Sixth Call for Proposals: Evaluate Canadian Biotechnologies with Randomized Controlled Trials

Application Instructions

- To apply your application must be endorsed by one of the 34 ACT Networks (details below)
- Please combine the following application components into a **single PDF** (maximum 7 pages in English or 8 pages in French):
  - Trial Summary: 1 page
  - Written proposal: Maximum of 4 pages in English or 5 pages in French (details of the formatting requirements are below)
  - Budget and budget justification: 1 page
  - References, figures, or tables: 1 page (optional)
- Submit the full application PDF to the online portal **[https://redcap.link/RFA6SubmissionPortal] by Friday, December 20, 2024 at noon EST**
- Email confirmation of receipt will be provided. 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 (April 2023) and Third (October 2024) ACT Consortium meetings were to make connections between ACT research Networks and Canadian biotechnology companies. The conferences brought these groups together to learn about available products and needs, and to 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 sixth request for applications (RFA).

Given that most biotechnologies require RCTs demonstrating efficacy and safety to obtain regulatory approvals, the objective of this 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.

Details

- The focus of this RFA 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 the following: drug (including natural health products), vaccines, living organisms (or parts of them), biological systems to create products, devices, applications (including software), data systems, and diagnostic tests.
    - Examples of how Canadian biotechnologies could be incorporated into a trial include the following: the trial could evaluate the effects of a Canadian biotechnology (e.g., new drug), the trial could incorporate the use of a Canadian biotechnology in the trial (e.g., monitoring technology to identify eligible patients or an outcome event), or the trial could use Canadian biotechnology database system to conduct the trial.
- Trials must be **Canadian led**, meaning:
    - The principal trial investigator will have their substantive role in Canada for the duration of the project's term[1] and is a member of an ACT network
        - their primary affiliation is in Canada; or
        - they spend at least 50% of their time at the designated Canadian institution.
    - The biotechnology company partner must be Canadian-controlled.
    - The centre which coordinates the RCT must be Canadian and cannot be a for-profit contract research organization (CRO).
- Principal investigator(s) must report their shareholding status in the company.
- 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.
- Each funded proposal will be expected to collect and report data on sex and ethnicity.
- Proposals are encouraged to include team members who have lived experience with the condition being studied (e.g., patients and caregivers); include partnerships with Indigenous peoples; address equity, diversity, inclusion, and accessibility considerations; and engage several components of ACT (e.g., ACT CTUs, portfolio hospitals).
- 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.
- CIHR policies regarding trial reporting must be followed: Policy Guide – Requirements for Registration and Disclosure of Results from Clinical Trials.
- Each team must submit a 1-page annual progress report to ACT, according to a template (to be provided in the future).

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, it will facilitate phase 2, pilot, or Vanguard trials. Trials that assess safety, recruitment potential, and feasibility are also welcome provided they are an RCT.

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

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.
3. The trial must evaluate a biotechnology and the biotechnology company partner must be Canadian-controlled.
4. The proposal is an RCT and not a product validation observational study.
5. The trial must be endorsed by one of the 34 ACT Networks.
    - Applicants only list one principal ACT Network and each application is restricted to a single RCT.
    - Each Network can endorse a maximum of three applications to this competition.
    - Networks should endorse proposals most relevant to their constituents, especially their patients.
    - No letter of support is required from the supporting ACT Network.
6. Investigators must provide confirmation from their institution that the proposed budget is CIHR eligible.
7. Applicants will acknowledge ACT Consortium partnership and funding in all related presentations and publications.
8. 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.
9. Applicants commit to making their trial results publicly available (open-access publication).

Proposal Sections

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"];

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

A. Trial Summary: 1 page
B. Written proposal: Maximum of 4 pages if written in English or 5 pages if written in French
C. Trial budget and justification: 1 page
D. References, figures, or tables: 1 page (optional)

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

Sections

- **Trial Summary** (1 page)
    - Proposal Title
    - Confirm ACT Eligibility (4 bullet points):
        1. Canadian Led Trial: <*list nominated PI(s)*; *confirm that NPI will have their substantive role in Canada for the duration of the project's term*; *location of trial data coordinating centre; PI(s) shareholding status in biotech company*>.
        2. Canadian-Controlled Biotech company: <*company name and business number*; *Canadian ownership as relates to CCPC>.*
        3. Indicate which one of the 34 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).

- **Written Proposal** (4 pages in English or 5 pages in French)
    - Describe the problem the trial will address with the potential of the technology **[30% of the score]**
        - How will the trial improve the evidence base of the biotech
    - 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 by June 2026 **[15% of the score]**

- **Budget and Budget Justification** (1 page)
    - 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. 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.
- Flag whether secondary review of the budget by the ACT Finance Committee is recommended.

Each eligible 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. Applicants will receive brief written comments and scores.

Timelines

- Announcements through the ACT networks: **Tuesday, November 5, 2024**
- Deadline for Proposals: **Friday, December 20, 2024 at noon EST**
- Awardees Announced: by **Monday, January 27, 2025.**

The ACT Canada Consortium is supported by the Canadian Institutes of Health Research (CIHR).