

Stem Cell Réseau de Network Cellules Souches

Powering Regenerative Medicine

Propulsons la médecine régénératrice

2023-2025 Research Funding Programs Information Webinar

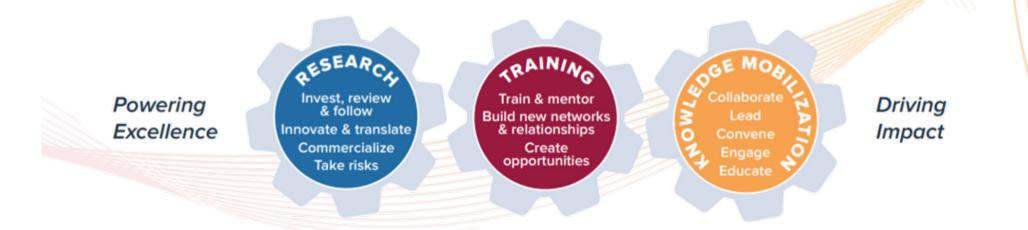


About the Stem Cell Network

SCN is a national not-for-profit that supports three main objectives:

- > stem cell and regenerative medicine research;
- training the next generation of highly qualified personnel;
- and supporting the knowledge mobilization and transfer of stem cell and regenerative medicine research.

SCN's Hallmarks of Success



New Era, New Mandate

For over 20 years, SCN has built stem cell research strength in Canada and established an outstanding international reputation.

In April 2022, SCN launched its **new three-year Strategic Plan**, *IGNITE*, kicking off an exciting new chapter at the Network.



Our Vision

To power life-saving therapies and technologies through regenerative medicine research for the benefit of all.

Our Mandate

To be a national research leader dedicated to accelerating regenerative medicine and its translation for the benefit of Canada.

Our Values

Five organizational values are cornerstones of our work and the work of the community across our Network:

- ➤ Excellence and innovation first
- Continual learning and improvement
- Integrity in our research and a commitment to ethical practice
- Equity, diversity and inclusion
- ➤ An environment that fosters collaboration

SCN by the Numbers 2001 to 2022

- ➤ \$139M direct investment in research, training & outreach
- ➤ \$148M in research partnerships
- ➤ 225+ translational research projects supported
- **≥231** research groups funded
- ➤ 5,000 trainees & highly qualified personnel trained
- ≥ 27 clinical trials funded
- ▶ 23 regenerative medicine biotech companies catalyzed

Research Funding Round 1, 2022-2025

On May 12, 2022, SCN announced \$19.5M in funding for 32 regenerative medicine research projects and clinical trials involving more than 400 researchers, clinicians, and trainees from across Canada.

This investment is SCN's largest funding injection in its 20-year history.

Of note, 59% of the projects are led by women, with 12 projects led by early-career investigators. In total, the projects cover 20 different disease areas.



2022-2025 Round 1 Funding Competition Results



The regional breakdown for these projects is as follows: Ontario, 17 projects; British Columbia, 7 projects; Quebec, 6 projects; Prairie provinces, 2 projects.

To view SCN's full list of funding results visit: https://stemcellnetwork.ca/research/research-competition-results/

Defining 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.

Source: Nature.com (https://www.nature.com/subjects/regenerative-medicine)

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



Eligible Projects

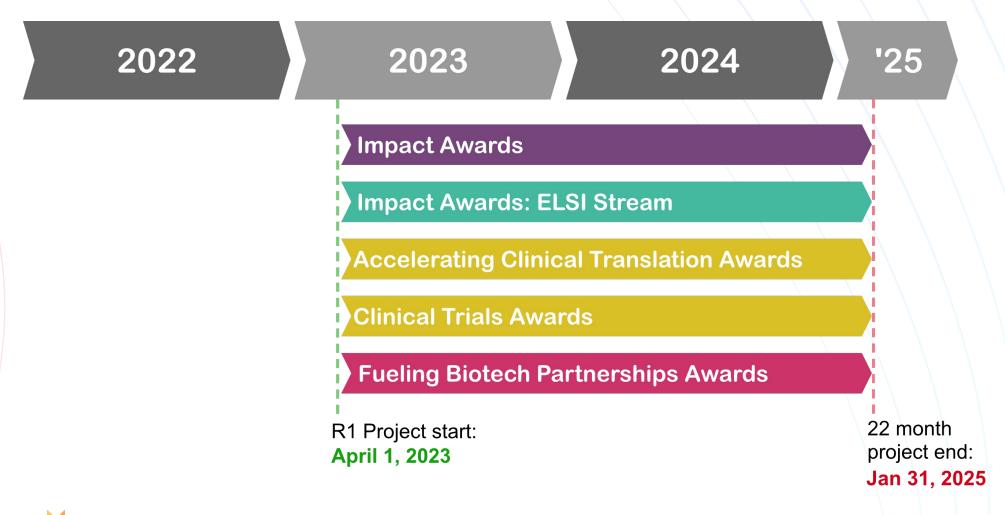
Regenerative medicine projects that are eligible for SCN funding centre on one or more of the following topics:

- Developing or testing therapeutic approaches that are regenerative in nature, including cell and/or gene therapies;
- Addressing the role and function of stem cells in a tissue or disease;
- Using stem cells as a necessary component for the generation of functional cell types; or
- Investigating a small molecule or biologic that acts on or is dependent on endogenous stem cells for its therapeutic effect.
- Addressing Ethical, Legal and Social Implications (ELSI) opportunities or challenges associated with regenerative medicine research or translation.

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.



Round 2 Programs



Round 2 Competition Timeline



SCN Application Submission:



- Reference documents available through Proposal Central and SCN website:
 - LOI instructions.
 - Program-specific application instructions.
 - Program-specific guidelines.
- Lead and co-applicants must be registered as a user on ProposalCentral.
- Your designated institutional signing authority and financial officer must be registered on ProposalCentral
 and you must grant them access to your application.
- Only investigators receiving SCN funding should be listed as lead and co-investigators.
- Institutional affiliation for each investigator must match the institution that will receive the project funding.

ProposalCentral customer help desk: 800-875-2562 (toll-free) or pcsupport@altum.com.



Common Criteria

- Projects must have a RM focus and the potential to move along a translational pathway.
- Projects must include aims, milestones and deliverables.
- Projects must include a description of the best practices and measures that will be adopted to ensure
 robust, unbiased, and reproducible results, including the integration sex and gender considerations into
 the research, when appropriate. Risk mitigation strategies are also required.
- Projects must include a description of the project **Equity, Diversity, and Inclusion (EDI)** considerations for hiring/team composition, training, and scientific methodologies.
- Knowledge mobilization & training plans must be clearly outlined within project proposals.
- Include non-federal partnerships that provide in-kind and cash contributions. Partnerships and leveraged funding (in-kind and/or cash) will increase the application's ranking. Partner letters of support are required.
- 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**.

Required Training

Lead and co-investigators will be required to show they have completed the following training:

1. Research Security:

- 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
 - Insider and Outsider Threats.

2. Sex and Gender in Research:

• Completed and obtained certificates for the three courses comprising the CIHR Online Training Modules: Integrating Sex and Gender in Health Research.







Impact Awards - Up to \$250K/award for 22 months

- Projects that may be funded within this program can involve proof-of-principle experiments for gene and/or cell therapy development, development of new models, and expression and epigenetic studies to understand behavior of stem and progenitor cells in disease relevant settings.
- Projects must articulate a translational "bench to bedside" path of the research and where the proposed research stands along the path.
- Seed research avenues or build intellectual property (IP) that will yield Canadian translational or commercialization activity.
- Awards can be to support work in an individual lab.
- Should include collaborators from outside of the Lead Investigator's institution to further the Network and research impact.
- Supportive preliminary data is an important component for all applications submitted to the Impact Awards Program



Impact Awards: ELSI Stream - Up to \$200K/award for 22 months

- Support the knowledge translation of regenerative medicine.
- Projects can focus on a social, economic, technological, regulatory, patient or ethical question or challenge that should be addressed to support the knowledge and advancement of RM in Canada and globally.
- Projects may focus on outputs that go beyond traditional academic research products including digital, educational & cultural materials.
- Project plans should include details on how the research will be tailored for and used by receptors (e.g. policy & regulatory users, patient groups, academic stakeholders, media, the general public etc). Should include letters from receptors that demonstrate their interest in the outputs.
- Awards can be to support work in an individual lab.
- Note: the creation and maintenance of databases should not represent a major component of the activities funded by this award.



Accelerating Clinical Translation AWARDS



Accelerating Clinical Translation Awards - Up to \$600K/award for 22 months

- Support multi-disciplinary research projects focused on stem cell-related technologies or cell
 therapies expected to reach clinical trials activity within five years; basic research projects are not
 eligible for funding.
- Projects can include translational research activities (including Ethical Legal and Social Implications (ELSI) questions) associated with an ongoing clinical trial that will enable the trials next phase of activity
- Projects can focus on pre-clinical & toxicity tests, technology development & scale up, manufacturing requirements, validation research, proof of principle experiments in small or large animal models using novel cells, compounds/drugs, or novel transplantation approaches
- Up to 20% of the project budget can be directed towards methodological support for clinical study design and anticipated outcomes; data collection & management; data safety monitoring and oversight; preparation of regulatory documents; pre-clinical and clinical systematic reviews; early economic analysis; protocol development; conducting patient consultations and strategies to support clinical trial study design.



Clinical Trial Awards - Up to \$750K/award for 22 months

- Support early phase clinical trials that focus on therapies or technologies relevant to regenerative medicine and that will be made available to Canadian patients.
- Trials should use a collaborative team-based approach, and Phase II trials should include more than one site.
- SCN will contribute a maximum of 40% for the costs of a clinical trial.
- Funded projects must include a robust study design & clinical protocol.
- Trial proposals must also provide a patient engagement plan, health-economic analysis that demonstrates need and viability for reimbursement.
- REB and CTA approvals must be in place prior to funding.
- Clinical trials funded through this program MUST be registered at ClinicalTrials.gov (after award notification but before patient recruitment starts).



Clinical Trial Awards - Up to \$750K/award for 22 months

- Funding can be used to offset the costs of manufacturing a cell product that will be delivered to patients. A letter of support from cell manufacturer is required.
- Applications should describe risk mitigation strategies to overcome challenges that could prevent clinical trial success (e.g. patient enrollment, manufacturing, partner and receptor engagement)
- For multi-site trials a training plan must be in place for all those who will be participating in the trial and delivering the product to patients and tracking outcomes.
- An academic or clinical institution should serve as the sponsor on SCN funded clinical trials. However, if a trial is sponsored by an SME, then a **risk mitigation letter from the SME will be required at the point of submitting the full application.**



Fueling Biotechnology Partnerships AWARDS



Fueling Biotechnology Partnerships - Up to \$400K/award for 22 months

- Supports partnerships between RM academics and early-stage Canadian start ups who have a focus in regenerative medicine.
- Supports projects in the regenerative medicine space, that are novel and competitively differentiated, and that resolve a key translational question or bottle neck that will enable a technology or therapy to move into the clinic or market within five years.
- Projects must be led by an academic at a Canadian institute and the partnering receptor company must be a
 Canadian SME in the field.
- Projects must be focused on advancing a Canadian regenerative medicine innovation that will have global relevance.
- Projects must provide a development plan and commercialization assessment that clearly articulates a commercial pathway, competitive differentiation, and value-creating deliverables.
- Note: Projects can use a portion of the project funds to offset costs for IP filings or for licensing agreements (up to \$60K for a max of 2 filings or licensing activities).

Questions and Answers



Join us at the 2022 Till & McCulloch Meetings!



The Till & McCulloch Meetings hosted by the Stem Cell Network, will take place October 3-5, 2022 at the Hyatt Regency Hotel in Vancouver, BC















