Call for Proposals: Evaluate Canadian Biotechnologies with Randomized Controlled Trials

Application Instructions

- To apply your application must be endorsed by one of the 28 ACT Networks (details below)
- Please combine the following application components into a **single PDF** (maximum 7 pages in English or 8 pages in French):
  - Written proposal: Maximum of 5 pages if written in English or 6 pages if written in French (details of the formatting requirements are below); page count includes a 1-page trial summary.
  - Budget and justifications (required, up to 1 page)
  - References, figures, or tables (optional, up to 1 page)
- Submit the full application PDF to **act-aec@phri.ca** by **noon EST on July 7th, 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

Canadian biotechnology and clinical trials communities rarely intersect, and consequently few Canadian researchers undertake randomized controlled trials (RCTs) evaluating Canadian biotechnologies. Few, if any, small- and medium-size biotechnology companies in Canada have the capital to fund the clinical trials required to obtain regulatory approval of their products, and few major pharmaceutical or biotechnology companies have their headquarters in Canada, which limits opportunities for Canadians to lead clinical trials. Accelerating Clinical Trials (ACT) Canada wants to help Canadian biotechnology companies grow by facilitating clinical trials evaluating Canadian biotechnologies.

A key objective of the First ACT Consortium meeting that was held in April 2023 was to make connections between ACT research Networks and Canadian biotechnology companies. The conference brought these groups together to learn about available products and needs and promote partnerships. Substantial time was given for networking between members of the ACT Consortium and the Canadian biotechnology community. Moreover, networks are now being encouraged to further connect with the Canadian biotechnologies that are relevant to their area of research to organize further connections between ACT Network members and Canadian biotechnology companies to create partnerships for this request for applications (RFA).

Given that most biotechnologies require randomized controlled trials (RCT) demonstrating efficacy and safety to obtain regulatory approvals, the objective of this request for applications (RFA) is to fund trials evaluating products from Canadian-controlled biotechnology companies in partnership with ACT Network clinical trialists. Through this RFA, ACT aims to provide foundational support to Canada's Biomanufacturing and Life Sciences Strategy (BLSS) by enabling Canada's best researchers and companies to undertake the clinical trials efficiently, aligned with BLSS, Pillar 3: Growing Businesses by Doubling Down on Existing and Emerging Areas of Strength; the goal being to improve the health of Canadians.

Notes

- The focus is on partnerships between Canadian trialists and biotechnology companies, deemed Canadian-Controlled Private Corporation (CCPC), to evaluate technologies through an RCT in human subjects. Our definition of a CCPC is a private corporation, incorporated in Canada that is not controlled by non-residents or public corporations, meaning non-Canadian residents cannot directly or indirectly control the company or own more than 50% of the company or of its voting power via the board.
- Biotechnology, or biotech, is the intersection of biological, engineering and computer sciences. Examples of biotech include: drug (including natural health products), living organisms (or parts of them), biological systems to create products, devices, applications (including software), data systems, and diagnostic tests.
- Trials must be Canadian led – referring to trials in which the principal trial investigator is affiliated with an institution eligible to hold CIHR funds, will have their substantive role in Canada for the duration of the project's term[1] and is a member of an ACT network – the central coordinating centre must be in Canada, and the biotechnology company partner must be Canadian-controlled.
- All phases of trials (e.g., phase 1, 2, 3) are welcome as long as the design is an RCT. We also welcome applications for pilot, vanguard phase, or full trials.
- It is encouraged - but not required - that the biotech company provide in-kind support (e.g., providing the technology free for testing in the RCT) or matching funding.
- Principal investigators must report their shareholding status in the company.
- Each team must submit a 1-page annual progress report to ACT, according to a template (to be provided in the future).
- We welcome proposals that include team members who have lived experience with the condition being studied (e.g., patients and caregivers).
- We welcome proposals that include partnerships with Indigenous peoples.
- We welcome proposals that address equity, diversity, inclusion, and accessibility considerations. Each funded proposal will be expected to collect and report data on sex and ethnicity.
- We welcome engaging several components of ACT (e.g., ACT CTUs, networks, training).
- The centre which coordinates the RCT must be Canadian and cannot be a for-profit contract research organization (CRO).
- CIHR policies regarding trial reporting must be followed: Policy Guide – Requirements for Registration and Disclosure of Results from Clinical Trials.

Funds Available

A total of $2.0 million is available for this RFA. The maximum requested budget for any application is $400,000. Although the funding available may not be sufficient for a full-scale study, phase 2 and pilot or Vanguard trials to assess, for example, safety, recruitment potential, and feasibility are welcome.

Eligibility

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

1. The nominated principal investigator must be a Canadian researcher who is a member of an ACT Network. Leadership must be in partnership with a biotech company representative.
2. The nominated principal investigator(s) can only submit one application to this competition.

[1] In accordance with Part 3: CIHR Applicant Eligibility, section 3.1, Nominated Principal Applicant of the CIHR Application Administration Guide.

3. The trial must evaluate a biotechnology and the biotechnology company partner must be Canadian-controlled.
4. Eligibility for biotechnologies companies is not limited to those present at the meeting on April 17-18, 2023, at the First Annual ACT Consortium Meeting.
5. Endorsed by one of the 28 ACT Networks.
6. Each Network can endorse a maximum of three applications to this competition, and each application is restricted to a single RCT.
7. For this criterion, applicants only list one principal ACT Network.
    - Networks should endorse proposals most relevant to their constituents, especially their patients. No letter of support is required from the supporting ACT Network.
8. Applicant agrees to transfer funds to an organization eligible to hold CIHR funding; this organization will report the use of funds according to CIHR-eligible expenses. Investigators must provide confirmation from their institution that the proposed budget is CIHR eligible.
9. Applicant will acknowledge ACT Consortium partnership and funding in all related presentations and publications.
10. If funded, the applicant must be accountable for their progress, which will be summarized in annual ACT reports. A summary of their project will also be shared within ACT to raise awareness and foster new collaborations. Applicants also commit to making their trial results publicly available (open-access publication).
11. The proposal is an RCT and not a product validation observational study.

Proposal Sections

Applicants submit their maximum 7-page pdf proposal in English, or maximum 8-page pdf proposal French.

- Written proposal: Please 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"]; Maximum of 5 pages if written in English or 6 pages if written in French, this page limit includes the 1- page trial summary.
- A maximum of 1 page can be used for the trial budget and justification (required).
- Optional - Can have a maximum of 1 additional page to include any references, figures, or tables.

Each proposal that meets eligibility for review will receive a mark out of 100 (we will not grade ineligible applications).

<u>Sections</u>

- First page (Trial Summary page)
    - Proposal Title
    - Confirm ACT Eligibility (4 bullet points):
        1. Canadian Led Trial: <*list nominated PI(s)*; *confirm that NPI is affiliated with an institution eligible to hold CIHR funds and will have their substantive role in Canada for the duration of the project's term*>, <*list location of trial data coordinating centre*>.
        2. Canadian-controlled Biotech company: <list the name of the company, *business number*>
        3. Indicate which of the 28 ACT Networks endorses the proposal.
        4. Confirm proposal is an RCT.
    - Provide a summary of the trial proposal (i.e., structured abstract) listing key trial elements (e.g., rationale, question, participants, intervention, outcomes, and anticipated impact).

- Four pages (or 5 pages if written in French):
    - Describe the problem the trial will address with the potential of the technology [30% of the score]
    - Describe the trial (objectives, design, outcomes) [40% of the score]
    - Describe the team/partnerships [15% of the score].
    - Describe how the project will be completed and reported publicly by January 15, 2025 [15% of the score]
- 1 page budget and budget justification. Include a statement: "I have confirmed my institution (which will hold the grant funds) has reviewed my proposed budget and deems all items to be CIHR eligible."

Adjudication Process

ACT personnel will review each application for eligibility. ACT will not further consider any ineligible application based on the information provided. We recognize that a modest amount of funding is available to applicants through this RFA to conduct an RCT. Additional partnership funding to conduct the RCT is acceptable and welcomed.

Applications will be circulated to reviewers (after they confirm they have no conflict with the application) to:

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

Reviewers are asked to flag whether secondary review of the budget by the ACT Finance Committee is recommended.

Each application will receive an average score out of 100.

Applications with an average score <60 are ineligible for funding. We will fund applications with a score of 60 or more based on rank until we reach the maximum budget for this RFA. If trials have tied scores for the remaining funds, we will recirculate to reviewers for a rank order. Where applications have received the same scores, preference will be given to those that have secured in-kind or matched funds.

Feedback to Applicants

We will provide the principal applicant of each eligible application information on the number of eligible applications submitted to this RFA, the number awarded, and whether they were successful. We will provide brief written comments from reviewers back to applicants, along with each reviewer's score.

Timelines

- Opportunity announced at ACT conference April 16/17/18,
- Announcements through the ACT networks: **Friday, May 12th, 2023**
- Deadline for Proposals: **Thursday, July 7rd, 2023**
- Awardees Announced: by **Monday, September 8th, 2023.**