Pfizer Announces a Quality Improvement Grant Program:

Treatment Patterns of CDK 4/6 Inhibitor Utilization in HR+/HER2- Metastatic Breast Cancer

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 practice gaps as outlined in the specific RFP.

For all independent quality improvement 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 or monitoring of the quality improvement program.

This RFP uses an internal Pfizer decision-making process.

II. Eligibility

Geographic Scope	United States only
Applicant Eligibility Criteria	• The types of organizations eligible for this RFP are listed in the Target Audience section below. • 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	September 9, 2019
Clinical Area	Oncology – Breast Cancer
RFP Background	The use of cyclin dependent kinase (CDK) 4/6 inhibitors in combination with endocrine therapy in patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer (MBC) has demonstrated improved progression free survival (PFS) across landmark trials relative to endocrine therapy alone.[1-3] Guidelines recommend CDK 4/6 inhibitors in combination with endocrine therapy for the treatment of women with HR+/HER2- MBC.[4] Quality Improvement (QI) is a cyclic process of systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of healthcare in specific settings.[5] The Commission on Cancer (CoC) as well as the Quality Oncology Practice Initiative (QOPI) endorse utilizing data for continuous quality improvement as well as using nationally recognized guidelines to drive treatment selection.[6,7]

General Area of Interest for this RFP	The intent of this QI RFP is to support cancer care facilities interested in identifying and reducing unwarranted variations and/or disparities in care by: - Exploring utilization patterns of CDK 4/6 inhibitors for the treatment of HR+/HER2- MBC - Implementing process improvement intervention(s) to address identified issues Examples of variations in care that might be examined include treatment patterns across multiple affiliated sites, geographic differences, ethnicity- or age-related biases. Each grant recipient and their QI team can decide which aspect(s) of quality-care-improvement to address once the data analysis stage is complete. It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered. Information on how to submit requests for support of clinical research projects can be found at www.Pfizer.com/isr.
Target Audience	Cancer care facilities including community cancer centers, hospitals, health-systems, comprehensive cancer centers, and networks of oncology clinics. Individual physician-owned practices are not eligible.
Expected Approximate Monetary Range of Grant Applications	• Individual projects requesting up to $100,000 will be considered. The estimated total available budget related to this RFP is $1 million. • Grant funds can be used for project management costs, data analysis costs, QI team activities, technology-based enhancements, professional or patient education, process improvement implementation costs etc. Grant funds cannot be used to cover the costs of patient-care delivery or medications.
Key Dates	• RFP release date: September 9, 2019 • Grant Application due date: November 4, 2019 Please note the deadline is 23:59 Eastern Standard Time (e.g. New York, GMT -5). • Anticipated Grant Award Notification Date: December 2, 2019 • Grants will be distributed following a fully executed agreement. • Anticipated Project Start and End Dates: January 2020 to June 2021 (1.5-year maximum project length, projects may be shorter)

How to Submit	• Please go to www.cybergrants.com/pfizer/QI and sign in. First-time users should click "Create your password".
	• In the application:
	  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-L "Treatment Patterns of CDK-4/6 Inhibitor Utilization in HR+/HER2- Metastatic Breast Cancer"*
	  o Select the following Primary Area of Interest: Oncology – Breast Cancer
	• Requirements for submission:
	Complete all required sections of the online application and upload your project proposal (see Appendix) in the Full Proposal 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 Grant Officer, Jacqueline Waldrop (Jacqueline.Waldrop@pfizer.com), with the subject line "Treatment Patterns of CDK-4/6 Inhibitor Utilization in HR+/HER2- Metastatic Breast Cancer"
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.

References:

1. Finn, RJ, Crown JP, Lang I, et al. The cyclin-dependent kinase 4/6 inhibitor palbociclib in combination with letrozole versus letrozole alone as first-line treatment of oestrogen receptor-positive, HER2-negative, advanced breast cancer (PALOMA-1/TRIO-18): a randomised phase 2 study. *Lancet Oncol* 2015; 16: 25–35.
2. Finn RS, Martin M, Rugo HS, et al. Palbociclib and Letrozole in Advanced Breast Cancer. N Engl J Med 2016;375:1925-36.
3. Cristofanilli M, Turner NC, Bondorenko I, et al. Fulvestrant plus palbociclib versus fulvestrant plus placebo for treatment of hormone-receptor-positive, HER2-negative metastatic breast cancer that progressed on previous endocrine therapy (PALOMA-3): final analysis of the multicentre, double-blind, phase 3 randomised controlled trial.
4. National Comprehensive Cancer Network. Breast Cancer (Version 1.2019 – March 2019). https://www.nccn.org/patients/default.aspx. Accessed August 12, 2019.
5. Lynn J, Baily MA, Bottrell M, et al. The Ethics of Using Quality Improvement Methods in Health Care. Ann Intern Med. 2007;146(9):666-673.

6. American College of Surgeons Commission on Cancer: Cancer Program Standards: Ensuring Patient-Centered Care, 2016 edition. Available at https://www.facs.org/quality-programs/cancer/coc/standards. Accessed August 12, 2019.
7. McNiffK, BonelliK, and Jacobson J. American Society of Clinical Oncology/ Quality Oncology Practice Initiative Certification Program: Overview, Measure Scoring Methodology, and Site Assessment Standards. J OncolPractice 5(6): 2009.

Appendix A
Quality Improvement Project Full Proposal

Applications will be accepted via the online portal. Full Proposal documents should be no longer than 10-15 pages in length (12-point font and 1-inch margins) excluding Organization Detail and References. When uploading your Full Proposal please ensure it addresses the following*:

Goals and Objectives	• Briefly state the overall goal of the project. Also describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s). • List the *overall* objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.
Assessment of Need for the Project	• Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), 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. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information.
Target Audience	• Describe the primary audience(s) targeted for this project. Also 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 and the way it addresses the established need. • If your methods include educational activities, please describe succinctly the topic(s) and format of those activities
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.
Evaluation and Outcomes	• In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Describe how you expect to collect and analyze the data. • Quantify the amount of change expected from this project in terms of your target audience.

	• Describe how the project outcomes will 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 / associations that will support and facilitate the execution of the project and the leadership of the proposed project. Articulate the specific role of each partner in the proposed project.

*The online application also includes the fields noted above. The text in those fields should be the same text that is included in your Full Proposal document.