# Pfizer Independent Grants for Learning & Change Request for Proposals (RFP) Reducing the Burden of Cardiovascular Disease in Indonesia

#### **I.Background**

Pfizer is offering a new grant opportunity focused on improving care for patients with high levels of cardiovascular risk in Indonesia, with a particular focus on primary and/or secondary prevention of cardiovascular disease (CVD).

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 asks only for reports about the results and the impact of the projects in order to share them publicly.

On February 22, 2017, Pfizer convened a select group of participants from Indonesia's Ministry of Health Committee on CVD Prevention, World Heart Federation, Indonesian Heart Association (PERKI), Indonesian Heart Foundation, cardiovascular research experts, and educationalists to solicit input on the following: (1) the current state of CVD burden in Indonesia- epidemiology and evidence base; (2) the current state of healthcare service in Indonesia; (3) the needs that must be addressed to reduce gaps; (4) elements that constitute a proposal for an innovative CVD risk reduction program in Indonesia.

The intent of this document is to encourage organizations with a focus on healthcare professional education and/or clinical quality improvement to submit a letter of intent (LOI) in response to a Request for Proposal (RFP) that is related to initiatives in a specific disease state, therapeutic area, or broader area of educational or clinical 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 (<a href="www.pfizer.com/independentgrants">www.pfizer.com/independentgrants</a>) 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 organizations, as deemed appropriate.

#### **II. Eligibility**

Geographic Scope:	✓ International – scope limited to Indonesia only
	Focusing on patients with – or at high risk of cardiovascular disease (eg,
	risk as estimated by using the WHO risk chart)

# Applicant Eligibility Criteria:

Only local organizations in Indonesia or organizations that demonstrate a significant partnership with an Indonesian organization may submit Letter of Intent to this RFP. Partnering and collaboration is strongly encouraged. Preference will be given to organizations that bring into their project appropriate partners such as academic medical centers, hospitals or healthcare systems, and other societies or associations. These partners may include Indonesian health care institutions, large or small; health care professional organizations and other organizations with a mission related to healthcare improvement; and government agency partners with the capacity to reach patients at risk for cardiovascular disease.

More information on organizations eligible to apply directly for a grant can be found at:

http://www.pfizer.com/files/IGLC OrganizationEligibility effJuly2015.pdf.

Collaborations within institutions (e.g., between departments and/or inter-professional agencies), as well as between different institutions, organizations, or associations are encouraged. Please note all partners must have a relevant role and the requesting organization must have a key role in the project.

For programs offering Continuing Professional Development (CPD) credit, the requesting organization must be the accredited grantee.

# III. Requirements

Date RFP Issued:	May 1, 2017
Clinical Area:	Cardiovascular - primary and/or secondary prevention of CVD
Specific Area of Interest	Expectation is that proposed projects will have to
for this RFP:	identify and examine an intervention/strategy that has the
	potential to reduce CVD burden in Indonesia:
	<ul> <li>Using existing evidence of what works in primary prevention in high risk individuals and/or secondary prevention</li> </ul>
	b. Incorporating situational analysis of community needs
	c. Focusing on the enablers/opportunities and critical barriers
	(e.g. access, awareness, knowledge, skills, adherence) to implement tactics as demonstrated by the evidence and overcome barriers at the least cost (e.g. using population attributable risk)
	d. Aligning the strategy to national standards
	e. Having measurable outcomes and data collection to demonstrate the impact of the initiative
	f. Recognizing that the intervention must be adapted to usual practice, fit within existing health service context and be sustainable
	g. Capacity development

# Specific Area of Interest for this RFP (continued)

Examples of potential approaches to be evaluated include:

- Identification and implementation of strategies among health care professionals (HCP) to improve the control of dyslipidemia, hypertension, and/or diabetes in the context of CVD and/or diabetes (with an emphasis on overall cardiovascular risk) as primary risk factors among HCPs
- Implementation of strategies to raise awareness among patients of dyslipidemia, hypertension, and/or diabetes in the context of CVD (with an emphasis on overall cardiovascular risk) as linked to the prevention of heart attack and stroke
- Incorporation of multiple ways to communicate with patients
- Combining educational and clinical approaches to achieve the specific goal
- Collaborations that bring special expertise to the project, such as with research clinics, information technology, and clinical communications centers of expertise
- Incorporation of treatment guidelines into standard practice forms and checklists
- Provision of decision support mechanisms at the point of care
- Plan for maintenance and expansion of strategies and program elements demonstrated to be effective

Programs limited to focus on only smoking cessation will not be eligible for consideration. Priority will be given to initiatives that examine total CV risk management, not single risk factors. If the project includes an element of screening, the project must include an intervention designed to reduce the risk in screened individuals.

Interprofessional and multi-disciplinary collaborations are encouraged when appropriate. Each collaborating discipline and/or profession must have a relevant role.

It is expected that projects will be evidence-based (education and/or clinical quality improvement) and any proposed research/evaluation element will follow generally accepted scientific principles. During review the intended outcome of the project is given careful consideration based on the project goal, projects with the maximum likelihood to directly impact patient outcomes will be given high priority. Proposals that include an educational element can find more information on principals of learning and behavior change for health professionals at:

 $\underline{www.pfizer.com/files/HealthProfessionalsLearning} and Behavior Change \\ A Few Principles.pdf.$ 

There is a considerable amount of interest in receiving responses from projects that utilize system-based changes. [Although educational efforts for HCPs and patients may be entirely appropriate components in responses to this RFP, projects that include an overt description of system change 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. Information on how to submit requests for support of clinical research projects can be found at <a href="https://www.Pfizer.com/iir.">www.Pfizer.com/iir.</a>

#### **Target Audience:**

Primary care providers and their teams

# Disease Burden Overview:

Great strides have made in the management of (CVD). Advances in medicine and public health have helped to control the epidemic of atherosclerotic disease [coronary heart disease (CHD) and stroke], which peaked several decades ago. While the rate of CVD mortality is declining worldwide, this is not reflected in low- and middle-income countries where it remains very high compared to high income countries.<sup>1</sup>

The World Heart Federation (WHF) is dedicated to leading the global fight against CVD, including heart disease and stroke, with a focus on low- and middle-income countries. They have aligned their efforts around the World Health Organization goal to reduce premature deaths from non-communicable diseases (NCD) by 25% by 2025 (25by25).<sup>2</sup> WHF recognizes that to achieve this target will require a primary focus on CVD - the world's number one killer, which makes up 50% of all NCD deaths.<sup>3</sup> The development of the WHF Roadmaps, which are broader than clinical practice guidelines, provide an approach that may help facilitate implementation of cost-effective evidence based interventions.<sup>4,5,6</sup>

Economic stability and sustainable growth is creating improved standards of living in Indonesia. Along with growth come changes in lifestyles and a shift to NCDs making a greater contribution to the nation's burden of illness. It is predicted that the largest number of deaths due to CVD will occur in countries like Indonesia. CVD is the leading cause of death in Indonesia:

- In 2012, 37% of deaths were due to CVD
- 21% (328,500 people) due to stroke
- 9% (138,400 people) due to CHD
- 6% (100,400) due to diabetes<sup>8</sup>

Disease Burden Overview (continued):	The burden of CVD is associated with well-established risk factors that can be modified (high blood pressure, high cholesterol, high blood sugar levels, and smoking). People who are not being treated or who are not being treated appropriately for abnormal cholesterol, high blood pressure and type 2 diabetes are a growing concern. Change is needed on how risks for CVD are managed and in many cases this requires developing innovative approaches to implement existing therapies more effectively. In addition, interventions including the control of dietary salt, energy intake and physical inactivity should be considered. <sup>9</sup>
Recommendations and Target Metrics:	<ul> <li>Related Guidelines and Recommendations</li> <li>Indonesian Heart Association Guidelines 2013 – 2015</li> <li>World Health Organization (WHO) 2025 framework on reducing Noncommunicable Diseases (NCD) globally.</li> </ul>
	<ul> <li>The World Heart Federation cardiovascular disease roadmaps</li> <li>http://www.globalheart-journal.com/issue/S2211- 8160(15)X0003-2</li> <li>Incorporating Success Factors for Scaling Up Global Health Interventions<sup>10</sup></li> <li>Reducing the burden of Cardiovascular Disease in Indonesia<sup>11</sup> http://www.georgeinstitute.org.au/sites/default/files/reducing-the-burden-of-cvd-in-indonesia.pdf</li> </ul>
Gaps Between Actual and Target, Possible Reasons for Gaps:	There is a significant burden of 4 primary NCDs on Indonesian households. Hypertension, diabetes, CHD and stroke account for 8% of the nation's out of pocket health expenditures <sup>12</sup>
Barriers:	Age, education, CVD risk, guideline implementation, and access to appropriate care <sup>13,14,15,16,17,18</sup>
Current National Efforts to Reduce Gaps:	Indonesia has developed a comprehensive strategy to target priorities in health, including CVD, with the Strategic Plan of the Ministry of Health. <sup>19</sup> In her introduction to the plan, the Minister of Health urges all parties including central and regional governments, cross-sector support and the wider business world to synergize with each other and carry out developments in health to achieve the Nation's goals for health.
Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to \$200,000 US dollars will be considered. The total available budget related to this RFP is \$600,000 US dollars.
	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: May 1, 2017
	LOI due date: June 30, 2017
	Please note the deadline is 11:59 pm Eastern Time (New York, GMT -5).
	Review of LOIs by External Review Panel: July 27, 2017 Anticipated LOI Notification Date: August 9, 2017 Full Proposal Deadline: September 14, 2017 *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: October 2017 Anticipated Full Proposal Notification Date: November 2017 Grants distributed following execution of fully signed Letter of Agreement Period of Performance: January 1, 2018 to December 30, 2019
How to Submit:	Please go to <a href="https://www.cybergrants.com/pfizer/loi">www.cybergrants.com/pfizer/loi</a> and sign in. First-time users should click "REGISTER NOW".
	Select the following Area of Interest: Reducing the Burden of Cardiovascular Disease in Indonesia
	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.
	<b>IMPORTANT:</b> Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.
Questions:	If you have questions regarding this RFP, please direct them in writing to the Grant Officer Angelo Carter (angelo.carter@pfizer.com), with the subject line "Reducing the Burden of Cardiovascular Disease in Indonesia"
Mechanism by which Applicants will be	All applicants will be notified via email by the dates noted above.
Notified:	Applicants may be asked for additional clarification or to make a summary presentation during the review period.

# References:

<sup>&</sup>lt;sup>1</sup> Institute of Medicine (US) Committee on Preventing the Global Epidemic of Cardiovascular Disease: Meeting the Challenges in Developing Countries; Fuster V, Kelly BB, editors. Washington (DC): National Academies Press (US); 2010.

https://www.cdc.gov/dhdsp/action\_plan/index.htm Accessed (February 27, 2017).

#### **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.

<sup>&</sup>lt;sup>2</sup> World Health Organization. Global action plan for the prevention and control of noncommunicable diseases 2013e2020. Available at: www.who.int/global-coordination-mechanism/publications/globalaction-plan-ncds-eng.pdf?ua¼1. Accessed (February 27, 2017)

<sup>&</sup>lt;sup>3</sup> Yusuf S, Wood D, Ralston J, Reddy S. The World Heart Federation's vision for worldwide cardiovascular prevention. Lancet 2015 Apr 16

<sup>&</sup>lt;sup>4</sup> World Heart Federation. A roadmap for reducing cardiovascular premature mortality through secondary prevention interventions. Global Heart 2015.

<sup>&</sup>lt;sup>5</sup> World Heart Federation. A roadmap for reducing cardiovascular mortality through prevention and management of raised blood pressure. Global Heart 2015.

<sup>&</sup>lt;sup>6</sup> World Heart Federation. A Roadmap for Reducing Cardiovascular Mortality through Tobacco Control. Global Heart 2015.

<sup>&</sup>lt;sup>7</sup> Cannon B. Biochemistry to behavior. Nature. 2013;493:S2–S3.

 $<sup>^{8}</sup>$  World Health Organization - Noncommunicable Diseases (NCD) Country Profiles , 2014

<sup>&</sup>lt;sup>9</sup> A Public Health Action Plan to Prevent Heart Disease and Stroke (2008). National Center for Chronic Disease Prevention and Health Promotion, Division for Heart Disease and Stroke Prevention, USA.

<sup>&</sup>lt;sup>10</sup> Yamey G 2011, PLOS Medicine

<sup>&</sup>lt;sup>11</sup> Cardiovascular Division & Health Services Research Centre. *Reducing the burden of CVD in Indonesia*. Newtown: The George Institute for Global Health, 2017.

<sup>&</sup>lt;sup>12</sup> Maharani A and Tampubolon G. Plos One 2014; 9 (8): e 105831

<sup>&</sup>lt;sup>13</sup> Hussain MA, et al. J Epidemiol 2016; doi.10.2188/jea.JE20150178

<sup>&</sup>lt;sup>14</sup> Arsana P, et al. JAFES 2014; 29 (2): 124 – 28

<sup>&</sup>lt;sup>15</sup> Gupta S, et al. J Rual Tropical Public Health. 2011;10:29-34

<sup>&</sup>lt;sup>16</sup> Rahajeng E, et al. Maj Kedoct Indon. 2009;59:50-587

<sup>&</sup>lt;sup>17</sup> Munawar M, et al. Act Cardiol Sin 2013; 29: 71 – 81

<sup>&</sup>lt;sup>18</sup> AsPac ACS Medical Management Working Group, Int J Cardiol 2015; (183): 63 – 75

<sup>&</sup>lt;sup>19</sup> Rencana Strategis Kementerian Kesehatan Tahun 2015-2019. -- Jakarta : Kementerian Kesehatan RI, 2015.

- 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 ensure compliance with applicable local law, Pfizer may publicly disclose the support it provides. Pfizer may disclose in any lawful manner the terms of the letter of agreement, the support or funding that Pfizer is providing under the letter of agreement, and any other related information, to the extent necessary for Pfizer to meet its obligations under those laws, regulations and industry codes that require Pfizer to report payments or other transfers of value to certain healthcare professionals and teaching hospitals (collectively, the "Transparency Laws"). Transparency Laws include, without limitation, section 6002 of the U.S. Affordable Care Act and the EFPIA Code on Disclosure of Transfers of Value. Disclosures may include identifying information for organizations and U.S. physicians, such as name, business address, specialty, National Provider Identifier (NPI), and licensure numbers. Grantee will agree to (and will cause other agents, employees and contractors to) reasonably cooperate with Pfizer in Pfizer's collection and disclosure of information to fulfill its Transparency Law obligations. Grantee will provide Pfizer with complete and accurate information about payments or other transfers of value reportable under Transparency Laws.

Frequently Asked Questions related to IGLC's Sunshine Act Reporting Requirements are available on our website (http://www.pfizer.com/files/IGLCsunshineFAQ\_updatedJan2016.pdf).

- 7. No portion of an independent grant may be used for food and/or beverages for learners and/or participants in any capacity. Grantee 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 Grantee 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: 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.

LOIs should include the following sections

Main Section (not to exceed 3 pages):

- A. Title
- B. Project Classification
  - 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 <u>Decision Matrix</u> posted on the <u>Tips & Templates</u>
    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 <a href="www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange\_AFewPrinciples.pdf">www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange\_AFewPrinciples.pdf</a>.
      - 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. 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.

### 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.

#### 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**.