Merck/EMD Serono

Grant for Multiple Sclerosis Innovation:
Program Description and Rules

The following rules apply to all proposals received from and grants awarded to academic researchers as part of the Grant for Multiple Sclerosis Innovation (GMSI) programme. The innovation grant rules and procedures may be changed by EMD Serono for projects based in the United States and Canada and by Merck to those based in the rest of the world at any time, without notice, in order to comply with applicable laws, rules, regulations, company policies or industry codes.

If you have any questions regarding any of the innovation grant rules please contact gmsi@merckgroup.com or visit www.grantformultiplesclerosisinnovation.org

I. PROGRAM DESCRIPTION

As part of the company commitment to advance science and medicine, the Grant for Multiple Sclerosis Innovation was launched in 2012. The aim of the innovation grant is to support translational research projects by academic researchers to improve understanding of multiple sclerosis for the ultimate benefit of patients. Potential research topics which could be funded through the Grant for Multiple Sclerosis Innovation include MS pathogenesis, predictive markers for treatment response and potential new treatments.

Merck, EMD Serono and their global pharmaceutical affiliates believe that medical research and dissemination of scientific and educational information are worthy undertakings deserving support. Support for research, however, must be carried out in an appropriate manner. Research grants awarded by the company must be consistent with all applicable laws, rules, regulations, company policies and industry codes and may not be used as a price concession, reward, or inducement to prescribe or purchase our company products.

II. AWARD CRITERIA

The following criteria must be met for all Grant for Multiple Sclerosis awards:

1. The research must take the form of short-term translational research projects by academic researchers with relevance to clinical practice. Some examples of this would include MS pathogenesis, predictive markers for treatment response and potential new treatments.
2. The research must not involve any Merck/EMD Serono products.

3. The research must be of legitimate scientific value to the company or the medical/scientific community at large and must be designed to provide meaningful information or conclusions.
4. The research must be innovative, feasible, have a strong scientific rationale and have the potential for practical utility.
5. The research must not compete with any research and development or clinical projects sponsored by Merck/EMD Serono or any of their global affiliates.
6. No preference will be given to individuals or entities for prescribing or purchasing Merck/EMD Serono products or to induce the prescription or purchase of Merck/EMD Serono products in the future. Grant recipients are not expected or obliged to prescribe or purchase a Merck/EMD Serono product.
7. The amount awarded for the research must not exceed the legitimate costs to be incurred in carrying out the research to be funded by the grant, and must be commensurate with and not exceed fair market value for the research activities.
8. All applicable regulatory requirements must be observed, including, as appropriate, regulatory filings and ethics committee/IRB review and approval.
9. The selected researchers must not be not currently excluded, debarred, suspended or otherwise ineligible to participate in their respective countries of citizenship, residence and/or practice. Any selected U.S.-based researcher must not be currently excluded, debarred, suspended or otherwise ineligible to participate in currently any U.S. Federal health care programs or in Federal procurement or non-procurement programs by the Office of Inspector General or the General Services Administration.
10. The selected researchers must have the appropriate training and expertise to conduct the research, as determined by the Grant for Multiple Sclerosis Innovation assessment committee.
11. Awarding research grants to an individual researcher not affiliated with an institution, as opposed to an institution or organization with a tax identification number, is discouraged but not prohibited, provided all other requirements of the innovation award are followed.

12. In addition to the rules set forth above, all grants must comply with all applicable laws, rules or regulations.

III. AUDIT AND MONITORING

All research activities carried out in connection with a Grant for Multiple Sclerosis Innovation are subject to audit and monitoring by Merck/EMD Serono to help ensure that the research programs comply with law and applicable Merck/EMD Serono policy.

IV. RESEARCHER OBLIGATIONS

Progress Reports

In order to ensure the appropriate progress of innovation award research projects, grant recipients must provide the company with periodic updates on the progress of each project, including updated budget information and substantiation of expenses, before any relevant milestone payments are made.

If a research project is not progressing satisfactorily, appropriate action will be taken, including but not limited to withdrawing any remaining funding and terminating the research project.

Final Report and Publication

Merck/EMD Serono desires to ensure that research undertaken as part of the Grant for Multiple Sclerosis Innovation program is completed and analyzed. All grant recipients must provide the company with final study results in the form of a final report.

Merck/EMD Serono supports the exercise of academic freedom by researchers and expects the results of research to be published, whether or not the results are favorable to Merck/EMD Serono.

V. CERTIFICATION

When a Grant for Multiple Sclerosis Innovation research project is completed or terminated, the researcher and/or institution conducting the research must certify to Merck/EMD Serono that:
(i) the research was conducted in accordance with the terms of the grant agreement, (ii) any unused funds provided by Merck/EMD Serono have been returned to the company, (iii) all safety reporting obligations were met, and (iv) if required, a manuscript or abstract has been submitted for publication, or the research was terminated early and a publication is not appropriate.

VI. RECONCILIATION

At the end of the research project, reconciliation will take place to ensure that funds were used solely for the purpose stated in the Grant for Multiple Sclerosis Innovation application and any unused funds are returned to Merck/EMD Serono.