

Pfizer Independent Grants for Learning & Change
Request for Proposals (RFP)
Improving Vaccine Utilization and Preventive Health Maintenance in IBD

I. Background

The American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA), the Crohn's & Colitis Foundation (Foundation), and Pfizer are initiating a Request for Proposal (RFP) for interventions that aim to improve vaccine utilization, health maintenance and preventive care services in patients with inflammatory bowel disease (IBD).

About the American College of Gastroenterology

Founded in 1932, the American College of Gastroenterology (ACG) is an organization with an international membership of over 14,000 individuals from 85 countries. The College's vision is to be the pre-eminent professional organization that champions the evolving needs of clinicians in the delivery of high-quality, evidence-based and compassionate health care to gastroenterology patients. The mission of the College is to advance world-class care for patients with gastrointestinal disorders through excellence, innovation and advocacy in the areas of scientific investigation, education, prevention and treatment. For more information visit www.gi.org.

About the American Gastroenterological Association

The American Gastroenterological Association (AGA) is the trusted voice of the GI community. Founded in 1897, the AGA has grown to more than 16,000 members from around the globe who are involved in all aspects of the science, practice and advancement of gastroenterology. The AGA Institute administers the practice, research and educational programs of the organization. For more information visit www.gastro.org.

About the Crohn's & Colitis Foundation

The Crohn's & Colitis Foundation is the largest non-profit, voluntary, health organization dedicated to finding cures for inflammatory bowel diseases (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 are affected by 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 furnishing supportive services for those afflicted with IBD. For more information visit www.crohnscolitisfoundation.org.

About Pfizer Independent Grants for Learning and Change

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 (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. This RFP will follow a one-stage process (i.e. Full Grant Proposal). 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:	<p>U.S. health care institutions; health care professional organizations and other organizations with a mission related to healthcare improvement; government agency partners with the capacity to reach patients with IBD. 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:	July 23, 2018
Clinical Area:	Vaccine utilization and preventive health maintenance in patients with IBD.
Specific Area of Interest for this RFP:	<p>It is our intent to support projects that focus on the development and implementation of systems-based interventions to improve vaccination utilization and/or preventive health maintenance among patients with IBD. While the focus of this RFP is on vaccination, we recognize that preventive health maintenance in patients with IBD also includes screening for cervical cancer, skin cancer, and osteoporosis; identification of depression and anxiety; smoking cessation; and maximizing communication between GI providers and primary care providers.</p> <p>It is expected that projects will be evidence-based and the proposed research will follow generally accepted scientific principles. During review, the intended outcome(s) of the project are given careful consideration and, if appropriate based on the project goal, projects with the maximum likelihood to directly impact patient care will be given highest priority. Projects including an educational element can find more information on principals of learning and behavior change for health professionals at www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf.</p> <p>Multi-disciplinary collaborations are encouraged when appropriate, but all partners must have a relevant role.</p>
Target Audience:	The target population comprises patients of all ages who have been diagnosed with IBD.
Disease Burden Overview:	IBD is a complex disease affecting approximately 1.6 million Americans with an annual financial burden of approximately \$31 billion. ^{1,2} There are rapidly expanding effective medical treatment options, but these treatments can lead to immune suppression and may have side effects that impact overall health. In addition, recent studies suggest that patients with IBD have lower rates of receiving preventive health services compared to general medical patients. ³ Thus, there is an important need to maximize vaccine utilization and preventive health maintenance in this population of patients.
Recommendations and Target Metrics:	<p><u>Related Guidelines and Recommendations</u></p> <p>In 2017, the American College of Gastroenterology (ACG) released guidelines for health maintenance in patients with IBD (http://gi.org/wp-content/uploads/2017/02/ACGIBDPreventiveCareGuideline2017.pdf). A key area of focus was administration of vaccinations. The ACG guidelines suggest that all patients with IBD receive influenza vaccination annually. Patients with IBD, regardless of immunosuppression status, can receive non-live vaccines, though there</p>

are exceptions for patients on low level immunosuppression. Among patients with IBD who are older than 50 years of age, the guidelines recommend administration of vaccination against varicella zoster. Adolescent patients with IBD should receive meningococcal vaccine. The guidelines address administration of other vaccines including Tetanus, diphtheria, and pertussis (Tdap), Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), and Human Papilloma Virus (HPV), which should be administered as outlined by the Advisory Committee on Immunization Practice. The ACG guideline panel suggested administering age-appropriate vaccinations before initiating immunosuppressive therapy, when possible.

The guidelines addressed other aspects of health maintenance including:

1. Cervical cancer screening in immunosuppressed women with IBD.
2. Screening for depression and anxiety in patients with IBD.
3. Screening for melanoma and non-melanoma skin cancers.
4. Screening for osteoporosis.
5. Counseling smoking cessation in Crohn's disease.

The American Gastroenterological Association has developed an IBD performance measurement set (<https://www.gastro.org/practice-guidance/quality-and-performance-measures>), which has been used for physician accountability and financial incentives. This measure set includes metrics for health maintenance that includes:

1. Corticosteroid related Iatrogenic injury – bone loss assessment.
2. Assessment of Hepatitis B virus (HBV) status before initiating Anti-TNF (Tumor Necrosis Factor) therapy.

Additionally, there are measures for colorectal cancer screening and surveillance.

The Crohn's & Colitis Foundation has also developed a Health Maintenance Checklist (<http://www.crohnscolitisfoundation.org/science-and-professionals/programs-materials/health-maintenance-checklist.pdf>).

The checklist includes:

1. Whether a patient with IBD who is on immunosuppressive therapy has been educated about appropriate vaccinations, including (1) annual inactivated influenza, (2) pneumococcal vaccination with a 5-year booster, and (3) general avoidance of live virus vaccines.
2. Cancer prevention.
3. DEXA scan.

	<ol style="list-style-type: none"> 4. PPD or IGRA. 5. Smoking status. 6. Depression check.
<p>Gaps Between Actual and Target, Possible Reasons for Gaps:</p>	<p>Vaccination Utilization: The safety of vaccinations for patients with IBD, as well as the efficacy of vaccinations, as studies have confirmed, decreased immunogenicity of vaccines in patients on immunosuppressive therapy.⁴ There is also a lack of communication on the topic of vaccinations between the GI provider, primary care provider, and the patient resulting in incomplete completion of appropriate vaccinations.⁵ Increased provider and patient education surrounding vaccination recommendations of patients with IBD is needed, as well as interventions to confirm administration of vaccines. This is the focus of the RFP.</p> <p>Additional preventive health maintenance considerations:</p> <p>Cervical dysplasia and cancer: Current recommendations for screening women with IBD are based on medication history and vary amongst providers.⁵ There is a need for additional research and education regarding HPV vaccination, screening for cervical cancer, and immunosuppression adjustment in patients who develop cervical cancer.</p> <p>Skin cancer: There is an increased risk of skin cancer in patients with IBD, especially those treated with thiopurines and anti-TNF agents and, for non-melanoma skin cancer, for those treated with tofacitinib.^{6,7} However, there is variability amongst practitioners in how this increased risk is managed. There is a need for enhanced education regarding skin cancer screening and for additional research and education regarding immunosuppression adjustment in patients who develop skin cancer.</p> <p>Depression: Anxiety and depression are prevalent amongst patients with IBD.^{5,8} Depression is associated with higher medical costs, as well as worse disease activity and patient outcomes. Patients have reported that they have to initiate psychosocial conversations with their providers, and mental health resources are lacking.^{9,10} Patients with IBD should be routinely screened for anxiety and depression by health care providers. Resources and support services should be provided for patients.</p> <p>Osteoporosis: Patients with IBD are at increased risk for osteoporosis due to poor calcium and vitamin D absorption and steroid use.¹¹ No large studies have been conducted that would otherwise change recommendations or management since the release of current guidelines. There is a need for additional research and education regarding screening and surveillance recommendations.</p>

	<p>Patient-Centered Concerns: There is often poor communication between GI providers and primary care providers in regards to managing disease, duration of medications, medication-related side effects, and preventive health maintenance.^{12,13} There is a need for education and increased communication amongst providers and with patients, including shared decision making, answering vaccination-related questions, and ensuring accommodations and supports to succeed in work and school.</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: July 23, 2018</p> <p>Submission due date: September 7, 2018</p> <p>Please note the deadline is midnight Eastern Daylight Time (New York, GMT -5).</p> <p>Review of full proposals by external review panel: October 2018</p> <p>Anticipated notification date: October 22, 2018</p> <p>Grants distributed following execution of fully signed Letter of Agreement.</p> <p>Period of performance: On or after January 1, 2019</p>

<p>How to Apply:</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: IBD-Vaccine Utilization/ Preventive Health Maintenance</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.</p> <p>Complete all required sections of the online application. In the “Required Uploads” section, please upload, as per below:</p> <ul style="list-style-type: none"> • "Letter of Intent" field: Upload full proposal. • "LOI Additional Required Uploads" field: Upload budget. <p>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.</p>
<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 Vaccine Utilization and Preventive Health Maintenance in IBD RFP” or send an e-mail to Orna Ehrlich, Senior Director of Professional Education & Innovative Programs, 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

Full proposals should be single-spaced using Calibri 12-point font and 1-inch margins. Note that the main section (section C, below) of the proposal has a 15-page limit and the organization detail (within section D, 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 D) as a separate document from the main section (section C) of the proposal. All proposals must follow the outline detailed below.

Proposals must 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 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 planned project 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 publicly 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 2-year period. Using a table format (no page limit), list the deliverables and a schedule for completion of each deliverable.

D. References (no page limit)

1. Organizational Detail and Capability (not to exceed 3 pages): 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., health care 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 and 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.

E. 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

F. **Staff Biosketches** (no page limit): Applicants must provide brief biosketches of all individuals listed in section E in an appendix. NIH Biosketches are an acceptable format, but not required.

G. **Letter(s) of Commitment** (no page limit): Letter(s) must be provided from all organizations listed in section E 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 towards 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

1. Kappelman MD, Rifas-Shiman SL, Porter CQ, et al. Direct health care costs of Crohn's disease and ulcerative colitis in US children and adults. *Gastroenterology* 2008;135:1907-13.
2. Shivashankar R, Tremaine WJ, Harmsen WS, et al. Incidence and prevalence of Crohn's disease and ulcerative colitis in Olmsted County, Minnesota from 1970 through 2010. *Clin Gastroenterol Hepatol* 2017; 15: 857-863

3. Selby L, Kane S, Wilson J et al. Receipt of preventive health services by IBD patients is significantly lower than by primary care patients . *Inflamm Bowel Dis* 2008 ; 14 : 253 – 8.
4. Nguyen DL, Nguyen ET, Bechtold ML. Effect of immunosuppressive therapies for the treatment of inflammatory bowel disease on response to routine vaccinations: a meta-analysis . *Dig Dis Sci* 2015 ; 60 : 2446 – 53.
5. Farraye FA, Melmed GY , Lichtenstein GR et al. ACG Clinical Guideline: Preventive Care in Inflammatory Bowel Disease. *Am J Gastroenterol* 2017; 112:241–258.
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7. Long MD, Martin CF, Pipkin CA et al. Risk of melanoma and nonmelanoma skin cancer among patients with inflammatory bowel disease.*Gastroenterology*. 2012 Aug;143(2):390-399.e1.
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9. Marín-Jiménez I, Montoya MG, Panadero A, et al. Management of the Psychological Impact of Inflammatory Bowel Disease: Perspective of Doctors and Patients- The ENMENTE Project. *Inflamm Bowel Dis* 2017;23:1492–1498.
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11. Ali T, Lam D, Bronze MS et al. Osteoporosis in inflammatory bowel disease. *Am J Med*. 2009 Jul;122(7):599-604.
12. Melmed GY. Immunizations and IBD: Whose responsibility is it? If I'm the prescribing doctor, shouldn't it be mine? *Inflamm Bowel Dis* 2012 ; 18 : 41 –2.
13. Farraye FA , Melmed GY , Lichtenstein GR, et al. ACG Clinical Guideline: Preventive Care in Inflammatory Bowel Disease. *Am J Gastroenterol* 2017; 112:241–258.