Call for Proposals: To Bring High-Impact Randomized Controlled Trials to Canada that Were Initiated and Are Led by a Non-Canadian Country

Application Instructions

- Please combine the following application components into a **single PDF**:
  - Summary: 1 page
  - Written proposal: Maximum of 3 pages if written in English or 4 pages if written in French
  - Budget and budget justification: 1 page
  - References, figures, or tables: (optional, maximum of 1 page)
  - Most recent version of the protocol
- Submit the full application PDF to https://act-aec.ca/call-for-proposals/ by **noon EST on September 30, 2024**
  - Once submitted, written confirmation of receipt will be provided within 24 hours of submission. If you do not hear back within 24 hours, please follow up to ensure successful delivery.

Description and Objectives

The fifth ACT call for proposals is designed to: (1) support ongoing and active, internationally led, high-impact randomized controlled trials (RCTs); (2) bring such trials to Canada so Canadian patients can have access to participate; and (3) have National Canadian Principal Investigators and Canadian Site Investigators contribute to an important internationally led trial and build international collaborations.

- Ongoing and active refers to trials that are currently recruiting patients.
- Internationally led refers to trials in which the overall Trial Principal Investigator, as listed in the protocol, is located in a country outside of Canada, and where the main data coordinating centre for the trial is located outside of Canada.
- High-impact trials refer to trials that test interventions designed to improve patient/citizen important health outcomes. In other words, the trial has a high probability it will lead to meaningful changes in health or how it is delivered.
- High-impact trials use high-quality methods, so that the trial findings are reliable. For example, publishing the trial protocol and pre-specifying the statistical analytic plan, before any outcome results are analyzed, improves the rigor of a trial. High-impact trials utilize high-quality design features (e.g., concealed allocation, complete follow-up, appropriate statistical power), are usually large, multi-centre and commonly have greater impact when they are international.
- All types of randomizations are eligible (e.g., parallel group, cluster/stepped wedge/cluster cross-over, factorial, platform).
- We welcome engaging components of ACT (e.g., ACT portfolio hospitals, networks, CTUs)

Funds Available

A total of $2 million dollars is available for this RFA. The maximum funding per application is $200,000.

Eligibility

For a trial to be eligible it must fulfill each of the following points:

1. Be registered with an organization such as clinicaltrials.gov;
2. The overall Trial Principal Investigator, as listed in the protocol, is located in a country outside of Canada and the main data coordinating centre for the trial is located outside of Canada; the overall Trial Principal Investigator must be collaborating with at least one designated National Canadian Principal Investigator who is a member of an ACT Network;
    - the designated National Canadian Principal Investigator(s) leading the application submission can only submit 1 application to this competition
3. Each application is restricted to a single RCT;
4. Be endorsed by one of the 34 ACT Networks;
    - each ACT Network can endorse a maximum of three applications to this competition
    - applicants can only list one principal ACT Network
    - *ACT Networks should endorse proposals most relevant to their constituents, especially their patients. No letter of support is required from the supporting ACT Network*
5. ACT funds can only be used to support the cost of having Canadians participate in the trial;
6. The trial cannot have previously received funding through a CIHR grant;
7. Agree ACT funds will be transferred to an organization eligible to hold CIHR funds; this organization will ensure and report that funds were used for CIHR eligible expenses; and
8. The overall Trial Principal Investigator and designated National Canadian Principal Investigator(s) will acknowledge ACT Consortium partnership and funding in all related presentations and publications.

Proposal Sections and Adjudication Criteria

The proposal, which can be written in English or French, use 12-point font size, black type; a minimum of single line spacing; a minimum margin of 2 cm (3/4 inch) around the page; letter size (21.25 X 27.5 cm / 8.5" X 11").

A. Trial summary will be a maximum of 1 page;
B. Written proposal will be a maximum of 3 pages if written in English or 4 pages if written in French;
C. Budget and budget justification will be a maximum of 1 page;
D. Applicants have an optional 1 additional page for any references, figures, or tables; and
E. Must include the most recent version of the protocol (and preferably also the most recent version of the statistical analytic plan).

Each proposal that meets eligibility for review will receive a mark out of 100. Ineligible applications will not be graded.

- ***Trial Summary****:* Maximum 1-page that includes trial registration information and key trial elements (e.g., eligibility criteria, intervention, outcomes).
    - *On the front page the applicant confirm they are eligible for this RFA:*

- The designated National Canadian Principal Investigator is located in Canada and is a member of an ACT network.
- The trial uses randomization.
- The trial is an internationally led trial in which the overall principal investigator is located outside of Canada and where the main data coordination centre for the overall trial is located outside of Canada.
- Trial is ongoing and active. Provide specific details (e.g., # recruited, if relevant # left to recruit, # of f/u visits completed, if relevant # f/u visits left to complete).
- How many patients will be recruited in Canada.
- How many Canadian sites will participate through this funding.

- ***Written Proposal:*** In up to 3 pages in English, or 4 pages if written in French, please convince reviewers:
  - *The trial will complete recruitment and follow-up of Canadian patients related to the ACT funding of this trial by June 30, 2026 (**mark: 30 out of 100**).*
    - The trial may take longer to finish, but the ACT funding must be utilized by this date. We recognize the timelines related to the ACT funding may be limited for large high-impact international trials. Therefore, ACT fully supports researchers using additional non-ACT funding to recruit additional patients or complete extended follow-up of patients recruited via ACT funding. Due to the timing of the overall ACT grant, the funding provided through this ACT RFA must be utilized by June 30, 2026
  - *The trial is high-quality in its design and execution (**mark: 30 out of 100**)*
    - e.g., concealed random allocation, complete follow-up, complete data collection, adequate statistical power for meaningful effect.
  - *There is a high probability that the trial will lead to meaningful impact (**mark: 40 out of 100**)*
    - e.g., intervention likely to improve the effectiveness, safety, people-centeredness, timeliness, equitability, efficiency, or integration of care.

Adjudication Process

Each application will be reviewed for eligibility. Any application deemed ineligible based on the information provided will not be considered further.

Applications will be circulated to reviewers after they confirm they have no conflict with the application.

- They will confirm the application is eligible for the competition.
- If eligible, they will provide a score out of 100.
- Reviewers will be asked to avoid scores that are exactly divisible by 10 (e.g. 60, 70, 80, 90), to reduce the chance different applications having tied scores.

Each application will receive an average score out of 100.

Applications with a score <60 will be ineligible for funding.

Applications with an average score of 60 or more will be ranked and funded until the maximum budget for this RFA is reached. If there are trials with tied scores for the last remaining funds, these trials will be recirculated to reviewers and rank ordered.

Feedback to Applicants

Investigators of eligible applications will be given information on the number of eligible applications submitted to this RFA, the number awarded, and whether they were successful.

Given the focus of this RFA is on mature trials that we anticipate will be of high quality, no written comments from reviewers will be provided back to applicants.

Timelines

- Announcements through the ACT networks begin August 30, 2024.
- Deadline for Proposals: noon EST on September 30, 2024.
- Awardees Announced: within 6 weeks after proposal deadline.