

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

Improving Patient Care in Inflammatory Bowel Disease (IBD) through Shared Decision-Making

I. Background

The American Gastroenterological Association Institute (AGA Institute) and the Crohn's & Colitis Foundation (Foundation) are initiating this Request for Proposal (RFP) for interventions that aim to improve shared decision-making and effective health communication between patients with inflammatory bowel disease (IBD) and their clinicians. This project is a multi-year endeavor being conducted in collaboration with Pfizer.

The AGA Institute, the Foundation, and Pfizer are not obligated to take any course of action as the result of this RFP. The AGA Institute, the Foundation, and Pfizer are not responsible for any costs incurred by any recipient company or other companies engaged by the recipient in its RFP response process. AGA Institute and the Foundation reserve the right to modify this RFP at any time and reserve the right to reject any and all responses to this RFP, in whole or in part, at any time.

About the American Gastroenterological Association

The American Gastroenterological Association is the trusted voice of the GI community. Founded in 1897, AGA has grown to include more than 16,000 members from around the globe who are involved in all aspects of the science, practice, and advancement of gastroenterology. AGA supports both researchers and clinicians in meaningful ways, supporting AGA's commitment To Advance the Science and Practice of Gastroenterology.

AGA, a 501(c)(6) organization, administers all membership and public policy activities, while the AGA Institute, a 501(c)(3) organization, runs the organization's practice, research, and educational programs, for both healthcare professionals and patients.

The AGA Institute publishes three highly respected journals, *Gastroenterology*, *Clinical Gastroenterology and Hepatology*, and *Cellular and Molecular Gastroenterology and Hepatology*.

The organization's annual meeting, Digestive Disease Week[®], held each May, is the largest international gathering of physicians, researchers, and academics in the fields of gastroenterology, hepatology, endoscopy, and gastrointestinal surgery.

AGA's educational programs engage professionals through multiple platforms that support all learning styles. Ranging from research protocols that help inform behavioral change to self-administered training modules, AGA's educational initiatives arm gastroenterologists and other members of the GI healthcare team with the tools needed to provide high-quality, efficient care.

About the Crohn's & Colitis Foundation

For 50 years, the Crohn's & Colitis Foundation (the Foundation) has led the way in research, education, support, and advocacy for the 1.6 million people living with Crohn's disease and ulcerative colitis,

otherwise known as inflammatory bowel diseases (IBD). The Foundation is the largest non-profit, voluntary, health organization dedicated to finding cures for IBD. The Foundation's mission is to cure Crohn's disease and ulcerative colitis and to improve the quality of life of children and adults who suffer from these diseases. The Foundation works to fulfill its mission by funding research; providing educational resources for patients and their families, medical professionals, and the public; and offering supportive services for those impacted by IBD.

About Pfizer's Global Medical Grants

The mission of Global Medical Grants (GMG) is to partner with the global health care 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 grant recipient organization. Pfizer has no influence over any aspect of the funded projects and asks only 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 (FP) 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.

II. Eligibility

Geographic Scope:	<input checked="" type="checkbox"/> United States Only <input type="checkbox"/> International
Applicant Eligibility Criteria:	<p>U.S. health care institutions, large and small; health care professional organizations and other organizations with a mission related to healthcare improvement; government agency partners with the capacity to reach patients with Inflammatory Bowel Disease.</p> <p>More information on organizations eligible to apply directly for a grant can be found at http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf.</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 grantee.</p>

III. Requirements

Date RFP Issued:	September 11, 2017
Clinical Area:	Inflammatory Bowel Disease (IBD)

Project Need:	<p>Shared decision-making is a process through which the clinician and patient engage in a dialogue to determine how best to manage a patient's course of treatment. As part of this process, the clinician explores with the patient the nature of the condition, facilitates comparisons around what options are available to manage it, helps the patient construct preferences about which option best fits their values and circumstances, and creates a plan with the patient around how to implement the chosen management strategy. These conversations are facilitated with trust and are often ongoing as the patient's life and disease-course change. To ensure success, it is often useful to include family or caregivers who can support the patient and help implement the chosen management strategy.</p> <p>This process has been advocated by the Institute of Medicine (now the National Academy of Medicine)ⁱ and recognized by legislators and clinical practice guidelinesⁱⁱ as a key component of patient-centered care. Despite the support of reputable organizations, evidence that it improves certain outcomes (such as patient knowledge, satisfaction, participation in decision-making, among others)ⁱⁱⁱ, and availability of existing shared decision-making tools for IBD (e.g. tools developed by BRIDGe Group and Emmi, as well as tools like IBDandMe), shared decision-making is not routinely implemented into practice. Barriers to implementation may include lack of awareness and/or access to existing tools, lack of time, lack of physician skills and training in shared-decision making, lack of patient interest or ability to participate in decision-making, and a lack of clarity around when shared decision-making is appropriate, in addition to the practical or operational challenges of implementing shared decision-making into busy clinical workflows.^{iv, v, vi, vii}</p> <p>To address the issue, and overcome potential barriers, the AGAI and the Foundation have issued an RFP to identify and/or establish best practices around shared decision-making that can be easily replicated, broadly disseminated, and widely adopted within the IBD community.</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 www.Pfizer.com/iir.</i></p>
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Areas of Exploration:

To assess current communication and shared decision-making practices, challenges, and opportunities between patients with IBD and their clinicians, the AGAI and the Foundation conducted a Harris Poll survey of 250 gastroenterologists who treat IBD and 250 patients with IBD. The survey highlighted several areas in which IBD patient/clinician communication can be improved. An executive summary outlining the survey results can be found at this link:

<http://www.crohnscolitisfoundation.org/science-and-professionals/research/pdfs/ibd-shared-decision-making-1.pdf>.

For the purposes of the RFP, applicants are encouraged to design programs or initiatives that explore or address gaps in communication identified by the survey, including:

1. Sex/intimacy
2. Mental health/coping with challenges of living with IBD
3. Other social issues and challenges related to IBD
4. Determining treatment options
5. Risk/benefit analyses of different treatment options, including effectiveness, potential side effects or harms, lifestyle factors, patient values and preferences, affordability, etc.

In addition to the above gaps, applicants are strongly encouraged to consider and explore one or more of the following issues and opportunities within their proposed project:

1. When is the optimal time to deliver shared decision-making interventions? (e.g. pre-visit vs. in-visit vs. post-visit vs. combination)
2. How active should clinicians be in shaping patient preferences?
3. How should shared decision-making education occur? (e.g. interventions targeting both patients and providers at the same time vs. those that focus solely on patients or solely on physicians)
4. How can shared decision-making protocols be better integrated into existing, busy clinical workflows to facilitate practical implementation?
5. Who should be involved in shared decision-making conversations? (e.g. physician vs. nurse, family or caregiver involvement)
6. How can shared decision-making be personalized and/or targeted? (e.g. consideration of risk prediction models, identifying where the patient is in their life and care with IBD [i.e., the patient journey], consideration of how interested and/or confident a patient is in becoming involved in the decision-making process, consideration of the patient's literacy level and numeracy level, etc.).
7. What policies, procedures, incentives, or interventions can be used to increase shared decision-making adoption rates among healthcare providers?
8. What incentives or interventions can be used to increase a patient's willingness or confidence to engage in shared decision-making?

<p>Specific Area of Interest:</p>	<p>Successful applications will address the areas identified in the survey and consider the issues highlighted above. Examples of possible projects include, but are not limited to:</p> <ol style="list-style-type: none"> 1. The creation of novel tools to facilitate shared decision-making conversations in IBD (<i>If developing a novel tool, preference will be given to tools that can easily fit into the clinical workflow, and that can potentially be used by all kinds of medical centers that see patients with IBD, including large academic institutions and community practices</i>) 2. Studies examining the implementation of existing tools, including examination of effectiveness, barriers to implementation, and strategies for widespread dissemination and implementation (within an institution and outside an institution), if appropriate 3. Studies comparing existing shared decision-making tools 4. Studies examining the effectiveness and implementation of shared decision-making training programs such as AHRQ’s SHARE approach^{viii} <p>Using an expert panel, the AGAI, the Foundation, and Pfizer will select two projects for funding by December 2017. Two projects will be fully funded from 2018 – 2019 in the amount of up to \$500,000 each, over two years.</p>
<p>Expected Approximate Monetary Range of Grant Applications:</p>	<p>Individual projects requesting up to \$500,000 will be considered. The total available budget related to this RFP is \$1M.</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>Key Dates:</p>	<p>RFP release date: September 11, 2017</p> <p>Submission due date: October 13, 2017 Please note the deadline is midnight Eastern Time (New York, GMT -5).</p> <p>Review of Full Proposals by External Review Panel: November 17, 2017</p> <p>Anticipated Notification Date: November 22, 2017</p> <p>Grants distributed following execution of fully signed Letter of Agreement</p> <p>Period of Performance: On or after January 1, 2018.</p>

<p>How to Submit:</p>	<p>Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click “REGISTER NOW”.</p> <p>Select the following Area of Interest: Improving Patient Care in IBD RFP</p> <p>Requirements for submission: Complete all required sections of the online application and upload the completed RFP template (see Appendix).</p> <p>Please 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:</p> <table border="1" data-bbox="516 701 1364 819"> <thead> <tr> <th>For Field Name:</th> <th>Please Upload:</th> </tr> </thead> <tbody> <tr> <td>Letter of Intent</td> <td>Full Proposal</td> </tr> <tr> <td>LOI Additional Required Uploads</td> <td>Budget</td> </tr> </tbody> </table> <p>If you encounter any technical difficulties with the website, please click the “Need Support?” link at the bottom of the page.</p> <p>IMPORTANT: Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.</p>	For Field Name:	Please Upload:	Letter of Intent	Full Proposal	LOI Additional Required Uploads	Budget
For Field Name:	Please Upload:						
Letter of Intent	Full Proposal						
LOI Additional Required Uploads	Budget						
<p>Questions:</p>	<p>If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Amanda Solis (amanda.solis@pfizer.com), with the subject line “Improving Patient Care in IBD RFP” or send an e-mail to Orna Ehrlich, Senior Director of Professional Education at the Crohn’s & Colitis Foundation at oehrlich@crohnscolitisfoundation.org.</p>						
<p>Mechanism by which Applicants will be Notified:</p>	<p>All applicants will be notified via email by the dates noted above.</p> <p>Applicants may be asked for additional clarification or to make a summary presentation during the review period.</p>						

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 must be single-spaced, using Calibri 12-point font and 1-inch margins. Note that the main section (section D, below) of the proposal has a 15-page limit and the organization detail (section F, below) has a 3-page limit. **Please limit the number of attachments uploaded in the system.** There is no reason to submit the organization detail (section F) as a separate document from the main section (section D) of the proposal. **All proposals must follow the outline detailed below.**

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. Reviewer Comments (not to exceed 1 page) *Please briefly describe how you addressed any review panel comments you were provided following their review of your letter of intent.*

D. 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 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. Include a description of the measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.
 - e. If appropriate, show how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.
 - f. If your project includes the development of tools note if they be available publically at no cost.

5. **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.

6. **Detailed Workplan and Deliverables Schedule:** Include a narrative (which counts toward the 15-page limit) describing the workplan and outlining how the project will be implemented over the X-year period. Using a table format (no page limit), list the deliverables and a schedule for completion of each deliverable.

E. **References (no page limit)**

1. **Organizational Detail** (not to exceed 3 pages) **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):
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 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.
 - *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 Biosketches 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.

Submission: Proposals should be submitted online via the Pfizer Independent Grants for Learning & Change website www.pfizer.com/independentgrants

Proposals should be single-spaced using Calibri 12-point font and 1-inch margins. Please adhere to the page limits listed for each section. There is no page limit for the reference section. Tables and Figures should be included in the main section of your proposal and do count to the page count. Only sample forms or other full page documents can be included as an appendix. Please consult with the Grant Officer before submitting such additional documents.

All required sections (aside from the budget) 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 full proposal. Budgets should be submitted in a separate excel file.

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 proposal.

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

References:

ⁱ Institute of Medicine. 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/10027>.

ⁱⁱ Spatz ES, Elwyn G, Moulton BW, Volk RJ, & Frosch DL. (June 2017). Shared decision-making as part of value-based care: New U.S. policies challenge our readiness. *Zeitschrift fur Evidenz, Fortbildung und Qualitat im Gesundheitswesen*, 124: 104-108. Doi: <https://doi.org/10.1016/j.zefq.2017.05.012>

ⁱⁱⁱ Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Thomson R, Trevena L. Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews* 2017, Issue 4. Art. No.: CD001431. DOI: 10.1002/14651858.CD001431.pub5

^{iv} Legare F & Thompson-Leduc P. (September 2014). Twelve myths about shared decision-making. *Patient Education and Counseling*, 96(3): 281-6. DOI: 10.1016/j.pec.2014.06.014

^v Legare F, Ratte S, Gravel K, & Graham ID. (December 2008) Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. *Patient Education and Counseling*, 73(3): 526-35. DOI: 10.1016/j.pec.2008.07.018

^{vi} Elwyn G, Scholl J, Tietbohl C, Mann M, Edwards AG, Clay C, Légaré F, van der Weijden T, Lewis CL, Wexler RM, Frosch DL. (2013). "Many miles to go ...": a systematic review of the implementation of patient decision support interventions into routine clinical practice. *BMC Medical Informatics and Decision-Making*, 13 (Suppl. 2): S14.

^{vii} Legare F., Witteman HO. (February 2013). Shared Decision Making: Examining Key Elements and Barriers To Adoption Into Routine Clinical Practice . *Health Affairs*, 32(2): 276-84. DOI: 10.1377/hlthaff.2012.1078

^{viii} Agency for Healthcare Research and Quality. (July 2014). *The SHARE Approach*. Retrieved from <https://www.ahrq.gov/professionals/education/curriculum-tools/shareddecisionmaking/index.html>