Pfizer Quality Improvement RFP Optimizing the management of mBC HER2-patients / Oncology

Competitive Grant Program - using Expert Review Panel

Overview

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The intent of this Request for Proposal (RFP) is to support innovative proposals focusing on the management of patients with metastatic breast cancer (mBC), in order to improve their quality of life.

Geographic Scope

Italy

Project Types and Area of Interest

The intent of this RFP is to encourage proposals supporting the implementation of strategies that will improve the management and quality of care of mBC HER2-patients.

Of particular interest are new interventions that will address the gaps in care that could be identified in the management of patients.

Key Milestones

- Application submission deadline: 24 May 2023
- Anticipated decision notification date: September 2023
- Anticipated project start date: From October 2023 onwards

Funding Range and Project Length

Funding support is available up to 70000 euros for projects that will be completed within 24 months.



I. Eligibility

Geographic Scope:

Italy

Applicant Eligibility Criteria

- Only organizations are eligible to receive grants, not individuals or medical practice groups.
- The following may apply: public healthcare bodies (hospitals, aziende sanitarie locali [ASLs], universities, Istituto di Ricovero e Cura a Carattere Scientifico [IRCCS] or accredited private hospitals that are involved in the care of oncological patient.
- 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.

II. Requirements

Date RFP Issued

6 March 2023

Clinical Area

Metastatic Breast Cancer

Specific Area of Interest for this RFP:

It is our intent to support projects that focus on quality improvement for the management of patients affected by HER2-mBC.

Proposals may include, but will not be limited to, digital projects and/or projects using artificial intelligence.

Projects must be aimed at supporting the patient in the therapeutic management or follow-up plan for their disease condition. Projects should aim to improve the patient's quality of life (QoL), from the perspective of disease management, rather than focusing on symptomatic improvement linked to specific treatments.

Projects might include these features, but are not limited to them:

- improve patients' quality of life using qualitative and quantitative parameters
- leverage a multi-disciplinary team and approach to improve the quality of mBC care delivered
- have a positive impact on therapy management
- incorporate a new technology to enhance the quality of delivery of healthcare services to mBC patients
- improve patient adherence to mBC treatment.
- medical reports systems to improve patient management
- nursing support to facilitate treatment delivery
- Multi-disciplinary collaborations, are encouraged when appropriate, but all partners must have a relevant role.



• It is expected that projects will be evidence-based and the proposed research/evaluation will follow generally accepted scientific principles. During review the intended outcome of the project is given careful consideration and, if appropriate based on the project goal, projects with the maximum likelihood to directly impact patient care will be given high priority. There is a considerable amount of interest in receiving responses from projects that utilize system-based changes. Although educational efforts for grantees and patients may be entirely appropriate components in responses to this RFP, projects that include an overt description of system changes will be given high priority.

It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered.

Target Audience

Patients with HER2-metastatic breast cancer

Disease Burden Overview

In women, breast cancer is the most frequent cancer with an estimated 55.700 cases in Italy in 2022. It is also the neoplastic disease with the highest prevalence among women (834.154 cases, 43% of the total). Five years after diagnosis, net survival is 88%.(1).

Over the past years, much clinical effort has been expended in the treatment of breast cancer, leading to improved survival. This increases the number of patients with metastatic disease with 37.000 cases in 2022 in Italy (1).

Metastasis not only reduces overall survival but adversely affects the quality of life of the patient. Health-related quality of life is now considered an important endpoint in cancer clinical trials. It has been shown that assessing the quality of life in cancer patients could contribute to improved treatment and could even be prognostic (2-4).

Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to 70000 Euros will be considered. The estimated total available budget related to this RFP is 200000 Euros. Click or tap here to enter text.
- The amount of the grant Pfizer will be prepared to fund for any project will depend upon the expert review panel's evaluation of the proposal and costs involved, and will be stated clearly in the approval notification

Key Dates:

- RFP Release Date: 6 March 2023
- Full Proposal Due Date: 24 May 2023
- Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Review of Full Proposals by ERP: July 2023
- Anticipated Full Proposal Notification Date: September 2023
- Grants will be distributed following a fully executed agreement and submission of Final Protocol, documentation of IRB/IEC approval, regulatory approval (if applicable), exemption or waiver.

How to Submit:

Note: Please read this section carefully since applications submitted not following these instructions will not be accepted and will be cancelled



- Please go to <u>www.cybergrants.com/pfizer/QI</u> and sign in. First-time users should click "Create your password". [Note: there are individual portals for each grant application type. Please be sure to use the URL above.]
- Click the Choose an item. button.
- In the application:
 - For the question "Competitive Grant?" select Yes
 - Select the following Competitive Grant Program Name: 2023 Onc Italy Optimizing the management of mBC HER2-patients
- 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.

Questions:

 If you have questions regarding this RFP, please direct them in writing to <u>GMGEMEA@pfizer.com</u>, with the subject line "2023 Onc Italy Optimizing the management of mBC HER2-patients, March 2023."

Grant Agreements:

- If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click <u>here</u> 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.
- Payment will only be made to requesting Institution.

Review and Approval Process

- A specific grant program RFP uses an expert review panel (ERP) to make final grant decisions.
- The panels are comprised of professionals from the medical community with advanced degrees and expertise in particular clinical areas, or specific needs of a geographic region/learner group, or expertise in research, continuing professional development or quality improvement

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. "I numeri del cancro in Italia 2022"
- 2. Montazeri A, Gillis CR, McEwen J: Measuring quality of life in oncology: is it worthwhile? Part I. Meaning, purposes, and controversies. Eur J Cancer Care 1996, 5:159-167.
- 3. Montazeri A, Gillis CR, McEwen J: Measuring quality of life in oncology: is it worthwhile? Part II. Experiences from the treatment of cancer. Eur J Cancer Care 1996, 5:168-175.



4. Montazeri A, Milroy R, Hole D, McEwen J, Gillis CR: How quality of life data contribute to our understanding of cancer patients' experiences? A study of patients with lung cancer. Quality of Life Research 2003, 12:157-166.



About Pfizer Global Medical Grants

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 expert 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.



Specific RFP Submission Requirements

Applications will be accepted via the online portal listed in the How to Submit section. Project Proposals/Protocols should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 15-page limit exclusive of references. When uploading your Full Proposal please ensure it addresses the following sections:

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 ensure 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.

Budget Detail

- The budget amount requested must be in Euros (EUR).
- While estimating your budget please keep the following items in mind:
 - General organizational running costs such as insurances, heating, lighting, rent, building maintenance may be included. Pfizer does not provide funding for capital purchases (infrastructure expenses such as equipment, purchases of software or software licenses, technology or bricks and mortar). Equipment hire/leasing is acceptable and may be included in project budget.
 - The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
 - It should be noted that grants awarded through GMG cannot be used to purchase Pfizer therapeutic agents (prescription or non-prescription).
- Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects. Please <u>click here</u> for details.

