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What is the GFI?

The Grant for Fertility Innovation (GFI) is an initiative funded by EMD Serono, a business of Merck KGaA, Darmstadt, Germany, to further our understanding in the fertility area, including, but not limited to, gamete function, embryo development and endometrial function related to implantation. Investigators leading innovative research projects, who have the potential to advance science and innovative technologies in the fertility field, are invited to apply. The selection of the GFI awards is based on the goal that research projects should demonstrate innovation and relevance to real-world practice for the benefit of couples seeking fertility assistance. **A total, annual grant of up to €1,000,000 will be shared by a number of selected projects.**

Research proposals with budgets of up to €150,000 will be considered.

Since 2010, Merck KGaA, Darmstadt, Germany, has awarded grants that total up to €12 million to translational research projects in a number of fields. The GFI was launched at the 25th Annual Meeting of the European Society of Human Reproduction and Embryology (ESHRE) in June 2009. The GFI supports the advancement of science and innovative technologies in the fertility field that could potentially improve take home baby rate for the benefits of patients. Over the last eight years, more than 900 grant applications from over 50 countries have been received and reviewed. Grant applications are reviewed by the GFI Scientific Steering Committee.

Scientific Steering Committee

Applications will be evaluated by an external, fully independent Scientific Steering Committee consisting of internationally renowned experts in fertility.

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How to participate in the GFI

Researchers from around the world may apply for a grant if they are involved in innovative clinical and translational research projects associated with drugs, processes and/or technologies applied during treatment with assisted reproductive technology, which could potentially provide an improvement in implantation, pregnancy and live birth rate.

Applicants must be aware that to be eligible to apply they must have completed a clinical or pre-clinical pilot study with positive outcomes in the improvement of implantation, pregnancy and live birth rates.

Clinical trials testing, safety and efficacy of marketed drugs as primary outcomes are not within the scope of the grant.

All research proposals need to be submitted in English.

The application phase for the 2018 GFI is now open

The deadline to submit proposals is December 20th, 2017

Grant sum
A total, annual grant of up to €1,000,000 will be shared by the number of selected projects.
Research proposals with budgets up to €150,000 will be considered

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How to Apply

The Grant for Fertility Innovation (GFI) program is being run again for 2018. The following information outlines the application and selection process for researchers who wish for their projects to be considered.

1. Who is eligible to apply for the GFI?

Researchers from around the world may apply for a grant if they are involved in innovative clinical and translational research projects associated with drugs, processes and/or technologies applied during treatment with assisted reproductive technology, which could potentially provide an improvement in implantation, pregnancy and live birth rate.

Applicants must be aware that to be eligible to apply they must have completed a clinical or pre-clinical pilot study with positive outcomes in the improvement of implantation, pregnancy and live birth rates.

Clinical trials testing, safety and efficacy of marketed drugs as primary outcomes are not within the scope of the grant.

All research proposals need to be submitted in English.

2. How to apply?

Step 1: Check if your proposal is in line with inclusion and exclusion criteria.

Inclusion criteria

We suggest submitting projects investigating on HOW TO REDUCE TIME TO LIVE BIRTH within assisted reproductive technology by:

- Optimising prediction models
- Stratifying treatment approaches
- Using fertility technologies related to objective assessment of gametes, embryos and/or uterine implantation
- Basic research projects with translational potential leading to innovation in areas of high unmet need in infertility such as: biomarkers, methods to monitor the efficiency of treatment during ART cycles, new insights into physiology/physiopathology of human reproduction and infertility

Projects may involve products from EMD Serono or competitors, if used on-label and if the primary aim of this project is not to compare the efficacy and safety of these products.

Projects with prospective sampling are considered if they are part of non-interventional studies* and not part of interventional clinical trials (e.g., biological material collected and discarded during standard clinical practice).†

Exclusion criteria

- Projects involving products from EMD Serono or competitors, if the primary aim is to compare the efficacy and safety of these products
- Projects with prospective sampling if they are part of interventional studies†
- Animal research projects
- Research projects including embryo invasive technologies such as preimplantation genetic diagnosis (PGD) or screening (PGS), are also unsuitable for the GFI.

*A non-interventional study as defined as a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization.

The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice, and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data, and not part of interventional clinical trials (e.g., biological material collected and discarded during standard clinical practice).

†An interventional clinical trial is defined as a clinical study in which participants are assigned to receive one or more interventions so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

Step 2: Applicants should submit their completed Grant Application Form - (download the 2018 Grant Application Form here: Downloads) to gfi@emdserono.com. In response, they will receive an acknowledgment of the completion of their submission.

Applications for the GFI 2018 will be open until December 20th, 2017.

3. The review process

The GFI Scientific Steering Committee (SSC), consisting of embryologists and PhDs in reproductive biology, undertakes a rigorous process of review and assessment of eligible projects, before making a final selection of grant awardees.

The names of the applicants and their institutions are completely blinded and unknown to the members of the SSC to avoid any bias and to keep the scientific merit of the proposals the key criteria for selection.

All proposals are evaluated in two rounds of review and rated from 1–5 (with 5 being the highest) against each of the following criteria:

- Clinical Impact
- Feasibility
- Innovation

- Preliminary data
- Potential to shorten time to live birth

A final score is then calculated and the projects ranked accordingly.

After each round of review, the GFI secretariat will contact applicants individually to inform them of the status of their application. Additional information may be requested.

All projects that are selected for the second round of review will have to submit the formal protocol, a detailed budget proposal, their CV and a signed document, confirming their acceptance of the GFI rules and regulations (Full Grant Terms and Conditions) for advanced (shortlisted) applications.

Data protection information: by submitting the information requested in the Grant Application Form (and, if applicable, your full research proposal), you understand and agree that EMD Serono may share personally identifiable data about you with outside companies or agents working on our behalf, as well as the company's subsidiaries and affiliates, to help process the submissions.

All these companies and agents are required to comply with the terms of our privacy policies. Some of this data may be stored or processed on computers located in other jurisdictions, such as the United States, whose data protection laws may differ from those in the jurisdiction in which you live. In such cases, we will ensure that appropriate protections are in place to require the data processor in that country to maintain protections on the data that are equivalent to those that apply in Germany.

4. How is the awarding of the grant formalized?

The awarding of the Grant is subject to the signature of a Grant Agreement between the investigator's Institution and EMD Serono. This Grant Agreement documents the conditions of the grant and the further collaboration between EMD Serono and the awardee(s).

5. Do awardees have to get involved in publicity surrounding the GFI?

EMD Serono retains the exclusive right to make any press release or any kind of public communication about the GFI project, the grant(s) and the awardee(s).

6. What happens to applications that are not successful?

EMD Serono treats all submissions confidentially and information relating to submissions that are not selected for a grant is destroyed.

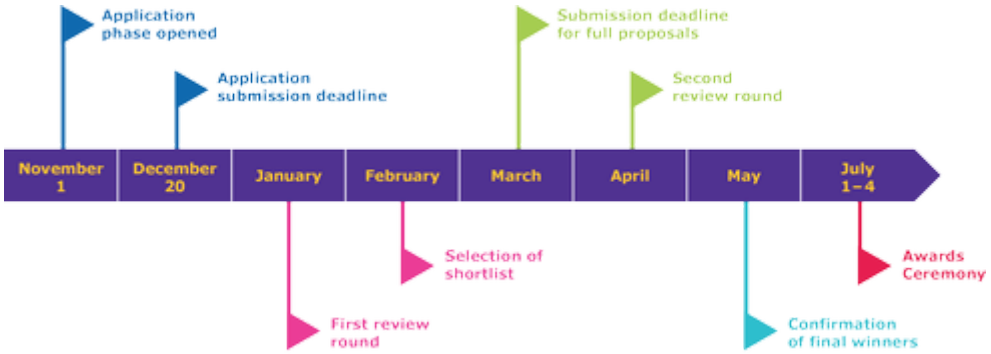
7. What are the timelines?

Applications

- **December 20th, 2017:** deadline for applications; format of application: completed Grant Application Form which includes a short description of the research project; review and shortlisting will be completed by the end of January 2018 and applicants will be informed about the outcome of the first round review in the first week of February 2018

Shortlist

- **Mid-March 2018:** deadline for shortlisted applicants to submit their full proposal, including a formal protocol, a detailed budget proposal, their CV and a signed document (Full Grant Terms & Conditions), confirming their acceptance of the GFI rules and regulations for advanced (shortlisted) applications. Review of submitted applications will be completed by late April 2018 and applicants will be informed about the outcome of this second round review by the end of April 2018



A total, annual grant of up to €1,000,000 is shared by a number of selected projects.

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The review process

The GFI Scientific Steering Committee (SSC) is fully independent and comprises internationally renowned experts in the field. The SSC undertakes a rigorous process of review and assessment of eligible projects before validating its selection of grant awardees.

In the first review round, the names of the applicants and their institutions are completely blinded to the members of the SSC to keep the scientific merit of the proposals the key criteria for selection. All proposals are rated from 1–5 (with 5 being the highest) against each of the following criteria:

- Clinical impact
- Feasibility
- Innovation
- Preliminary data
- Potential to shorten time to live birth

A final score is then calculated and the projects ranked accordingly. After each round of selection, the GFI secretariat will contact unsuccessful and successful applicants individually to inform them of the status of their application and, if necessary, request additional information.

All projects that pass to the second round of review will have to submit the formal project outline, budget and a signed document that confirms their acceptance of the Full Grant Terms & Conditions for advanced applications. Based on this information, the SSC will make their final selection of the grant awardees.

How is the awarding of the GFI formalized?
The applicant's institution will enter into a written Grant Agreement with EMD Serono which documents the conditions of the grant and the further collaboration between EMD Serono and the awardee(s).

What about publicity?
EMD Serono retains the exclusive right to make any press release or any kind of public communication about the GFI, the grant(s) and the awardee(s).

What happens to applications that are not successful?
EMD Serono treats all submissions confidentially and information relating to submissions, which are not selected for a grant, is destroyed.

Data protection information
EMD Serono processes personal information about you in accordance with the 'Privacy and cookies policy' of this website. By submitting the information requested in the Grant Application Form, you consent to such processing. Please review the information provided on how we treat and process your personal data in the 'Privacy and cookie policy'.

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Last Update 06.11.2017

US/NPR/1017/0418

Programme description and rules

The following rules apply to all proposals received from and grants awarded to researchers as part of the Grant for Fertility Innovation (GFI) programme. The grant rules and procedures may be changed by EMD Serono for projects based in the United States and by Merck KGaA, Darmstadt, Germany 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 the grant rules please contact gfi@emdserono.com or visit www2.grantforfertilityinnovation.com.

1. Programme description

As part of EMD Serono's commitment to advance science and medicine, the GFI was launched in 2009. The selection of the GFI awards is based on the goal that research projects should demonstrate innovation and relevance to real-world practice for the benefit of couples seeking fertility assistance. With our long-term commitment to addressing infertility, EMD Serono is dedicated to integrating both drugs and technologies within fertility management strategies, in a patient-centred way, to ultimately reduce the time to live birth. Our focus on innovation, both through our own sponsored research, and that supported by GFI, drives our aim to answer key research questions in fertility, which will help enable clinicians to improve outcomes for couples following assisted reproduction techniques.

EMD Serono and its 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.

2. Award criteria

The following criteria must be met for all GFI awards:

a. The research must take the form of short-term research with relevance to clinical practice. Some examples of this would include biomarkers for treatment response, development of new targeted treatments or technology platforms for the routine analysis of molecular biomarkers

b. 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

c. The research must be innovative, feasible, have a strong scientific rationale, have the potential for practical utility and the potential for personalisation

d. The research must not compete with any research and development or clinical projects sponsored by EMD Serono or any of its global affiliates

e. No preference will be given to individuals or entities for prescribing or purchasing EMD Serono products or to induce the prescription or purchase of EMD Serono products in the future. Grant recipients are not expected or obliged to prescribe or purchase EMD Serono products

f. 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

g. All applicable regulatory requirements must be observed, including, as appropriate, regulatory filings and ethics committee/Institutional Review Board review and approval

h. The selected researchers must not be 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 healthcare programmes or in Federal procurement or non-procurement programmes by the Office of Inspector General or the General Services Administration

i. The selected researchers must have the appropriate training and expertise to conduct the research, as determined by the GFI Scientific Steering Committee

j. Awarding research grants to an individual researcher not affiliated with an institution, as opposed to an institution or organisation with a tax identification number, is discouraged but not prohibited, provided all other requirements of the innovation award are followed

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

l. Partial funding declaration: if partial funding of the project has been obtained, the applicant(s) must declare the source and amount of funding already available
If no other source of funding is available at the time of this application and the applicant is awarded a grant sum, which does not cover the full project costs (as cited in the submitted proposal), then the applicant must provide documentation confirming that the remaining, necessary funds will be obtained from an additional source/sources **before the first milestone payment can be disbursed**
This partial funding declaration is intended to ensure that the applicant(s) has/have all necessary funding to cover the cited budget and will be able to successfully complete the research project

3. Audit and monitoring
All research activities carried out in connection with a GFI are subject to audit and monitoring by EMD Serono to help ensure that the research programmes comply with law and applicable EMD Serono policy. In addition, the name of the grant recipient and amount of the grant will be publicly disclosed to the extent required by law and applicable EMD Serono policy.

4. 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, as outlined in their Grant Agreement. These reports (Interim Reports and the Final Report) much include 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
EMD Serono desires to ensure that research undertaken as part of the GFI programme is

completed and analysed. All grant recipients must provide the company with final study results in the form of a Final Report as well as a Final Certification, as outlined in their Grant Agreement. Publication (manuscripts or abstracts) of the research results in peer-reviewed journals is also to be strived for, as outlined in the Grant Agreement.

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 favourable to EMD Serono.

5. Certification

When a research project is completed or terminated, the researcher and/or institution conducting the research must certify to EMD Serono that: (i) the research was conducted in accordance with the terms of the Grant Agreement; (ii) any unused funds provided by 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.

6. 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 GFI application and any unused funds are returned to Merck.

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Last Update 10.11.2017

US/NPR/1017/0418