

## Alberta/Novartis Translational Research Fund Opportunity Program Guide 2014/2015

### OBJECTIVES

Alberta Innovates - Health Solutions (AIHS), Novartis Pharmaceuticals Canada Inc. (Novartis), and the Government of Alberta have partnered to create the **Alberta/Novartis Translational Research Fund**. Alberta's health research and innovation capacity coupled with the translational strength of Novartis will catalyze the development of innovations in health that support the interests and priorities of Alberta, Novartis and their partners.

This funding opportunity is designed to support translational research and innovation projects that focus on Multiple Sclerosis (MS) with the aim to translate novel innovations, evaluation methods, and/or care pathways into practice. Results from the investment are expected to lead to improvements in the care of MS patients and further the understanding of the disease. Overall, the funding opportunity contributes to optimizing health, societal, and economic outcomes through AIHS investments in health research and innovation.

### PROJECT DESCRIPTION

Support will be provided for translational research and innovation projects with a strong potential to advance MS patient care and/or research over the short or medium term (3 to 5 years). Research and innovation projects will be assessed on the basis of their outstanding translational potential, relevance to the health priorities of the Alberta/Novartis Translational Research Fund, scientific quality, innovative approach, and potential to advance evidence informed decision making to improve the health outcomes of MS patients.

Applicants will be asked to describe within their project an approach of how results will be translated to practice and to propose a structured plan of action based on expected deliverables, along with appropriate and specific milestones.

### PRIORITY TOPIC AREAS

Relevance to the following clinical priority topic areas, **with an emphasis on priority topic area 1 – Development and Implementation of Evidence-based Care**, will form part of the assessment criteria:

- 1. Development and Implementation of Evidence-based Care:** Optimization of care pathways and patient outcomes by designing and implementing better patient assessment and care guidelines through:
  - Engagement of MS patients and their health care practitioners;
  - Identification of compliance issues for MS drugs and impact on burden of illness including clinical outcomes, quality of life measures and economic burden; and,
  - Implementation of evidence informed programs to improve compliance and outcomes for MS patients.

2. **Delivery of Patient Care:** Development of comprehensive integrated services for improved community care and coordination of MS patient services.
3. **Advancement of MS Research and Innovation:** Understanding mechanisms of disease and/or advancement of technologies for treatment, prevention, early diagnosis and/or monitoring of disease progression through:
  - Provincial coordination of MS research initiatives;
  - Development of therapeutic technologies that offer neuroprotection while reducing inflammation and preventing disease progression;
  - Development of diagnostic technologies for early diagnosis and monitoring of disease progression;
  - Elucidating the mechanisms of disease progression, neuroprotection, inflammation and repair; and,
  - Consideration for primary progressive MS.
4. **Patient Engagement:** Support of empowerment and self-management of MS patients through:
  - Knowledge translation activities, including public education activities that include an evaluation component to determine effectiveness of methods and/or approach.

See **Appendix A** for examples of potential projects in each priority topic area.

**Please Note:** Clinical trial activities are NOT eligible under this funding opportunity.

## RESEARCH LOCATION

An Alberta-based comprehensive academic research institution or an institution administered by Alberta Health Services.

## VALUE AND TERM OF AWARD

This translational research opportunity will provide up to \$100,000 per year, for a maximum 3 year term (non-renewable).

## AWARD MANAGEMENT

Release of funds will be based on an agreed upon set of objectives, milestones and expenditures as outlined in the Research Management Plan (RMP). The RMP will act as a reference point towards progress of research activities that will be monitored on a semi-annual basis. Adequate progress for a reporting period will initiate the release of subsequent research funds during the tenure of the award.

## ELIGIBLE EXPENDITURES

- Salaries of research personnel essential to the project (excluding the principal applicant's and co-principal applicant(s), if applicable), including the support of graduate and post-graduate trainees;
- Purchase and/or leasing of equipment required and justified in the project for funding;
- Research material (including cost for access to data) required for the research project.

## INELIGIBLE EXPENDITURES

- Indirect costs related to the pursuit of research projects;
- Costs associated with intellectual property filings, commercial landscape analysis, and patents, and;
- Costs associated with clinical trials.

## APPLICATION AND REVIEW PROCESS

### Application Process

The application process for the Alberta/Novartis Translational Research Fund Opportunity will be a two phase process consisting of a Letter of Intent (LOI, Phase 1) and a Full Application (Phase 2).

### Review Committee

LOIs and Full Applications will be assessed by an expert review committee appointed by AIHS, based on recommendations from the Alberta/Novartis Translational Research Fund Steering Committee. The review committee will have a proven track record of scientific, clinical care, commercialization and translational research expertise in the area of MS. AIHS may solicit additional scientific review or relevant advice from external expert reviewers as well as input from collaborative partners regarding relevance of proposed activities to the scope of the program. This information may be included as part of the input to the review committee for assessment of applications in addition to the assessment criteria outlined below.

### Assessment Criteria

#### 1. Significance and Relevance

- Does the project align to the Alberta/Novartis Translation Research Fund priority topic areas? Is the relevance to a stated clinical priority topic area clear?
- How important is the health issue/question being addressed? Will the anticipated findings be of interest and applicability to the identified clinical priority topic area?
- How well will the project enhance the understanding and accelerate the resolution of the health question, problem or issue identified?
- How important and original are the contributions expected from the research proposed? What is the translational potential of the project?

- What is the potential for important new knowledge or impact to improve the health outcomes of MS patients?

## 2. Feasibility and Innovation

- How will the proposed research address the hypotheses or research questions?
- Has the relevant literature been appraised and evaluated in a critical fashion?
- How original are the hypotheses or the questions to be addressed, and how clearly are they formulated? Does the project challenge existing paradigms? Does it use novel concepts, approaches, methodologies, or tools?
- Is the research approach innovative, realistic, and does it contain deliverables derived from an evidence-based approach?
- Is the health question, problem or issue approached through an original, cohesive/integrated and feasible research plan that will generate valid, reliable and useful knowledge?
- Is the research plan cutting-edge and innovative?
- Where applicable to the type of research proposed, does the project take into account the social, cultural and environmental factors surrounding the research problem?
- Is there a plan to link with, and disseminate the research findings to knowledge-/end-user groups who will utilize and apply the results?
- Does the project identify the roles and contributions of all the parties in planning, execution, and evaluation as well as management activities?

## 3. Environment

- Does (do) the applicant(s) have the expertise and track record to complete the proposed project?
- Does the research environment contribute to the probability of success?
- Is the environment poised for uptake, adoption and implementation of research findings? Does the environment contribute to the probability of successful implementation of outcomes?
- Are specific knowledge-/end-user group(s) that have a particular interest in the results of the proposed research identified?

## 4. Translational Potential

- Are the appropriate knowledge-/end-users engaged in the proposed translational research activities? How is that knowledge-/end-user group being engaged and targeted for specific knowledge transfer and exchange activities?
- Are the expected outcomes clearly articulated and the likely next steps identified upon attainment of the projects objectives/goals?
- Does the project demonstrate the involvement of the necessary partners/knowledge-/end-users in the planning and execution of the research plan, and the application of the research results? Will this involvement facilitate research activities and outcomes that would not otherwise be possible?
- Are the appropriate knowledge-/end-users ready and able to adopt and implement research outcomes?

- Is there an appropriate and feasible plan to mobilize translational research results to optimize health impacts for MS patients?

### **Letter of Intent (Phase 1)**

Phase 1 of the review process will provide an initial determination of the eligibility of the applicants for support and will focus on the relevance of the proposed project to the program's objectives and the priority thematic areas outlined above, with an emphasis on clinical priority topic area 1 – Development and Implementation of Evidence-based Care.

Only applicants whose Letters of Intent are selected by the review committee to be of the highest relevance, quality, and merit, based on the assessment criteria outlined above, will be invited to provide a Full Application.

Comments and recommendations from the review committee (Phase 1) will need to be considered by the applicants in the submission of their Full Application.

### **Full Application (Phase 2) and Funding Recommendations**

Full Applications will be reviewed on the basis of the assessment criteria outlined above

Funding recommendations will be made based on a process that recognizes applications of the highest relevance, quality and merit based on the assessment criteria outlined above. There will be an emphasis on supporting at least one application in clinical priority topic area 1 – Development and Implementation of Evidence-based Care.

The recommendation process consists of three steps as outlined below:

#### **Step 1:**

From the submitted applications, the review committee will identify a fundable pool of applications with the highest relevance, quality, and merit based on the assessment criteria, and rank them accordingly.

#### **Step 2:**

If applicable, the highest ranked application in clinical priority topic area 1 - Development and Implementation of Evidence-based Care, within the fundable pool of applications, will be recommended to receive funding support regardless of the overall rank order. Funding recommendations for applications remaining in the fundable pool will then be based on overall rank order. A final funding recommendation list (confirming the scope, schedule and proposed budget for each recommended project) will be provided to the Steering Committee for endorsement.

#### **Step 3:**

Final approval of funding recommendations will be determined by the AIHS CEO.

## TIMELINES

The deadline for submission of Letters of Intent for Phase 1 of the competition is **February 13, 2015**. Full Applications will be requested from successful Phase 1 applicants by **June 30, 2015**.

## APPLICANT'S AGREEMENT

In accepting the award, the awardee agrees to abide by the Terms and Conditions of the Alberta/Novartis Translational Research Fund Opportunity. Awardees must also submit the required progress reports in the prescribed format and frequency (described above) for this funding opportunity. The award will be revoked if the awardee fails to observe the Terms and Conditions of the award.

## Appendix A

**1. Development and Implementation of Evidence-based Care:** Optimization of care pathways and patient outcomes by designing and implementing better patient assessment and care guidelines.

- Interventions to improve medication compliance
- Role of nurse training and core competencies
- Promoting function through exercise and rehabilitation
- Management of fatigue due to secondary causes (e.g. sleep disorders)
- Quantification of disability (e.g. the Expanded Disability Status Scale versus other scales)
- Investigating links between compliance and clinical outcomes, quality of life as well as economic burden
- Measure how interventions influence compliance and ultimately patient outcome
- Translation of evidence to clinical practice

**2. Delivery of Patient Care:** Development of comprehensive integrated services for improved community care and coordination of MS patient services.

- Care at home
- Links between patient and HCP
- Patient navigation
- Assist with travel
- Housing for those at need

**3. Advancement of MS Research and Innovation:** understanding mechanism of disease and/or advancement of technologies for early diagnosis and monitoring of disease progression through:

- Prevention of brain atrophy
- Enhanced neural protection
- Mechanism of disease progression, especially in primary and secondary progression states
- Diagnostic mechanisms correlated with brain injury (e.g. optic neuritis and optical coherence tomography)
- Management of fatigue due to primary causes
- Role of proinflammatory cytokines and T-cells

**4. Patient Engagement:** Support of empowerment and self-management of MS patients.

- Evaluation of effective approaches to group therapy
- Knowledge transfer activities (evidence to practice)