

Call for Proposals: Supporting the Completion of High-Impact Randomized Controlled Trials

Application Instructions

- Please combine the following application components into a **single PDF**:
 - Written proposal: Maximum of 3 pages if written in English or 4 pages if written in French (see formatting requirements in section titled, *Proposal Sections and Adjudication Criteria* below); includes 1 page trial summary
 - References, figures, or tables (optional, up to 1 page)
 - Letter of support from an ACT Network (up to 1 page)
 - Most recent version of the protocol, and preferably the most recent version of the statistical analytic plan
- Submit the full application PDF to act-aec@phri.ca by **noon EST on April 3rd, 2023**
 - 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 first ACT call for proposals is designed to support ongoing and active, Canadian-led, high-impact randomized controlled trials (RCTs) that need additional funding for successful completion and will publicly report their results by January 15, 2025.

- Ongoing and active refers to trials that are currently recruiting patients or completing follow-up visits, data collection and cleaning, or the main trial analyses.
- Canadian-led refers to trials in which the trial principal investigator, as listed in the protocol, is a Canadian citizen/permanent resident, and where the main data coordinating centre for the trial is in Canada.
- A need for additional funding refers to trials that have inadequate funding to successfully complete and report the trial because of unforeseen events such as the covid-19 pandemic.
- 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.
- 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. According to the World Health Organization framework for quality care, this means the trial has a good chance of showing the intervention improves effectiveness, safety, people-centeredness, timeliness, equitability, efficiency, or integration of care.
- All types of randomizations are eligible (e.g., parallel group, cluster/stepped wedge/cluster cross-over, factorial, platform).

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. Be led by a Canadian researcher who is a member(s) of an ACT Network
 - the principal investigator(s) of any trial can only submit 1 application to this competition
3. Have a letter of support from an ACT network
 - each Network can provide a maximum of 3 support letters to this competition, and
4. Agree 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 the researchers 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)

- Will be a maximum of 3 pages if written in English or 4 pages if written in 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"]);
- Can have a maximum of 1 additional page for any references, figures, or tables;
- Must include a maximum of a 1-page letter of support from an ACT Network. In their support letter the ACT Network will provide a rationale of why they believe the application meets the competition eligibility (including why they believe the trial intervention will improve patient/citizen important health outcomes), and why they are endorsing the trial for funding; and
- 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).

Sections

- *A 1-page trial summary* that includes trial registration information and key trial elements (e.g., eligibility criteria, intervention, outcomes).
 - *On the front page the applicant will also confirm they are eligible for this RFA:*
 - Applicant is a member of the ACT Network
 - The trial uses randomization.
 - The trial is Canadian led, the trial Principal Investigator is Canadian citizen / permanent resident, and the main data coordinating centre for the trial is in 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])

In up to 2 pages, or 3 pages if written in French, please convince reviewers:

- *Why the requested funding is needed to complete the trial* (does reviewer agree with funding need yes or no; if no, the reviewer is deeming the application ineligible). Applicant to disclose all other funding

sources and/or outstanding funding commitments, and confirm no other funding is needed to complete the trial other than the requested amount.

- *The trial will be publicly reported by January 15, 2025* (mark: 30 out of 100)
- *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.

Reviewers for this RFA will be investigators who have led and completed a high-impact randomized trial.

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.
- In the instructions, 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.

Any application that receives scores that differ by 30 or more will be circulated to additional reviewers.

Each application will receive an average score out of 100.

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

Applications with a score of 60 or more will be ranked and will be 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 as attested within the ACT Network support letter, no written comments from reviewers will be provided back to applicants.

Timelines

- Announcements through the ACT networks begin Feb. 27th, 2023.
- Deadline for Proposals: 5 weeks after announcement.
- Awardees Announced: 6 weeks after proposal deadline.