Independent Grants for Learning & Change (IGLC)
Track 2 - Call for Grant Applications (CGA)
Improving HCP Counseling of Patients on the Appropriate Selection and Use of OTC Analgesics

I. Background

The mission of Pfizer Independent Grants for Learning & Change (IGL&C) 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.

Through this CGA we encourage organizations to submit grant requests that, if funded, will support education in a specific disease state, therapeutic area, or broader area of educational need. Educational activities should not be focused on products specific to Pfizer.

When a CGA is issued, it is posted on the IGL&C website in the *Grants Process* section and is sent via e-mail to all registered users in our grants system. Some CGAs may also be posted on the websites of other relevant organizations.

II. Eligibility

Geographic Scope:	☑ United States Only
Applicant Eligibility Criteria:	The following may apply: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations and medical societies; medical education companies; and other entities with a mission related to healthcare professional education and/or healthcare improvement. More information on organizations eligible to apply directly for a grant can be found at http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf. Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions/organizations/associations, are encouraged. All partners must have a relevant role, and the requesting organization must have a leadership role.

III. Requirements

Date CGA Issued:	April 4, 2018
Clinical Area:	Pain
Specific Area of Interest for this CGA:	It is our intent to support projects that focus on: • Development of Continuing Medical Education materials to ***improve the healthcare professional's ability to counsel adult and adolescent patients on the appropriate selection and use of over-the-counter (OTC) analgesics,*** based on an evaluation of the patient's profile, an understanding of the different mechanisms of action of analgesics, as well as their different efficacy and safety profiles. Over-the-counter (OTC) analgesics such as nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen (APAP) are widely used for the self-treatment of a variety of acute painful conditions, e.g., headache, dental pain, dysmenorrhea, minor pain of arthritis, backache, muscular pain, and for fever. Traditional NSAIDs reduce pain and inflammation by reducing the synthesis of pro-inflammatory prostaglandins via inhibition of the enzyme cyclooxygenase-2 (COX-2), and also inhibit gastroprotective prostaglandins via inhibition of COX-1 (Brune et al, 2015). The mechanism of action of APAP involves weak inhibition of COX-1 and COX-2 without anti-inflammatory activity (Cannon et al, 2012). Because of their different mechanisms of action, NSAIDs and APAP have different safety and efficacy profiles. Traditional, non-selective NSAIDs prescribed by a physician for chronic painful conditions such as osteoarthritis and rheumatoid arthritis are associated with an increased risk of gastrointestinal, cardiovascular, and renal adverse events due to the reduction of beneficial prostaglandins via non-selective inhibition of COX-1 in addition to COX-2, whereas APAP has been reported to have a better safety profile with chronic use. However, as approved for OTC use, NSAIDs such as ibuprofen and naproxen are administered at lower doses and for shorter durations (maximum 10 days) than prescription use. Recent reviews have demonstrated that OTC NSAIDs as well as APAP are associated with a low risk of gastrointestinal, hepatic (Moore et al, 2018) or cardiorenal (White et al, 2018) adverse events. However, acute APAP overdose can lead to serious hepatic toxicity and possible liver failure (Moore et al, 2018). Conversely, non-aspirin NSAIDs such as ibuprofen (White et al, 2018) or naproxen (Gurbel et al, 2018) under certain dosing conditions may interfere with the antiplatelet effects of aspirin in people taking aspirin for cardioprotection. Literature reviews and meta-analyses have reported that OTC NSAIDs, particularly ibuprofen, provide superior analgesic efficacy to APAP in acute dental pain (Bailey et al, 2013; Moore et al, 2015a) and acute and chronic osteoarthritis pain (Moore et al, 2015b). A recent report using multicriteria decision analysis indicated that salt and solubilized formulations of ibuprofen, which provide rapid pain relief, have the best benefit-risk profile among OTC analgesics (Moore et al, 2017). Recent survey studies have reported that analgesic users may exceed the daily dosing limit of OTC NSAIDs and APAP (Kaufman et al, 2018; Shiffman et al, 2015). Since the risk of adverse events is dose-related, it is important to remind patients and consumers not to exceed the labeled dose. Further, individual patient characteristics such as medical conditions, underlying cause of pain (e.g., inflammatory or non-inflammatory), and duration or severity of pain should be taken into consideration when recommending an OTC analgesic. Based on the variable efficacy and safety profiles of OTC analgesics, and the emerging science, there is a need to improve the ability of healthcare professionals (including PCPs, PAs, NPs, pharmacists, etc.) to counsel patients on the appropriate selection and use of OTC analgesics, based on an accurate evaluation of their benefit/risk profiles, an understanding of different mechanisms of action, and individual patient profiles. More information on principles of learning and behavior change for health professionals can be found at www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf.

Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to $80,000 will be considered. The total available budget related to this CGA is $80,000. The grant amount Pfizer will be prepared to fund will depend upon the evaluation of the proposal and costs involved and will be stated clearly in the approval notification.
Key Dates:	CGA release date: April 4, 2018 Grant application due date: June 21, 2018 Please note the deadline is midnight Eastern Time (New York, GMT -5). Anticipated Grant Award Notification Date: August 16, 2018 Grants distributed following execution of fully signed Letter of Agreement Period of Performance: Maximum of 2 years in duration Projects to commence after September 1, 2018
How to Submit:	Please go to the specific application log-in page and sign in. First-time users should click "REGISTER NOW". Select the following Educational Area: **CGA - OTC Analgesics** Requirements for submission: Complete all required sections of the online application and upload the completed CGA 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. **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 CGA, please direct them in writing to , Jessica Romano, at Jessica.Romano@pfizer.com, with the subject line "CGA - OTC Analgesics."
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. Bailey E, Worthington HV, Van Wijk A et al. Ibuprofen and/or paracetamol (acetaminophen) for pain relief after surgical removal of lower wisdom teeth. *Cochrane Database Syst. Rev.12*; CD004624, 2013.
2. Brune K, Patrignani P. New insights into the use of currently available non-steroidal anti-inflammatory drugs. *J. Pain Res. 8*; 105-118, 2015.
3. Cannon CP, Cannon PJ. COX-2 inhibitors and cardiovascular risk. *Science 336*; 1386-1387, 2012.
4. Gurbel PA, Bliden KP, Zhu J, Troullos E et al. Thromboxane inhibition during concurrent therapy with low-dose aspirin and over-the-counter naproxen sodium. *J. Thrombosis Thrombolysis 45*:18–26, 2018.

5. Kaufman DW, Kelly JP, Battista DR et al. Exceeding the daily dosing limit of nonsteroidal anti-inflammatory drugs among ibuprofen users. Pharmacoepidemiol. Drug Saf epub ahead of print. http://onlinelibrary.wiley.com/doi/10.1002/pds.4391/epdf. Accessed February 25, 2018.
6. Moore A, Crossley A, Ng B, et al. Use of multicriteria decision analysis for assessing the benefit and risk of over-the-counter analgesics. *J. Pharm. Pharmacol. 69;* 1364-1373, 2017
7. Moore N and Scheiman JM. Gastrointestinal safety and tolerability of oral non-aspirin over-the-counter analgesics. *Postgrad. Med.* epub ahead of print. https://doi-org.proxy1.athensams.net/10.1080/00325481.2018.1429793. Accessed February 25, 2018.
8. Moore RA, Derry S, Wiffen PJ et al. Non-prescription (OTC) oral analgesics for acute pain - an overview of Cochrane reviews. *Cochrane Database Syst. Rev. 11*; CD010794, 2015a.
9. Moore RA, Derry S, Wiffen PJ et al. Overview review: comparative efficacy of oral ibuprofen and paracetamol (acetaminophen) across acute and chronic pain conditions. *Eur. J. Pain 19*; 1213-1223, 2015b.
10. Shiffman S, Rohay JM, Battista D et al. Patterns of acetaminophen medication use associated with exceeding the recommended maximum daily dose. *Pharmacoepidemiol. Drug Saf. 24*; 915-921, 2015.
11. White WB, Kloner RA, Angiolillo DJ and Davidson, M. Cardiorenal safety of OTC analgesics. *J. Cardiovasc. Pharmacol. Therap. 23*; 103-118, 2018

IV. Terms and Conditions

Please take note every Call for Grant Applications (CGA) released by Pfizer Independent Grants for Learning & Change (IGLC) is governed by specific terms and conditions. These terms and conditions can be reviewed here: **http://www.pfizer.com/files/PfizerIGLC_CGA_TermsandConditions_2017Nov.pdf**

Appendix: CGA Grant Submission Template

Grant Applications should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a **15-page limit** exclusive of references. Please include the following:

A. Title
B. Organizational Detail: Describe the attributes of the institutions/organizations that will support and facilitate the execution of the project, the leadership of the proposed project, and the specific role of each partner in the proposed project.
C. Goal: Briefly state the overall goal of the project.
D. Objectives: List the objectives you plan to meet with your project, in terms of learning and expected outcomes.
E. Assessment of Need: Include a quantitative baseline data summary, initial metrics, 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.
F. Target Learner Audience: Describe the primary audience(s) targeted for this project. 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.
G. Project Design and Methods: Describe the planned project, the educational approach, and the way the planned methods address the established need.
H. Innovation: Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed. 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.
I. Outcomes Evaluation: In terms of the metrics used for the needs assessment, describe how you will determine if the gap was addressed for the target group. Identify the sources of data you anticipate using to make the determination. Describe how you expect to collect and analyze the data. Explain the method used to control for other factors outside this project (e.g., use of a control group or comparison with baseline data). Quantify the

amount of change expected from this project in terms of your target audience. Describe how you will determine if the target audience was fully engaged in the project.

J. Dissemination Plan: Describe how the project may have extended benefit beyond the grant. Will the teaching materials be made available to others to use? Will there be tools or resources that are made publicly available beyond the initial project. Describe how the project outcomes might be broadly disseminated.
K. Timeline
L. Additional Information: 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.
M. References (outside the 15-page limit)
    - There is no designated format for references
N. Budget (See template available in application)
    - While estimating your budget please keep the following items in mind:
        - Grants awarded by IGLC cannot be used to purchase therapeutic agents (prescription or non-prescription).
        - Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for projects.
        - A separate Excel file should be uploaded. This does not count toward the page limit.
            - An example of the budget template can be found here: http://cybergrants.com/pfizer/docs/KnowledgeGapBudgetTemplate2015.xls
            - At the conclusion of your program, a reconciliation of expenses is required using the original budget file submitted.

Grant Applications should be single-spaced using Calibri 12-point font and 1-inch margins. There is a **15-page limit** exclusive of references. If extensive, references may be included on 1-2 additional pages.