

Pfizer Independent Grants for Learning & Change Request for Proposals (RFP)

Implementation of MenB Vaccine Recommendations in Older Adolescents/Young Adults

I. Background

The mission of Pfizer Independent Grants for Learning & Change (IGLC) is to partner with the global healthcare community to improve patient outcomes in areas of mutual interest through support of measurable learning and change strategies. “Independent” means that the projects funded by Pfizer are the full responsibility of the recipient organization. Pfizer has no influence over any aspect of the projects and only asks for reports about the results and the impact of the projects in order to share them publicly.

The intent of this document is to encourage organizations with a focus in healthcare professional education and/or quality improvement to submit a letters of intent (LOI) in response to a Request for Proposal (RFP) that is related to education in a specific disease state, therapeutic area, or broader area of educational need. The RFP model is a two-stage process. Stage 1 is the submission of the LOI. After review of the LOI, you may be invited to submit your Full Grant Proposal. Stage 2 is the submission of the Full Grant Proposal.

When a RFP is issued, it is posted on the Pfizer IGLC website (www.pfizer.com/independentgrants) in the Request for Proposals section and is sent via e-mail to all registered users in our grants system. Some RFPs may also be posted on the websites of other relevant organizations, as deemed appropriate.

II. Eligibility

Geographic Scope:	<input checked="" type="checkbox"/> United States Only <input type="checkbox"/> International(specify country/countries)_____
Applicant Eligibility Criteria:	<p>The following may apply: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations; government agencies; and other entities with a mission related to healthcare improvement.</p> <p>More information on organizations eligible to apply directly for a grant can be found at http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf.</p> <p>Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions/organizations/associations, are encouraged. Please note all partners must have a relevant role and the requesting organization must have a key role in the project.</p> <p>For programs offering credit, the requesting organization must be the accredited provider.</p>

III. Requirements

Date RFP Issued:	February 18 th , 2016
Clinical Area:	Implementation of MenB Vaccine Recommendations in Older Adolescents/Young Adults
Specific Area of Interest for this RFP:	<p>It is our intent to support projects that focus on implementing the current Category B serogroup B meningococcal (MenB) ACIP recommendations and increasing immunization against MenB in the older adolescent/young adult population. Projects should address the various barriers related to immunization in this population [see Barriers] as well as potential barriers related to the implementation of a Category B recommendation in the practice setting.</p> <p>It is expected that projects will be evidence-based (education and/or quality improvement) and the proposed research/evaluation will follow generally accepted scientific principles. During review the intended outcome of the project is given careful consideration and, if appropriate based on the project goal, projects with the maximum likelihood to directly impact patient care will be given high priority. Projects including an educational element can find more information on principals of learning and behavior change for health professionals here.</p> <p>There is a considerable amount of interest in receiving responses from projects that utilize system-based changes. Although educational efforts for providers and patients may be entirely appropriate components in responses to this RFP, projects that include an overt description of system changes will be given high priority.</p> <p><i>It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered. Information on how to submit requests for support of clinical research projects can be found at www.Pfizer.com/iir.</i></p>
Target Audience:	Healthcare providers working to immunize the 16-23 year old population. Including, but not limited to, healthcare providers working in the areas of pediatrics, adolescent health, college health and immunization.

<p>Disease Burden Overview:</p>	<ul style="list-style-type: none"> • Annual number of meningococcal disease cases worldwide is estimated to be at least 1.2 million, with 135,000 deaths related to the disease¹ <ul style="list-style-type: none"> – Serogroups B and C account for majority of cases in Europe and the Americas^{2,3} • Among adolescents and young adults, those 16 through 23 years old have the highest rates of meningococcal disease.³ • N. meningitidis serogroup B accounts for approximately half of all meningococcal cases among persons aged 17–22 years in the U.S.⁴ • Outbreaks of serogroup B meningococcal disease have been reported from college campuses in the United States during the last several years⁵ <ul style="list-style-type: none"> – Epidemics or outbreaks of serogroup B meningococcal disease may be prolonged compared to those caused by other serogroups⁶ – Seven outbreaks of serogroup B meningococcal disease have occurred on college campuses since 2009 (range = 2–13 cases), resulting in 41 cases and three deaths⁷ • The impact of meningococcal disease may be severe and long lasting. <ul style="list-style-type: none"> – Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, amputations, nervous system problems, or severe scars from skin grafts.⁸
<p>Recommendations and Target Metrics:</p>	<p>Related Guidelines and Recommendations</p> <p>ACIP</p> <p>MenB vaccine series may be administered to adolescents and young adults aged 16–23 years to provide short-term protection against most strains of serogroup B meningococcal disease. The preferred age for MenB vaccination is 16–18 years (recommendation Category B)⁷</p>

<p>Gaps Between Actual and Target, Possible Reasons for Gaps:</p>	<p>Although 78.8% of adolescents aged 17 years received ≥ 1 dose of MenACWY, only 28.5% received the complete the 2-dose series.⁹</p> <p>While the specific MenB vaccination recommendation is new, vaccination coverage in general among adolescents aged 13-17 varied among the 50 states and DC.⁹</p> <ul style="list-style-type: none"> • Differences in coverage estimates by vaccine in this age group indicate many missed opportunities for simultaneous administration of vaccines.⁹ <p>Racial/ethnic disparities continue to exist in vaccination coverage in the older adolescent/young adult age range.^{9,10}</p>
<p>Barriers:</p>	<ul style="list-style-type: none"> • Although immunizations have been a long-standing focus of the preventive care of young children, they have not been a major component of adolescent preventive care, largely because there were few vaccines to offer adolescents¹¹ • Older adolescents are least likely to be targeted for immunization assessment and administration of all recommended vaccines. • Adolescents have fewer health care and preventive care assessment visits¹¹ <ul style="list-style-type: none"> – As adolescents age into their late teens, visits to primary care physicians decline substantially, reducing opportunities for immunizations.¹¹ – Among adolescents aged 13 to 17 years, 33% had no preventive care visits and 40% had only one preventive care visit¹² <ul style="list-style-type: none"> • Older adolescents are more likely to receive care from a family or internal medicine practice (50% of visits for females and 70% of visits for males).¹² • More than one third (35%) of older female adolescents receiving preventive care (not including prenatal care) sought that care from obstetric/gynecologic clinicians.¹¹ • Vaccinations are provided almost exclusively during preventive visits^{11, 13} • Adolescents lack knowledge about preventive care and do not perceive that they are susceptible.¹⁴ <ul style="list-style-type: none"> – Low public and peer awareness about immunization coverage in this age group¹⁵ • Lack of population-based immunization registries that include adolescents¹⁵

<p>Current National Efforts to Reduce Gaps:</p>	<p>Many efforts have been made to promote vaccination. Below are some examples of efforts made by various organizations both public and private. Many more exist.</p> <p>Substantial resources from the CDC, ranging from extensive reports on ACIP recommendations and practical Vaccine Information Statements to The Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases, patient-focused materials on frequently asked questions, and more (http://www.cdc.gov/vaccines/pubs/default.htm)</p> <p>The National Foundation of Infectious Diseases hosts a number of resources tailored to specific vaccinations (http://www.nfid.org/default.aspx) as well as a patient focused educational website (http://www.adolescentvaccination.org/)</p> <p>CDC’s Preteens and Teens Still Need Vaccines http://www.cdc.gov/vaccines/who/teens/index.html</p> <p>Community Preventive Services Task Force. The guide to community preventive services. Increasing appropriate vaccination: universally recommended vaccinations. Atlanta, GA: US Department of Health and Human Services, CDC; 2011. Available at http://www.thecommunityguide.org/vaccines/index.html</p> <p>National Vaccine Advisory Committee. Recommendations from the National Vaccine Advisory Committee: standards for adult immunization practice. Public Health Rep 2014; 129:115–23.</p>
<p>Expected Approximate Monetary Range of Grant Applications:</p>	<p>Individual projects requesting up to \$300,000 will be considered. The total available budget related to this RFP is \$900,000.</p> <p>The amount of the grant Pfizer will be prepared to fund for any project will depend upon the external review panel’s evaluation of the proposal and costs involved, and will be stated clearly in the approval notification.</p>

<p>Key Dates:</p>	<p>RFP release date: Thursday, February 18th, 2016</p> <p>LOI due date: Monday, April 4th, 2016 Please note the deadline is midnight Eastern Time (New York, GMT -5).</p> <p>Review of LOIs by External Review Panel: Week of May 16th</p> <p>Anticipated LOI Notification Date: Monday, May 23rd</p> <p>Full Proposal Deadline: * Monday, June 27, 2016 *Only accepted LOIs will be invited to submit full proposals Please note the deadline is midnight Eastern Time (New York, GMT -5).</p> <p>Review of Full Proposals by External Review Panel: week of July 18th</p> <p>Anticipated Full Proposal Notification Date: Tuesday, July 26th</p> <p>Grants distributed following execution of fully signed Letter of Agreement</p> <p>Period of Performance: August 15, 2016 to September 2018</p>
<p>How to Submit:</p>	<p>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.</p> <p>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.</p> <p>Select the following Area of Interest: Implementation of MenB Vaccine Recommendations</p> <p>Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix).</p> <p>If you encounter any technical difficulties with the website, please click the "Need Support?" link at the bottom of the page.</p>
<p>Questions:</p>	<p>If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Amanda Stein (amanda.j.stein@pfizer.com), with the subject line "Implementation of MenB Vaccine Recommendations 2/18/16."</p>
<p>Mechanism by which Applicants will be Notified:</p>	<p>All applicants will be notified via email by the dates noted above.</p> <p>Applicants may be asked for additional clarification or to make a summary presentation during the review period.</p>

References:

1. Jafri R, Ali A, Messonnier N, et al. Global epidemiology of invasive meningococcal disease. *Population Health Metrics*. 2013;11(1):17.
2. Centers for Disease Control and Prevention. Meningococcal disease in other countries. <http://www.cdc.gov/meningococcal/global.html>. Accessed January 11, 2016.
3. Centers for Disease Control and Prevention. Meningococcal disease Surveillance. <http://www.cdc.gov/meningococcal/surveillance/index.html>. Accessed January 11, 2016.
4. Soeters HM, McNamara LA, Whaley M, et al. Serogroup B Meningococcal Disease Outbreak and Carriage Evaluation at a College - Rhode Island, 2015. *MMWR. Morbidity and mortality weekly report*. Jun 12 2015;64(22):606-607.
5. Department of Health and Human Services. Centers for Disease Control and Prevention. Meningococcal Disease: <http://www.cdc.gov/meningococcal/about/index.html>. Accessed September 28, 2015.
6. Mandal S, Wu HM, MacNeil JR, et al. Prolonged University Outbreak of Meningococcal Disease Associated With a Serogroup B Strain Rarely Seen in the United States. *Clinical Infectious Diseases*. August 1, 2013 2013;57(3):344-348.
7. Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices, United States, 2015. *MMWR* 2015;64(41):1171-6. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm>
8. Centers for Disease Control and Prevention. Vaccine Information Sheet: Serogroup B Meningococcal Vaccine (MenB) What You Need to Know: <http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mening-serogroup.pdf>. Accessed January 11, 2016.
9. Centers for Disease Control. National, Regional, State and Selected Local Area Vaccination Coverage Amount Adolescents Aged 13-17 Years- United States, 2014. *MMWR*. 2015; 64(29):784-792. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6429a3.htm>. Accessed January 11, 2016.
10. Centers for Disease Control. Vaccination Coverage Among Adults, Excluding Influenza Vaccination- United States, 2013. *MMWR*. 2015; 64(04):95-102. Available at: <http://www.cdc.gov/Mmwr/preview/mmwrhtml/mm6404a6.htm>. Accessed January 11, 2016.
11. Rand CM, Shone LP, Albertin C, Auinger P, Klein JD, Szilagyi PG. National Health Care Visit Patterns of Adolescents: Implications for Delivery of New Adolescent Vaccines. *Arch Pediatr Adolesc Med*. 2007;161(3):252-259. doi:10.1001/archpedi.161.3.252.
12. Nordin JD, Solberg LI, Parker ED. Adolescent Primary Care Visit Patterns. *Annals of Family Medicine*. 2010;8(6):511-516. doi:10.1370/afm.1188.
13. Lee GM, Lorick SA, et al. Adolescent Immunizations: Missed Opportunities for Prevention. *Pediatrics* 2008; 122: 711-717.
14. Broder KR, Cohn AC, Schwartz B, et al. Adolescent immunizations and other clinical preventive services: a needle and a hook? *Pediatrics*.2008;121 :S25– S34
15. Oster NV, McPhillips-Tangum CA, Averhoff F, Howell K. Barriers to adolescent immunization: a survey of family physicians and pediatricians. *J Am Board Fam Pract*. 2005;18(1):13–19.

IV. 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 IGLC 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 Dissemination and Implementation 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, 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.
 - A statement that the research will be conducted in compliance with relevant provisions of the International Conference on Harmonisation, Good Clinical Practice, or Good Pharmacoepidemiology Practice guidelines and all applicable local legal and regulatory Requirements

Appendix A: Letter of Intent Submission 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 not meeting these standards will not be reviewed. It is helpful to include a header on each page listing the requesting organization.***

LOIs should include the following sections

Main Section (not to exceed 3 pages):

A. Title

B. Project Classification

1. There are multiple project types that are eligible for funding through this RFP. Please indicate which of the following best represents your project. More information on these classifications can be found in the [Decision Matrix](#) posted on the [Tips & Templates](#) tab the IGLC website.

- Dissemination and Implementation (D&I) Research
- Quality Improvement
- Education or Educational research

2. Background Information

- It is expected that D&I research projects follow generally accepted principals. For all research projects the institution(s) must agree to assume all responsibilities as sponsor of the study as outlined in the proposal. These are listed in the **RFP Terms and Conditions (#9)**.
 - At the time of approval of a full proposal, applicants will be required to sign a research contract, submit IRB approval and a research protocol.
- Quality improvement projects should be described in terms of generally accepted principles of improvement science such as those described by the IHI model for improvement or LEAN.
 - At the time of approval of a full proposal, applicants will be required to sign a letter of agreement.
- Educational projects should be planned using generally accepted principals of adult learning. More information on principals of learning and behavior change for health professionals can be found at www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf.
 - At the time of approval of a full proposal, applicants will be required to sign a letter of agreement.

C. Goal and Objectives

1. 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).
2. List the *overall* objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.

D. Assessment of Need for the Project

1. Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), 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. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information.

E. Target Audience

1. 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 sample population

F. Project Design and Methods

1. Describe the planned project and the way it addresses the established need.
2. If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.

G. Innovation

1. Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.
2. 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. Evaluation and Outcomes

1. 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. Describe how you expect to collect and analyze the data.
2. Quantify the amount of change expected from this project in terms of your target audience.
3. Describe how the project outcomes will be broadly disseminated.

I. Anticipated Project Timeline

J. Requested Budget

1. A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable.
2. The budget amount requested must be in U.S. dollars (USD).
3. While estimating your budget please keep the following items in mind:
 - 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. Please note: Pfizer does not provide funding for capital equipment.
 - The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.

- It should be noted that grants awarded through IGLC cannot be used to purchase therapeutic agents (prescription or non-prescription).
- Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.

K. Additional Information

1. If there is any additional information you feel Pfizer 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 support and facilitate the execution of the project and the 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.

Please note that any project partners listed in this section should also be listed within the online system. Tax-IDs of partner organizations will be requested when entering this information. If a partnership is only proposed, please indicate the nature of the relationship in the Organizational Detail section of your LOI.

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 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.

*Please note the formatting and page limit for the LOI. The LOI is inclusive of additional information of any kind. A submission exceeding the page limit **WILL BE REJECTED and RETURNED UNREVIEWED.***