Pfizer Announces

Patient Registries In Metastatic Breast Cancer

Competitive Grant Program

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 specific area of interest, sets timelines for review and approval, and uses an external review panel (ERP) to make final grant decisions. Organizations are invited to submit an application addressing the specific gaps in practice as outlined in the specific RFP.

For all 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.

II. Eligibility

Geographic Scope:	Japan
Applicant Eligibility Criteria	• The following may apply: medical, dental,, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations; government agencies; and other entities with a mission related to healthcare improvement. • More information on organizations eligible to apply directly for a grant can be found at http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf. • Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions / organizations / associations, are encouraged. Please note all partners must have a relevant role and the requesting organization must have a key role in the project. • For programs offering credit, the requesting organization must be the accredited grantee.

III. Requirements

Date RFP Issued	• Apr 26 , 2019
Clinical Area	• Oncology – Breast Cancer
Specific Area of Interest for this RFP:	• A patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defied by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purpose[1]. • It is our intent to support projects that focus on enhancing infrastructure of registry for metastatic breast cancer, contributing to quality improvements of research and treatment environment for MBC. The Grantee would establish and maintain this registry. Extensions to existing BC registries will also be considered. • *It is not our intent to support interventional 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/iir.

Target Audience:	● Institutions caring for diagnosed metastatic breast cancer (MBC) patients
Disease Burden Overview:	Breast cancer is the most frequent female cancer in Japan, and the number of breast cancer patients continues to increase[2]. Currently, data are not collected on how many people experience a recurrence of early stage breast cancer as MBC or the number of people living with the disease[3]. We have only estimates of how many women diagnosed with early stage breast cancer will experience a recurrence.
Recommendations and Target Metrics:	● **Related Guidelines and Recommendations** ● Cardoso F et al., 4th ESO-ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC4) https://academic.oup.com/annonc/article/29/8/1634/5055519 ● Clinical Practice Guideline: Breast Cancer, 2018 http://jbcs.gr.jp/guidline/2018/ ● Aihara T. et al.:Breast Cancer.23(3):329-342,The Japanese Breast Cancer Society Clinical Practice Guideline for systemic treatment of breast cancer, 2015 edition. ● Rugo HS et al., Endocrine Therapy for Hormone Receptor-Positive Metastatic Breast Cancer: American Society of Clinical Oncology Guideline, 2016 http://ascopubs.org/doi/full/10.1200/JCO.2016.67.1487 ● Project for Promoting Clinical Innovation Network (AMED) https://www.amed.go.jp/en/program/list/05/01/015.html
Gaps Between Actual and Target, Possible Reasons for Gaps:	● Efforts on infrastructure development for registry utilization are advancing, but target disease is limited (ex: rare disease). ● Suitable treatment options for individual patients become more complicated, as treatment options for MBC increase[4]. In addition, application of RCT results in daily practice of clinical decision-making is limited because the strict eligibility criteria in RCT mean that results are rarely generalizable to broader population. ● Registries for EBC is tracked, and the data only includes the presence or absence of recurrence is captured, but detailed data, for example, patients' condition and treatment sequence, is limited[5,6]. ● Registries from single or some facilities are available, but there is a lack of coverage of registered data, or limitation on the use of data.
Barriers:	● Because breast cancer returns after a few months or as long as up to 5years or more after initial diagnosis, it is difficult to acquire data on relapse and outcome in cases like postoperative recurrence[3].

	• It is necessary to build a registry including highly versatile data and technically versatile system for clinicians and researchers.
Current National Efforts to Reduce Gaps:	Database or registry systems are established to create more reliable and superior research or treatment environments, especially due to rare diseases[7].
Expected Approximate Monetary Range of Grant Applications:	• Individual projects requesting up to 12,000,000 yen will be considered. The total available budget related to this RFP is 12,000,000 yen. • The amount of the grant Pfizer will be prepared to fund for any project will depend upon the external review panel's evaluation of the proposal and costs involved, and will be stated clearly in the approval notification.
Key Dates:	• RFP release date: Apr 26, 2019 • LOI due date: June 28, 2019 Please note the deadline is midnight Eastern Time (New York, GMT -5). • Review of LOIs by External Review Panel: July, 2019 • Anticipated LOI Notification Date: August, 2019 • Full Proposal Deadline: September, 2019* *Only accepted LOIs will be invited to submit full proposals Please note the deadline is midnight Eastern Time (New York, GMT -5). • Review of Full Proposals by External Review Panel: October, 2019 • Anticipated Full Proposal Notification Date: October, 2019 • Grants distributed following execution of fully signed Letter of Agreement • Period of Performance: 2020 to 2021
How to Submit:	• Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click "REGISTER NOW". • Select the following Competitive Grant Program Name: Registry for metastatic breast cancer patients /Oncology-Breast Cancer • Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix). • 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 through the wrong application type and/or 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, Akihiro Kamina (meg.japan@pfizer.com), with the

	subject line “Registry for metastatic breast cancer patients /Oncology-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 or to make a summary presentation during the review period.

References:

1. Gliklich RE and Dreyer NA. Registries for evaluating patient outcomes, 3rd edition: A User's guide, 2014.
2. Katanoda K., Hori M., Matsuda T. An updated report on the trends in cancer incidence and mortality in Japan, 1958–2013. Jpn J Clin Oncol. 2015;45:390–401.
3. MBC alliance. Changing the landscape for people living with metastatic breast cancer.
4. Salkeni MA and Hall SJ. Metastatic breast cancer: Endocrine therapy landscape reshaped. Avicenna J Med. 2017; 4: 144-152.
5. Saji S et al, Trends in local therapy application for early breast cancer patients in the Japanese Breast Cancer Society Registry during 2004-2009. 2012. Breast Cancer; 19:1-3.
6. Miyata H et al, Challenges and prospects of a clinical database linked to the board certification system. 2014, Surg Today; 44: 1991-1999.
7. Project for Promoting Clinical Innovation Network (AMED). https://www.amed.go.jp/en/program/list/05/01/015.html

IV. Terms and Conditions

Please take note every Request for Proposal (RFP) released by Pfizer Independent Grants for Learning & Change (IGLC), as well as a RFP released jointly with a Partner(s), is governed by specific terms and conditions. Click **here** to review these terms and conditions.

Appendix A

Letter of Intent Requirements

The Letter of Intent (LOI) will be accepted via the online application. When answering the LOI questions in the application please keep the following in mind:

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. [Optional: The RFP includes a national assessment of the need for the project. Please do not repeat this information within the LOI (you may reference the RFP, if necessary). Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis, if appropriate.]
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. Letters of support from partner organizations will be required at the Full Proposal stage only and should not be included with the LOI.
Budget Detail	● A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable. ● The budget amount requested must be in yen. ● While estimating your budget please keep the following items in mind: o Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment. o The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP. o It should be noted that grants awarded through GMG cannot be used to purchase therapeutic agents (prescription or non-prescription). ● Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects