

Pfizer Independent Grants for Learning & Change Request for Proposals (RFP) *Immunizations in Young Adolescents*

I. Background

The mission of Pfizer Independent Grants for Learning & Change (IGL&C) 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 letter 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 a Full Grant Proposal. Stage 2 is the submission of the Full Grant Proposal.

When a RFP is issued, it is posted on the Pfizer IGL&C website (www.pfizer.com/independentgrants) 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; and other not-for-profit entities with a mission related to healthcare improvement.</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>

III. Requirements

Date RFP Issued:	4/18/14
Clinical Area:	Immunizations in Young Adolescents
Specific Area of Interest for this RFP:	<p>It is our intent to support projects that address the various barriers related to immunization in young adolescents, be they HCP-related, patient or caregiver related, or systems-based. Programs must focus on adolescent immunization in general. Programs limited to a focus on one vaccine will not be eligible for consideration.</p> <p>Multi-disciplinary collaborations are encouraged when appropriate, but all partners must have a relevant role.</p> <p>Projects are expected to 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.</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 response to this RFP, projects that include an overt description of system changes will be given high priority.</p>
Target Audience:	Healthcare providers (e.g., physicians, nurses, pharmacists, allied health professionals and trainees) and system administrators working to immunize the adolescent outpatient population
Disease Burden Overview:	<p>Adolescents make up a significant portion of the US population.¹ Illness and death among this population is not common and the leading causes are mostly preventable.²</p> <p>Meningococcal disease kills 10-14 % of infected adolescents and young adults, leaving 11-19% of its survivors with serious long-term complications such as hearing loss, brain damage or amputation.³⁻⁵</p> <p>There are an estimated 1-3 million cases of pertussis per year.^{6,7} Infected adolescents commonly act as reservoirs of infection for neonates and put others at higher risk of serious illness or death from pertussis.⁸⁻¹¹</p> <p>The 6 million new HPV infections annually in the US, though typically cleared by the immune system, can become chronic and lead to cervical cancer.¹²</p>

Recommendations and Target Metrics:

Healthy People 2020 Objectives^{13, 14}

Objective: Increase routine vaccination coverage levels for adolescents

	Baseline (2008)	2012 ¹⁴	Target
1 dose of tetanus-diphtheria-acellular pertussis (Tdap) booster vaccine for adolescents by age 13-15 years	62%	84.6%	80%
2 doses of varicella vaccine for adolescents by age 13-15 years (excluding children who have had varicella)	52%	94.7%	90%
1 dose meningococcal conjugate vaccine for adolescents by age 13-15 years	55%	74.0%	80%
3 doses of human papillomavirus (HPV) vaccine for females by age 13-15 years	23%	33.4% (girls) 20.8% (boys)	80%

Objective: Increase the percentage of children aged 5 to 12 and 13 to 17 years who are vaccinated annually against seasonal influenza

	Baseline (2008)	Target
children aged 13-17 years who are vaccinated annually against seasonal influenza	13%	80%
children aged 5-12 years who are vaccinated annually against seasonal influenza	30%	80%

Objective: Increase the number of States (including DC) that have 80 percent of adolescents with 2 or more age-appropriate immunizations recorded in an immunization information (IIS) system among adolescents aged 11 to 18 years.

	Baseline (2009)	Target
80 percent of among adolescents aged 11-18 years with 2 or more age-appropriate immunizations in an immunization information system (IIS)	14 States	40 States

	<p>ACIP</p> <p>For children ages 11-18, ACIP recommends:¹⁵</p> <ul style="list-style-type: none"> • One dose of Tdap at age 11-12 • 3-dose series of HPV at age 11-12 • Initial dose of the meningococcal vaccine at age 11-12 (or 13-15 for catch-up) and one booster dose at age 16 (or 16-18 for catch-up) • One annual dose of influenza vaccine • Single dose of each pneumococcal vaccine for high risk patients • Complete the 2-dose series of Hepatitis A for high risk patients • Complete the 3-dose series of Hepatitis B for catch-up • Complete the 3-dose series of Inactivated Poliovirus for catch-up • Complete the 2-dose series of MMR for catch-up • Complete the 2-dose series of Varicella for catch-up
<p>Gaps Between Actual and Target, Possible Reasons for Gaps:</p>	<p>The National Immunization Survey (NIS) collects data on vaccine coverage. Data from 2012 shows progress toward the Healthy People 2020 goals related to adolescent vaccination coverage, though this progress varies from vaccine to vaccine.^{13,14}</p> <p>In 2012 coverage for ≥1 Tdap vaccine dose rose to 84.6% (from 78.2% in 2011), for the first time achieving the Healthy People 2020 goal of 80%. Coverage for ≥1 dose of varicella vaccine continues to meet the Healthy People 2020 goal of 90% and rose to 94.7% (from 92.3%). Coverage for ≥1 MenACWY vaccine dose rose to 74% (from 70.5%), still short of the Healthy People 2020 goal. Greater than one dose of HPV vaccine rose in males (from 8.3% to 20.8%) but did not change for females, both falling far short of the Healthy People 2020 goals.¹⁴</p> <p>While national averages may be high for some vaccines, coverage estimates vary greatly from state to state. For example, coverage for ≥1 Tdap vaccine dose ranged from 53.5% (Mississippi) to 96.3% (New Hampshire), and for ≥1 MenACWY vaccine dose, from 37.5% (Arkansas) to 94.3% (Rhode Island).¹⁴</p>

Barriers:	<p>Immunization gaps among adolescents are impacted by decreased contact with the healthcare system.¹⁶ Adolescent vaccine coverage varies widely among states and could be related to differing vaccination-promotion initiatives among local health agencies and communities.¹⁷</p> <p>Common vaccine-promotion initiatives among 3 states with highest vaccination coverage (MA, RI, WA)¹⁷:</p> <ul style="list-style-type: none">• Strong working relationships and communication between state immunization programs and vaccination providers, local professional organizations, and schools;• school vaccination requirements; and• promotion of the use of reminder/recall systems <p>Additional factors that might play an important role in vaccination coverage include:</p> <ul style="list-style-type: none">• Health-care infrastructure, local outbreaks, and communication efforts leading to increased consumer demand.¹⁷• While vaccine financing has been a barrier in the past, the implementation of the Patient Protection and Affordable Care Act of 2010 could change that as non-grandfathered private health plans and qualified health plans on the new health exchanges must offer, at no cost to beneficiaries, vaccines that are recommended by ACIP.¹⁴ <p>States with middle-school vaccination requirements are associated with higher coverage for those specific vaccines but not other ACIP recommended vaccines.¹⁷</p> <p>There seems to be a barrier to providing all recommended vaccines during the same visit.¹⁶</p>
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<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> <ul style="list-style-type: none"> • Substantial resources from the CDC, ranging from extensive reports on ACIP recommendations and practical Vaccine Information Statements to <i>The Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases</i>, patient-focused materials on frequently asked questions, and more (http://www.cdc.gov/vaccines/pubs/default.htm) • CDC Child, Adolescent & "Catch-up" Immunization Schedules http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html • CDC's Preteens and Teens Still Need Vaccines http://www.cdc.gov/vaccines/who/teens/index.html • The College of Physicians of Philadelphia created The History of Vaccines, an interactive website that chronicles the historical contribution of vaccines and antibodies to human health, explains the role of immunization in healthcare, and describes the work of pioneering vaccine researchers. (http://www.historyofvaccines.org/) • The National Foundation of Infectious Diseases hosts a number of resources tailored to specific vaccinations (http://www.nfid.org/index.html) as well as a patient focused educational website (http://www.adolescentvaccination.org/) • The National Network for Immunization Information (NNii) provides up-to-date, science-based information to healthcare professionals, the media, and the public. (http://www.immunizationinfo.org/) • US Department of Health and Human Services patient focused educational site (http://www.vaccines.gov/)
<p>Expected Approximate Monetary Range of Grant Applications:</p>	<p>Individual projects requesting up to \$500,000 will be considered. The total available budget related to this RFP is \$1,000,000.</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>

Key Dates:	<p>RFP release date: April 18, 2014</p> <p>LOI due date: May 21, 2014</p> <p>Review of LOIs by External Review Panel: May 22 – June 27, 2014</p> <p>Anticipated LOI Notification Date: June 25, 2014</p> <p>Full Proposal Deadline will be communicated on approval of an LOI* *Only accepted LOIs will be invited to submit full proposals</p> <p>Review of Full Proposals by External Review Panel: August 2014</p> <p>Anticipated Full Proposal Notification Date: September 2014</p> <p>Grants distributed following execution of fully signed Letter of Agreement</p> <p>Period of Performance: Nov 2014 to May 2017</p>
How to Submit:	<p>Please go to the website at www.pfizer.com/independentgrants and click on the button “Go to the Grant System”.</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: Young Adolescent Immunization</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>
Questions:	<p>If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Susan Connelly, at (susan.connelly@pfizer.com), with the subject line “Young Adolescent Immunization 4-21-14.”</p>
Mechanism by which Applicants will be Notified:	<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. U.S. Census Bureau. 2008 population estimates: National characteristics, national sex, age, race and Hispanic origin. Washington: 2008.
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3. CDC. Prevention and control of meningococcal disease. *MMWR* 2005;54 (RR-7):1-21.
4. Kirsch EA, Barton P, Kitchen L, Giroir BP. Pathophysiology, treatment, and outcome of meningococemia: a review and recent experience. *Pediatr Infect Dis J* 1996;15:967-979.
5. Edwards MS, Baker CJ. Complications and sequelae of meningococcal infections in children. *J Pediatr* 1981;99:540-545.
6. Forsyth K. Pertussis, still a formidable foe. *Clin Infect Dis* 2007;45(11): 1487-1491.
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8. Long SS, Welton CJ, Clark JL. Widespread silent transmission of pertussis in families: antibody correlates of infection and symptomatology. *J Infect Dis* 1990;161(3):480-486.
9. Deen JL, Mink CA, Cherry JD, et al. Household contact study of *Bordetella pertussis* infections. *Clin Infect Dis* 1995;21(5):1211-1219.
10. Izurieta HS, Kenyon TA, Strebel PM, Baughman AL, Shulman ST, Wharton M. Risk factors for pertussis in young infants during an outbreak in Chicago in 1993. *Clin Infect Dis* 1996;22(3):503-507.
11. Halperin SA, Wang EE, Law B, et al. Epidemiological features of pertussis in hospitalized patients in Canada, 1991-1997; report of the Immunization Monitoring Program-Active (IMPACT). *Clin Infect Dis* 1999;28(6):1238-1243.
12. Weinstock H, Berman S, Cates W Jr. Sexually transmitted diseases among American youth: incidence and prevalence estimates, 2000. *Perspect Sex Reprod Health* 2004;36:6-10.
13. US Department of Health and Human Services. Healthy People 2020 objectives. Available at: <http://www.healthypeople.gov/2020/topicsobjectives2020/pdfs/immunization.pdf>. Accessed March 25, 2014.
14. Centers for Disease Control. National and State Vaccination Coverage Among Adolescents Aged 13 Through 17 Years — United States, 2012. *MMWR*. 2013;62(34):685-693. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6234a1.htm>. Accessed March 25, 2014.
15. Department of Health and Human Services. Centers for Disease Control and Prevention. Recommended immunization schedule for children aged 7 through 18 years—United States, 2012 Available at: <http://www.cdc.gov/vaccines/who/teens/downloads/parent-version-schedule-7-18yrs.pdf>. Accessed March 25, 2014.
16. Lee GM, Lorick SA, et al. Adolescent Immunizations: Missed Opportunities for Prevention. *Pediatrics* 2008; 122: 711-717.
17. Centers for Disease Control. National and State Vaccination Coverage Among Adolescents Aged 13 Through 17 Years — United States, 2010. *MMWR*. 2011;60(33):1117-1123. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6033a1.htm>. Accessed March 25, 2014.

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 IGL&C. 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 the Open Payments (Physician Payments Sunshine Act) ("Sunshine Act") under non-exempt conditions, Provider (sponsor) must provide names and other required information for 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, if applicable. 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. Be advised Pfizer will not make any payments to any individuals; grant funding shall be paid directly to Provider (sponsor).
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.

Appendix: 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.***

LOIs should include the following sections

Main Section (not to exceed 3 pages):

- A. Title
- B. Goal
 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).
- C. Objectives
 1. List the *overall* objectives you plan to meet with your project both in terms of learning and expected outcomes. Do not include individual activity objectives.
 - Objectives should describe the 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. The RFP includes a national assessment of the need for the project. Please do not repeat this information within the LOI (you may reference the RFP, if necessary). Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis, if appropriate.
 2. 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
- E. Project Design and Methods
 1. 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.
- F. 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.
- G. Design of Outcomes Evaluation

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.
 - Identify the sources of data you anticipate using to make the determination.
 - Describe how you expect to collect and analyze the data.
 - Explain the method used to control for other factors outside this project (e.g., use of a control group or comparison with baseline data).
2. Quantify the amount of change expected from this project in terms of your target audience.
3. Describe how you will determine if the target audience was fully engaged in the project.
4. Describe how the project outcomes might be broadly disseminated.

H. Project Timeline

I. Requested Budget

1. A total amount requested is the only information needed at this time.
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.
 - 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.

J. 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.

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).

Make every effort to submit as **few** documents as possible—you are encouraged to include all required sections in one document. 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**.*