Pfizer Research Grant Request for Proposals (RFP)

Health Services Research to Improve Management of mBC Patients Treated with Tucatinib

Competitive Grant Program –Pfizer Internal Review Process

Overview

The intent of this RFP is to support **Investigator Sponsored/General Research** projects that will implement and assess the impact of therapy management approaches for patients with **HER2+ Metastatic Breast Cancer (mBC)** receiving tucatinib in combination with trastuzumab and capecitabine.

Geographic Scope/Location of Project

Global

Project Types and Area of Interest

Organizations are invited to submit proposals for initiatives that will implement innovative and community-accessible approaches to improving therapy management with the 3-drug regimen of tucatinib, trastuzumab and capecitabine, including increasing patients' understanding, quality of life, or adherence to treatment and/or facilitate follow-up or symptom management in daily clinical practice.

Projects should be aimed at improving patient care and outcomes using a research framework or "Health Services Research" type approach to evaluate and assess the impact of the interventions.

Key Milestones

- Application submission deadline: **Thursday, January 30, 2025**
- Anticipated Notification Date: **Monday, March 17, 2025**

Funding Range and Project Length

- Individual projects requesting up to **$250,000** will be considered.
- **18-month** suggested project length (may be shorter or longer)

Pfizer

I. Eligibility

Geographic Scope/Location of Project/Study:

- Global

Applicant Eligibility Criteria

- Only organizations are eligible to receive grants, not individuals or medical practice groups (i.e., an independent group of physicians not affiliated with a hospital, academic institution, or professional society).
- The PI must have a medical or postdoctoral degree (MD, PhD, or equivalent), an advanced nursing degree (BSN with a MS/PhD), or a terminal degree in Pharmacy, Social Work, or other relevant discipline.
- The applicant must be the PI or an authorized designee of such individual (e.g., PI's research coordinator).
- The PI must be an employee or contractor of the requesting organization.
- Requesting organization must be legally able to receive award funding directly from Pfizer Inc.

II. Requirements

Date RFP Issued

- Monday, November 11, 2024

Clinical Area

- HER2+ Metastatic Breast Cancer (MBC)

General Area of Interest for this RFP:

Projects that will be considered for Pfizer support will be Investigator Sponsored/General Research proposals to improve therapy management of patients receiving tucatinib in combination with trastuzumab and capecitabine in clinical practice using innovative and community-accessible approaches that may impact patients adherence to treatment, quality of life, or symptom management, and/or facilitate follow-up in daily clinical practice.

Therapy management programs may include interventions including but not limited to:

- Use of digital tools that may ease patients monitoring (i.e. Apps)
- Education tools on safety profile and adverse events management such as infographics, training sessions, Patient Advocacy Group engagement.
- Multidisciplinary management: Primary Care Provider or General Practitioner engagement, oncology nurse consultations, call center, etc.

Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to **$250,000** will be considered. The estimated total available budget related to this RFP is $500,000.
- Requests should be for funding only. Tucatinib drug supply is not in-scope for this Health Services Research RFP.
- Total grant request amounts should include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and any indirect costs.

Key Dates:

- RFP release date: **Monday, November 11, 2024**
- Grant Application due date: **Thursday, January 30, 2025**
  Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Anticipated Grant Award Notification Date: **Monday, March 17, 2025**
- 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.
- Approximate anticipated Project Start and End Dates: **July 2025 to December 2026** (research projects may have longer or shorter timelines; approximately 18-month project timelines are a general guide for this RFP)

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 www.cybergrants.com/pfizer/Research 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 "Start a New Research Grant Application" button.
- In the application:
  - For the question “Competitive Grant?” select **Yes**
  - Select the following Competitive Grant Program Name: **2024 ONC Global tucatinib therapy management RES**
  - 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 Proposal/Protocol 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 the Grant Officer, Nicola Fenderico (Nicola.Fenderico@Pfizer.com) with the subject line “2024 ONC Global tucatinib therapy management RES.”
- Please click here to view Frequently Asked Questions regarding the Competitive Grant Program.

Grant Agreements:

- 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.
- Under Pfizer's competitive grant program, modifications to grant agreements will not be reviewed unless a genuine conflict exists as between applicable law and the terms of the relevant grant agreement. Applicant is encouraged to share the core terms with counsel for approval prior to submitting an application.
- Except where prohibited by applicable law and, in any case, subject to review by Pfizer Legal, payment of grant funding may only be paid to the grantee organization.
- This RFP is supported by Pfizer Inc. and, if approved, payment will be sent from the United States.

Review and Approval Process

- Grant requests received in response to a general RFP are reviewed by Pfizer colleagues to make final grant decisions.

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.

About Pfizer Global Medical Grants & Partnerships

Pfizer Global Medical Grants & Partnerships (GMGP) 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 GMGP 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 research gaps as outlined in the specific RFP.

For all Investigator Sponsored Research (ISRs) and general research grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, sponsorship, and conduct of the independent initiative supported by the grant, including compliance with any regulatory requirements. Pfizer must not be involved in any aspect of study protocol or project development, nor the conduct or monitoring of the research program. An ISR grant request cannot be submitted for a study that has already commenced and was not originally supported by Pfizer.

Appendix

General 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 no page limit for this RFP. When uploading your Full Proposal please ensure it addresses the following sections:

Goals and Objectives

- Provide the main goal of the study and the study population (if applicable). Provide a detailed definition that is directly linked to the primary objective.

Assessment of Need for the Project

- This should reflect your study rationale. Provide a brief description of the medical/scientific question and the rationale of how this trial or study addresses the question.

Target Audience

- Describe the primary audience(s) targeted for this project. For Investigator Sponsored Clinical Trials, please specify the age, gender and other demographic information for trial population.
- 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 concisely the research design and methods for achieving the stated goals. For a clinical interventional study, include inclusion/exclusion criteria, treatment plan and statistical plan.

Innovation

- Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects. 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

- Specify type and frequency of safety, efficacy, and/or outcome measures. Also indicate the method(s) used to assess measures.
- Provide a publication plan describing intended submission of abstracts to (a) congress(es) or intended submission of (a) publication(s) to peer-reviewed journals.

Anticipated Project Timeline

- Provide an anticipated timeline for your project including project start/end dates.
    - An ISR grant request cannot be submitted for a study that has already commenced and was not originally supported by Pfizer.

Additional Information

- If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here.
- Early-career applicants: Letter(s) of support from mentor(s) and collaborators describing how the award will advance the applicant's career.

Organization Detail

- This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used [laboratory, animal, clinical and “other”]. If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project.

Budget Detail

- While estimating your budget please keep the following items in mind:
  - General organizational running costs such as legal fees, insurance, heating, and lighting etc. should be included in an Institutional Overhead (if required). These costs are not specific to a grant request and therefore, should not appear as line items in budgets. However, costs that are specific to the study (e.g., some countries require insurance to be taken out on a per-study basis for clinical research) would be acceptable to be included as line items.
    - The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
  - 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.
  - It should be noted that grants awarded through GMGP cannot be used to purchase Pfizer therapeutic agents (prescription or non-prescription).
- Pfizer maintains a company-wide, maximum allowed Institutional Overhead rate of 28% for independent studies and projects. Please click here for details.