Canadian National TRANSPLANT Research Program | Programme national de recherche en TRANSPLANTATION du Canada

CNTRP Astellas Research Innovation Grant Competition - 2017

BACKGROUND

In November 2012, Astellas Pharma Canada, Inc. ("Astellas") established a partnership with the Canadian National Transplant Research Program (CNTRP). This partnership resulted in a 5- year funding commitment from Astellas to support CNTRP research and innovation in addressing barriers within the field of transplant, with the ultimate goal of advancing long-term health outcomes and quality of life for Canadian transplant patients.

Enhancing Astellas's sustained commitment to research and development within the transplant scientific community is the continuation of the CNTRP Astellas Research Innovation Grant Competition. This collaborative effort between Astellas and the CNTRP is intended to seed new and innovative pilot projects in the transplant and donation field. Astellas will provide the funding for the Grants. The CNTRP's New Initiatives Committee (NIC) will set guidelines for the competition, receive and process the applications, and evaluate and rank the applications through a competitive peer reviewed process. The Canadian Liver Foundation, partner and supporter of the CNTRP, will provide financial administration for the research grant funds on behalf of the CNTRP and will disburse research funding to each of the selected Grant recipient(s).

In August 2015, the Multi-Organ Transplant Program at the University Health Network (UHN) joined this competition to provide additional funding to support UHN researchers participating in this competition to bring their new and innovative pilot projects into the CNTRP. Grants funded with this additional funding will be recognized as a "CNTRP UHN Innovation Grant" and will be awarded to the UHN researcher(s) ranked highest by the NIC in the CNTRP Competition but who was/were not successful in obtaining a CNTRP Astellas Research Innovation Grant.

KEY DATES

Competition Launch: June 14, 2017
Application Deadline: October 19, 2017
Notification Date: February 5, 2018
Funding Start Date: March 1, 2018, or upon confirmation of REB approval
Study update submitted to NIC: Within 18 months of Funding Start Date

OBJECTIVES AND SCOPE

The objective of the CNTRP Astellas Research Innovation Grant competition is to support new peer- reviewed pilot research project(s) that align with CNTRP's overall objective to increase organ and tissue donation in Canada and enhance the survival and quality of life of Canadians living with a transplant with the ultimate goal of improving patient care.

The primary area of focus for this competition is to **catalyze new translational focused research in donation and transplantation to improve health outcomes**. These projects must be new stand-alone studies that will be used to generate preliminary data to support further investigation.

Translational focused research refers to research that combines disciplines, resources, expertise, and techniques across the biomedical, clinical, health services and population health pillars to promote enhancements in prevention, diagnosis, and therapies that will improve outcomes for transplant recipients. The applicant is expected to define how their approach will directly increase organ and tissue donation in Canada and/or enhance the survival and quality of life of Canadians living with a transplant. These approaches should be applicable to the clinical setting today and are expected to result in - improved health outcomes.

Grant recipients are expected to integrate their proposed study within the CNTRP research structure.

Each grant will be awarded to the successful applicant(s) via the Primary Applicant's institution. It is anticipated that **six (6) grants of $30,000 CDN/each** will be provided by the CNTRP Astellas Research Innovation Grant competition over an 18-month performance period.

The Multi-Organ Transplant Program at the University Health Network will provide **one (1) additional grant of $30,000 CDN** to the top ranked **unfunded UHN researcher** through the CNTRP UHN Research Innovation Grant competition over an 18-month performance period.

ELIGIBILITY AND RELEVANCE

The NIC shall receive and process applications and shall evaluate the submitted proposals for relevance and eligibility to the competition prior to peer review. Proposals will be deemed eligible and relevant based on the following:

Eligible Applicants

The Principle Applicant must:

- Be an independent researcher working at a Canadian University or research institution
- Be a Canadian resident, and conduct the research at a Canadian institution (study subjects may be enrolled from other countries)
- Agree to integrate their study within the CNTRP structure if funded and agree to become a participating CNTRP Investigator
- Must include an existing CNTRP Investigator as a co-applicant on the submission if the Principal Applicant is not a current CNTRP Investigator (see list of CNTRP Investigators: under construction)
- Agree to sign a Research Grant Acceptance Form with the Canadian National Transplant Research Program who, in partnership with the Canadian Liver Foundation, will provide financial administration for the CNTRP Astellas Research Innovation Grant
- Agree to enroll recruited human subjects into the CNTRP patient registration database
- Agree to provide a progress report, including publication plan, to the CNTRP in dissemination of study results
- Agree to publish their work on behalf of the CNTRP and list the CNTRP as one of their author affiliations
- Agree to acknowledge the CNTRP and Astellas funding on any related publications arising from the study
- If successful, agree to have their application shared in confidence with Astellas for internal documentation and auditing purposes
- Agree that Astellas may disclose the amount and nature of the Grant publically on its website and in connection with any other public disclosure of payments/funding to healthcare professionals and healthcare organizations

Eligible Research Proposals

In 2017, the research proposals being considered will be those **catalyzing new translational focused research in donation and transplantation to improve health outcomes**.

This funding is intended to support new/pilot projects that have not been previously funded and where this funding could help the researcher become competitive for large/national level grant funding.

The research proposal may belong to one of the following categories, but are not limited to:

- Clinical, translational, interventional studies
- New tests/techniques that provide clinical risk stratification, genetic studies
- Epidemiology, health outcomes, and quality of life studies

The proposed application should describe a 'stand alone' project. The grant is not meant to complete funding for larger projects. The study must be completed within 18 months of receipt of funding; no renewals will be considered, but one extension of 12 months will be considered upon request.

Non-eligible Research Proposals

The following types of proposals will not be eligible:

- Proposals for projects that have received funding from another source, including government or industry sponsors, will not be eligible to receive a CNTRP Astellas Grant unless said funding is shown by the applicant to be directed to a portion of the overall project/research that is separate and distinguishable from the portion to which the proposal relates.
- Proposal budgets in excess of $30,000 CDN will not be considered unless there are **confirmed** leveraged funds from another source.
- Proposals for pharmaceutical product development (including studies on non-approved indications for drugs) and/or product comparison, or product promotion will not be considered.
- Successful applicants from the 2016 CNTRP Research Innovation Grant competitions or the 2016 National Child Health Transplant Team Grant competition will not be considered for this competition. Applicants may submit multiple unique applications to the CNTRP Research Innovation Grant competition; however, they can only accept one award from the CNTRP Research Innovation competition per year.
- Grant funds should not be used as matching funding for a CNTRP training grant, and should not be used for clinical training.

REVIEW CRITERIA

All proposals will be first reviewed by the NIC to ensure eligibility and relevance to the terms of the competition. If a member of the NIC is involved in the grant application he or she will recuse themselves from the decision making process. Applications that are deemed to be either not eligible or not relevant to the competition will be removed from the competition and will not be evaluated by the Peer Review committee. Relevant research proposals will be evaluated based on the following criteria:

Significance

- Scientific merit (validity, integrity, originality)
- Contribution to advancement of scientific knowledge in relevant therapeutic field
- Clinical relevance or potential clinical value and applicability

Feasibility

- Feasibility of study design, methodology, analysis
- Adequate power and sample size

- Study budget
- Suitable proposed timelines

Integration

- How would the proposal be integrated with the CNTRP and how does it fit with the specified CNTRP Project or Core
- How would the project contribute to the mandate of the CNTRP

Guidelines for Application Submission

The research proposal should be novel, previously unpublished and not exceed 3 pages (not including references), with a maximum of 3 additional pages for figures or tables.

In additional to the 3 page proposal, the application must:

- Submit a half-page summary of the research proposal that highlights how the research proposal will catalyze new translational focused research in donation and transplantation to improve health outcomes. This summary will be used to assess relevance of the application to the scope of the competition. (max ½ page);
- Attach a separate description of how the proposal will integrate and fit within a specific Project or Core of the CNTRP (max ½ page), and provide a letter of support from the lead of that Project/Core (www.cntrp.ca/research);
- Attach a lay abstract (max. 250 words) that can be used to explain the proposal to the general public and that if funded could be posted publically;
- Include a copy of a CIHR Academic Common CV for the Principal Applicant.
- Provide the names of 3 CNTRP Investigators that you suggest as potential reviewers for your application. We will consider these names as either potential external reviewers or members of our peer review committee; however, we cannot guarantee that these individuals will be selected.
- Provide the names of individuals that you think would be in conflict and should NOT review your application.
- Applicants may also include letters of support and/or commitment from the Chair of the Department/Division indicating the level of institutional and/or university support.

The completed application must be received by the NIC no later than **11:59pm PDT on October 19, 2017**. The magnitude of the project should match the size of the award; the award is not intended to supplement a major grant, however it is anticipated that this funding will be used to produce data to apply for large/national level grant funding.

Documentation received after the submission deadline will not be submitted for review. The applicant is responsible for ensuring completeness of the application and incomplete and unsigned applications will not be considered. Applicants must submit their application electronically to the CNTRP office as a single PDF file.

Suggested headings for the research proposal include 1) Statement of Objective(s), 2) Recent relevant research by applicant, 3) Brief review of literature and background information, 4) Hypothesis(es), 5) Design and Methodology, 6) Analysis of Data, 7) Anticipated Timeline, 8) Impact, Future research plans and Knowledge Translation, and 9) Budget. The applicant must use Times New Roman or Arial font, size 11 points or larger. Use at least 0.75 inch margins (top, bottom, left, and right) for all pages. The section name and the name of the Principal Applicant should appear in the header.

CONDITIONS OF THE CNTRP ASTELLAS RESEARCH INNOVATION GRANT

Research Ethics Board approval
The successful applicant must provide evidence of appropriate Ethics Committee approval along with consent forms where human subjects are involved in the study before the funding is released.

Financial Considerations
The amount of each grant should include direct costs (labour and study costs), study drug costs (if applicable), and indirect costs (publication, and software license fees). Institutions are expected to waive overhead fees that might otherwise apply to industry-funded research as funding cannot be used to support institutional overhead costs.

Research Grant Administration
A copy of the Research Grant Acceptance Form, signed by the Grant recipient must be returned to the CNTRP prior to disbursement of Grant funds. Upon review and approval of the signed Research Grant Acceptance Form and receipt of evidence of ethics committee approval, the CNTRP will authorize the Canadian Liver Foundation to initiate disbursement of research grant funds for the CNTRP Astellas Research Innovation Grant. The CNTRP UHN Grant recipient will receive their funding directly from the MOT UHN upon receipt and approval of the signed Template Grant Agreement.

Studies must be designed to be completed within 18 months after receipt of funding, yielding results that would merit submission as an abstract to a scientific meeting and subsequent publication in a peer-reviewed journal.

Patient Registration
The Grant recipient must agree to enroll recruited human subjects into the CNTRP patient registration database.

Progress Reports
The Grant recipient must provide a progress report to the CNTRP within 18 months of receipt of the Grant summarizing work completed, including presentations, abstracts and publications, as well as an accounting for funds.

Publications and Presentations
Grant recipients are expected to present their findings at scientific meetings, including the CNTRP Annual Scientific Meeting, and to submit their work for publication in peer-reviewed journals. The NIC shall require a copy of all proposed publications upon submission for publication or other public disclosure and the NIC shall provide said information to Astellas and UHN MOT forthwith.

Grant recipients are expected to list the CNTRP as one of their author affiliations in their related publications. All publications that result from a project supported by the CNTRP Astellas Research Innovation Grant should carry the following acknowledgement: “This research was supported by the *CNTRP Astellas Research Innovation Grant* funded by Astellas Pharma Canada, Inc. and jointly established by Astellas Pharma Canada, Inc. and the Canadian National Transplant Research Program.”

Grant Recipient Responsibilities
The following responsibilities must be assumed and carried out by the Grant recipient:

- Study contract review and execution (for clinical studies)
- Must become a CNTRP Investigator (if not already one) and comply with all current CNTRP investigator responsibilities

- Research Ethics Board submission and approval (if applicable)
- Health Canada Clinical Trial Application (CTA) submission and approval (if applicable)
- Ensure study conduct according to all applicable regulations or guidelines (e.g. ICH-GCP, etc.)
- Study-related activities such as data management, statistical analysis, medical writing, monitoring, etc.
- Registration and posting of study results on http://prsinfo.clinicaltrials.gov, if applicable
- Safety Reporting to Health Canada, the research ethics board (as per local requirements), and if a drug product is involved, the Product Safety/Pharmacovigilance group for the appropriate company. Please refer to the Serious Adverse Events and Lack of Therapeutic Efficacy Reporting Section.
- Communication of progress updates to the NIC
- Integration of the study into the CNTRP structure
- Forward copy of abstract(s)/manuscripts(s) to the NIC upon submission to congress/journal

Serious Adverse Events (SAE) and Lack of Therapeutic Efficacy

1. As sponsor of the study, the grant recipient is responsible for reporting SAEs and Lack of Therapeutic Efficacy directly to **Health Canada** (pursuant to the Canadian Food and Drug Regulations) and to the local REB, as required.
2. If a drug product is involved, the Grant recipient is also required to notify the Product Safety/Pharmacovigilance group for the appropriate company[1]

A **Serious Adverse Event** is any untoward adverse event/adverse drug reaction that at any dose, results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/ incapacity, is a congenital anomaly/birth defect, or results in other medically important events.

Lack of Therapeutic Efficacy – If a health product fails to produce the expected intended effect, there may be an adverse outcome for the patient, including an exacerbation of the condition for which the health product is being used. Clinical judgment should be exercised by a qualified health care professional to determine if the problem reported is related to the product itself, rather than one of treatment selection or disease progression since health products cannot be expected to be effective in 100% of the patients.

Notification of Decision for the CNTRP Astellas Research Innovation Grant Competition
Grant recipients will be notified of the decision regarding funding in February 2018. Both successful and unsuccessful applicants will receive a summary and a constructive critique from the NIC.

Address for Submissions
Please send completed submissions, as a single PDF file, no later than **October 19, 2017 at 11:59pm PDT** to:

Stephanie Maier
Program Manager
Canadian National Transplant Research Program
maiers [at] ualberta.ca

[1] If the research involves a drug product marketed by Astellas Pharma Canada, Inc.,

Also required to be collected by the Independent Investigator

Product Safety Information ("PSI") including but not necessarily limited to:

1. Death (always considered serious)
2. Abuse/Misuse/Overdose
3. Medication Errors (in prescribing, dispensing, or administration)
4. Drug Exposure during impregnation, pregnancy, breastfeeding or as a result of one's occupation
5. AEs reported in association with suspected or confirmed quality defects or counterfeit reports
6. Suspected transmission of an infectious agent