

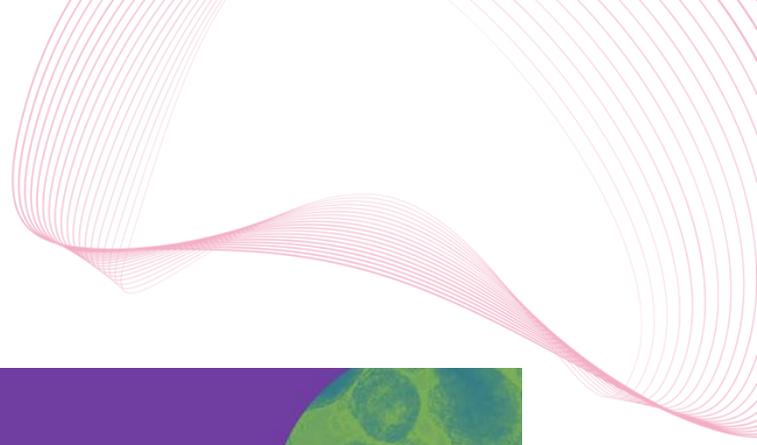


**Stem Cell
Network**

Powering
Regenerative
Medicine

**Réseau de
Cellules Souches**

Propulsons
la médecine
régénératrice



Clinical Trials Awards - Program Guidelines

SCN will provide up to \$750,000 to support early-stage clinical trial projects with high translational potential.

Timeline:

- Letter of Intent submissions open on Thursday, September 1, 2022.
- Letter of Intent submission deadline is Thursday, September 22, 2022, at 11:59 p.m. Pacific.
- Full application submission will be opened to eligible LOI submitters on Tuesday, September 27, 2022.
- Full application submission deadline is Thursday, December 1, 2022, at 5:00 p.m. ET (2:00 p.m. PT)

The Letter of Intent and full application must be submitted using the ProposalCentral online submission platform.

Upon successful submission of an LOI and/or full application, a confirmation message will appear on the screen within ProposalCentral and a confirmation email from

pcsupport@altum.com will be sent to the applicant. Add pcsupport@altum.com to the safe senders list to ensure receipt of submission confirmation.

If a confirmation email is NOT received from ProposalCentral 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.

About the Stem Cell Network:

Formed more than 20 years ago, the Stem Cell Network (SCN) is a national non-profit that supports stem cell and regenerative medicine research, training the next generation of highly qualified personnel, and delivering outreach activities across Canada. SCN's goal is to advance science from the lab to the clinic for the benefit of Canadians. SCN has been supported by the Government of Canada since inception in 2001. This strategic funding, valued at \$139M, has benefitted over 200 world-class research groups and 5,000 trainees and has catalyzed more than 25 clinical trials. Powering research for better health.

The Clinical Trial Award Program:

SCN is pleased to invite proposals under the Clinical Trial Award Program. The program will support projects that focus on novel gene, 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. All clinical trials must be registered on ClinicalTrials.gov. 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.

Clinical Trial Awards are for up to \$750,000 each for 22 months (award term is April 1, 2023 to January 31, 2025). Full applications 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 companies/industry, not-for-profit organizations, foundations, charities, research institutions/hospitals/universities, and government bodies are a valuable component of project proposals. Partnerships and leveraged funding (in-kind and/or cash) will increase the application's ranking. Principal Investigator salaries and indirect costs can be listed as in-kind institutional support (PI salaries at 10% and indirect costs at 40%). In

addition, applications that include collaborations with other Canadian-based investigators and have multidisciplinary expertise will also be ranked more highly.

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 (No Objection Letter) from Health Canada for the proposed trial must be in place and shared with SCN by February 21, 2023 to be eligible for funding.
- Clinical trials funded through this program MUST be registered at ClinicalTrials.gov. Registration at ClinicalTrials.gov can occur after award notification but must be in place at or before the onset of patient enrollment.
- 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 expected 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.
- Please note, academic or clinical institutions should serve as the sponsor on SCN funded clinical trials. However, if a trial is sponsored by an SME, then a risk mitigation letter will be required at the point of submitting the full application.

General Requirements:

- Projects must be relevant to regenerative medicine; regenerative medicine is the branch of medicine that develops methods to regrow, repair or replace damaged or diseased cells, organs or tissues. Regenerative medicine includes the generation and use of therapeutic stem cells, tissue engineering and the production of artificial

organs. *Research applications that are focused on cancer must be regenerative in nature and/or use stem cells for addressing the proposed problem.*

- 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.
- Projects must demonstrate research excellence, Canadian leadership and innovation.
- Projects must be in the translational space.
- Project milestones and deliverables must be realistic and reasonable based on the supporting budget.
- International collaboration is also encouraged to strengthen the research activity and potential global impact.
- Projects must include a robust Highly Qualified Personnel (HQP) training plan that integrates trainees and facilitates meaningful exposure and development across the spectrum of project disciplines.
- A knowledge mobilization plan must be submitted and describe how the research will be made accessible to knowledge users outside of academia. Please note it is expected that the [Tri-Council Open Access Policy](#) will be followed to ensure research results are made publicly accessible. *SCN strongly encourages the funded teams to publish their clinical trial protocols in open access journals.*
- Projects must include a description of the best practices and measures that will be adopted to ensure robust, unbiased, and reproducible results, including any laboratory/project management, data governance, good documentation practices and how sex and gender considerations are integration into the research. Note: All proposed research should be conducted in accordance with the [Tri-Agency Framework: Responsible Conduct of Research](#).
- All applications must include a plan that describes the project Equity, Diversity, and Inclusion (EDI) considerations for hiring/team composition, training, and scientific methodologies.
- Sex and Gender in Research Training: Applicants must have completed and obtained certificates for the three courses comprising the CIHR [Online Training Modules: Integrating Sex and Gender in Health Research](#).
- Research Security Training: Applicants must have attended in-person SCN's July 20, 2022 Research Day OR be familiar with the [Safeguarding Your Research](#) Portal and completed the following training courses and obtained certificates: [Introduction to Research Security](#), [Dual-Use in Life Science Research](#) and [Insider and Outsider Threats](#).
- Each Project must be distinct from any other application(s) submitted to SCN to avoid 'double dipping' across SCN's research funding programs.

- An applicant is limited to act as Lead Investigator on only one LOI submission and project application per program.
- Investigators requesting funds from SCN must be based at a Tri-Council eligible institution and must themselves be eligible to receive Tri-Council funding.
- To receive funding, successful applicants must execute a standard SCN Agreement, and take on all of the associated rights and obligations. These obligations include the requirement to provide SCN office with project reports as requested, and recognition of SCN as a funder.

General information about SCN's Round 2 competition:

Regenerative medicine projects that are eligible for SCN funding centre on one or more of the following topics: 1) Developing or testing therapeutic approaches that are regenerative in nature, including cell and/or gene therapies; 2) Addressing the role and function of stem cells in a tissue or disease; 3) Using stem cells as a necessary component for the generation of functional cell types; or 4) Investigating a small molecule or biologic that acts on or is dependent on endogenous stem cells for its therapeutic effect.

SCN values the individual differences, lived experiences, expertise, and knowledge of those in the community regardless of age, ancestry, culture, physical ability, gender identity, race, religion, and sexual orientation. All applications must include a plan that describes the project Equity, Diversity, and Inclusion (EDI) considerations for hiring/team composition, training, and scientific methodologies.

All applications to SCN funding competitions are treated as new applications. If a project was submitted to a previous SCN funding round, it is at the applicant's discretion to address any issues raised in prior peer review feedback. Peer reviewers will not be provided access to prior peer review feedback for any previous version of an application.

Eligible applications will be reviewed through an expert peer review process, comprised mainly of international reviewers. Projects will then be considered for strategic fit with SCN's mandate by the [Research Management Committee](#) (RMC), and funding decisions will be taken by the Board based on RMC recommendations. Successful applicants will provide the SCN office with project reports as requested and will be regularly monitored by SCN's RMC to ensure appropriate progress is being made. More details regarding SCN's peer and strategic review process can be found [here](#).

Submission process for the Clinical Trial Awards program:

A Letter of Intent (LOI) submission is mandatory for this program. LOIs will be used to identify peer review requirements, gauge the level of interest in SCN's programs, and ensure projects fall within SCN's regenerative medicine mandate. Eligible LOIs will be invited to submit a full application on Tuesday, September 27, 2022.

LOI and full application-related questions should be addressed to Jon Draper (jdraper@stemcellnetwork.ca).