

**Independent Grants for Learning & Change (IGLC)**  
**Track 2 - Call for Grant Applications (CGA)**  
**Real World Evidence (RWE) in Breast Cancer**

**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.

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. The content or format of educational activities or related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest. Educational activities should not be focused on products specific to Pfizer.

When a CGA is issued, it is posted on the IGLC 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**

<b>Geographic Scope:</b>	<input checked="" type="checkbox"/> United States Only
<b>Applicant Eligibility Criteria:</b>	<p>The following may apply: medical, 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.</p> <p>More information on organizations eligible to apply directly for a grant can be found at <a href="http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf">http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf</a>.</p> <p>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.</p>

### III. Requirements

<b>Date CGA Issued:</b>	June 6, 2018
<b>Clinical Area:</b>	RWE in Breast Cancer
<b>Specific Area of Interest for this CGA:</b>	<p>Real World Data (RWD) is healthcare data collected from a variety of sources including electronic health records, insurance claims, patient registries, and digital health solutions outside of conventional clinical trials.</p> <p>Real World Evidence (RWE) is defined as clinical evidence regarding the use and potential benefits or risks of a drug derived from analysis of RWD.</p> <p>Randomized Clinical Trials (RCTs) have been considered the gold standard to provide evidence about the efficacy of new medications for regulatory approval. However, RCTs do not necessarily reflect the “real-world” experience because RCTs are usually conducted in a sample of homogeneous patients that meet a rigorous set of study inclusion and exclusion criteria and patients are closely monitored following a strict protocol. It is unknown whether or to what extent the findings from RCTs could be generalized to various patients in the routine clinical practice. In addition, some rare adverse events are impossible to be observed in a small sample of patients during a short time of clinical trial period. Real-world evidence (RWE) obtained from real-world data (RWD) may be more generalizable to patients in the routine clinical practice and has become increasingly important as a complementary source to RCT data. However, RWD may yield misleading evidence and efforts must be made at the stages of database selection, study design, statistical analysis and interpretation to minimize the bias and confounding effects.</p> <p>In Oncology and in particular in the field of breast cancer it is important that oncologists, physician assistants, pharmacists, nurse practitioners and all health care professionals involved in the treatment of breast cancer understand the value and challenges of RWE for clinical decision making.</p> <p>Through this CGA, it is our intent:</p> <ol style="list-style-type: none"><li>1. To support educational initiatives and tools to help health care professionals analyze and interpret RWE in terms of the study validity, study design, and data source so that they can accurately interpret the findings.</li><li>2. To help health care professionals understand the evidence that currently exists in terms of the real world clinical experience in the field of CDK 4/6 inhibitors.</li><li>3. Teach health care professionals how to incorporate and appropriately apply RWE into daily practice and decision making.</li></ol>

	<p>All activity types will be considered through this CGA including single or multi-part series, on-agenda sessions at live meetings, national or regional multi-topic symposia, online courses, newsletters, print materials and other enduring materials. Activities may be certified for CME/CE credit although this is not required.</p> <p>Efforts should be made to encourage interaction, incorporate patient case discussions, and provide opportunities to extend and reinforce learning beyond the live setting. More information on principles of learning and behavior change for health professionals can be found at <a href="http://www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf">www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf</a>.</p>
<b>Expected Approximate Monetary Range of Grant Applications:</b>	<p>Individual projects requesting up to \$250,000 will be considered although smaller projects in the \$50K to \$100K range are strongly encouraged. The total available budget related to this CGA is \$500,000 (USD).</p> <p>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.</p>
<b>Key Dates:</b>	<p>CGA release date: June 6, 2018</p> <p>Grant application due date: July 24, 2018 Please note the deadline is midnight Eastern Time (New York, GMT -5).</p> <p>Anticipated Grant Award Notification Date: August 31, 2018</p> <p>Grants distributed following execution of fully signed Letter of Agreement.</p>
<b>How to Submit:</b>	<p>Please go to the specific <a href="#">application log-in page</a> and sign in. First-time users should click "REGISTER NOW".</p> <p>Select the following Educational Area: CGA- RWE in Breast Cancer</p> <p>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.</p> <p><b>IMPORTANT:</b> Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.</p>
<b>Questions:</b>	<p>If you have questions regarding this CGA, please direct them in writing to Beth Brillinger, at (<a href="mailto:Beth.Brillinger@Pfizer.com">Beth.Brillinger@Pfizer.com</a>), with the subject line "CGA-RWE in Breast Cancer."</p>
<b>Mechanism by which Applicants will be Notified:</b>	<p>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.</p>

#### **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](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.