Pfizer Independent Grants for Learning & Change Request for Proposals (RFP) *Pediatric Immunization Series Completion*

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 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 IGL&C website (<u>www.pfizer.com/independentgrants</u>) 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.

<u>II. Eligipiiity</u>	
Geographic Scope:	☑ United States Only
	International(specify country/countries)
Applicant Eligibility	The following may apply: medical, dental, nursing, allied health, and/or
Criteria:	pharmacy professional schools; healthcare institutions (both large and
	small); professional associations; government agency partners; and other not-for-profit entities with a mission related to healthcare improvement.
	More information on organizations eligible to apply directly for a grant can be found at: http://www.pfizer.com/files/IGLC OrganizationEligibility 2015.pdf.
	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.

II. Eligibility

III. Requirements	
Date RFP Issued:	6/22/15
Clinical Area:	Pediatric Immunization
Specific Area of Interest	It is our intent to support projects that focus on improving
for this RFP:	immunization series completion by assessing and addressing current
	barriers which lead to missed immunizations in the underimmunized pediatric population. Applicants should be able to document that their
	target community has low rates of vaccine completion relative to
	national numbers.
	Multi-disciplinary collaborations are encouraged when appropriate, but all partners must have a relevant role.
	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 at www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf.
	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.
	It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered.
Target Audience:	Healthcare providers working to immunize the pediatric population

Disease Burden	Each day, nearly 12,000 babies are born in the United States who will
Overview:	need to be immunized before age two against 14 vaccine-preventable diseases. Recent cases and outbreaks in the United States (e.g. measles ⁽¹⁾ , mumps ⁽²⁾ , pertussis ⁽³⁾) serve as a reminder that vaccine preventable diseases still exist. Without vaccines, epidemics of many preventable diseases could return, resulting in increased illness, disability and death. ⁽⁴⁾
	National coverage with the recommended combined vaccines series was 70.4% in 2013 ⁽⁵⁾ . Only 18% of children in the United States receive all vaccinations by the recommended times. Under-immunization contributes to the overall reduction of community immunity to various vaccine-preventable illnesses, thus increasing the risk for a disease outbreak. Delayed or inappropriately timed vaccinations have administrative, programmatic, and cost implications ^(6,7)
	National, State, and Selected Local Area Vaccination Coverage Among Children Aged 19–35 Months — United States, 2013: <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6334a1.htm</u> ⁽⁵⁾

Recommendations and	Related Guidelines and Recommendations
Target Metrics:	
	Department of Health and Human Services. Centers for Disease Control and Prevention. 2015 Recommended Immunizations for Children from Birth Through 6 Years Old. <u>http://www.cdc.gov/vaccines/parents/downloads/parent-ver-sch-0-6yrs.pdf</u>
	Standards for Child and Adolescent Immunization Practices. National Vaccine Advisory Committee. Pediatrics 2003; 112:4 958-963 <u>http://pediatrics.aappublications.org.proxy1.athensams.net/content/1</u> <u>12/4/958.full</u>
	Immunization Training Guide & Practice Procedure Manual. American Academy of Pediatrics Childhood Immunization Support Program <u>http://www2.aap.org/immunization/pediatricians/pdf/immunizationtra</u> <u>iningguide.pdf</u>
	Centers for Disease Control and Prevention. Immunization Strategies for Healthcare Practices and Providers In <i>Epidemiology and Prevention</i> <i>of Vaccine-Preventable Diseases</i> . Atkinson W, Wolfe S, Hamborsky J, eds. 12th ed., second printing. Washington DC: Public Health Foundation, 2012.
	Marshall, G. (2015). The Vaccine Handbook: A Practical Guide for Clinicians ("The Purple Book") 5th Edition. West Islip, NY: Professional Communications, Inc.
	Guide to Community Preventive Services. Increasing appropriate vaccination: health care system-based interventions implemented in combination (abbreviated).
	www.thecommunityguide.org/vaccines/universally/healthsysteminterv entions.html. Last updated: October 2014.

Gaps Between Actual and Target, Possible Reasons for Gaps:	Rates of vaccine doses given in the first year of life are generally above Health People 2020 goals, yet rates for series that include vaccines due past 12 months of age, especially those that require 4 doses, are below national goals. ⁽⁵⁾
	Coverage was below the Healthy People 2020 targets for ≥4 doses of diphtheria, tetanus, and pertussis vaccine (DTaP) (83.1%; target 90%); ≥4 doses of pneumococcal conjugate vaccine (PCV) (82.0%; target 90%); the full series of Haemophilus influenzae type b vaccine (Hib) (82.0%; target 90%); ≥2 doses of hepatitis A vaccine (HepA) (54.7%; target 85%); rotavirus vaccine (72.6%; target 80%); and the HepB birth dose (74.2%; target 85%). ⁽⁵⁾
	Children living below the federal poverty level had lower vaccination coverage compared with children living at or above the poverty level for many vaccines, with the largest disparities for \geq 4 doses of DTaP (by 8.2 percentage points), full series of Hib (by 9.5 percentage points), \geq 4 doses of PCV (by 11.6 percentage points), and rotavirus (by 12.6 percentage points).

Barriers:	 The demographics of parents with underimmunized children in a local community may differ from those of the national community at large. ⁽⁸⁾ With this being said, it is important that the proposed project seeks to identify the particular barriers within the identified setting. Some common reasons childhood immunizations are delayed/missed/refused include: HCP Barriers: Lack of clinician awareness of their patients' immunization rates ^(6, 9) Although many studies have demonstrated the benefits of reminder measures to address patient under-immunization and improve immunization coverage, they are not widely implemented by healthcare providers. Implementing provider-based recall is challenging for pediatric practices. ⁽¹⁰⁻¹²⁾ The burden of communicating with parents about vaccines is high, especially among pediatricians. The barriers to communication include time constraints. ^(9, 13) Language barriers ^(14, 15) Non-physician office staff awareness and lack of shared responsibility ⁽⁹⁾ Barriers related to implementation of standing orders (e.g. inconsistent use, staff feeling the need to check with providers)⁽¹⁶⁾ Parent/Patient Barriers: Low level of knowledge of vaccine preventable disease⁽¹⁷⁻¹⁹⁾ Difficulty finding time to immunize^(8, 20,21) Inconvenient office hours, long waits^(9, 22) Transportation issue⁽¹⁵⁾ Belief that children should not be vaccinated when they have a minor illness⁽¹²⁾ Language comprehension⁽¹⁴⁾ Confusion for parents regarding the immunization schedule is a common barrier to having an adequately immunized child nationwide ^(6, 24) Concern around child's pain/crying/anxiety⁽⁸⁾
	 System Barriers: Fragmentation of patient care makes it more likely that providers will not have complete immunization records ⁽⁹⁾ Lack of registries and communication between registries⁽⁹⁾ Missed opportunities, missed visits ⁽⁹⁾ Lower likelihood of doctor visits for undocumented children⁽²⁵⁾

Current National Efforts to Reduce Gaps:	 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. Substantial resources from the CDC, ranging from extensive reports on ACIP recommendations and practical Vaccine Information Statements patient-focused materials on frequently asked questions, and more (http://www.cdc.gov/vaccines/pubs/default.htm) CDC's National Infant Immunization Week Educational Resources (http://www.cdc.gov/vaccines/events/niiw/ed-resources.html) US Department of Health and Human Services patient focused educational site (http://www.vaccines.gov) Substantial resources from the American Academy of Pediatrics for both providers and parents/patients (www.aap.org and http://www.healthychildren.org/)
Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to \$250,000 will be considered. The total available budget related to this RFP is \$750,000. 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.

Key Dates:	RFP release date: 6/22/15
	LOI due date: <i>8/13/15</i> Please note the deadline is midnight Eastern Time (New York, GMT -5).
	Review of LOIs by External Review Panel: week of 9/14/15
	Anticipated LOI Notification Date: week of 9/23/15
	Full Proposal Deadline: *11/4/15 *Only accepted LOIs will be invited to submit full proposals Please note the deadline is midnight Eastern Time (New York, GMT -5).
	Review of Full Proposals by External Review Panel: week of 12/7/15
	Anticipated Full Proposal Notification Date: 12/15/15
	Grants distributed following execution of fully signed Letter of Agreement
	Period of Performance: January 2016 to December 2017
How to Submit:	Please go to the website at <u>www.pfizer.com/independentgrants</u> 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: Pediatric Immunization Series Completion
	Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix).
	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, Amanda Stein at (<u>amanda.j.stein@pfizer.com</u>), with the subject line "Pediatric Immunization Series Completion 6/22/15."
Mechanism by which	All applicants will be notified via email by the dates noted above.
Applicants will be Notified:	Applicants may be asked for additional clarification or to make a summary presentation during the review period.

References:

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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. 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 (<u>http://www.pfizer.com/files/IGLC_SunshineFAQ_Oct2014.pdf</u>).

- 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 <u>single-spaced</u> using <u>Calibri 12-point font</u> and <u>1-inch margins</u>. Note there is a <u>3-page limit</u> 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 and project lead.

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.
 - 2. 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. Anticipated Project Timeline
- I. 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.
- 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. 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. <u>Final submissions should not exceed 5 pages in total</u> (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.