Pfizer Independent Grants for Learning & Change
Request for Proposals (RFP)
Patient Decision Aids for Inflammatory Conditions

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 letter 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.

Areas of expertise for development

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 and Canada
Applicant Eligibility Criteria:	The following may apply: medical, 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. The External Review Panel will assess each applicant's prior experience in developing Patient Decision Aids (PDAs) and will use the criteria set by the International Patient Decision Aid Standards (IPDAS) in order to guide their decisions. Please refer to Appendix 1 for more information on these criteria. More information on organizations eligible to apply directly for a grant can be found at http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf. For programs offering continuing education credit in any component, the requesting organization must be the accredited grantee.

III. Requirements

Date RFP Issued:	January 29, 2018
Clinical Areas:	Inflammation & Immunology (Ulcerative Colitis, Rheumatoid Arthritis, Atopic Dermatitis, and Psoriatic Arthritis)
Specific Area of Interest for this RFP:	Frustration and dissatisfaction exists amongst some patients because they do not feel like they have input in decisions their healthcare providers make about their treatment plan. Shared decision-making is a model of patient-centered care, which enables and encourages patients to participate in medical decisions pertaining to their health.[1] Patient Decision Aids (PDAs) support and empower patients in shared decision-making with their physicians. The PDA makes clear the decision that needs to be made, provides information about options and outcomes based on evidence based medical literature, and clarifies and incorporates patient personal values into their treatment decisions. Patient Decision Aids are meant to complement, rather than replace, counseling from a health practitioner.[2] It is our intent to support projects that focus on the development of a PDA for several therapeutic areas, including: ulcerative colitis (UC), psoriatic arthritis (PsA), Atopic Dermatitis (AD, and rheumatoid arthritis (RA) for patients to be used when being treated by specialists or other primary care healthcare providers. It is expected that projects will be evidence-based, the proposed evaluation will follow generally accepted scientific principles and the patient decision aid will be designed according to the 2005 International Patient Decision Aids Standards (IPDAS) Collaboration checklist criteria for judging the quality of patient decision aids. 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. When developing the proposal, please consider including details on the organization's past experience in developing PDAs, specifically: 1) Which therapeutic area/disease state? 2) Was the material targeted to patients or HCPs? 3) Was the IPDAS criteria utilized to develop the material? 4) Key take-away and learnings from developing PDA materials Additionally, it is anticipated that proposals will include information on how the material will be updated and kept relevant according to national guidelines and evidence-based literature. 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.

	It is NOT our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered. Information on how to submit requests for support of clinical research projects can be found at www.Pfizer.com/iir.
Target Audience:	Rheumatologists, Gastroenterologists, Dermatologists, and/or Primary Care healthcare providers and the team caring for patients with or at risk for these conditions.
Related Guidelines and Recommendations	**Related Guidelines and Recommendations** **Patient Decision Aids** International Patient Decision Aid Standards (IPDAS) Collaboration Glyn Elwyn, Annette O'Connor, Dawn Stacey et al. on behalf of the International Patient Decision Aids Standards (IPDAS) Collaboration. *Developing a quality criteria framework for patient decision aids: online international Delphi consensus process.* British Medical Journal. 2006 Aug 26;333(7565):417. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1553508/pdf/bmj3330041 7.pdf IPDAS http://ipdas.ohri.ca/index.html **Rheumatoid Arthritis:** American College of Rheumatology (ACR) Singh, J. A., Saag, K. G., Bridges, et al. (2016), 2015 American College of Rheumatology. *Guidelines for the Treatment of Rheumatoid Arthritis.* Arthritis Care & Research, 68: 1–25. https://www.rheumatology.org/Portals/0/Files/ACR%202015%20RA%20Gui deline.pdf European League Against Rheumatism (EULAR) Smolen JS, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. Ann Rheum Dis 2017;0:1–18. http://ard.bmj.com/content/annrheumdis/early/2017/03/17/annrheumdis-2016-210715.full.pdf **Gastroenterology:** American College of Gastroenterology (ACG)

	Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters Committe Am J Gastroenterol 2010; 105:501–523 http://www.nature.com/ajg/journal/v105/n3/pdf/ajg2009727a.pdf American Gastroenterologic Association (AGA) *American Gastroenterological Association Institute Guideline on the Medical Management of Microscopic Colitis* Gastroenterology. American Gastroenterological Association Institute Guideline on the Medical Management of Microscopic Colitis 2016; 150;1:242-246 http://ac.els-cdn.com/S001650851501625X/1-s2.0-S001650851501625X-main.pdf?_tid=dc7d552a-628a-11e7-b7af-00000aacb35f&acdnat=1499373600_ac14e063311bca874f20f200881493c3 Crohn's and Colitis Foundation of America (CCFA) *Variation in Care of Inflammatory Bowel Diseases Patients in Crohn's and Colitis Foundation of America Partners: Role of Gastroenterologist Practice Setting in Disease Outcomes and Quality Process Measures* Inflamm Bowel Dis 2016;22:2672–2677 http://journals.lww.com/ibdjournal/fulltext/2016/11000/Variation_in_Care_of_Inflammatory_Bowel_Diseases.13.aspx **Psoriatic Arthritis** European League Against Rheumatism (EULAR) Gossec L, Smolen J, Ramiro S, et al. *European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies.*2015 update. Ann Rheum Dis 2015;0:1–12. http://ard.bmj.com/content/early/2015/12/07/annrheumdis-2015-208337 American Academy of Dermatology (AAD) Gottlieb, A, Korman, N Gordon,K, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. J Am Acad Dermatol 2008;58:851-64 https://www.aad.org/File%20Library/.../Guidelines-psoriasis-sec-2.pdf Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) GRAPPA 2015: Coates LC, Kavanaugh A, Mease PJ, et al. *Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 treatment*

	recommendations for psoriatic arthritis. Arthritis Rheumatol. 2016;68(5):1060-1071. http://onlinelibrary.wiley.com/doi/10.1002/art.39573/pdf American College of Rheumatology/National Psoriasis Foundation Guideline for the Management of Psoriatic Arthritis final publication anticipated in 2018. Documents related to this guideline: https://www.rheumatology.org/Portals/0/Files/ACR-NPF%20Psoriatic%20Arthritis%20Guideline%20Project%20Plan.pdf **Atopic Dermatitis** American Academy of Dermatology (AAD) Eichenfield L, Tom W, Chamlin S, et al. *Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and assessment of atopic dermatitis* Journal of the American Academy of Dermatology, Volume 70, Issue 2, 2014, pp. 338-351 http://www.sciencedirect.com/science/article/pii/S0190962213010955 Eichenfield L, Tom W, Chamlin S, et al. *Guidelines of care for the management of atopic dermatitis. Section 2 Management and treatment of atopic dermatitis with topical therapies*. J Am Acad Dermatol. 2014 Feb;70(2):338-51. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4326095/ Sidbury, R et al. *Guidelines of care for the management of atopic dermatitis: Section 3. Management and treatment with phototherapy and systemic agents."* Journal of the American Academy of Dermatology 71(2) 2014: 327-349. http://www.sciencedirect.com/science/article/pii/S019096221401264X Sidbury, R, et al. *Guidelines of care for the management of atopic dermatitis: Section 4. Prevention of disease flares and use of adjunctive therapies and approaches*. Journal of the American Academy of Dermatology 2014.71(6): 1218-1233. http://www.sciencedirect.com/science/article/pii/S0190962214018878 American Academy of Allergy, Asthma & Immunology (AAAAI) Schneider L, Tilles S, Lio P, et al. *Atopic dermatitis: A practice parameter update 2012*. J ALLERGY CLIN. 2013. 131(2):295-299. https://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/Atopic-dermatitis-2013.pdf

Gaps Between Actual and Target, Possible Reasons for Gaps:	It has been recognized that patient outcomes are improved when patients are involved with their healthcare with informed choices and autonomy.[3] However, patients are often forced to make decisions between many complex medications with incomplete knowledge of both risks and benefits of each therapy.[4] Additionally, studies have shown that patients were dissatisfied with explanations of their condition and information they received during consultations. Discussions of the patient's condition occurred in less than 25% of consultations.[5] Informing patients and involving them in decisions is a healthcare provider's (HCP) responsibility. Despite increased recognition of its importance, it has been documented that informed and shared decision making rarely occurs in practice.[1,6]
Barriers:	Studies have shown perceived barriers to shared decision making include not enough evidence showing that patient choice is effective, negative attitudes by HCPs towards shared decision-making, resource constraints, time constraints and a lack of proper training to communicate effectively when discussing shared decision-making with patients.[5]
Current National Efforts to Reduce Gaps:	The concept of patient-centered care was introduced by the Institute of Medicine (IOM) report *Crossing the Quality Chasm*[7] as the core approach to improving the quality of U.S. health care. This document defined patient-centered care as "care that is respectful of and responsive to individual patient preferences, needs, and values" and ensures "that patient values guide all clinical decisions." There is clear emphasis on the importance of clinicians and patients working together to produce the best outcomes possible.[8] The Agency for Healthcare Research and Quality (AHRQ) is advancing patient-centered care through its Consumer Assessment of Healthcare Providers and Systems (CAHPS®) program by providing surveys and information to help patients make better health care decisions. One component of the CAHPS program is to provide strategies for improving the patient experience. Shared Decision-Making using evidenced-based PDAs is one of listed tools to help improve the quality of treatment decisions.[9] There is also legislation in the Affordable Care Act that requires practitioners to comply to the implementation of shared decision making and use of PDAs with patients: -Washington State Legislature Health Care bill SB 5930 - 2007-08. -United States Government Patient Protection and Affordable Care Act. 2010.

	Finally, international standards for the development of PDAs were created to provide guidance for developers as well as users in order to enhance the quality and effectiveness of PDAs. These standards established a shared evidence-informed framework with a set of criteria for improving content, development, implementation, and evaluation of PDAs.[10]
Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to $350,000 will be considered. The total available budget related to this RFP is $1,000,000. The amount of the grant Pfizer will be prepared to fund for any project will depend upon the external review panel's evaluation of the proposal and costs involved, and will be stated clearly in the approval notification.
Key Dates:	RFP release date: January 29, 2018 LOI due date: March 9, 2018 Please note the deadline is midnight Eastern Time (New York, GMT -5). Review of LOIs by External Review Panel: Early April 2018 Anticipated LOI Notification Date: April 20, 2018* Full Proposal Deadline: May 28, 2018 *Only accepted LOIs will be invited to submit full proposals Please note the deadline is midnight Eastern Time (New York, GMT -5). Review of Full Proposals by External Review Panel: Early June 2018 Anticipated Full Proposal Notification Date: June 29, 2018 Grants distributed following execution of fully signed Letter of Agreement Period of Performance: On or after August 1, 2018
How to Submit:	Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click "REGISTER NOW". Select the following Area of Interest: Patient Decision Aids Inflammatory Conditions 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 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.

Questions:	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 "Patient Decision Aids Inflammatory Conditions."
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. Agency for Healthcare Research and Quality (AHRQ). Shared Decision-Making.2015. U.S. Department of Health and Human Services. https://www.ahrq.gov/cahps/quality-improvement/improvement-guide/6-strategies-for-improving/communication/strategy6i-shared-decisionmaking.html. Accessed 7-11-2017
2. Ottawa Hospital Research Institute: Patient Decision Aids. 2015. https://decisionaid.ohri.ca/index.html Accessed 7-11-2017
3. Greenfield S, Kaplan S, Ware JE Jr. Expanding patient involvement in care. Effects on patient outcomes. Ann Intern Med 1985;102(4):520-8.
4. Martin R, Enck R, Tellinghuisen D et al. Comparison of the Effects of a Pharmaceutical Industry Decision Guide and Decision Aids on Patient Choice to Intensify Therapy in Rheumatoid Arthritis. Med Decis Making. 2017. 37(5):577-588
5. Elwyn G, Edwards A, Kinnersley P. Shared decision-making in primary care: the neglected second half of the consultation. British Journal of General Practice, 1999; 49: 477–482.
6. Towle, A., Godolphin, W., Grams, G. and LaMarre, A. (2006), Putting informed and shared decision making into practice. Health Expectations, 9: 321–332. doi:10.1111/j.1369-7625.2006.00404.x
7. National Research Council. Crossing the quality chasm: a new health system for the 21st century. Washington, DC: National Academies Press, 2001.
8. Barry MJ, Edgman-Levitan S. Shared decision making--pinnacle of patient-centered care. N Engl J Med 2012;366(9):780-1.
9. Agency for Healthcare Research and Quality (AHRQ). The CAHPS Ambulatory Care Improvement Guide: Practical Strategies for Improving Patient Experience. 2017. U.S. Department of Health and Human Services. https://www.ahrq.gov/cahps/quality-improvement/improvement-guide/improvement-guide.html Accessed 7-11-2017
10. Elwyn G, O'Connor A, Stacey D et al. On behalf of the International Patient Decision Aids Standards (IPDAS) Collaboration. Developing a quality criteria framework for patient decision aids: online international Delphi

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 ensure compliance with applicable local law, Pfizer may publicly disclose the support it provides. Pfizer may disclose in any lawful manner the terms of the letter of agreement, the support or funding that Pfizer is providing under the letter of agreement, and any other related information, to the extent necessary for Pfizer to meet its obligations under those laws, regulations and industry codes that require Pfizer to report payments or other transfers of value to certain healthcare professionals and teaching hospitals (collectively, the "Transparency Laws"). Transparency Laws include, without limitation, section 6002 of the U.S. Affordable Care Act and the EFPIA Code on Disclosure of Transfers of Value. Disclosures may include identifying information for organizations and U.S. physicians, such as name, business address, specialty, National Provider Identifier (NPI), and licensure numbers. Grantee will agree to (and will cause other agents, employees and contractors to) reasonably cooperate with Pfizer in Pfizer's collection and disclosure of information to fulfill its Transparency Law obligations. Grantee will provide Pfizer with complete and accurate information about payments or other transfers of value reportable under Transparency Laws.

   Frequently Asked Questions related to IGLC's Sunshine Act Reporting Requirements are available on our website (http://www.pfizer.com/files/IGLCsunshineFAQ_updatedJan2016.pdf).

7. No portion of an independent grant may be used for food and/or beverages for learners and/or participants in any capacity. Grantee 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 Grantee 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 1: International Patient Decision Aid Standard (IPDAS) Collaboration

Table 3. IPDAS Patient Decision Aid Checklist for Users

I. Content: Does the patient decision aid ...

Provide information about options in sufficient detail for decision making?

- ☐ describe the health condition 2.1
- ☐ list the options 2.2
- ☐ list the option of doing nothing 2.3
- ☐ describe the natural course without options 2.4
- ☐ describe procedures 2.5
- ☐ describe positive features [benefits] 2.6
- ☐ describe negative features of options [harms / side effects / disadvantages] 2.7
- ☐ include chances of positive / negative outcomes 2.8

Additional items for tests

- ☐ describe what test is designed to measure 2.9
- ☐ include chances of true positive, true negative, false positive, false negative test results 2.10
- ☐ describe possible next steps based on test result 2.11
- ☐ include chances the disease is found with / without screening 2.12
- ☐ describe detection / treatment that would never have caused problems if one was not screened 2.13

Present probabilities of outcomes in an unbiased and understandable way?

- ☐ use event rates specifying the population and time period 3.1
- ☐ compare outcome probabilities using the same denominator, time period, scale 3.2, 3.3, 3.6
- ☐ describe uncertainty around probabilities 3.4
- ☐ use visual diagrams 3.5
- ☐ use multiple methods to view probabilities [words, numbers, diagrams] 3.7
- ☐ allows the patient to select a way of viewing probabilities [words, numbers, diagrams] 3.8
- ☐ allow patient to view probabilities based on their own situation [e.g. age] 3.9
- ☐ place probabilities in context of other events 3.10
- ☐ use both positive and negative frames [e.g. showing both survival and death rates] 3.13

Include methods for clarifying and expressing patients' values?

- ☐ describe the procedures and outcomes to help patients imagine what it is like to experience their physical, emotional, social effects 4.1
- ☐ ask patients to consider which positive and negative features matter most 4.2
- ☐ suggest ways for patients to share what matters most with others 4.3

Include structured guidance in deliberation and communication?

- ☐ provide steps to make a decision 6.1
- ☐ suggest ways to talk about the decision with a health professional 6.2
- ☐ include tools [worksheet, question list] to discuss options with others 6.3

II. Development Process: Does the patient decision aid ...

Present information in a balanced manner?

- ☐ able to compare positive / negative features of options 9.1
- ☐ shows negative / positive features with equal detail [fonts, order, display of statistics] 9.2

Have a systematic development process?

- ☐ includes developers' credentials / qualifications 1.1
- ☐ finds out what users [patients, practitioners] need to discuss options 1.2, 1.3
- ☐ has peer review by patient / professional experts not involved in development and field testing 1.8a, 1.8b
- ☐ is field tested with users [patients facing the decision; practitioners presenting options] 1.4, 1.5

The field tests with users [patients, practitioners] show the patient decision aid is:

- ☐ acceptable 1.6, 1.7
- ☐ balanced for undecided patients 9.3
- ☐ understood by those with limited reading skills 10.6

Use up to date scientific evidence that is cited in a reference section or technical document?

- ☐ provides references to evidence used 11.1
- ☐ report steps to find, appraise, summarise evidence 11.2
- ☐ report date of last update 11.3
- ☐ report how often patient decision aid is updated 11.4
- ☐ describe quality of scientific evidence [including lack of evidence] 11.5a, 11.5b
- ☐ uses evidence from studies of patients similar to those of target audience 11.6

Disclose conflicts of interest?

- ☐ report source of funding to develop and distribute the patient decision aid 7.1, 7.2
- ☐ report whether authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aid 7.3, 7.4

Use plain language?

- ☐ is written at a level that can be understood by the majority of patients in the target group 10.3
- ☐ is written at a grade 8 equivalent level or less according to readability score [SMOG or FRY] 10.4
- ☐ provides ways to help patients understand information other than reading [audio, video, in-person discussion] 10.5

Meet additional criteria if the patient decision aid is Internet based

- ☐ provide a step-by-step way to move through the web pages 8.1
- ☐ allow patients to search for key words 8.2
- ☐ provide feedback on personal health information that is entered into the patient decision aid 8.3
- ☐ provides security for personal health information entered into the decision aid 8.4
- ☐ make it easy for patients to return to the decision aid after linking to other web pages 8.5
- ☐ permit printing as a single document 8.6

Meet additional criteria if stories are used in the patient decision aid

- ☐ use stories that represent a range of positive and negative experiences 5.2
- ☐ reports if there was a financial or other reason why patients decided to share their story 7.5
- ☐ state in an accessible document that the patient gave informed consent to use their stories 5.5

III. Effectiveness: Does the patient decision aid ensure decision making is informed and values based?

Decision processes leading to decision quality. The patient decision aid helps patients to ...

- ☐ recognise a decision needs to be made 12.1
- ☐ know options and their features 12.2, 12.3
- ☐ understand that values affect decision 12.4
- ☐ be clear about option features that matter most 12.5
- ☐ discuss values with their practitioner 12.6
- ☐ become involved in preferred ways 12.7

Decision quality. The patient decision aid ...

- ☐ improves the match between the chosen option and the features that matter most to the informed patient 12.8

Appendix 2: 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 (specifically, term #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.
        - 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. The RFP includes a national assessment of the need for the project. Please do not repeat this information within the LOI (you may reference the RFP, if necessary). Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis, if appropriate.

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****.*