New Advances in Lipid Management
Request for Proposals (RFP)

The International Atherosclerosis Society and
Pfizer Independent Grants for Learning & Change

Release Date: August 24, 2015

I. Background

The International Atherosclerosis Society (IAS) and Pfizer are collaborating to offer a new grant opportunity focused on improving the care for patients who are at high risk of cardiovascular events due to elevated cholesterol levels.

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.

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 RFP 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 ultimately receive funding. Grant funding will be provided by Pfizer. Collectively, $2 million is available for award.

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 educational programs for healthcare providers and patients designed to improve the understanding of latest scientific advances and the use of monoclonal antibodies on new targets in the reduction of hyperlipidemia.

This RFP model employs a 2-stage process: Stage 1 is the submission of a LOI for review and consideration by the IAS Review Panel. A limited number of applicants will be invited to submit a 10-page Full Proposal accompanied by a line-item budget. The full proposal format will be shared with the invitation to submit. Stage 2 is the submission of the Full Proposal followed by final competitive review and grant decision-making by the IAS Review Panel.

II. RFP Clinical Areas of Interest

Significant progress has been made in the management of hypercholesterolemia and CV risk over the past several decades. CV outcome statin studies have demonstrated significant CV event reduction among patients at high CV risk and, as a result, have influenced present day clinical decision making and guideline development for CV risk management. Despite receiving the current standard of care, however, a number of patient populations remain at high risk for CV events. High risk patient populations may include both secondary prevention patients (i.e. previous heart attack or stroke), high risk primary prevention patients (i.e. patients with diabetes or CKD), patients who are intolerant to statin use, those with a genetic predisposition to dyslipidemia, those with severe mixed dyslipidemia, or other patients who may be treated with a statin and still have high LDL cholesterol levels. Both healthcare professionals and patients should understand the increased CV risk associated with hypercholesterolemia and be aware of new emerging therapeutic options.

Genetic predisposition to dyslipidemia or familial hypercholesterolemia (FH) is generally caused by a defect on chromosome 19. The defect makes the body unable to remove LDL cholesterol from the blood. A Consensus Statement on FH, published by the European Atherosclerosis Society in August 2013 concluded, "Owing to severe under-diagnosis and under-treatment of FH, there is an urgent worldwide need for diagnostic screening together with early and aggressive treatment of this extremely high-risk condition."[1] However, many healthcare professionals do not currently receive adequate instruction on FH during their medical, nursing, or pharmacy training.[2]

Phase 3 clinical programs have identified robust reduction of low density lipoprotein (LDL) cholesterol with PCSK9 inhibition, but questions remain on the long-term efficacy and safety of these agents. Ongoing CV outcome trials evaluating the impact of PCSK9 inhibition on CV events in distinct populations within the CV risk continuum will expand understanding of the role of lipid modulation in CV risk reduction. Healthcare professionals need to be familiar with the design of these studies to understand the potential impact and relevance of monoclonal antibodies and the PCSK9 inhibitor class.

As a fast growing class of therapeutic agents, the development of monoclonal antibodies has the potential to become a major advance in medicine. The structure and natural function of antibodies has provided a versatile platform for developing targeted therapies across many clinical areas, including cardiovascular medicine.[3] Several monoclonal antibodies are undergoing clinical development for hyperlipidemia to inhibit PCSK9-mediated down-regulation of the LDL receptor to improve LDL cholesterol clearance from serum.[4] Healthcare professionals need continuing education in order to understand the rationale for modifying antibodies for desired properties and how engineering monoclonal antibody therapy for PCSK9 inhibition can lower LDL cholesterol.

III. Types of Proposals to Be Considered

RFP seeks to fund programs that incorporate new advances in the scientific understanding of monoclonal antibodies for PCSK9 inhibition and other novel targets in lipid management. Three broad categories of project proposals are envisioned as follows:

Category 1 – Educational programs or resources for healthcare professionals

Category 2 – Clinical practice tools such as risk calculators or treatment algorithms

Category 3 – Educational materials, resources or advocacy programs for patients

Applicant organizations may choose to submit single or multiple LOIs for projects that are aligned with one or more of the above categories. Proposals may include combined projects that incorporate educational as well as clinical approaches. Partnering, coordination, and collaboration between organizations are strongly encouraged. Also welcomed are intra-organizational collaborations that bring special expertise to the project, such as research clinics, information technology, and clinical communications departments.

The following list of potential project examples is not intended to be all-inclusive. These are examples only and applicants are encouraged to submit all innovative ideas and approaches.

- new or updated sections in cardiology curricula for medical, pharmacy, or nursing students
- new or updated lipid management modules in a board review course in internal medicine
- incorporation of latest lipid-treatment guidelines into standard practice forms and checklists
- online course on managing lipids in high-risk patients with a point-of-care decision-support tool
- handbook or e-book on novel targets and the potential use of monoclonal antibodies in cardiovascular disease prevention
- live sessions at a conference series covering the different types of monoclonal anti-bodies – humanized, fully-humanized etc. and their potential use in cardiovascular risk reduction
- electronic tool or app for physicians to calculate 10-year risk for patients with FH, patients on statin therapy with residual risk, or other high-risk patients
- tool to define the high-risk patient in need of lipid lowering who may be appropriate for a PCSK9 inhibitor, considering affordability and cost-effectiveness
- patient assessment tool to identify genetically high-risk patients in the primary care or general practice setting
- printed materials or handouts for high risk patients with elevated LDL cholesterol or difficult to treat hyperlipidemia
- communication or shared-decision making tool for healthcare professionals to use with their patients to help improve adherence
- registry-based initiatives aimed at improving LDL management in high-risk patients

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. Potential obstacles to success should be identified and coupled with strategies to overcome the obstacles.

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

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). Consideration should be given regarding potential adaptation of a specific intervention to different geographic populations, clinician specialties, or practice settings.

Proposals should describe how a proposed project will be kept up-to-date with new information in this rapidly advancing area of medicine. For example, online course modules might be able to be routinely assessed and updated as part of the ongoing project implementation plan. Or a proposal for a practice-tool or treatment algorithm might include a plan for being kept up-to-date as the science advances and new therapeutic options become available.

Any tools or educational resources that are generated as a result of a grant-funded initiative must be made available in the public domain, free-of-charge for others to use or replicate.

IV. RFP key information

Total awards:	A total of $2.0M is available to fund grants for this RFP. Individual grant requests are expected to range from approximately $25K to $250K, depending on the size and scope of the projects.
Specific area of interest:	New Advances in Lipid Management
Target learners:	Healthcare professionals and patients
Geographic scope:	The geographic priority and primary focus of this RFP is North America and Europe, although LOI submissions will be considered from organizations in all countries.
Eligible applicants:	Organizations eligible to apply include but are not limited to member-driven professional societies or associations, academic medical centers, hospitals or healthcare systems. IAS member societies and their partner organizations are also encouraged to apply, however eligibility is not limited to only the member societies of the IAS.
Selection criteria:	Submissions will be evaluated on the basis of: • Alignment to RFP described area of interest • Applicant knowledge of and experience with the area • Capability of carrying out the work • Collaboration if appropriate • Potential impact and expected outcomes of the project • Dissemination strategies
Key dates/deadlines:	• August 24, 2015—RFP released • **October 6, 2015** 5pm U.S. Eastern time—Letters of Intent due • On or around December 1, 2015—LOI applicants notified via email; invited to submit full proposal • **February 4, 2016** 5pm U.S. Eastern time—Full Proposals due • On or around April 13, 2016—Notification of funding decisions via email • Grants distributed following execution of fully signed Letter of Agreement • On or after May 1, 2016—Funded projects start • Individual projects can be funded for up to a maximum of 24-months' duration.

How to Submit:	Please go to the website at www.pfizer.com/independentgrants and click on the button "Go to the Grant System". Registered users should select the LOI link under Track 1 – Learning & Change. If this is your first time visiting this site 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: New Advances in Lipid Management Requirements for submission: Complete all required sections of the online application and upload the LOI (see LOI Guidance below.) If you encounter any technical difficulties with the website, please click the "Need Support?" link at the bottom of the page
Questions:	If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Jacqueline Waldrop at (Jacqueline.Waldrop@pfizer.com), with the subject line "New Advances in Lipid Management RFP."

V. LOI Guidance

LOIs should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 3-page limit in the main section of the LOI. LOIs should include the following sections.

Main Section (not to exceed 3 pages):

A. Project Title.
B. Goal. Briefly state the overall goal of the project. Also describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s).
C. Objectives List the *overall* objectives you plan to meet with your project both in terms of learning and expected outcomes.
D. Assessment of Need for the Project. Please include a quantitative baseline data summary, initial metrics, or a project starting point (please cite data on gap analyses or relevant patient-level data that informs the stated objectives) in *your* target area.
E. Describe the primary audience(s) targeted for this project. Also indicate whom you believe will directly benefit from the project outcomes. Describe the overall population size as well as the size of your target population.
F. Project Design and Methods. Describe the planned project and the way it addresses the established need. If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.
G. Innovation. Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed. Describe how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.

H. Design of Outcomes Evaluation. In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Identify the sources of data you anticipate using to make the determination. Describe how you expect to collect and analyze the data. Describe how you will determine if the target audience was fully engaged in the project. Describe how the project outcomes might be broadly disseminated.
I. Anticipated Project Timeline
J. Requested Grant Amount. A total amount requested is the only information needed for the LOI stage. A full detailed budget is not required. The amount requested can be adjusted at the Full Proposal stage as needed. The budget amount requested must be in U.S. dollars (USD). While estimating your total budget please keep the following items in mind:
    1. Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel. The maximum allowed overhead rate is 28%.
    2. Grants awarded cannot be used to purchase therapeutic agents (prescription or non-prescription).
    3. Funding may not be used for capital equipment.
K. Additional Information. If there is any additional information you feel the IAS Review Panel should be aware of concerning the importance of this project, please summarize it in within the page limitations.

Organizational Detail (not to exceed 1 page)

Describe the attributes of the institutions/organizations/associations that will facilitate and support the execution of the project and the individual leadership of the proposed project. Articulate the specific role of each partner in the proposed project.

Letters of support from partner organizations will be required at the Full Proposal stage only and should not be included with the LOI.

Any project partners listed in this section should also be listed within the online grant system. Tax-IDs of partner organizations will be requested when entering this information.

LOIs should be single-spaced using Calibri 12-point font and 1-inch margins. There is a 3-page limit for the main section and a 1-page limit for organizational detail. If extensive, references may be included on 1 additional page. Final LOI submissions should not exceed 5 pages in total (3 pages for the main section, 1 page for organizational detail, and 1 page for references).

All required sections should be combined in one document (MS Word or Adobe PDF). There is no need to submit the organization detail or references in a document separate from the main section of the LOI.

VI. Pfizer RFP Terms and Conditions

1. This RFP does not commit Pfizer or its partners to award a grant or a grant of any particular size if one is awarded, nor to pay any costs incurred in the preparation of a response to this request.

2. Pfizer reserves the right to accept or reject any or all applications received as a result of this request, or to cancel this RFP in part or in its entirety, if it determines it is in the best interest of Pfizer to do so.

3. For compliance reasons and in fairness to all applicants, all communications about the RFP must come exclusively to Pfizer IGLC. Applicants should not contact other departments within Pfizer regarding this RFP. Failure to comply will disqualify applicants.

4. Consistent with its commitment to openness and transparency, Pfizer reports education grants provided to medical, scientific, and patient organizations in the United States. Pfizer reserves the right to announce the details of successful grant application(s) by whatever means insures transparency, such as on the Pfizer website, in presentations, and/or in other public media. In the case of this RFP, a list of all LOIs selected to move forward may be publicly disclosed. In addition, all approved full proposals, as well as all resulting materials (e.g., status updates, outcomes reports, etc.) may be posted on the IGL&C website and/or any other Pfizer document or site.

5. Pfizer reserves the right to share with organizations that may be interested in contacting you for further information (e.g., possible collaborations) the title of your proposed project and the name, address, telephone number, and e-mail address of the applicant from the requesting organization.

6. To comply with 42 U.S.C. § 1320a-7h and 42 C.F.R. §§ 403.900-.914 (the Sunshine Act), Provider (sponsor) must provide to Pfizer specific information for the U.S.-licensed physicians and U.S. teaching hospitals ("Covered Recipients," as defined by applicable law) to whom the Provider (sponsor) furnished payments or other transfers of value from the original independent grant awarded by Pfizer. Those payments or transfers-of-value include compensation, reimbursement for expenses, and meals provided to faculty (planners, speakers, investigators, project leads, etc.) and "items of value" (items that possess a discernible value on the open market, such as textbooks) provided to faculty and participants, if those faculty and/or participants meet the definition of Covered Recipient. Provider (sponsor) must submit the required information during the reconciliation process or earlier, upon Pfizer's request, so Pfizer can meet Sunshine Act reporting commitments. Be advised Pfizer will not make any payments to any individuals; grant funding shall be paid directly to Provider (sponsor).

   Frequently Asked Questions related to IGLC's Sunshine Act Reporting Requirements are available on our website (http://www.pfizer.com/files/IGLC_SunshineFAQ_Oct2014.pdf).

7. No portion of a Pfizer independent grant may be used for food and/or beverages for learners and/or participants in any capacity. Provider (sponsor) will be required to certify during the reconciliation process and/or the periodic collection of Sunshine reporting that funds were not used for food and/or beverages for learners and/or participants.

8. In the performance of all activities related to an independent grant, the Provider (sponsor) and all participants must comply with all applicable Global Trade Control Laws. "Global Trade Control Laws" include, but are not limited to, U.S. Export Administration Regulations; the International Traffic in Arms Regulations; EU export controls on dual-use goods and technology; Financial Sanctions Laws and Restrictive Measures imposed within the framework of the CFSP -

Treaty on European Union; and the economic sanctions rules and regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control.

9. For all research projects the institution(s) must agree to assume all responsibilities as sponsor of the study as outlined in the proposal, which includes obtaining institutional review board (IRB)/independent ethics committee (IEC) approval for studies involving human subjects or human tissue and obtaining a subsequent renewal of this approval as required by local regulations (e.g., yearly, biannually, etc.). In addition, the institution(s) must be responsible for obtaining any IRB/IEC approval for amendments to protocol as they pertain to the research; obtaining all required personal data privacy or informed consent documentation (as appropriate); obtaining all required regulatory approval(s) per local regulations; assuming all reporting obligations to local regulatory authorities; providing a statement that the research will be conducted in compliance with relevant provisions of the International Conference on Harmonisation to the extent they are consistent with FDA GCPs, Good Clinical Practice as adopted by the Food and Drug Administration ("FDA"), or Good Pharmacoepidemiology Practice guidelines and all applicable local legal and regulatory requirements.

References

1. Nordestgaard BG et.al. Familial hypercholesterolaemia is underdiagnosed and undertreated in the general population: guidance for clinicians to prevent coronary heart disease. *European Heart Journal* doi:10.1093/eurheartj/eht273EAS
2. Withycombe, B et.al. The extent of familial hypercholesterolemia instruction in US schools and colleges of medicine, pharmacy, and osteopathic medicine. *Journal of Clinical Lipidology.* 2015 in-press (accessed online May 29, 2015)
3. Foltz IN, Karow M, Wasserman SM. Evolution and Emergence of Therapeutic Monoclonal Antibodies. *Circulation*. 2013;127:2222-30.
4. Dadu RT, Ballantyne CM. Lipid lowering with PCSK9 inhibitors. *Nat Rev Cardiol.* 2014;11(10):563-75.