

# Pfizer Independent Grants for Learning & Change Request for Proposals (RFP)

## Haemophilia Early Arthropathy Detection with UltraSound (HEAD-US) Protocol for Routine Joint Assessment of Haemophilia Patients

### 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 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 IGLC website ([www.pfizer.com/independentgrants](http://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

<b>Geographic Scope:</b>	Western and Eastern Europe
<b>Applicant Eligibility Criteria:</b>	<p>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.</p> <p>More information on organizations eligible to apply directly for a grant can be found at <a href="http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf">http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf</a>.</p> <p>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.</p> <p>For programs offering credit, the requesting organization must be the accredited provider.</p>

### III. Requirements

<b>Date RFP Issued:</b>	Wednesday, June 8, 2016
<b>Clinical Area:</b>	Haemophilia
<b>Specific Area of Interest for this RFP:</b>	<p>It is our intent to support quality improvement projects that focus on identifying and addressing barriers to implementing the Haemophilia Early Arthropathy Detection with UltraSound (HEAD-US) protocol for routine joint assessment of haemophilia patients.</p> <p>Multi-disciplinary collaborations, are encouraged when appropriate, but all partners must have a relevant role.</p> <p>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.</p> <p>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 <a href="http://www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf">www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf</a>.</p> <p><i>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="http://www.Pfizer.com/iir">www.Pfizer.com/iir</a>.</i></p>
<b>Target Audience:</b>	Healthcare providers caring for Haemophilia patients that have been previously exposed to the HEAD-US training programme
<b>Disease Burden Overview:</b>	<p>Patients with severe haemophilia frequently experience spontaneous intra-articular haemorrhages, mainly in the ankles, knees and elbows. Over the long-term, repeated episodes of haemarthrosis may cause irreversible damage to the joint, leading to haemophilic arthropathy, a polyarticular disease characterized by joint stiffness, chronic pain and a severely limited range of motion.<sup>1</sup></p> <ul style="list-style-type: none"><li>• Around 50% of patients with haemophilia will develop a severe arthropathy.<sup>2</sup></li></ul>

<p><b>Recommendations and Target Metrics:</b></p>	<p><b>Related Guidelines and Recommendations</b></p> <ul style="list-style-type: none"> <li>• One of the major aims of haemophilia care is the prevention of damaging arthropathy and, given the high prevalence of this chronic complication in patients with haemophilia, a growing attention has been given to the inclusion of a periodic assessment of joint status in the frame of the comprehensive care of haemophilia <sup>3, 4, 5</sup> <ul style="list-style-type: none"> <li>○ A simplified ultrasound scanning procedure and scoring method, named Haemophilia Early Arthropathy Detection with UltraSound [HEAD-US], has been developed to evaluate joints of patients with haemophilic arthropathy <sup>6</sup></li> <li>○ It is proposed that in daily practice, the HEAD-US system would find its place as a supplement to physical examination assessment tools, such as the Haemophilia Joint Health Score (HJHS), in order to provide more objective assessment of findings and increase sensitivity in detecting joint abnormalities<sup>7</sup></li> </ul> </li> </ul>
<p><b>Gaps Between Actual and Target, Possible Reasons for Gaps:</b></p>	<p>Physical assessment of joint status often falls below the standards of due care. <sup>7</sup></p> <p>Early arthropathy might go unnoticed by haemophilic children and their parents. <sup>8</sup></p>
<p><b>Barriers:</b></p>	<p>It is important that the proposed project seeks to identify the particular barriers within the identified setting. A few example barriers to the use of Point of Care-US in haemophilia care include:</p> <ul style="list-style-type: none"> <li>• Lack of training, competency evaluation and certification in the use of this specific modality. <sup>9</sup></li> <li>• POC-US should be performed by ad-hoc trained personnel, as there is a possibility of negative outcomes if the modality is not properly applied.<sup>9</sup></li> <li>• Concerns regarding scope of practice for the health professional performing POC-US and the need for medical directives. <sup>9</sup></li> </ul>

<p><b>Expected Approximate Monetary Range of Grant Applications:</b></p>	<p>Individual projects requesting up to \$225,000 will be considered. The total available budget related to this RFP is \$450,000.</p> <p>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.</p>
<p><b>Key Dates:</b></p>	<p>RFP release date: June 8, 2016</p> <p>REVISED LOI due date: <b>August 2, 2016</b></p> <p><i>Please note the deadline is by end of day August 2, 2016.</i></p> <p>Review of LOIs by External Review Panel: week of September 5, 2016</p> <p>Anticipated LOI Notification Date: September 12, 2016</p> <p>Full Proposal Deadline: <b>October 14, 2016*</b></p> <p><i>*Only accepted LOIs will be invited to submit full proposals Please note the deadline is by end of day October 14, 2016.</i></p> <p>Review of Full Proposals by External Review Panel: week of November 7, 2016</p> <p>Anticipated Full Proposal Notification Date: week of December 5, 2016</p> <p>Grants distributed following execution of fully signed Letter of Agreement</p> <p>Period of Performance: January 2017 to December 2018</p>
<p><b>How to Submit:</b></p>	<p>Please go to the specific <a href="#">application log-in page</a> and sign in. First-time users should click "REGISTER NOW".</p> <p>Select the following Area of Interest: Implementation of HEAD-US Protocol- Europe</p> <p>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 grant management system, please click the "Need Support?" link at the bottom of the page.</p> <p><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.</p>

<b>Questions:</b>	If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Amanda Stein ( <a href="mailto:amanda.j.stein@pfizer.com">amanda.j.stein@pfizer.com</a> ), with the subject line “Implementation of HEAD-US Protocol for Routine Joint Assessment of Haemophilia Patients 6/8/16.”
<b>Mechanism by which Applicants will be Notified:</b>	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. Leslie, R. and Catherine, M. (2007), Modern management of haemophilic arthropathy. *British Journal of Haematology*, 136: 777–787. doi: 10.1111/j.1365-2141.2007.06490.x
2. Hemophilia, Musculoskeletal Complications by Ray F DECKilcoyne from [emedicine.com](http://emedicine.com). [Hemophilia, Musculoskeletal Complications](#)
3. COLVIN, B. T., ASTERMARK, J., FISCHER, K., GRINGERI, A., LASSILA, R., SCHRAMM, W., THOMAS, A., INGERSLEV, J. and FOR THE INTER DISCIPLINARY WORKING GROUP (2008), European principles of haemophilia care. *Haemophilia*, 14: 361–374. doi: 10.1111/j.1365-2516.2007.01625.
4. Di Minno, M. N. D., Iervolino, S., Soscia, E., Tosetto, A., Coppola, A., Schiavulli, M., ... & Di Minno, G. (2013). Magnetic resonance imaging and ultrasound evaluation of “healthy” joints in young subjects with severe haemophilia A. *Haemophilia*, 19(3), e167-e173.
5. MUÇA-PERJA, M., Riva, S., Grochowska, B., Mangiafico, L., Mago, D., & Gringeri, A. (2012). Ultrasonography of haemophilic arthropathy. *Haemophilia*, 18(3), 364-368.
6. Martinoli C, Della Casa Alberighi O, di Minno G, et al. Development and definition of a simplified scanning procedure and scoring method for Haemophilia Early Arthropathy Detection with Ultrasound (HEAD-US). *Thrombosis and Haemostasis*. 2013;109(6):1170-1179.
7. Martinoli, C., Di Minno, M. N. D., Pasta, G. and Tagliafico, A. (2016), Point-of-care ultrasound in haemophilic arthropathy: will the HEAD-US system supplement or replace physical examination?. *Haemophilia*, 22: 20–21. doi: 10.1111/hae.12840
8. Foppen, W., van der Schaaf, I. C. and Fischer, K. (2016), Value of routine ultrasound in detecting early joint changes in children with haemophilia using the ‘Haemophilia Early Arthropathy Detection with UltraSound’ protocol. *Haemophilia*, 22: 121–125. doi: 10.1111/hae.12769
9. Strike, K. L., Iorio, A., Jackson, S., Lawson, W., Scott, L., Squire, S., & Chan, A. K. (2015). Point of care ultrasonography in haemophilia care: recommendations for training and competency evaluation. *Haemophilia*, 21(6), 828-831.

#### **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.
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/IGLCsunshineFAQ\\_updatedJan2016.pdf](http://www.pfizer.com/files/IGLCsunshineFAQ_updatedJan2016.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 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 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. 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

1. 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 [Decision Matrix](#) posted on the [Tips & Templates](#) 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 [www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange\\_AFewPrinciples.pdf](http://www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf).
  - 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.
- 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.
- I. 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**.*