Global Bridges at Mayo Clinic and Pfizer Independent Grants for Learning and Change Request for Proposals (RFP) EUROPEAN PROGRAM

17 November, 2015

I. Background

Global Bridges: Healthcare Alliance for Tobacco Dependence Treatment, hosted at Mayo Clinic, and Pfizer Independent Grants for Learning and Change (IGLC) are collaborating to offer a new grant opportunity focused on treating tobacco dependence.

IGLC provides independent grant support to organizations for healthcare quality improvement and education projects related to tobacco dependence. IGLC's goal is to increase the number of people who stop smoking by improving the frequency and effectiveness of treatment interventions (e.g., counseling and/or evidence-based pharmacotherapy) provided by healthcare professionals.

Global Bridges was established in 2010 through an unrestricted educational grant from Pfizer. Since then Global Bridges and its regional partners have created training curricula based on established best practice and trained over 3600 healthcare professionals from 63 countries to treat tobacco dependent patients and promote policies which facilitate decisions to stop using tobacco. Through the creation of a multilingual website, webinars, distance learning program and listservs, Global Bridges has also facilitated collaboration among its members within and across regions. (www.globalbridges.org)

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

II. Requirements

Projects should be consistent with the Global Bridges Mission: to create and mobilize a global network of healthcare professionals and organizations dedicated to advancing evidence-based tobacco dependence treatment and advocating for effective tobacco control policy. Successful grantees will be required to join and contribute to the Global Bridges online network. We are particularly interested in funding projects and programs which promote collaborations across multiple countries and across regions, which build and expand the number of healthcare professionals committed to treating tobacco dependence, and promote policies which facilitate stopping tobacco use.

Specific Area of	Category 1: Capacity Building
Interest for this RFP:	
interest for this Ki i .	Grant support available for capacity building initiatives for
	healthcare professionals in tobacco dependence treatment which
	help build the Global Bridges network in the WHO European Region.
	Proposals must be based on evidence and best practice. Eligible
	organizations may apply to build on a prior or ongoing project that
	has been demonstrated to build treatment capacity, improve clinical
	practice, and/or lead to positive health outcomes. Documentation
	must be provided that the initiative has achieved success in the past
	and how additional funding can expand or improve the effort. Grant
	requests must not exceed \$200,000 over 2 years.
	Category 2: Advocacy/Article 14 Implementation
	FCTC Article 14 obliges Parties to the treaty to develop
	comprehensive national guidelines and to take effective measures to
	promote tobacco dependence treatment, and the <u>Article 14</u>
	<u>guidelines</u> offer detailed recommendations on how to achieve this.
	Grant support for this category will focus on healthcare professional
	advocacy programs aimed at implementation of Article 14 and its
	guidelines at the national level. The key objective of these projects
	should be to assist in implementation of the Article 14 guidelines.
	Grant requests must not exceed \$100,000 over two years.
	Ref: World Health Organization (WHO) Framework Convention on Tobacco
	Control (FCTC). Article 14 "Guidelines on demand reduction measures
	concerning tobacco dependence and cessation" November 2010.
	Applicants may submit applications in both categories, either as
	separate proposals or combined into one project proposal.
	Priority will be given to projects that show evidence of sustainability
	and/or exportability.
Target Learner Audience	Healthcare professionals
Geographic Scope	The intent of this RFP is to focus on work in the European Region as
	defined by the World Health Organization
	(http://www.euro.who.int/en/countries).
	See Applicant Eligibility Criteria, below.
Applicant Eligibility	Credentialed medical, dental, nursing, allied health, public health,
Criteria	and/or pharmacy professional schools, universities, healthcare
	institutions, hospitals, for-profit health systems, professional
	associations, member societies, state agencies involved with tobacco
	control, and other not-for-profit entities working in the WHO
	European Region may apply.

	Project work must be focused on capacity building and/or Article 14 implementation in the WHO European Region. Collaborations are encouraged, provided that the conditions above are met.
	Applicants who have accepted any funds from the tobacco industry in the past five years are not eligible to apply.
Maximum Grant	The total available budget related to this RFP is two million U.S.
Request Amounts	dollars (\$2,000,000), including indirect costs. The maximum allowed
Request Amounts	overhead rate is 28%, and the maximum dollar amounts delineated
	above include overhead costs. All amounts listed are in U.S. dollars
	(USD).
Key Dates	All applicants MUST submit a Letter of Intent (LOI) by
•	Thursday, 21 January 2016 at 5:00pm U.S. Eastern Standard Time
	Anticipated LOI Notification Date: 3 March 2016 Please note: full proposals can only be submitted following acceptance of an LOI.
	Full Proposal Deadline (Anticipated): Thursday, 7 April 2016 at 5:00pm U.S. Eastern Daylight Time
	Anticipated Full proposal Award Notification Date: 13 June 2016
	Grants awarded following execution of fully signed Letter of Agreement (LOA)
	Grantee Meeting: March, 2017 (details to be provided at later date)
	Period of Performance: approximately September 2016 to December 2018, or as specified in proposal within this date range
How to Submit	Please go to the website at www.pfizer.com/independentgrants and
	click on the button "Go to the Grant System".
	If this is your first time visiting this site 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: Global Bridges 2016 Smoking Cessation.
	Requirements for submission:
	Complete all required sections of the online application and upload your completed LOI template (see Section IV below).
	In your project title, please state the category to which you are

	applying: Category 1 (Capacity Building) or Category 2 (Advocacy/Article 14). Start the project title with the appropriate category number. If a proposal addresses both categories then please list them both. For example "Category 1 and 2 - Initiative to
	Address"
Questions	If you have questions regarding this RFP, please direct them in
	writing to the Pfizer IGLC Grant Officer, Jacqueline Waldrop via email
	(jacqueline.waldrop@pfizer.com) or to Katherine Kemper at Global
	Bridges (kemper.katherine@mayo.edu).

III. Terms and Conditions

See Section V below for Terms and Conditions of this program. Complete TERMS AND CONDITIONS for Certified and/or Independent Professional Healthcare Educational Activities are available upon submission of a grant application on the Pfizer IGLC website.

IV. Letter of Intent Submission Guidance

LOIs must be in English. 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

- I. Main Section (not to exceed 3 pages):
 - A. Title of project
 - B. Goal
 - 1. Briefly state the overall goal of the project.
 - 2. Describe how this goal aligns with the focus of the RFP and the goals of the applicant organizations.
 - C. Objectives
 - 1. List the overall objectives you plan to meet with your project both in terms of learning and expected outcomes.
 - D. Baseline data summary, initial metrics or project starting point. What is the practice gap that will be addressed or improved?
 - E. Technical Approach
 - 1. Describe the planned project and the way it addresses the established need.

2. Describe the overall population size as well as the size of your sample population. Describe the primary audience(s) targeted for this project. Also indicate whom you believe will directly benefit from the project outcomes.

F. Innovation

1. Describe how this project builds upon existing work, pilot projects, or ongoing projects, etc., developed either by your institution or other institutions related to this project.

G. Outcomes Evaluation

- 1. Describe how you will measure the success of your project. How will you determine if the practice gap was addressed for the target group?
- 2. 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. Institutional overhead and indirect costs may be included within the grant request. The maximum overhead rate established for this RFP by Pfizer is 28%.
- II. Organizational Detail (not to exceed 1 page, in addition to main section)
 Describe the attributes of the institutions/organizations/associations that will facilitate or support the execution of the project and the leadership of the proposed project, including relevant prior or ongoing projects. Articulate the specific role of each partner in the proposed project.

Final submissions should not exceed 4 pages in total (3 pages for the main section, and 1 page for organizational detail). If your LOI has extensive references, it is acceptable to include 1 additional page to accommodate these references. All required sections (main section + organizational detail) should be submitted in one single document.

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.

V. TERMS AND CONDITIONS

 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 dualuse 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, 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