Pfizer Announces

CDK 4/6 Inhibitors & Understanding Real World Evidence

Medical Education Competitive Grant Program - Europe

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 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:	• European healthcare professional audiences are the main priority for this RFP. • US-based and other non-European organizations can apply for support for global programs that focus on the educational needs in Europe in particular.
Applicant Eligibility Criteria	• The following may apply: medical, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations, patient education or patient advocacy organizations, medical societies; medical education companies; 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. • If your organization is not based in Europe, as long as the educational focus is on Europe you can still apply.

III. Requirements

Date RFP Issued	October 23, 2019
Clinical Area	Oncology – Breast Cancer – Advanced or Metastatic Breast Cancer
General Area of Interest for this RFP:	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 reflecting treatment practices and outcomes in a naturalistic “real world” setting. 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. 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. The patients enrolled in randomized clinical trials may not represent the broad population of people affected by the disease under study. 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 routine clinical practice and is increasingly recognized as an important complementary evidence regarding the benefits and risks of a treatment. Real world evidence has limitations as well and the value of the evidence generated is dependent on the suitability of the data used, the design of the study and the scientific question the study is designed to answer as well as the statistical analysis and interpretation of the data. In Oncology 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 interpretation of RWE for clinical decision making. **Through this RFP, it is our intent:** 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 in an oncology setting.** 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 in metastatic breast cancer.** 3. **Teach health care professionals how they might incorporate and appropriately apply RWE into daily practice and decision making in a metastatic breast cancer setting.** All activity types will be considered through this RFP 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.
Target Audiences:	Clinical oncologists and other healthcare professionals involved in the care of patients with breast cancer.
Expected Approximate Monetary Range of Grant Applications:	• Individual projects requesting up to $250,000 USD will be considered. • The estimated total available budget related to this RFP is $500,000 USD.
Key Dates:	• RFP release date: October 23, 2019 • Grant Application due date: November 21, 2019 • Please note the deadline is midnight Eastern Standard Time (e.g.

	New York, GMT -5). • Anticipated Grant Award Notification Date: December 9, 2019 • Grants will be distributed following a fully executed agreement. • Anticipated Project Start and End Dates: January 2020 to December 2021 (2-year maximum timeline, projects may be shorter)
How to Submit:	• Please go to www.cybergrants.com/pfizer/knowledge and sign in. First-time users should click "Create your password". • In the application: o For the question "What type of request are you submitting?" select Response to a Request for Proposal (RFP) o For the question "Are you replying to a Request for Proposal as part of the Competitive Grant Program?" select Yes o Select the following Competitive Grant Program Name: 2019 Oncology G – CDK 4/6 Inhibitors & Understanding Real World Evidence o 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. **IMPORTANT:** Be advised applications 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 GMG Regional Grant Officer, Jo Harbron (Jo.Harbron@Pfizer.com) with the subject line "CDK 4/6 Inhibitors & Understanding Real World Evidence"
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 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	• 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	• 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	• 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	• Describe the planned project, the educational approach, and the way the planned methods address the established need.
Innovation	• 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	• 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	• 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	• Provide an anticipated timeline for your project including project start/end dates.
Additional Information	• If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here.
Organization 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 institution in the proposed project.
Budget Narrative	• 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: o Independent Medical Education Grants awarded by GMG cannot be used to purchase therapeutic assets (prescription or non-prescription). o Overhead rates of up to 28% of the total proposed project budget may be supported by Pfizer.