



Pfizer Announces an **Independent Medical Education Grant RFP**

Real World Evidence for CDK 4/6 inhibitors in Shared Clinical Decision Making

Competitive Grant Program - internal Pfizer review process

I. Background

Pfizer Global Medical Grants (GMG) supports the global healthcare community's independent initiatives (e.g., research, quality improvement, or education) to improve patient outcomes in areas of unmet medical need that are aligned with Pfizer's medical and/or scientific strategies.

Pfizer's GMG competitive grant program involves a publicly posted general Request for Proposal (RFP) that provides detail regarding a general area of interest, sets timelines for review and approval, and uses an internal Pfizer review process to make final grant decisions. Organizations are invited to submit an application addressing the knowledge gaps as outlined in the specific RFP.

For all **independent medical education grants**, the grant requester (and ultimately the grantee) is responsible for the design, implementation, and conduct of the independent initiative supported by the grant. Pfizer must not be involved in any aspect of project development, nor the conduct of the independent education program.

II. Eligibility

Geographic Scope:	United States
Applicant Eligibility Criteria	<ul style="list-style-type: none"> • 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; patient advocacy groups and other entities with a mission related to healthcare professional education and/or healthcare improvement. • If the project involves multiple departments within an institution and/or between different institutions / organizations / associations. all institutions must have a relevant role and the requesting organization must have a key role in the project. • For projects offering continuing education credit, the requesting organization must be accredited.

III. Requirements

Date RFP Issued	October 5, 2022
Clinical Area	Oncology –Breast - Metastatic Breast Cancer (mBC)
General Area of Interest for this RFP:	<p>The availability of CDK 4/6 inhibitors (CDK 4/6is) in combination with an aromatase inhibitor (AI) in HR+/HER2- Metastatic Breast Cancer (mBC) has led to the extension of progression free survival (PFS) for patients vs. an AI alone. These findings have been demonstrated in real world studies in addition to pivotal randomized controlled trials (RCTs). Despite this evidence, patients appropriate for CDK 4/6is may still receive endocrine monotherapy.</p> <p>The goal is to close gaps in care so that all appropriate HR+/HER2- mBC patients have equal access and an understanding of these therapeutic options.</p> <p>Variations in guideline-based care and understanding of data still exist in the HR+/HER2-mBC setting. In order to reinforce standard of care, it would be beneficial for HCPs to better understand and have the ability to discuss with patients in an unbiased way the totality of CDK 4/6 evidence including data from RW studies in addition to RCT data.</p> <p>While HCPs are accustomed to discussing the outcomes of randomized controlled trials with their patients, there is a lack of communication of rigorous real world evidence (RWE) studies between doctor and patient. In</p>

	<p>particular, outcomes from studies of patients in routine clinical practice is often absent from shared decision-making discussions.</p> <p>RWE has the potential to compliment the findings of RCTs by adding evidence of outcomes and experiences of diverse patients reflecting actual clinical practice that can help inform shared decision making for patients and providers. Education and tools to aid in these discussions with patients are a welcomed addition to enhance patient/provider discussions, especially when discussing the complexities of mBC treatment options. This can help close the gap in care and understanding.</p> <p>The intent of this RFP is to support education and tools to enable clinicians to better analyze, evaluate the quality of, and interpret relevant findings from real world studies of CDK 4/6is in terms of the validity, design, and source, so that they can incorporate this knowledge into their daily practice and shared clinical decision-making discussions with their patients.</p> <p>Proposals should include novel, effective, interactive discussion tools to enhance the quality of patient education, awareness and applicability of RWE findings in the CDK 4/6i class.</p> <p>Independent education proposals should underscore the important design and data source elements that must be considered to critically evaluate available RWE studies for the CDK 4/6i class and suggest tools to translate the understanding to help patients assess their treatment choices.</p> <p>This RFP is for <u>education</u> grants only. It is not our intent to support clinical research projects. Projects evaluating the efficacy / effectiveness of a therapeutic agent or diagnostic agents will not be considered.</p>
<p>Target Audience:</p>	<ol style="list-style-type: none"> 1) Oncologists and all healthcare professionals responsible for the care of patients with HR+/HER2- mBC 2) Patients with mBC and their caregivers
<p>Expected Approximate Monetary Range of Grant Applications:</p>	<ul style="list-style-type: none"> • Individual projects requesting up to \$200,000 will be considered. • Submissions requesting lesser amounts are always encouraged. • The estimated total available budget related to this RFP is \$725,000.
<p>Key Dates:</p>	<ul style="list-style-type: none"> • RFP release date: October 5, 2022 • Grant Application due date: November 2, 2022 <p>Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).</p> <ul style="list-style-type: none"> • Anticipated Grant Award Notification Date: November 21, 2022 • Grants will be distributed following a fully executed agreement. <p>Anticipated Project Start Date: January 2023 (2-year project maximum length)</p>

<p>How to Submit:</p>	<ul style="list-style-type: none"> • Please go to http://www.cybergrants.com/pfizer/knowledge and sign in. First-time users should click “Create your password”. • In the application: <ul style="list-style-type: none"> ○ For the question “What type of request are you submitting?” select Response to a Request for Proposal (RFP) ○ For the question “Are you replying to a Request for Proposal as part of the Competitive Grant Program?” select Yes ○ Select the following Competitive Grant Program Name: “2022 Onc US: RWE for CDK 4/6 Inhibitors.” ○ Select the following Primary Area of Interest: Oncology – Breast • Requirements for submission: Complete all required sections of the online application and upload your project proposal (see Appendix) in the General RFP Submission field. • If you encounter any technical difficulties with the website, please click the “Technical Questions” link at the bottom of the page. <p>IMPORTANT: Be advised applications 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, Dewayne Brumlow (dewayne.brumlow@pfizer.com), with the subject line “2022 Onc US: RWE for CDK 4/6 Inhibitors.”</p>
<p>Grant Agreements:</p>	<ul style="list-style-type: none"> • If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click here to view the core terms of the agreement. • Pfizer has drafted the terms of these agreements to be balanced and reasonable and to further the goals of both parties. Negotiating grant agreements requires significant resources, so please ensure that your institution (including your legal department) is able and willing to abide by these terms before proceeding with submission of your application as they will need to be accepted in their entirety.
<p>Review and Approval Process</p>	<ul style="list-style-type: none"> • Grant requests received in response to a general RFP are reviewed by Pfizer to make final grant decisions.
<p>Mechanism by which Applicants will be Notified:</p>	<ul style="list-style-type: none"> • All applicants will be notified via email by the dates noted above. • Applicants may be asked for additional clarification during the review period.

Appendix A

General RFP Submission Requirements

Project Proposals 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:

Goals and Objectives	<ul style="list-style-type: none"> • Briefly state the overall goal of the project. • List the objectives you plan to meet with your project, in terms of learning and expected outcomes.
Needs Assessment for the Project	<ul style="list-style-type: none"> • Include a description of your organization’s needs assessment for this proposed project which may 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.
Target Audience	<ul style="list-style-type: none"> • 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.
Project Design and Methods	<ul style="list-style-type: none"> • Describe the planned project, the educational approach, and the way the planned methods address the established need.
Innovation	<ul style="list-style-type: none"> • Explain what measures you have taken to assure that this project 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.
Evaluation and Outcomes	<ul style="list-style-type: none"> • In terms of the metrics used for the needs assessment, describe how your organization will determine if the gap was addressed for the target group. Identify the sources of data your organization anticipates using to make the determination. Describe how your organization is expected 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 the target audience. Describe how your organization will determine if the target audience was fully engaged in the project.
Dissemination Plan	<ul style="list-style-type: none"> • 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.

Anticipated Project Timeline	<ul style="list-style-type: none"> • Provide an anticipated timeline for your project including project start/end dates.
Additional Information	<ul style="list-style-type: none"> • If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here.
Organization Detail	<ul style="list-style-type: none"> • 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 institution in the proposed project.
Budget Narrative	<ul style="list-style-type: none"> • Please include a budget narrative that describes in greater detail the line items specified in the budget submitted within the application • While estimating your budget please keep the following items in mind: <ul style="list-style-type: none"> ○ Independent Medical Education Grants awarded by GMG cannot be used to purchase therapeutic assets (prescription or non-prescription). ○ Overhead rates of up to 28% of the total proposed project budget may be supported by Pfizer. Please click here for details.