

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

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Since our last meeting...

(Charlottetown, PEI, Sept 21-22, 2023)

- ACT regulatory working group led submission to Health Canada recommending changes to the draft ICH E6 (R3))
- ACT contracts working group has implemented Data and Samples Sharing Agreement in over 45 Canadian centres
- Activated ACT Portfolio hospitals
- Held stakeholder meeting in Vancouver (Feb 2024) to discuss single national REB process
 - Call for proposals initiated May 2024

Since our last meeting...

(Charlottetown, PEI, Sept 21-22, 2023)

- Publication and impact of several trials funded by ACT
- Contributed to international efforts
 - WHO guidance for best practices for clinical trials
- Created new committee of Big Biotech Companies
- Held 3 funding opportunities
 - RFA 3 – Canadian Biotech
 - RFA 4 – New Networks
 - RFA 5 – International Trials

RFA 3 – Canadian Biotech Trials

- Targeted peer review process
 - Each application reviewed and scored by 10 independent reviewers
 - 5 biotechnology reviewers to assess technology potential
 - 5 clinical trialist reviewers to assess trial and budget
- 5 successful applicants announced November 3, 2023
- Total \$2 million in funding

PI name(s)	Biotech	RFA 3 Funded RCT
Dr. Hance Clarke, Dr. Paul Karanicolas	AmacaThera	AMT-143: A Phase 1 Randomized Controlled Trial Evaluating AMT-143 in Healthy Volunteers to Assess Sustained Analgesic Release for Non-Opioid Pain Treatments
Dr. Michael Walsh, Dr. Peter Margetts, Dr. Pavel Roshanov	Qidni	EQUAL Dialysis: Evaluation of Qidni Urea And metabolite cLearence in maintenance Dialysis
Dr. Karen EA Burns, Dr. Andrew Seely	Therapeutic Monitoring Systems Inc.	LEADS: Liberation from ventilation through Extubation Advisor Decision Support
Dr. Rebecca Auer, Dr. Paul Karanicolas	Qu Biologics	PERIOP-06: A Phase II Study of Perioperative QBECO Site Specific Immunomodulator in Patients with Metastatic Colorectal Adenocarcinoma Within the Liver Undergoing Resection
Dr. Matthew James, Dr. Neesh Pannu, Dr. Daniel Muruve	Arch Biopartners Inc.	PONTIAC: Prevention of Nephrotoxin-induced AKI with Cilastatin Trial

RFA 4 – New Networks

- RFA announced November 20, 2023
- Call for new ACT Trial Networks
 - Mental Health identified as area of interest by Ministers of Health
- Submission deadline January 29, 2024
- 46 applications (4 mental health, 42 other areas of needs)

RFA 4 – New Networks

- Targeted peer review process
 - Each application was reviewed and scored by 8 independent reviewers
 - 3 reviewers - 2 patient partners and 1 Indigenous partner/researcher - to assess patient engagement, Indigenous engagement, and EDI
 - 5 clinical trialist reviewers to assess need for network; model or plans for governance; membership, geographic spread, and experience with RCTs; plans for developing, funding, undertaking, and initial RCT
- Total \$900,000 funding available (6 networks x \$150,000 each)
 - Awardees announced March 25, 2024

PI name(s)	RFA 4 Funded New Network
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Dr. Reshma Amin	CanHMVr: The Canadian Home Mechanical Ventilation Research Network
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Dr. Kelly Vogt	CANUCS: Canadian Collaborative on Urgent Care Surgery
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Dr. Paul Hebert	CCARE-LTC: Collaborative for Caring for Long-Term Care
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Dr. Jason Busse; Dr. Hance Clarke	CMCN: Canadian Medical Cannabis Clinical Trials Network
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Dr. Mandi Newton	CYMH Trials Network: Canadian Network for Child and Youth Mental Health Trials
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Dr. Peter J Gill	PIRN: Canadian Paediatric Inpatient Research Network
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RFA 5 – To bring high-impact RCTs to Canada

- Announced Aug 30
- Submission deadline Sept 30
- Reviews underway

Single National REB Approval Process with Strict Timelines for Multi-Centre RCTs

- February 2024: held meeting of leaders in research ethic boards, institutional leaders, and patient representatives
- Discussed establishing national single research ethics board (REB) review and approval process with strict timelines
- May 2024: announced RFA for group to set up and run pan-Canadian, distributive, single REB review and approval process with strict timelines; application deadline was Aug 16, 2024
- International selection committee with Canadian regional representation

Reflections

- A lot has been achieved over the past year
- 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

- RFA 6 funding for Canadian biotech trials
- Activation of single national distributive REB model with strict timelines
- Master clinical trial agreements for CIHR funded trials
- Initiating Indigenous trials

Goals of Meeting

- Engage in discussion on international efforts to improve trial best practices
- Bring Canadian biotech and trialists together
- Discuss optimization of Health Canada inspections
- Start debate on who can contact patients to participate in trials
- Celebrate and showcase our success
- Discuss possibility of ACT2