Pfizer Independent Grants for Learning & Change
Request for Proposals (RFP)
Hemophilia PUP Registry

I. Background

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 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 full proposal 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.

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. Some RFPs may also be posted on the websites of other relevant organizations, as deemed appropriate.

II. Eligibility

Geographic Scope:	☑ United States Only
Applicant Eligibility Criteria:	The following may apply: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations; government agencies; and other 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_effJuly2015.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. For programs offering credit, the requesting organization must be the accredited grantee.

III. Requirements

Date RFP Issued:	April 6, 2018
Clinical Area:	Hemophilia
Specific Area of Interest for this RFP:	A patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. The use of registries in medical science offers the opportunity to fill in important gaps in knowledge about rare diseases.[1-3] Through this RFP, it is our intent to support the creation of a PUP (previously untreated patient) registry to measure quality of care in this specific hemophilia patient population. The Grantee would establish and maintain this registry. Extensions to existing Hemophilia registries will also be considered. *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:	Previously untreated hemophilia patients
Disease Burden Overview:	• Existing data collection efforts to describe outcomes such as major bleeding and inhibitor formation among PUPs are frequently hemophilia factor replacement product-specific and may suffer from resulting selection bias; are mostly external to the US; and/or lack rigor in certain assessments such as laboratory investigation.[4-7]
Recommendations and Target Metrics:	**Related Guidelines and Recommendations** • Gliklich R, Dreyer N, Leavy M, eds. Registries for Evaluating Patient Outcomes: A User's Guide. Third edition. Two volumes. (Prepared by the Outcome DEcIDE Center [Outcome Sciences, Inc., a Quintiles company] under Contract No. 290 2005 00351 TO7.) AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014. https://effectivehealthcare.ahrq.gov/topics/registries-guide-3rd-edition/research. • Srivastava A et al. Guidelines for the Management of Hemophilia (2nd edition). 2013; https://www.wfh.org/en/resources/wfh-treatment-guidelines (accessed March 15, 2018).[8]
Gaps Between Actual and Target, Possible Reasons for Gaps:	• Limited information is available on clinical outcomes among the hemophilia A and B previously untreated patient (PUP) population, especially in the United States.[4-7]

Barriers:	• Identifying newly diagnosed patients (PUPs)[1,9] • Recruiting and retaining participants in a registry[1] • Necessary technical infrastructure (e.g., electronic platform, user-accessible database) [1]
Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to $125,000 will be considered. The total available budget related to this RFP is $125,000. 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: April 6, 2018 Full Proposal Deadline: May 22, 2018 Please note the deadline is midnight Eastern Time (New York, GMT -5). Review of Full Proposals by External Review Panel: June 2018 Anticipated Full Proposal Notification Date: July 2018 Grants distributed following execution of fully signed Letter of Agreement Period of Performance: September 2018 to September 2020

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<td>How to Submit:</td>
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Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click “REGISTER NOW”.

Select the following Area of Interest: Hemophilia PUP Registry

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

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<tr><th>For field name</th><th>Please upload</th></tr>
<tr><td>Letter of Intent</td><td>Full Proposal (see application guidelines in Appendix)</td></tr>
<tr><td>LOI Additional Uploads</td><td>Complete budget template which is available at the following link: https://www.cybergrants.com/pfizer/docs/BudgetTemplate2017.xls</td></tr>
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See Appendix for details on requirements for the Full Proposal.

Given that this program is utilizing a one-stage submission process, please remember to consider the following when drafting your proposal:

• Consider carefully whether your proposal is aligned to the scope of the RFP. If your proposal is outside of scope of the RFP, it cannot be funded.
• Review your project design and methods. Are you adequately and appropriately explaining what you plan to do to an audience who may not be familiar with your previous work?
• Review your evaluation plan. Is your plan for evaluating the success of your project appropriate and valid?
• Ensure that your budget is comprehensive and fully itemized.

If you encounter any technical difficulties with the website, please click the “Need Support?” link at the bottom of the page.

IMPORTANT: Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.
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Questions:	If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Amanda Stein (amanda.j.stein@pfizer.com), with the subject line "Hemophilia PUP Registry."
Mechanism by which Applicants will be Notified:	All applicants will be notified via email by the dates noted above. Applicants may be asked for additional clarification or to make a summary presentation during the review period.

References:

1. Gliklich R, Dreyer N, Leavy M, eds. Registries for Evaluating Patient Outcomes: A User's Guide. Third edition. Two volumes. (Prepared by the Outcome DEcIDE Center [Outcome Sciences, Inc., a Quintiles company] under Contract No. 290 2005 00351 TO7.) AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014. https://effectivehealthcare.ahrq.gov/topics/registries-guide-3rd-edition/research
2. D'Agnolo HM, Kievit W, Andrade RJ, Karlsen TH, Wedemeyer H, Drenth JP. Creating an effective clinical registry for rare diseases. *United European Gastroenterology Journal*. 2016;4(3):333-338. doi:10.1177/2050640615618042.
3. Gliklich R, Dreyer N, Leavy M, eds. Registries for Evaluating Patient Outcomes: A User's Guide. Third edition. Two volumes. (Prepared by the Outcome DEcIDE Center [Outcome Sciences, Inc., a Quintiles company] under Contract No. 290 2005 00351 TO7.) AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014. http://www.effectivehealthcare.ahrq.gov/registries-guide-3.cfm.
4. Keipert C et al. Clinical trials and registries in haemophilia: Opponents or collaborators? Comparison of PUP data derived from different data sources. Haemophilia 2018; epub ahead of print.
5. Peyvandi F et al. A Randomized Trial of Factor VIII and Neutralizing Antibodies in Hemophilia A. N Engl J Med 2016;374:2054-64.
6. Fischer K et al. Prospective observational cohort studies for studying rare diseases: the European PedNet Haemophilia Registry. Haemophilia 2014;20:e280-e286.
7. Soucie JM, et al. National surveillance for hemophilia inhibitors in the United States: Summary report of an expert meeting. Am J Hematol 2015;89: 621–625.
8. Srivastava A et al. Guidelines for the Management of Hemophilia (2nd edition). 2013; https://www.wfh.org/en/resources/wfh-treatment-guidelines (accessed March 15, 2018).
9. Kessler CM, Ma AD, Al-Mondhiry HAB, Gut RZ, Cooper DL. Assessment of acquired hemophilia patient demographics in the United States: the Hemostasis and Thrombosis Research Society Registry. Blood Coagulation & Fibrinolysis. 2016;27(7):761-769. doi:10.1097/MBC.0000000000000582.

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.

Appendix: Full Proposal Submission Guidance

Proposals should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 15-page limit 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. 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 $125,000.*
    - *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:*
    - *Office equipment (e.g., furniture, computers)*
    - *Registration and travel costs for professional development meetings or courses not related to this project*
    - *Health care subsidies for individuals*
    - *Construction or renovation of facilities*

- *Therapeutic agents (prescription or non-prescription)*
- *Food and/or beverages for learners and/or participants in any capacity*
- *Lobbying*

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****.*