



Reducing Cardiovascular Risk Globally Through Improved Dyslipidemia Awareness and Treatment

Request for Proposals (RFP)

The International Atherosclerosis Society (IAS) and Pfizer Independent Grants for Learning & Change (IGLC)

October 2, 2013

I. Background

The International Atherosclerosis Society (IAS) and Pfizer are collaborating to offer a new grant opportunity focused on improving care for patients with medium or high levels of cardiovascular risk, with a particular focus on dyslipidemia.

The IAS is an international federation of 64 national and regional societies whose basic missions are to promote the scientific understanding of the etiology, prevention, and treatment of atherosclerosis. The IAS exists to coordinate the exchange of scientific information among its member societies, to foster research into the development of atherosclerosis and related cardiometabolic diseases, and to help translate this knowledge into improving the effectiveness of programs designed to prevent and treat this disease. As such, the IAS is able to create partnerships worldwide, especially in those areas of the world where the epidemic of atherosclerosis and its related diseases is exploding and thus meet the growing needs in countries in Central and South America, in Eastern Europe, in Africa, in the Gulf Region and in South and South-East Asia.

The mission of Pfizer Independent Grants for Learning & Change (IGLC) is to accelerate the adoption of evidence-based innovations that align the mutual interests of patients, healthcare professionals, and Pfizer, through support of independent professional education activities. The term "independent" means the initiatives funded by Pfizer are the full responsibility of the recipient organization. Pfizer has no influence over any aspect of the initiatives, and only asks for reports about the results and impact of the initiatives which it may share publicly.

This Request for Proposals is being issued by both organizations. The IAS is the lead organization for review and evaluation of applications. A review committee, led by the IAS, will make decisions on which proposals will receive funding. Grant funding will be provided by Pfizer. Collectively, up to \$2 million is available for award.

II. Purpose

The intent of this RFP is to encourage organizations to submit letters of intent (LOIs) describing concepts and ideas for design and implementation of scalable, sustainable programs for healthcare providers and patients designed to improve the management of dyslipidemia and other cardiovascular risk factors.

Only the member societies of the IAS or their partner organizations may submit Letters of Intent to this RFP. Partnering and collaboration is strongly encouraged. Organizations interested in responding to this RFP should reach out to the IAS member society in their country or region of the world and submit a collaborative proposal. Similarly, IAS member societies interested in responding to this RFP should bring into their project appropriate partner organizations such as academic medical centers, hospitals or healthcare systems, and other societies or associations.

III. Specific Area of Interest for this RFP

Comprehensive management of lipids is increasingly recognized as an integral component of CV risk reduction. However, there remains a wide gap that separates treatment recommendations and real-world lipid management. This is especially evident in economically developing countries.

According to the World Health Organization, cardiovascular disease accounted for nearly 1 of every 3 deaths in 2004, and approximately 80% of these deaths occurred in low- and middle-income countries.ⁱ In 2010 the Institute of Medicine issued a report, commissioned by the National Heart, Lung, and Blood Institute, to address the increasing burden of cardiovascular disease in developing countries.ⁱⁱ This report identified numerous barriers to the control of global cardiovascular disease, as well as specific recommendations to increase investment and implementation of cardiovascular disease prevention and management efforts in low- and middle-income countries. Crucial to these efforts are an increased awareness of chronic diseases as a public health priority and coordination among global, national, and regional stakeholders to strengthen healthcare systems.

Risk factors for cardiovascular disease, including dyslipidemia, smoking, physical inactivity, and poor diet, also predispose to other chronic diseases. Abnormal lipids have been identified as the strongest risk factor for coronary heart disease in all geographical regions of the world.ⁱⁱⁱ Meta-analyses indicate that intensive treatment of dyslipidemia, particularly with statins, is associated with better clinical outcomes.^{iv} Yet control of dyslipidemia remains suboptimal globally, with evidence of a persistent gap between treatment guidelines and clinical practice. For example, data from the recent EUROASPIRE III survey showed that among patients with coronary heart disease in Europe, half had cholesterol levels that were above target.^v Among asymptomatic high-risk patients, two-thirds had elevated cholesterol levels.^{vi}

In the past decade, there have been important developments in the field of lipid management. Technological advances in imaging have led to improvements in the detection and evaluation of atherosclerosis. New clinical outcomes studies have yielded additional insights on the efficacy and safety of various approved and experimental lipid-modifying agents. Basic science investigations have further elucidated the roles of inflammation and genetics in the development of atherosclerotic vascular disease.

On October 1, 2012, Pfizer convened a select group of cardiologists, lipidologists, internists and educationists, to solicit input on the following: (1) the current care gaps in lipid and CV risk management; (2) the educational needs that must be addressed to reduce these gaps; (3) the key principles and tools that motivate continuous learning among clinicians; and (4) elements that constitute a proposal for an innovative CV risk reduction education program for developing countries. Philip Barter, MBBS, Ph.D., FRACP, current President of the IAS was one of the participants. Discussions raised the following key points:

- The majority of Continuing Medical Education (CME) activities around the world are conducted in suboptimal settings, resulting in participants losing interest in the activity or dropping out altogether
- Traditional CME does not translate to changes in clinician behavior because it is not directed at patient health
- Evidence-based empiric strategies are effective only in individuals who are ready for change; strategies based on coercion are most likely to cause clinicians to resist change
- The different facets of human behavior underscore the need for different learning/teaching methodologies
- The gaps in patient health status, clinical performance and clinician competency are interdependent, underscoring the need for an educational intervention
- Clinicians, policy makers and other stakeholders must recognize the importance of lifetime management of atherosclerosis, requiring early prevention of broadly defined risk factors
- The efforts and resources put into preventive care should be considered an “investment” in arterial health
- CV risk assessment based on the lifetime risk of CVD has been found to be more pragmatic and easier for patients to understand; outcome metrics for CVD should include (1) heart age (vs. chronological age) and (2) the predicted age of onset of first CV event
- Patient communication skills are critical, and should be considered as a clinical competence
- The two key elements that may constitute a strategy for an innovative CV risk reduction education program are: (1) assessment of both needs and outcomes, to ensure the effectiveness of change strategies; and (2) localization of strategies to ensure that they reach a larger pool of practitioners at the local level
- Bringing continuing education into the healthcare system loop is key to maintaining a competent medical workforce aimed at improving patient care and population health
- Change strategies need to take into account the culture and diversity of a population in order to produce a culturally sensitive and relevant curriculum
- Government support is essential to facilitate implementation of educational interventions
- Local pilot studies can provide valuable insights and the evidence base needed by the government to review its healthcare delivery system and policies
- CME initiatives should strive to bridge the gap between ideal and current practice

IV. Practice gaps and barriers to closing them

The growing awareness worldwide of the importance of dyslipidemia as a cause of premature cardiovascular disease has led to many countries adopting evidence-based guidelines for managing dyslipidemia. In some countries, these guidelines have been developed by local experts and are designed to address local needs. Most countries, however, have not developed their own guidelines and tend to adopt those developed in regions such as North America and Europe, a practice that does not address local needs.

But even more disturbing is the fact that, regardless of whether a country has its own guidelines or adopts those from another region, real world management remains far from what is recommended in the guidelines in terms of best practice for both lifestyle and drug interventions. Poor adherence to lifestyle recommendations is a major factor in the escalating worldwide epidemic of obesity, while inadequate adherence to proven lipid lowering drug therapy leaves many people at an unacceptably high risk of having a cardiovascular event.

There are many reasons for this poor adherence to recommended guidelines. In some countries, the healthcare system is a barrier to implementing clinical guidelines. In other countries there is a problem with cost of drugs such that poor people cannot afford the recommended treatment. In many countries, policy makers are simply not aware of the evidence that reducing LDL and non-HDL cholesterol reduces CV risk and prolongs life.

And a final problem relates to the fact that many health care providers find guidelines to be too complex and too difficult to understand and implement.

With the aim of addressing these issues, the IAS recently reviewed its recommendations on treatment of high level of blood cholesterol and dyslipidemia for the purpose of reducing risk for atherosclerotic cardiovascular disease. The Writing Panel, made of 15 internationally renowned experts and chaired by Dr. Scott M. Grundy, reviewed existing evidence-based recommendations and consolidated them into a Position Paper on the Management of Dyslipidemia. The purpose of the Position Paper is not to replace national guidelines but rather to amplify existing ones, to offer an international framework for future guideline development, and to provide a simplified approach to the management of dyslipidemia. The full report can be found at the following link:

<http://www.athero.org/IASPositionPaper.asp>

V. Letters of Intent/Proposals

This RFP model employs a 2-stage process: Stage 1 is the submission of the LOI. If your LOI is selected, you will be invited to submit a full program proposal. Stage 2 is the submission of the Full Grant Proposal.

Successful proposals will include a detailed plan to generate quantitative evidence that the educational intervention has had an effect on physician behavior that is likely to be long-lasting and that this change in behavior is associated with changes in clinical outcomes.

Programs must describe how the intervention, when implemented, will directly affect patient care and provide evidence of scalability (e.g., integration with an electronic medical record system) and sustainability (e.g., plan for dissemination/applicability beyond the proposed institution).

Successful applicants will be able to describe the specific clinical practice gaps that exist for their own providers, healthcare system, or patient community and describe what they will do to close these gaps or problems. Site-specific obstacles to success should be identified and coupled with strategies to overcome the obstacles.

Examples of potential approaches include

- Identification and implementation of strategies to raise awareness of dyslipidemia as a primary risk factor among HCPs
- Implementation of strategies to raise awareness among patients of dyslipidemia's link to the prevention of heart attack and stroke
- Incorporation of multiple ways to communicate with patients
- Combining educational and clinical approaches to achieve the specific goal

- Adaptation of a specific intervention to different geographic populations, clinician specialties, and practice settings
- Collaborations that bring special expertise to the project, such as research clinics, information technology, and clinical communications
- Incorporation of treatment guidelines into standard practice forms and checklists
- Provision of decision support mechanisms at the point of care.
- Plan for maintenance and expansion of strategies and program elements demonstrated to be effective in raising awareness and increasing appropriate assessment and management of dyslipidemia
- Development of innovative approaches to measure outcomes
- Setting up an evaluation for a population-based intervention monitoring
- Use of a control group or comparison group
- Development of a self-sustaining program

Pfizer and the IAS are particularly vested in supporting programs that develop and implement interventions that are followed by rigorous assessment of the efficacy of the program, examining outcomes that may include short- and long-term improvements in physician effectiveness and patient care. Partnering and collaboration with other organizations is encouraged.

Proposed interventions should aim to effect meaningful change in clinical outcomes, such as an increase in provider and patient knowledge of dyslipidemia and an increase in appropriate management of cardiovascular risk factors. Applicants should estimate the amount of change in these clinical outcomes that they are expecting to see as a result of their proposed intervention.

Proposals should address one or more of the following:

- 1) At the individual clinician level: the clinical gap in knowledge or competence or actual performance in practice
- 2) At the systems level: the individual physician or healthcare professional has the knowledge and required abilities but the system does not permit efficient use of such knowledge or its translation into practice
- 3) At the patient level: the role of the patient themselves in understanding their risk factors and adhering to treatment regimens or lifestyle changes

VI: Potential outcomes and metrics

Milestones, metrics and/or outcomes are expected.

VII. RFP key information

Total awards	Up to \$2.0M is available to fund grants for this RFP. Grant requests should range from \$50K to \$500K, depending on the size and scope of the project. Individual projects can be funded for up to a maximum of 24-months' duration.
Specific area of interest	Reducing Cardiovascular Risk Globally
Target settings	The focus of the program should be generating meaningful change in primary care providers such as general practitioners and internists.

	Cardiologists and selected other specialties may also be targeted for learning and change strategies.
Geographic scope	The scope of this RFP is limited to countries in Central and South America, in Eastern Europe, in Africa, in the Gulf Region and in South and South-East Asia. Please note, North America and Western Europe are NOT part of target geography for this RFP
Recommended format	Educational research protocol, with Institutional Review Board (IRB) approval if necessary. This RFP is NOT seeking basic or clinical research proposals. Interventions should be educational, or systems-based in nature.
Eligible applicants	IAS member societies are the primary focus of the RFP. They may respond alone or in conjunction with other organizations and institutions. IAS Federations (for the Americas, Europe, and the Asia-Pacific region) are also encouraged to become involved. Collaboration with other organizations with similar goals is strongly encouraged.
Selection criteria	Applicant organizations will be evaluated on the basis of <ul style="list-style-type: none"> • Knowledge of and experience with the area • Capability of carrying out the work • Collaboration if appropriate • Potential effect and expected outcomes of the project • Dissemination strategies
Key dates/deadlines	October 2, 2013 —RFP released October 31, 2013 —Letters of Intent due Week of December 2, 2013 —Applicants notified via email; invited to submit full proposal January 30, 2013 —Full proposals due date Week of March 31, 2014 —Notification of decisions April 2014 —Funded projects start

VIII. How to Submit:

Please go to the website at www.pfizer.com/independentgrants and click on the button “Go to the Grant System”.

If this is your first time visiting this site in 2013 you will be prompted to take the *Eligibility Quiz* to determine the type of support you are seeking. Please ensure you identify yourself as a first-time user.

Select the following Area of Interest: Reducing Cardiovascular Risk Globally

Complete all required sections of the online application and upload the completed LOI template.

The LOI is a brief concept document that describes the proposed project at a high level. The Proposal Review Committee will select letters of intent that are best aligned with the purpose of the RFP. All applicants will be notified with either an acceptance or a declination. Successful applicants will be asked to submit a full grant proposal for funding consideration.

IX. Letter of Intent Submission Guidance

Submission requirements

1. The letter of intent should be no more than three (3) pages, single spaced, using Calibri 12-point font and 1-inch margins. It should contain the following information about the proposed project:
 - a. Project title
 - b. Organization(s) involved
 - c. Principal investigator
 - d. High-level project description, including
 - i. Primary goal(s)
 - ii. Description of how the proposal builds on existing work, projects, or programs
 - iii. Anticipated challenges and solutions
 - iv. Expected outcome and how the impact of the project will be evaluated
 - e. Deliverables and dissemination strategies
2. A letter of intent longer than three pages will be **RETURNED UNREVIEWED**
3. Submit the letter of intent online via the Pfizer IGLC website
 - a. Please go to the website at www.pfizer.com/independentgrants and click on the button "Go to the Grant System."
 - b. If this is your first time visiting this site in 2013 you will be prompted to take the *Eligibility Quiz* to determine the type of support you are seeking. Please ensure you identify yourself as a first-time user.
 - c. Submit your letter of intent in the Cardiovascular Risk clinical area.
4. Complete all required sections of the online application and upload the completed letter of intent template

X. Full proposals

A limited number of applicants will be invited to submit for consideration a full proposal of no more than 10 pages, accompanied by a line-item budget. The full proposal format will be shared with the invitation to submit.

XI. Questions

If you have questions regarding this RFP, please direct them in writing to the Grant Officer for this clinical area, Jacqueline Waldrop at Jacqueline.waldrop@pfizer.com with the subject line, "IAS RFP."

XII. Terms and conditions

1. Complete **TERMS AND CONDITIONS** for Certified and/or Independent Professional Healthcare Educational Activities are available on submission of a grant application on the IGLC website at www.pfizer.com/independentgrants.
2. This RFP does not commit Pfizer or the IAS to award a grant or to pay any costs incurred in the preparation of a response to this request.
3. Pfizer reserves the right to accept or reject any or all applications received as a result of this request or to cancel in part or in its entirety this RFP, if it is in the best interest of Pfizer to do so.

4. Pfizer reserves the right to announce the details of successful grant application(s) by whatever means ensures transparency, such as on the Pfizer website, in presentations, and/or in other public media.
5. For compliance reasons and in fairness to all applicants, all communications about this RFP must come exclusively from the Pfizer IGLC or the IAS. Failure to comply will automatically disqualify applicants.
6. All output (e.g., products, research, data, software, tools, processes, papers, and other documents) from funded projects will reside in the public domain.
7. U.S. Foreign Corrupt Practices Act: Provider (sponsor) acknowledges that it has not and will not directly or indirectly offer or pay, or authorize such offer or payment, of any money or anything of value to improperly or corruptly seek to influence any government official. Note: Additional documentation requirements could be required of an applicant prior to an approval of a grant.
8. Sunshine Act: To comply with the Federal Physician Payments Sunshine Act, Provider (sponsor) must provide names and other required information of the US-licensed physicians and US teaching hospitals (Covered Recipients, as defined by Centers for Medicare and Medicaid Services) to whom the Provider (sponsor) furnished payments or other transfers of value stemming from the original independent grant awarded by Pfizer. This includes compensation, reimbursement for expenses, and meals provided to faculty (planners, speakers, investigators, project leads, etc.) and “items of value” (items that possess a value on the open market, such as textbooks) provided to faculty and participants, if such faculty and/or participants meet the definition of „Covered Recipient“. Such required information is to be submitted during the reconciliation process or earlier upon Pfizer’s request in order to meet certain Sunshine Act reporting commitments. The parties agree that, pursuant to this Agreement, Pfizer will not make any payments directly to any physician, and all payments shall be directed to Institution. The parties further agree that all payments made pursuant to this Agreement will be considered research payments under the Federal Physician Payments Sunshine Act.
9. Food and Beverage Clause: No portion of a Pfizer independent grant will be used for food and/or beverage for learners and/or participants in any capacity. Provider (sponsor) will be required to certify during final grant reconciliation that the funds were not used for food and/or beverage for learners and/or participants.

XIII. Transparency

Consistent with our commitment to openness and transparency, Pfizer publicly reports its medical educational grants and support for medical and patient organizations in the United States. A list of all letters of intent selected to move forward may be publicly disclosed, and whatever emanates from this RFP is in the public domain. In addition, all approved full proposals, as well as all resulting materials (e.g., status updates, outcomes reports, etc.) may be posted on the website. Grantees will be required to submit periodic quarterly reports and/or updates.

Issued RFPs are posted on the Pfizer IGLC website at www.pfizer.com/independentgrants and are emailed to all registered organizations and users in our grants system.

XIV. References

ⁱ World Health Organization (WHO). Cardiovascular Diseases (CVDs). Fact Sheet No. 317. Geneva, Switzerland: WHO; 2011. <http://www.who.int/mediacentre/factsheets/fs317/en/print.html>. Accessed May 16, 2012.

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- ⁱⁱ Institute of Medicine (IOM). Fuster V, Kelly BB eds. *Promoting Cardiovascular Health in the Developing World: A Critical Challenge to Achieve Global Health*. Washington, DC: National Academies Press; 2010. http://www.nap.edu/catalog.php?record_id=12815. Accessed May 16, 2012.
- ⁱⁱⁱ Yusuf S, et al. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study. *Lancet* 2004;364:937-53.
- ^{iv} Cholesterol Treatment Trialists' (CTT) Collaboration. Efficacy and safety of more intensive lowering of LDL cholesterol: a meta-analysis of data from 170,000 participants in 26 randomised trials. *Lancet*. 2010;376(9753):1670-1681.
- ^v Kotseva K, et al, for the EUROASPIRE Study Group. Cardiovascular prevention guidelines in daily practice: a comparison of EUROASPIRE I, II, and III surveys in eight European countries. *Lancet* 2009;373:929-40.
- ^{vi} Kotseva K, et al. EUROASPIRE III. Management of cardiovascular risk factors in asymptomatic high-risk patients in general practice: cross-sectional survey in 12 European countries. *Eur J Cardiovasc Prev Rehabil* 2010;17(5):530-40.