Independent Grants for Learning & Change (IGLC) Track 2 - Call for Grant Applications (CGA) Understanding Oncology Clinical Trial Outcomes and Comparative Assessment

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 (<u>www.cybergrants.com/pfizer/knowledge</u>) in the <u>Grants Process</u> <u>section</u> 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 | |
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| Geographic Scope: | United States only |
| Applicant Eligibility | The following may apply: medical, nursing, allied health, and/or |
| Criteria: | 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 <u>http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.p</u> <u>df</u> . |
| | 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. |

II. Eligibility

| III. Requirements | |
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| Date CGA Issued: | May 9, 2017 |
| Clinical Area: | Oncology Outcomes & Evidence |
| Specific Area of Interest for this CGA: | It is our intent to support continuing professional development programs (CME/CE) for managed care decision-makers, formulary decision-makers, other payor decision-makers, pharmacists/pharmacy directors, and medical oncologists/medical directors. Proposed programs should focus on increasing the understanding of one or more of the following topics, in order of priority: |
| | Formulary Class Review & Considerations: Examining Current and Emerging Agents in the CDK 4/6 Inhibitor Class for the Treatment of HER2(-)/ER(+) Advanced or Metastatic Breast Cancer The use of Patient Reported Outcomes (PROs) in Oncology Versus Other Therapeutic Areas and a Primer for Payers to the PRO-Common Terminology Criteria for Adverse Events Tool |
| | (PRO-CTCAE tool) 3) Application & Limitations of Evidenced-Based Methods for Indirect Treatment & Trials Comparisons: Value frameworks (ASCO Value Framework, NCCN Evidence Blocks, etc) and Real World Data for indirect treatment comparisons; and Network Meta-Analysis (NMA), Simulated Treatment Comparison (STC), Match Adjusted Treatment Comparison (MAIC), etc. for indirect trials comparisons 4) Challenges with Oncology Trial Design/Approvals & Endpoints in Value Assessment. For example: Overall Survival (OS) vs. Progression Free Survival (PFS) Earlier FDA approvals based upon Phase 2 data The Quality Adjusted Life-Years (QALY) dilemma Forthcoming novel primary endpoints or endpoints analyses (invasive disease free survival (iDFS), restricted- mean survival times (RMST), intermediate survival endpoints, durable response, etc.) |
| | All activity types will be considered through this CGA including live events, on-agenda sessions, satellite symposia, workshops, online courses, print materials, other enduring materials. Of particular interest are activities taking place at the Academy of Managed Care Pharmacy (AMCP) Nexus in October 2017 and/or the AMCP Annual Meeting in April 2018; and/or Fall or Spring Managed Care Forums of the American Association of Integrated Healthcare Delivery Systems (AAIHDS), the American Association of Managed Care Nurses (AAMCN), and the National Association of Managed Care Physicians (NAMCP). Efforts should be made to encourage interaction, incorporate patient case discussions, and provide opportunities to extend and reinforce |

| | summary presentation during the review period. |
|----------------------|--|
| Notified: | Applicants may be asked for additional clarification or to make a |
| Applicants will be | An applicants will be notified via email by the dates noted above. |
| Mechanism by which | "CGA- Oncology Outcomes & Evidence." All applicants will be notified via email by the dates noted above. |
| | to Derek Warnick at (<u>derek.warnick@pfizer.com</u>), with the subject line |
| Questions: | If you have questions regarding this CGA, please direct them in writing |
| | reviewed by the committee. |
| | application type and/or submitted after the due date will not be |
| | IMPORTANT: Be advised applications submitted through the wrong |
| | |
| | technical difficulties with the grant management system, please click the "Need Support?" link at the bottom of the page. |
| | completed CGA template (see Appendix). If you encounter any |
| | Complete all required sections of the online application and upload the |
| | Requirements for submission: |
| | |
| | Evidence |
| | Select the following Educational Area: CGA- Oncology Outcomes & |
| | |
| How to Submit: | Please go to the specific <u>application log-in page</u> and sign in. First-time users should click "REGISTER NOW". |
| Harrista Cultura't | Period of Performance: July 2017 to July 2019 |
| | |
| | Agreement |
| | Grants distributed following execution of fully signed Letter of |
| | Anticipated Grant Award Notification Date: August 2, 2017 |
| | Anticipated Grant Award Notification Date: August 2, 2017 |
| | Please note the deadline is midnight Eastern Time (New York, GMT -5). |
| | Grant application due date: June 21, 2017 |
| | |
| Key Dates: | CGA release date: May 9, 2017 |
| | in the approval notification. |
| | 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 |
| | |
| Grant Applications: | The total available budget related to this CGA is \$200,000. |
| Monetary Range of | although smaller-scope/lower-cost proposals are strongly encouraged. |
| Expected Approximate | Individual projects requesting up to \$200,000 will be considered |
| | |
| | www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange |
| | be found at |
| | principles of learning and behavior change for health professionals can |

IV. Terms and Conditions

1. This CGA 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 CGA 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 CGA must come exclusively to Pfizer IGL&C. 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.
- 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 (<u>http://www.pfizer.com/files/IGLCsunshineFAQ_updatedJan2016.pdf</u>).

- 7. No portion of a Pfizer 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.

Appendix: CGA Grant Submission Template

Grant Applications should be single-spaced using <u>Calibri 12-point font</u> and <u>1-inch margins</u>. Note there is a <u>15-page limit</u> 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: <u>http://cybergrants.com/pfizer/docs/KnowledgeGapBudgetTemplate2015.xls</u>
 - 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 <u>Calibri 12-point font</u> and <u>1-inch margins</u>. There is a <u>15-page limit</u> exclusive of references. If extensive, references may be included on 1-2 additional pages.