

Update on Accelerating Clinical Trials (ACT) Consortium and Goals of Meeting

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Since our last meeting...

(Quebec City, October 2024)

- Single national REB review and approvals process with strict timelines (CanReview) has launched
- ACT contracts working group has implemented the Master Clinical Trials Agreement for CIHR-funded trials
- CTU group has selected RAN Bio Links as the preferred eTMF vendor
- Ongoing engagement and advocacy with provincial/federal stakeholders on future funding for ACT 2.0

Since our last meeting...

(Quebec City, October 2024)

- Publication and impact of several trials funded by ACT
- Contributed to international efforts
 - Promotion of WHO guidance for best practices for clinical trials
 - Application to the WHO's Global Clinical Trials Forum
- Held 2 funding opportunities
 - RFA 6 – Canadian Biotech
 - Knowledge Mobilization RFA
- Initiation of Indigenous demonstration projects

RFA 5 – To bring high-impact RCTs to Canada

- RFA announced August 30, 2024
- Call to encourage new collaborations between Canadian researchers and international, high-impact RCTs
- Submission deadline September 30, 2024
- 19 applications from 12 networks

RFA 5 – To bring high-impact RCTs to Canada

- Targeted peer review process
 - Each application was reviewed and scores by 5 independent reviewers with clinical trial experience
- Total \$2 million in funding available
 - 10 applications x \$200,000 CAD each
- Successful applications announced November 22, 2024
 - Includes collaborations across 5 countries - Australia, Finland, Germany, United Kingdom, United States

PI names	Country	RFA 5 Funded International RCT Brought to Canada
Dr. Reshma Amin, Dr. David Berlowitz	Australia	The 3TLA Study: A Randomized Controlled Trial of Polysomnographic Titration of Non-invasive Ventilation in Amyotrophic Lateral Sclerosis
Dr. Georg Schmölzer, Dr. Calum Roberts	Australia	SURFSUP: SURFactant Administration by SUPraglottic Airway
Dr. David Collister, Dr. Meg Jardine	Australia	BEAT-Calci: Better Evidence And Translation for Calciphylaxis
Dr. Philippe Violette, Dr. Arnav Agarwal, Dr. Kari Tikkinen	Finland	ARTS: Avoiding Risks of Thrombosis and bleeding in Surgery
Dr. Jason Andrade, Dr. Paulus Kirchhof	Germany	EASThigh: Early atrial fibrillation ablation for stroke prevention in patients with high comorbidity burden
Dr. Ratika Parkash, Dr. Pier Lambiase	United Kingdom	CRAAFT-HF: Cryoballoon/Radiofrequency Ablation of Atrial Fibrillation versus Medical Treatment for Heart Failure
Dr. François Lamontagne, Dr. Neill Adhikari, Dr. Donald Arnold, Dr. Peter Watkinson	United Kingdom	Threshold for Platelets (T4P): 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. Derek Dillane, Dr. Mark Neuman	United States	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. Laura Marie Drudi, Dr. Manesh R Patel	United States	IMPROVE-AD: IMPROving Outcomes in Vascular diseaseE – Aortic Dissection
Dr. Maral Ouzounian, Dr. David Wood, Dr. Philippe Pibarot, Dr. Raj Makkar	United States	BELIEVERS: Imaging Substudy of Bicuspid aortic valve replacement: EvaLuation of transcathetEr Versus surgEry-PILOT Trial

RFA 6 – Canadian Biotech Trials II

- RFA announced November 5, 2024
- Call to fund trials evaluating biotechnologies from Canadian-controlled private corporations (CCPCs) in partnership with Canadian clinical trialists from ACT Networks
- Submission deadline January 5, 2025
- 31 applications from 19 networks

RFA 6 – Canadian Biotech Trials II

- Targeted peer review process
 - Each application reviewed and scored by 9 independent reviewers
 - 4 biotechnology reviewers to assess technology potential
 - 5 clinical trialist reviewers to assess trial and budget
- Total \$2 million in funding available
 - 5 applications x \$400,000 each
- Successful applicants announced February 19, 2025

PI name(s)	Biotech	RFA 6 Funded RCT
Dr. Sean Dukelow Dr. Janice Eng Dr. Mark Bayley	VIBRAINT Inc.	ANIMATOR: brAin controlled robotic arM rehabilitation fOr stRoke
Dr. Sonny Dhanani Dr. Andrew Seely	TMS (Therapeutic Monitoring Systems)	Donation Advisor: Improving deceased organ donation and transplantation: a multicenter feasibility implementation randomized controlled trial of the Donation Advisor tool
Dr. Scott Halperin Dr. Brian Ward Dr. Joanne Langley	InventVac	HiaVaccinePhase2: A phase 2 randomized controlled trial of a Haemophilus influenzae type a vaccine in healthy Indigenous and non-Indigenous adults
Dr. Yasbanoo Moayed Dr. Vivek Rao Dr. Phyllis Billia	Traferox Technologies	PROTECT PGD: Prospective Reduction Of Transplant complications through EnhanCed Preservation Therapy to prevent Primary Graft Dysfunction Pilot Randomized Trial
Dr. James Downar	Filament Health, Psilo Scientific Ltd.	PSYCHED-PAL: Psilocybin microdose for psychological distress in patients with advanced illness: A phase 3 double-blind, placebo-controlled, parallel-arm clinical trial

Knowledge Mobilization (KM) Awards

- Announced February 10, 2025
- Knowledge Mobilization projects for high-impact RCTs
 - RCT must be completed by August 31, 2025
 - KM project must be completed by December 12, 2025
 - Up to \$10,000 available per project (\$40,000 total)
 - Evaluated by 4 reviewers: 2 trialists, 2 KM specialists
- Submission deadline March 24, 2025
- Awardees announced May 5, 2025

Knowledge Mobilization (KM) Awards

Study Title	PI
Your Answers When Needing Sleep in New Brunswick (YAWNS NB)	Dr. David Gardner, Dr. Andrea Murphy
Prevention of persistent pain with LidocAine iNfusions in breast cancer surgery	Dr. James Khan
Walk 'N Watch Study	Dr. Janice Eng
Emergency Department Ondansetron Dispensing to Optimize Outcomes Through Knowledge Mobilization and Implementation	Dr. Stephen Freedman, Dr. Terry Klassen, Dr. Megan Bale-Nick
Virtual Rehabilitation for Long COVID: Knowledge Mobilization for Greater Impact	Dr. Tania Janaudis-Ferreira

Review of CIHR Grant Milestones

Establish a pan-Canadian Consortium of excellence in clinical trials

Milestone	Status
Establish working groups	COMPLETE
Recruit personnel for Consortium Administration (Consortium Manager, Coordinators)	COMPLETE

Expand and support existing clinical trial networks and develop networks in areas of need

Milestone	Status
Clinical Trials Support Network Portfolio staff recruited	COMPLETE
Recruitment of EDI & Patient Engagement postdoctoral fellow	COMPLETE
Thesis completion/final report	In Progress – on track
RFA 1 – High-impact RCTs that needed additional funding	COMPLETE
RFA 2 – Non-traditional trial designs / trials evaluating methods to improve conduct of trials	COMPLETE
RFA 3 – Canadian Biotech	COMPLETE
RFA 4 – New Networks	COMPLETE
RFA 5 – International Trials	COMPLETE
RFA 6 – Canadian Biotech	COMPLETE

Accelerate the conduct and efficiency of clinical trials research in Canada

Milestone	Status
Ethics WG: Conduct pan-Canadian mapping exercise of study initiation challenges and metrics collected	Pivoted approach to single national REB based on stakeholder meetings
Ethics WG: Expand CTO QuickSTART and refine based on metrics mapping	
Contracts WG: Develop mCTA agreement	COMPLETE – implementation underway
NEW: Establish a single national REB review and approval process for CIHR-funded trials with strict timelines	COMPLETE – implementation underway

Expand Canadian participation in international trials, and international participation in Canadian-led trials

Milestone	Status
Develop database of international trials including ACT Networks or CTUs	Pivoted to collecting information on CTU PIs, their areas of focus, and countries they work in
Set up ACT insurance	Milestone removed; assessment completed and goal no longer feasible

Strengthen the coordination of Canadian clinical trials, and facilitate collaboration and harmonization among trial units, research networks, stakeholders

Milestone	Status
Develop and implement Terms of Reference for Networks, CTUs, and industry to work together	Not started; collaborations and networking happening informally
Implement eTMF	In Progress – vendor selected and implementation underway

Foster collaboration across trial units, networks, and relevant stakeholders, establishing and implementing best-practices related to trial design and conduct

Milestone	Status
Consortium Annual Meeting – Year 1	COMPLETE
Consortium Annual Meeting – Year 2	COMPLETE
Consortium Annual Meeting – Year 3	COMPLETE

Ensure that trial units have the resources needed to conduct high-quality, high-impact trials

Milestone	Status
Appoint CTU HQPs (CTU Facilitators, Contracts personnel, Quality Assurance, Data Science HQP)	COMPLETE

Establish a communications strategy to enhance Canadians' understanding of clinical trials

Milestone	Status
Develop key messages/concepts (public and healthcare institutions)	COMPLETE
Roll-out	In Progress – on track
Evaluation Survey	Not Started

Democratize clinical trials by enhancing access for all Canadian citizens to participate, and by fostering a robust EDI approach to clinical trials

Milestone	Status
Recruit postdoctoral fellow to undertake multi-method evaluation research (e.g. surveys, interviews, data collection)	COMPLETE
Report on EDI barriers and facilitators	COMPLETE
Develop KM materials	COMPLETE

Improve the process of involving Indigenous peoples in trials and establishing a process to identify Indigenous health priorities and interventions for evaluation

Milestone	Status
Establish Elder Advisory Council (EAC)	COMPLETE
Develop approach to engage with Indigenous cohorts	COMPLETE
Conduct process to identify health priorities	COMPLETE
Initiate demonstration projects	In Progress – 1/3 underway

Maximize knowledge mobilization and impact through the ACT Consortium with engaged and diverse partners and experts in the field

Milestone	Status
Recruit Research Staff (Knowledge Mobilization Coordinator, Communications Specialist, Web Developer)	COMPLETE
Additional KM Coordinator	COMPLETE
Develop KM materials	In Progress

Partner with other groups applying for funding through other major BLSS initiatives

Milestone	Status
Make contact with Canada Biomedical Research Fund and Clinical Trial Training Platform awardees	COMPLETE
Identify areas of synergy and collaboration	In Progress - Ongoing
Develop call for identified training programs for HQP	In Progress - Ongoing

Reflections

- A lot has been achieved over the past 2 years
- Gratitude for:
 - co-chairs and committee and working group members who have worked diligently towards ACT goals
 - ACT networks and CTUs
 - RFA reviewers
 - partners (CIHR, pharma, device companies, Bayer, IMC, Canadian biotech, Health Canada, patients)
 - central ACT support team

Immediate Upcoming Work

- Driving adoption of the Master Clinical Trial Agreement
- Supporting implementation of single national distributive REB model with strict timelines (CanReview)
- Stakeholder engagement and Advocacy for ACT 2.0

Goals of Meeting

- Exploring alternative consent models
- Presentation of select completed trials and portfolio hospital updates
- Promoting investment in Canadian biotech
- Promoting WHO global action plan for clinical trials
- Removing barriers to the inclusion of populations traditionally excluded from clinical trials
- Supporting adoption and implementation of CanReview (single national REB) and master clinical trial agreement
- Discussion around potential for ACT 2.0