

The Advancing Clinical Trials Program

Guidelines

SCN will provide up to \$1,000,000 to support early stage clinical trial projects with high translational potential

About the Stem Cell Network:

Supporting and building Canada's stem cell and regenerative medicine research sector has been the *raison d'être* of the Stem Cell Network (SCN) since its inception in 2001. Its work has been supported by the Government of Canada from the beginning, and most recently with an \$18 million commitment to fund research and training through 2019-22.

SCN's mandate is to act as a catalyst for the translation of stem cell research into clinical applications, commercial products and public policy. In just over 18 years SCN has forged a national community that has transformed stem cell research and moved it to the point where regenerative medicine is changing clinical practice. SCN has supported 170 research groups nationally; invested over \$100 million for translational research, leveraging nearly \$100M in partner contributions; catalyzed 19 clinical trials and 21 biotech start-ups. In addition, SCN established the annual Till & McCulloch Meetings and has provided training for more than 3,000 individual trainees.

The Advancing Clinical Trials Program:

SCN is pleased to invite full proposals under its Advancing Clinical Trials Program. The program will support projects that focus on novel cellular or stem cell-related therapeutic approaches to tissue repair and regeneration for specific diseases.

Eligible clinical trials must be testing Canadian innovations at the Phase I or II stage, have received both Research Ethics Board (REB) and Clinical Trials Approval (CTA) from Health Canada, and are not duplicative of other research taking place globally. It is expected that successful projects will show incremental benefit to the patient and provide a preliminary economic analysis of the potential cost of treatment compared to current standard of care to demonstrate the value to the Canadian health care system.

Awards of up to \$1,000,000 for 25 months will be available through this program (January 1, 2020 – January 31, 2022). The application will require a strategic plan and a budget justification that corresponds with the plan. In addition, a separate detailed budget for the requested SCN funding is required. Partnerships with foundations, institutions, health charities or industry are

an important and mandatory component of the project proposals. Partnerships and leveraged funding (in-kind and/or cash) will increase the application's ranking. All project applications will be subject to peer review and assessment by the Stem Cell Network's Research Management Committee. Successful projects will provide the SCN office with project reports as requested and will be regularly monitored by SCN's Research Management Committee to ensure appropriate progress is being made.

Specific Criteria:

- Eligible clinical trials must be at the Phase I or II stage and have both CTA and REB approvals. Please note, trials that are in the process of obtaining CTA approval from Health Canada can be submitted to SCN for review but a CTA approval letter from Health Canada for the proposed trial must be in place and shared with SCN by November 14, 2019 to be eligible for funding.
- Projects must be within the field of regenerative medicine and led by a Canadian academic and testing a Canadian innovation.
- Projects must have an achievable patient recruitment strategy and have patient representatives who provide insight on trial design and rollout.
- Projects are encouraged to take a collaborative team-based approach. Phase II trials should include multiple sites.
- Where applicable, a clear manufacturing plan must be provided with a letter from the manufacturer committing to meeting the clinical trial deliverables.
- Projects must describe the need and economic feasibility of the therapy for the health care system.
- Applications should describe risk mitigation strategies to overcome challenges that could prevent clinical trial success (e.g. patient enrollment, manufacturing, partner and receptor engagement)
- SCN will contribute a maximum of 40% for the costs of a clinical trial
- Projects must include non-federal partnerships that provide in-kind and cash contributions.

General Requirements:

- Projects must be relevant to stem cells and regenerative medicine.
- Projects must demonstrate research excellence, Canadian leadership and innovation.
- Research applications that are focused on cancer must be regenerative in nature and/or use stem cells for addressing the proposed problem.

- Projects should integrate sex and gender considerations into the research, when appropriate.
- Project milestones and deliverables must be realistic and reasonable based on the supporting budget.
- Projects should be collaborative in nature - supported by dynamic, multi-disciplinary teams that are diverse and reflective of Canadian society and of *all* research career stages. International collaboration is also encouraged to strengthen the research activity and potential global impact.
- Where appropriate teams should include an ELSI (Ethical, Legal and Social Implications) expert who can address translational issues specific to the research (e.g. patient engagement, health economics, regulatory issues, privacy and data collection)
- A trainee education plan must be submitted with the funding application.
- A knowledge mobilization plan must be submitted with the funding application, and adhere to the [Tri-Council Open Access Policy](#) to ensure research results are made publicly accessible.
- Each Project must be distinct from any other application(s) submitted to SCN to avoid 'double dipping' across SCN's research funding programs.
- Investigators requesting funds from SCN must be based at a Tri-Council eligible institution and must themselves be eligible to receive Tri-Council funding.

The full application package for the Advancing Clinical Trials Program consists of:

- The application form (document 1)
- Investigator CVs (document 2)
- Letters of support (document 3)
- Project budget for requested SCN funds (document 4)
- Supporting documents, including Research Ethics Board and CTA approval from Health Canada, and contract agreements between the principal study site and participating sites (document 5)
- Institution and investigator signatures form (document 6)

The deadline to submit the full application package to info@stemcellnetwork.ca is **Thursday, August 8, 2019 at 11:59 PM Pacific Time**

A confirmation email will be sent within 48 hours of SCN receiving the submitted application package. If a confirmation email is **NOT** received from SCN within 48 hours of submission **it is the responsibility of the lead applicant** to contact SCN and ensure that the application package has been received by SCN.

Funding is dependent on the completion of SCN's 2018-19 contribution agreement with the Government of Canada.