CANVECTOR

2020 Call for Proposals

CanVECTOR Pilot Trials Funding Opportunity

Background

We are pleased to announce the fifth call for proposals for **CanVECTOR Pilot Trials Funding**. The **Can**adian **V**enous Thrombo**E**mbolism **C**linical **T**rials and **O**utcomes **R**esearch (**CanVECTOR**) Network is a pan-Canadian, patient-oriented Community Development Program centered on Venous Thromboembolism-related research, training, and knowledge translation. Our mission is to decrease the health, social and economic burden of venous thromboembolism (VTE) on affected individuals, their families, and on Canadians as a whole.

The purpose of this funding opportunity is to build research capacity related to VTE and to enable CanVECTOR scientists to collect pilot data that will inform the conduct of larger multicentre clinical trials and increase the ability to attract external peer-reviewed funding.

Funding Details

A total of $100,000 is available to fund one or more pilot studies between October 2020 and September 2022. Funding for individual projects may be awarded over one or two years.

It is expected that the applicants will seek peer-reviewed funding for the full trial within 3 years of receiving CanVECTOR funds.

Eligibility

Applicants

- The project team for the pilot study will include an investigator triad (senior investigator, an early or mid-career investigator, and a thrombosis fellow or trainee). It is also expected that a methods expert will be included on the team.
- At least one of the investigators in the triad must be a CanVECTOR member.
- Any investigator in the triad can be the lead investigator for the application.
- Inclusion of investigators from less-established research sites is encouraged.
- CanVECTOR is committed to conducting research that is meaningful to patients and their families and to including trained patient partners on project teams. Applications should include a patient engagement strategy and/or patient partner. To request assistance, please contact the co-leads of the Patient Partners Platform: Lisa Duffett (lduffett@toh.ca) or Jessica Emed (jessica.emed@mcgill.ca).

Projects

- The project is expected to collect pilot data at two or more sites to inform a randomized controlled trial (RCT) that will be conducted at multiple CanVECTOR sites. Though it is often considered preferable, it is not an absolute requirement for the pilot study to have an RCT design; for example, it can be a cohort study that's collecting pilot data that is needed to design a full RCT.
- The pilot project must be completed within two years.
- The research focus is to be related to prevention, diagnosis, or treatment of venous thromboembolism or its sequelae.

- Applicants are encouraged to refer to the following online resources (open access) that outline methodology and best practices for pilot studies

  CONSORT 2010 statement: extension to randomised pilot and feasibility trials
  http://www.consort-statement.org/randomised-pilot-and-feasibilitytrials

  Pilot trials in thrombosis: Purpose and pitfalls
  https://onlinelibrary.wiley.com/doi/epdf/10.1002/rth2.12117

Pilot Project Application Requirements

Please send completed applications to info@canvector.ca

Format

The Pilot Proposal should be no more than **4 pages** (single-spaced, size 11 Arial font, 1 inch margins). References may be included at the end. Additional appendices may NOT be included.

The application can be collated as a single electronic (PDF) copy or may be submitted as 4 separate (PDF) documents: 1) Application Form, 2) Pilot Proposal and references, 3) Lay Summary, and 4) Budget.

Submission Requirements

1. Application form (**1 page**)

The application form can be downloaded from the CanVECTOR website: Application Form

2. Pilot proposal - recommended content (maximum **4 pages**)
   - Study overview (1 paragraph)
   - Background and rationale
   - Research question(s) and specific aims
   - Significance and novelty of research question(s)
   - Description of the investigator team
   - Patient engagement plan
   - Study design
   - Study population and sample size
   - Intervention studied (if applicable)
   - Measurement of outcomes
   - Planned analyses
   - Description of any potential ethical issues and how these will be addressed
   - Description of the next steps: Indicate how the pilot project will facilitate the development of a full-scale research proposal.
   - Detailed timeline for each specific aim (Note: Pilot projects must be completed within 2 years of receiving funds)

Please spell out all acronyms in the proposal and lay summary.

3. References

References to the pilot proposal may be included after the proposal and do not count towards the 4-page limit.

4. Lay summary (maximum **1 page**)

The lay summary is a brief summary of a research project that is used to explain complex ideas and medical and scientific terms to people who do not have prior knowledge about the subject.

In language suitable for a lay audience, describe the following:

- Purpose of the research (pilot study and eventual full RCT)
- Relevance of the research
- General approach (methods) of the pilot study

5. Budget and budget justification (maximum **2 pages:** spreadsheet + justification)

Budget items must *specifically relate to the pilot project*, and may include:

- Costs of research personnel salaries (e.g. research assistants, study coordinators, technicians, programmers, statisticians) and benefits (according to institutional rates)
- Supplies and expendables
- Equipment (carefully justified, with cost quotations provided)
- Participant costs (e.g. reimbursement for hospital parking)
- Patient partner costs (e.g. honorarium, reimbursement for transportation)
- Presentation/Publication (to a maximum of $1500)

Ineligible expenses:

- Institutional or administrative overhead (any indirect costs)
- Salary support for investigators or trainees
- Meals, alcohol, employee recognition

The applicant must state in the Budget if part of the Pilot Study will be funded from another source and justify the other source(s) of funding.

Review Process and Evaluation Criteria

- Applications must be submitted by email to the CanVECTOR Network: info@canvector.ca by the end of day **March 27, 2020**. Incomplete or late submissions will not be considered.
- Proposals will be reviewed by a minimum of 4 reviewers, including CanVECTOR members, international thrombosis experts and patient partners. The reviewers ratings will be considered by the co-chairs of the Clinical Trials Platform (Dr. Clive Kearon and Dr. Gregoire Le Gal) who will make recommendations for funding.
- Decisions will be announced by **the end of May 2020**. A letter of notification, including brief feedback from the review committee, will be sent to all lead applicants.
- Funds will be released to the lead investigator's institution as soon as the required paperwork is completed.

Rating system:

A 10-point rating system will be used by the scientific reviewers:

Component	Maximum Points
The research team (investigator triad, methods expert, patient engagement, inclusion of investigators at less established research sites)	2
The research proposal (including relevance to CanVECTOR's mission)	5
Feasibility of the pilot study and the full RCT	3

A 10-point rating system will be used by the patient partner reviewers:

Component	Maximum Points
The lay summary (clarity, appropriateness and relevance for a lay audience)	2
The patient engagement strategy (clear and appropriate plan for including patients)	2
The research project (relevance to patient interests and concerns, with the potential for the pilot study to lead to a future trial that may improve health, quality of life or quality of care for patients)	3
Requirements for patients (Balances and optimizes the needs of the study with the risks and burdens on participants; e.g. study visits, interventions, and tests that are outside of usual clinical care)	3

Administration and Conditions of Funding

- A summary of the successful pilot proposal will be posted on the CanVECTOR website**.**
- Registration of the pilot trial in a clinical trials registry (e.g. Clinicaltrials.gov) is required.
- Funds will only be released once evidence of Research Ethics Board approval is provided by the lead investigator.
- Funds will be released to the lead investigator's institution on an annual basis. The name of the institution's financial officer must be provided to CanVECTOR's Financial Officer.
- Use of funds must comply with CIHR guidelines and those outlined in the Tri-Agency Financial Administration Guide (2017).
- Successful applicants will complete a 1-page progress report after 1 year of receipt of funding, and a 1-2 page final report within 3 months after the 2nd year of funding is completed (if applicable).
- The funding recipient shall immediately notify CanVECTOR of his/her inability to complete the pilot project for any reason. In this case, any unused funding will be returned to the CanVECTOR Financial Office, and used funds must be justified or repaid.
- If the one-year progress report has not been submitted, or if progress of a 2-year project is deemed unsatisfactory, any unused funding will be returned to the CanVECTOR Financial Office and funding for the second year will not be released.
- The recipients of CanVECTOR pilot trial funding will be expected to present their proposal and/or results at CanVECTOR annual meetings. Additional knowledge translation activities are encouraged, regardless of the pilot study's results.
- CanVECTOR and CIHR funding must be acknowledged in any publication or presentation arising from the pilot study (see *Policy on acknowledgement of CanVECTOR in publications and presentations – version 2.0*).