Pfizer Independent Grants for Learning & Change and American College of Emergency Physicians
Request for Proposals (RFP)

Improving Assessment and Treatment of Acute Vaso-occlusive Crisis Pain in the ED Setting

I. Background

Pfizer and the American College of Emergency Physicians (ACEP) are collaborating to offer a new grant opportunity focused on supporting quality improvement (QI) initiatives that will result in more timely assessment and treatment of acute vaso-occlusive crisis pain for adult patients with sickle cell disease treated in Emergency Departments (EDs) in the United States and Canada.

The American College of Emergency Physicians (ACEP) is the largest emergency physician professional membership organization in the world, representing more than 38,000 emergency medicine physicians, residents and medical students. ACEP is a 501(c)(6) nonprofit organization founded in 1968 and is leading the charge to improve our nation's emergency care for the 136 million annual patient visits to US emergency departments.

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 grantee. 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 proposal in response to a Request for Proposal (RFP) that is related to closing gaps in care in a specific disease state, therapeutic area, or broader area of educational need.

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

II. Eligibility

Geographic Scope:	United States & Canada

| Applicant Eligibility Criteria: | U.S. or Canadian health care institutions, large and small; health care professional organizations and other organizations with a mission related to healthcare improvement; government agency partners all with the capacity to reach EDs.

Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions/organizations/associations, are encouraged when appropriate, but all partners must have a relevant role.

More information on organizations eligible to apply directly for a grant can be found at http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf.

For programs offering credit, the requesting organization must be the accredited grantee. |
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III. Requirements

Date RFP Issued:	January 29,2018
Clinical Area:	Sickle Cell Disease

Specific Area of Interest for this RFP:	Pain from vaso-occlusive crises (VOC) is the leading cause of emergency department (ED) visits for individuals living with sickle cell disease (SCD). The care that is delivered in the ED is often cited by patients with SCD as the area of health care in greatest need of improvement.[1] Through this RFP, it is our intent to support quality improvement projects that focus on a more timely assessment and treatment of acute sickle cell-related pain for patients with sickle cell disease treated in the Emergency Department.

Selected Grantees will be required to send 2 representatives for a day long Kick-off Meeting in early June and a day long Post-Project meeting with ACEP. At the Kick-off meeting, Grantees will present an overview of their project and will hear from experts on the state of the science on SCD/VOC treatments. During the Post-Project meeting, Grantees will present the outcomes of their QI projects and assist ACEP in developing best practice education based on their results. Expenses for the meetings will be paid for by ACEP. In addition, all awardees will be required to participate in monthly conference calls to provide updates on the project.

It is expected that projects will be evidence-based (education and/or quality improvement). 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 on patient care will be given high priority.

There is a considerable amount of interest in receiving responses on projects that utilize system-based changes. Although educational efforts for grantees 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. Information on how to submit requests for support of clinical research projects can be found at www.Pfizer.com/iir. |
| **Target Audience:** | Adult Sickle Cell Disease Patients treated in Emergency Departments in the United States and Canada |

Disease Burden Overview:	While there are other life and limb-threatening complications of SCD, VOCs are the hallmark acute complication for persons with SCD and manifests as acute severe pain. Although VOCs are often associated with excruciating pain of sudden onset, some people experience gradual onset of a VOC. Nearly all individuals affected by SCD will experience a VOC during their lifetime.[2]
Recommendations and Target Metrics:	**Related Guidelines and Recommendations** • Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014 (https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease) • The Emergency Severity Index (ESI) Version 4 triage system, which is used by more than half of emergency departments in the United States, suggests that persons with SCD be triaged as ESI level 2, a very high priority, and rapid placement be facilitated.[3]
Gaps Between Actual and Target, Possible Reasons for Gaps:	• Many SCD patients do not have access to coordinated care and rely on ED visits to manage their pain and their SCD, where they may encounter confusion about the disease and delayed and inconsistent pain treatment, leading to longer hospitalizations and patient distress. [4] • Some Individuals with SCD, who are felt to over utilize the hospital services, create the most difficult management problems for both hospital staff and other patients with SCD. This group is the minority of those affected with SCD, yet may account for the majority of ED visits and hospital admissions.

Barriers:	- Health providers in the ED may hold inaccurate beliefs about patients with SCD. Research shows that ED providers may suspect patients with SCD to be drug-seeking when they arrive in the ED.[5,6] - In fact, the rate of substance abuse in adults with SCD is similar to that in the community at large[7] - Inadequate care in SCD may be magnified by the **race and socioeconomic status** of patients experiencing VOC[8,9] - On average, African-American patients presenting to the ED with VOC waited **25%** longer than a general patient sample[8] - Most ED visits for SCD occur in EDs that see on average less than one person with SCD a day.[4]
Current National Efforts to Reduce Gaps:	- Centers for Disease Control and Prevention (CDC): Sickle Cell in the Emergency Department Resources located at https://www.cdc.gov/features/worldsicklecellday/index.html - http://www.scdcoalition.org - https://www.nhlbi.nih.gov/news/2016/nhlbi-awards-grants-help-improve-health-outcomes-teens-adults-sickle-cell-disease
Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to $50,000 will be considered. The total available budget related to this RFP is $300,000. 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:** January 29, 2018 **Proposals Due:** March 8, 2018 *Please note the deadline is midnight Eastern Time (New York, GMT -5).* **Anticipated Notification Date:** end of April 2018 **Kick-off Meeting:** June 4 or June 5, 2018 Grants distributed following execution of fully signed Letter of Agreement. Letter of Agreement must be signed before Kick-off Meeting. Period of Performance: June 1, 2018 – November 30, 2019

How to Submit:	*We are requesting that if you are interested in applying please notify us via email (rgay@acep.org) by February 5th. This will help us get a better understanding of how many requests we may receive. This is not a requirement. All complete proposals received by the deadline will be considered.*
	Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click "REGISTER NOW".
	Select the following Area of Interest: Acute VOC Crisis Pain in the ED
	Requirements for submission:
	Be advised the system is designed for a two-stage submission process: 1) Letter of Intent and 2) Full Proposal. However, for this RFP, we are not using a Letter of Intent. Instead, the only stage will be submission of the Full Proposal. Complete all required sections of the online application. In the "Required Uploads" section, please follow the table below

For field name	Please upload
Letter of Intent	Full Proposal
LOI Additional Uploads	Budget (https://www.cybergrants.com/pfizer/docs/BudgetTemplate2017.xls)

	See Appendix for details on requirements for the Full Proposal.
	IMPORTANT: 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 ACEP Grants Manager Riane Gay (rgay@acep.org) and Pfizer Grant Officer Amanda Stein (amanda.j.stein@pfizer.com), with the subject line "Improving Assessment and Treatment of Acute VOC Crisis Pain in the ED."
Mechanism by which Applicants will be Notified:	All applicants will be notified via email by the notification date indicated above in the key dates section.
	Applicants may be asked for additional clarification or to make a summary presentation during the review period.

References:

1. Glassberg JA. Improving Emergency Department-Based Care of Sickle Cell Pain. Hematology. American Society of Hematology. Education Program. Dec 8 2017;2017(1):412-417.
2. Platt OS, Thorington BD, Brambilla DJ, Milner PF, Rosse WF, Vichinsky E, et al. Pain in sickle cell disease. Rates and risk factors. *N Engl J Med*. 1991;325(1):11-6.
3. Gilboy N, Tanabe P, Travers DA, Rosenau AM. Emergency severity index (ESI): a triage tool for emergency department care, version 4. Implementation handbook 2012 edition. Rockville
(MD): Agency for Healthcare Research and Quality (US), 2011 Nov. (AHRQ Publication No.
12-0014).
4. Lanzkron S, Carroll CP, Haywood C. The Burden of Emergency Department Use for Sickle Cell Disease: An Analysis of the National Emergency Department Sample Database. *American journal of hematology*. 2010;85(10):797-799. doi:10.1002/ajh.21807.
5. Shapiro BS, Benjamin LJ, Payne R, Heidrich G. Sickle cell-related pain: perceptions of medical practitioners. J Pain Symptom Manage. 1997 Sep;14(3):168-74.
6. Waldrop RD, Mandry C. Health professional perceptions of opioid dependence among patients with pain. Am J Emerg Med. 1995 Sep;13(5):529-31.
7. Solomon, L. R. (2008). Treatment and prevention of pain due to vaso-occlusive crises in adults with sickle cell disease: an educational void. Blood, 111(3), 997-1003. Accessed January 10, 2018. https://doi.org/10.1182/blood-2007-07-089144
8. Haywood C, Tanabe P, Naik R, Beach MC, Lanzkron S. The Impact of Race and Disease on Sickle Cell Patient Wait Times in the Emergency Department. *The American journal of emergency medicine*. 2013;31(4):651-656. doi:10.1016/j.ajem.2012.11.005.

IV. Terms and Conditions

Please take note every Request for Proposal (RFP) released by Pfizer Independent Grants for Learning & Change (IGLC), as well as a RFP released jointly with a Partner(s), is governed by specific terms and conditions. Click **here** to review these terms and conditions.

<u>**Appendix: Proposal Submission Guidance**</u>

Proposals should be <u>single-spaced</u> using <u>Calibri 12-point font</u> and <u>1-inch margins</u>. Note there is a <u>15-page limit</u> in the main section of the proposal. ***Proposals not meeting these standards will not be reviewed.*** *It is helpful to include a header on each page listing the requesting organization.*

Proposal requirements will include the following sections:
A. **Cover Page** (do not exceed 1 page):
   1. ***Title***: *Please include the project title, Grant ID number and main collaborators.*
   2. ***Abstract****: Please include an abstract summary of your proposal including the overall goal, target population, methods and assessment. Please limit this to 250 words.*
B. **Table of Contents** (no page limit)
C. **Main Section of the proposal** (not to exceed 15 pages):
   1. ***Overall Goal & Objectives:*** *Describe the overall goal for this project. Describe how this goal aligns with the focus of the RFP, the goals of the applicant organizations and the proposed project. List the **key** objectives and how they are intended to address the established need for this project.*
   2. ***Current Assessment of need in target area***
        a. *Describe the need for this project in your target area. Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis if appropriate. Describe the need for your project in terms of "what is" versus "what should be".*
        b. *Please include quantitative baseline data summary, initial metrics (e.g., quality measures), or project starting point (please cite data on gap analyses or relevant patient-level data that describes the problem) 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.*
   3. ***Target Audience:*** *Describe the primary audience(s) targeted for this project.*
        a. *Describe the level of commitment from the potential participants including your plan for recruitment as necessary.*
        b. *Demonstrate how the scope of your target audience has a potential to impact the goal established in this proposal.*
        c. *Describe who will directly benefit from the project outcomes. Include in this description whom, beyond the primary target, would potentially benefit from the project in terms of this being a model for others to replicate or expand.*

4. ***Project Design and Methods:*** *Describe your project design and methods.*
    a. *Include a description of the overall strategy, methodology and analysis linking them to the goal of the project.*
    b. *Describe the way the project planned addresses the established need and produces the desired results.*
    c. *Indicate how you will determine if the target audience was fully engaged in the project.*
    d. *If your project includes the development of tools note if they be available publically at no cost.*

5. ***Innovation***
    a. *Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.*
    b. *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.*

6. ***Evaluation Design***
    a. *In terms of the metrics used to assess the need for this project, describe how you will determine if the practice gap was addressed for the target group.*
        - *Identify the sources of data that you anticipate using to make the determination.*
        - *Describe how you expect to collect and analyze the data.*
        - *Describe how you will determine if the results evaluated are directly related to the intervention described in this proposal*
    b. *Quantify the amount of change expected from this project in terms of your target audience (e.g., a 10% increase over baseline or a decrease in utilization from baseline between 20-40%)*
    c. *Describe how you plan for the project outcomes to be broadly disseminated.*
7. ***Detailed Workplan and Deliverables Schedule****: Include a narrative (which counts toward the15-page limit) describing the workplan and outlining how the project will be implemented over the 18 month period. Using a table format (no page limit), list the deliverables and a schedule for completion of each deliverable.*
D. **References (no page limit)**

E. **Organizational Detail** (not to exceed 3 pages)
   1. *Organizational Capability: Describe the attributes of the institution(s)/organization(s)/association(s) that will support and facilitate the execution of the project.*
   2. *Leadership and Staff Capacity: Include the name of the person(s) responsible for this project (PI/ project lead (PL) and/or project manager). The project manager, whether a current staff member or someone to be hired, is essential to the work outlined in your proposal. Demonstrate the PI/PL and project manager's availability, commitment, and capability to plan, implement, and evaluate the proposed project; describe how the project manager will oversee the project activities, including ensuring that tasks are accomplished as planned.*
      a. *List other key staff members proposed on the project (e.g., healthcare provider champion, medical advisor, statisticians, IT lead, etc.), if relevant, including their roles and expertise. Please list out key staff for each institution/organization/association the specific role that they will undertake to meet the goals of this project.*
      b. *When listing staff, please include staff first name, last name, professional credentials, and Country of Residence.*
      c. *NOTE Regarding Proposed Speakers: Pfizer shall not provide funding of CME when Pfizer has knowledge at the time of the decision to fund CME that a proposed CME faculty member has conducted a promotional speaking engagement on similar topic(s) on behalf of Pfizer in the past 12 months.*

F. **Detailed Budget** (Refer to/Complete **Budget Template**; no page limit for the Excel file or the narrative)**:**
   (**Budget Template:** https://www.cybergrants.com/pfizer/docs/BudgetTemplate2017.xls)
   1. *Upload a detailed budget, using the Excel template provided. Applicants are expected to customize the budget for their proposal, adding additional details and deliverables as appropriate.*
   2. *Provide **a written justification narrative** that contains a detailed explanation of each cost element proposed. Budget narratives should include a justification for all personnel, indicating the percentage of time allocated to the project. The budget should demonstrate appropriate and reasonable costs for project expenses.*
   3. *Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects. This must be included in the total requested amount which is capped at $50,000.*
      - *Institutional Overhead Costs: Costs to the institution for the support of your project. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance.*
   4. *Some examples of what awarded funds may **not** be used for are listed below:*
      1. *Office equipment (e.g., furniture, computers)*

2. *Registration and travel costs for professional development meetings or courses not related to this project*
3. *Health care subsidies for individuals*
4. *Construction or renovation of facilities*
5. *Therapeutic agents (prescription or non-prescription)*
6. *Food and/or beverages for learners and/or participants in any capacity*
7. *Lobbying*

5. Please note, the budget does <u>not</u> need to include travel expenses related to attending the Kick-off and Post-Project meetings. These expenses (airfare, hotel, etc) will be covered by ACEP.

G. **Staff Biosketches** (no page limit):

Applicants must provide brief biosketches of all individuals listed in section F in an appendix. NIH Bioschetches are an acceptable format but not required.

H. **Letter(s) of Commitment** (no page limit):

Letter(s) must be provided from all organizations listed in section F documenting their support and commitment to the project. Letters should be issued from an institutional authority or authorities and collaborators guaranteeing access, resources and personnel (as the case may be) for proposed project.

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 main section.

Please note the formatting and page limit for the Proposal. A submission exceeding the page limit **WILL BE REJECTED** *and* **RETURNED UNREVIEWED.**