR-funded clinical trials training platforms (CTTPs) and other groups within the Canadian clinical trials ecosystem. The ACT website features an extensive education resources webpage that highlights training opportunities offered through the CIHR-funded CTTPs. Additionally, the ACT Education weekly newsletter highlights Canadian clinical trials related educational opportunities and novel developments including webinars, training awards, and conferences. As of March 2026, 78 ACT Educational newsletters have been sent and opened more than 82,000 times resulting in more than 21,000 clicks for more information. Through collaborations with the partner CTTPs, content is refreshed weekly and ensures that Canadian clinical trialists and trainees have up-to-date information on training opportunities.

The ACT Training Committee also hosted a webinar series featuring 8 webinars that have been viewed over 900 times on the ACT YouTube channel.

The educational resources are available here:
https://act-aec.ca/education/

CAN TAP TALENT
CBITN RCIEC
CANSTAT
StrokeCog
Réseau de recherche sur les données de santé du Canada
Health Data Research Network Canada
Schulich MEDICINE & DENTISTRY
Western
IMPaCT
Accroître la capacité à conduire des essais cliniques avec les personnes enceintes et les enfants
Increasing capacity for Maternal and Paediatric Clinical Trials
CANTRAIN
CANADIAN CONSORTIUM OF CLINICAL TRIAL TRAINING

ACT Inclusion, Diversity, Equity, and Accessibility (IDEA) Committee

This group designed and led national IDEA surveys and focus groups with clinical trial units and networks across Canada, culminating in the creation of an IDEA Toolkit (CAN-IDEA) earlier this fiscal year. The toolkit explored ways we could systemically integrate sex and gender considerations across each step of the research process: design, patient recruitment, implementation, data analysis/interpretation, and the dissemination of results. This toolkit is now complete and is currently being translated in French to support broader accessibility and national uptake.

The CAN-IDEA Toolkit is positioned to become a national standard for embedding inclusion into trial start-up and recruitment.
The next phase will focus on implementation evidence to support refinement, scale-up, and sustainability across Canada.

International Advisory Board

ACT has a strong international advisory board (IAB) comprised of leading experts, including Dr. Vasee Moorthy (WHO), Dr. Marion Campbell (UK), Dr. Denis Xavier (IN), Dr. Martin Landray (UK), and Dr. Faisal Ahmed (UK). This board provides strategic advice, guidance, and global insights to inform the work of the Consortium. Insights from the IAB have been instrumental in shaping the design of our ACT Portfolio Hospital program (modelled after the UK), as well as our independent external review process led by international experts from the US, UK, and Canada to select a group to establish and run a pan-Canadian Research Ethics Board review and approval process for multi-site RCTs with strict timelines (CanReview).

For more information about the committees and co-chairs visit:
act-aec.ca/our-committees

Committee Co-Chairs*

*Active as of Dec 2025

ACT Operations Committee	**Dr. PJ Devereaux** **Dr. Guy Rouleau**
Finance Committee	Dr. Sanjit Jolly Dr. Andrew Demchuk
Scientific Committee	Dr. Louise Pilote Dr. Amit Garg
Clinical Trial Unit Committee	Dr. Justin Ezekowitz Dr. Ryan Zarychanski
Networks Committee	Dr. Clara Bohm Dr. Karthik Tennankore
Knowledge Mobilization Committee	Dr. David Campbell Dr. Justin Presseau
Systems Transformation Committee	Dr. Dean Fergusson Dr. Lawrence Richer
Indigenous Committee	Dr. Wayne Clark Dr. Wanda Phillips-Beck
Training Committee	Dr. Jean Bourbeau Dr. Shrikant Bangdiwala
Big Biotech Industry Committee	Dr. Shurjeel Choudhri Leslie Madden
Patient Engagement Committee	Dr. Stuart Nicholls Maureen Smith

Scientific Committee

Co-Chairs

- Dr. Amit Garg
- Dr. Louise Pilote

The Scientific Committee's focus is managing the consortium's Request for Applications (RFAs) by handling eligibility questions, supporting reviewers, and following up with funded RFAs

Accomplishments

- Developed 6 RFAs on critical areas to improve trials in Canada
- 2 of the RFAs were dedicated to supporting Canadian biotech companies through trial design
- Selected and supported excellent study teams
- The impact of the scientific committee led to increased trial capacity in Canada

"RFAs were essential in identifying needs to grow RCTs in Canada and provided a catalyst for larger initiatives."

Networks Committee

Co-Chairs

- Dr. Clara Bohm
- Dr. Karthik Tennankore

The Networks Committee connects with the leaders and coordinators of ACT's research networks to build a community of clinical trialists, in which networks of all structures and functions can participate and benefit

Accomplishments

- Consolidated tools from established networks to create a shared resources library for ACT research networks
- Coordinated the selection of 20 portfolio hospitals from a pool of 123 applicants
- Hosted 3 virtual All Networks meetings to facilitate information sharing, collaboration, and discussion across ACT research networks
- Evaluated the 6 newly formed research networks supported through RFA 4

"The committee helped sustain and strengthen networks, facilitated meaningful connections across ACT, and supported individual networks at different stages of maturity."

Systems Transformation Committee

Co-Chairs

- Dr. Dean Fergusson
- Dr. Lawrence Richer

The Systems Transformation Committee consists of the Contracts, Regulatory Processes, and Ethics working groups, which aim to optimize the pan-Canadian clinical trial process and improve the efficiency of RCTs

Accomplishments

- Supported the implementation of new clinical trial contracts across Canada
- Created a forum for discussion between Health Canada, CTU leaders, and other researchers
- Advised ICH E6 Expert Working Group on ICH E6(R3) draft to enhance international regulatory feasibility
- Assisted with the RFA process to select a national research ethics review system

"The committee remains committed to strengthening Canada's clinical trial ecosystem by reducing administrative barriers and accelerating trial start-up."

Patient Engagement Committee

Co-Chairs

- Dr. Stuart Nicholls
- Maureen Smith

The Patient Engagement Committee provides insight, leadership, and support within the ACT Consortium regarding patient engagement in clinical trials

Accomplishments

- Identified areas of need regarding patient engagement for ACT Networks through a baseline survey
- Conducted a rapid scoping review of Canadian tools and best practices for clinical trial engagement
- Collaborated with the ACT Education and Knowledge Mobilization Committees to host 3 webinars
- Selected to conduct the WHO review on patient engagement competencies for trial teams

"The engagement of patients, the public, or communities in the design and conduct of clinical research is now an ethical expectation incorporated within the Declaration of Helsinki and best practice for clinical trials, as outlined in the WHO Guidance for Best Practices in Clinical Trials. It is imperative that we continue to shine a light on, and show leadership in, patient engagement in order to achieve the goal of improving the quality of, and access to, clinical trials in Canada."

Indigenous Health Committee

Co-Chairs

- Dr. Wayne Clark
- Dr. Wanda Philips-Beck

The Indigenous Health Committee was established in May 2023 to advance ACT objective #10, "Improve the process of involving Indigenous Peoples in trials and establish a process to identify Indigenous Health Priorities and interventions for evaluation"

Accomplishments

- Identified key health priorities in clinical trial research through a human rights-based and sovereign approach
- Developed several demonstration projects to highlight Indigenous health priorities and practices
- Successfully established a guiding Grandmother's Council
- Developed distinctions-based cohorts (First Nation, Inuit, and Métis) to ensure accurate representation

"The ACT Indigenous Health Committee is transforming how clinical trials engage with, and are led by, Indigenous Peoples across what is now Canada. Importantly, this work is advancing clinical research that is by Indigenous Peoples and for Indigenous Peoples."

IDEA Committee

Co-Chairs

- Dr. Louise Pilote
- Dr. Marie-Annick Clavel
- Post Doc: Syamala Buragadda

The IDEA (Inclusivity, Diversity, Equity, and Accessibility) Committee promotes the democratization of clinical trials within ACT by assessing demographic representation, identifying barriers, and addressing challenges in forming diverse research teams

Accomplishments

- Identified barriers and facilitators to inclusive research through surveys and focus groups for Canadian CTUs and networks
- Analyzed participant diversity and inclusive trial design practices across Canadian RCTs
- Conducted a scoping review of EDI toolkits
- Developed CAN-IDEA Toolkit to guide Canadian trial teams in embedding IDEA into trial design, recruitment, and reporting

"The Committee established a strong evidence-to-action pipeline: identify barriers, quantify gaps, build tools, and evaluate implementation."

HDRN Committee

Co-Chair

- Dr. Amit Garg

The Health Data Research Network Canada (HDRN) Working Group is focused on making Canadian administrative health data sets more accessible to clinical trial researchers

Accomplishments

- Created a step-by-step guide to accessing data held at StatCan for RCTs
- Documented barriers and potential solutions to using health administrative data for RCTs
- Generated modules from demonstration projects to serve as method guides for trialists
- Supported 15 demonstration projects centered on building capacity for using admin data in RCTs

"Canada has rich administrative data assets. Let's use them to enable efficient Canadian-led, high-impact RCTs that address the priority needs of Canadians!"

KM Committee

Co-Chairs

- Dr. David Campbell
- Dr. Justin Presseau

The Knowledge Mobilization (KM) Committee supports ACT initiatives by mapping the consortium's KM assets and incentivizing activities that promote the sharing of knowledge in formats that benefit all audiences

Accomplishments

- Ran a KM needs assessment survey for ACT members
- Hosted a monthly KM webinar series on a variety of key topics based on survey results
- Produced an asset map of Canadian KM experts with experience in clinical trials
- Held an RFA to support novel KM approaches in ACT affiliated studies

"The KM Committee has laid the groundwork for a sustainable KM infrastructure within ACT by connecting people, practices, and platforms across networks and institutions."

Finance Committee

Co-Chairs

- Dr. Andrew Demchuk
- Dr. Sanjit Jolly

The Finance Committee ensures ACT funds are being allocated in accordance with the original CIHR grant by reviewing and approving budgets for other committees, RFAs, and meetings

Accomplishments

- Ensured compliance with all reporting obligations
- Developed a Conflict of Interests template for use across all of ACT
- Met with other ACT committees to review financial management plans
- Provided significant support for the planned use of funds for ACT's RFAs

CTU Committee

Co-Chairs

- Dr. Justin Ezekowitz
- Dr. Ryan Zarychanski

The Clinical Trial Units (CTU) Committee fosters collaboration between stakeholders, networks and CTUs, to ensure they have the resources needed to conduct high-quality, high-impact trials

Accomplishments

- Created a comprehensive package outlining CTU standards including job descriptions, SOPs, and QA processes
- Helped increase capacity and expertise at CTUs across Canada
- Established CTU accreditation standards
- Collaborated to select a preferred eTMF platform for ACT CTUs

"By participating in the ACT CTU Committee, Operations Committee, and recurring consortium meetings, our team has strengthened national partnerships, enhanced alignment of operational practices, and built strong relationships across the network"
- Population Health Research Institute

"The learning opportunities provided through ACT activities have been very well received by members and have contributed to sustained engagement across the network. These shared learning experiences have emerged as an important cohesion factor, helping to strengthen relationships, reinforce a sense of community, and keep members actively connected to the network beyond individual research." - *CANSPARK LTC*

Training Committee

Co-Chairs

- Dr. Shrikant Bangdiwala
- Dr. Jean Bourbeau

The Training Committee's overall goal is to collect and harmonize training resources from partner Clinical Trials Training Platforms to be used across the entire ACT network

Accomplishments

- Developed learning pathways to help research professionals navigate training options
- Established a weekly newsletter to connect ACT members to educational resources
- Collaborated with the Patient Engagement committee to develop a Patient Engagement Resource for researchers

Big Biotech Industry Committee

Co-Chairs

- Dr. Shurjeel Choudhri
- Leslie Madden

The Big Biotech Industry Committee serves as a networking body and connects the ACT Consortium to the broader biotech and pharmaceutical industries

Accomplishments

- Convened provincial partners for the adoption of standardized tool
- Provided guidance on the establishment of a single national Research Ethics Board, CanReview
- Developed the concept for a National Concierge for Clinical Trials