Policy Direction – Commercial Research Funding

Rationale and Relationship to Mission, Principles and Values

Since its inception in 1948, the MS Society of Canada has funded over \$140 million of research in multiple sclerosis (MS). This has resulted in the achievement of a number of significant advancements in understanding of the disease processes associated with MS. Research funded by the MS Society largely focuses on the detailed biological mechanisms of the disease, providing fundamental knowledge of how MS develops, as well as clinical and epidemiological aspects of MS. In addition to 'discovery research', the MS Society supports early stage research for new therapies, including validation of potential drugs in animal models of MS as well as a number of early stage clinical trials.

Discussions, involving people affected by MS, donors, researchers, clinicians, other health charities, business advisors, Board members, staff and volunteers, explored the opportunity of expanding MS Society funding to include specific funding to accelerate the delivery of treatments to people living with MS. This would be achieved by providing funding to important, early stage, translational research conducted by biotechnology and pharmaceutical companies.

This policy formalizes the MS Society's priority to accelerate the pace of research in order to translate research findings into treatments for people with MS, especially those living with progressive MS, through new forms of partnership and collaboration.

The MS Society has many assets that it can contribute to this effort, such as financial resources, access to scientific experts and a reputation for high credibility and neutrality in the MS community.

Policy Objective

The objectives of this policy are to ensure that:

• The MS Society can fund the highest quality research, wherever it resides; in academia or industry; in Canada or globally, to expedite treatments for people affected by MS, especially those living with progressive MS.

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Approved: September 4, 2014

Approved by: Board of Directors of the MS Society of Canada

- Funding for commercial research will add to and enhance the MS Society's existing portfolio of investments in traditional and targeted research in academia.
- Research which can lead to the development of new diagnostic tools and safe and effective therapies is being driven through development to a stage where commercial investment can make treatments available to people living with MS.
- The MS Society can collaborate with other health charities in Canada and elsewhere, as needed, to take advantage of prior experience investing in commercial research.
- The MS Society may collect a return on investment (ROI) from its commercial research investments, which will be used to further support research programs that benefit people affected by MS and especially those with progressive MS.

Policy Application

This policy applies to all MS Society funded researchers, volunteers and staff at all levels of the organization.

Authorizations

The policy was approved by the Board of Directors of the MS Society of Canada on September 4, 2014.

Policy Details

Commercial Research Funding

Any investment in commercial research will continue to be extramural. The MS Society will have no responsibility to lead, manage or direct research that it funds under this policy.

Funding outside of Canada

The MS Society recognizes that commercial research aimed at developing new clinical tools and therapies is taking place in leading institutions around the world. In recognizing this and the global collaborative research landscape, commercial research funded by the MS Society will not be restricted to Canadian companies. The MS Society will aim to fund the highest quality commercial research without regard to geography.

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Collaborations

It is anticipated that, at least initially, the MS Society will form collaborations with other health charities, investor groups and commercial research organizations in order to make investments in commercial research. The MS Society recognizes that other health charities have successfully worked with industry to accelerate the translation of research discoveries to new treatments. The MS Society will aim to leverage resources, experience and knowledge from these collaborations and avoid duplication of existing efforts in commercial research.

Diligence process

Any potential commercial research investment must undergo a highly disciplined scientific and business review process to ensure that standards for scientific merit, feasibility, and translational capacity are met. The review will take place by subcommittee of the Medical Advisory Committee (MAC), which will be selected by the Vice-President, Research with guidance from the MAC chair. The sub-committee will include ad-hoc scientific and business experts who will carefully assess the science and business aspects of the proposed investments and provide a recommendation to the MAC for informational purposes. The sub-committee will also include a member of the MAC and a person affected by MS. The MAC will provide feedback on the recommendation, and a final decision will be made by the National Board of Directors. Should the MS Society co-fund commercial research in collaboration with another organization, as mentioned above, they may choose to rely on the diligence process of the collaborating organization. In this event, selected delegates from the sub-committee, and/or the VP, Research, may serve as observers. Any outcomes from this process will be considered by the sub-committee before they advise the MAC for final recommendation to the National Board.

All commercial research investments will be made using a legal agreement that sets out the obligations of the MS Society and the company, to ensure monitoring of the research, delivery of the goals and key milestones that trigger payments for research achievements. All agreements will be reviewed by the MS Society's legal counsel to properly advise the National Board and mitigate risk.

Compliance with other MS Society policies

In funding commercial research, the MS Society will comply with other policies governing the funding of research.

Policy on stem cell research

Policy on the use of animals in research

Policy on the use of human subjects in research

Policy on indirect costs

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Policy on indemnification

In addition, the MS Society will conduct its' work using high ethical standards and in compliance with all laws and regulations governing funding to companies.

Intellectual Property

The MS Society will ensure that intellectual property generated from its investments in commercial research is appropriately protected to encourage further investment by other investors and potential commercial partners.

Return on investment

The MS Society recognizes that its primary mission is to advance science, accelerate treatments and improve quality of life for people affected by MS. Receiving a financial return on investment is a secondary goal of the Society. The MS Society may collect a reasonable financial return from its investments in commercial research. The funds collected will be used to further advance research programs that will accelerate treatment development and improve quality of life for people affected by MS.

Executive Champion

The Vice-President, Research is the Executive Champion of this policy

Monitoring and Compliance

The Commercial Research Funding policy takes effect immediately upon approval of the National Board of Directors. The Vice-President, Research is responsible for monitoring the application and compliance of this policy.

The Vice-President, Research is responsible for reporting to the President and Chief Executive Officer through quarterly compliance reports regarding compliance with this policy.

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Related Policies, Legislation

MS Society of Canada Research Funding Programs and Awards Policies and Procedures

Prohibition of Payment of Indirect Costs of Health Research Policy Direction

Policy Review

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The policy is to be reviewed at least once every five years following approval: September 2014.

Definitions:

Translational research, for the purposes of this policy, is defined as research that moves laboratory findings or basic science discoveries toward practical application for patients. As this relates to new treatments, translational research is often described as a series of steps that de-risk potential drugs before they enter clinical trials, serving as a bridge between discovery research and commercialization.

Commercial research, for the purposes of this policy, is defined as translational research taking place in companies.

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