Pfizer Research Grant Request for Proposals

The Value of axitinib in combination with Immuno-oncology (IO) in Patients with Metastatic Renal Cell Carcinoma (mRCC)

Competitive Grant Program –Pfizer Internal Review Process

Overview

This competitive program seeks to generate new evidence in the management of mRCC patients. Research projects to be supported should be focused on effectiveness and/or safety profile of axitinib+IO in mRCC.

Geographic Scope/Location of Project

China

Project Types and Area of Interest

Potential applicants are encouraged to identify and address data gaps for mRCC relating to axitinib in combination with IO treatments. This may include:

- First Line (1L) axitinib and Immuno-oncology (IO) combinations with supporting evidence
- Efficacy/AE management/PRO (Patient report outcomes) for axitinib combinations with IO
- Real World Data (RWD) studies

Key Milestones

- Application submission deadline: **February 17, 2025**
- Anticipated decision notification date: **April 30, 2025**
- Anticipated project start date: **August 2025**

Funding Range and Project Length

The estimated total available budget related to this RFP is $450,000 Individual projects requesting up to $50,000 will be considered.

Drug/compound requests are not in scope of this RFP. This RFP will only support requests for monetary funding for research studies. Drug supply requests cannot be part of these applications.

Maximum project length is 2 years.

Pfizer

I. Eligibility

Geographic Scope/Location of Project/Study:

- China

Applicant Eligibility Criteria

- The institution and Principal Investigator (PI) must be based in China.
- 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).
- 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.
- The PI must have a medical or postdoctoral degree (MD, PhD, or equivalent), an advanced nursing degree (BSN with a MS/PhD), or a degree in Pharmacy, Physiotherapy, or Social Work.
- 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 Investment Co., Ltd. We strongly recommend that applicants confirm this with their organization or institution prior to submitting an application. Grants awarded to organizations that are subsequently found to be unable to accept funding directly from Pfizer Investment Co., Ltd may be subject to rescission.

II. Requirements

Date RFP Issued

- October 10, 2024

Clinical Area

- Renal Cell Carcinoma

General Area of Interest for this RFP:

Potential applicants are encouraged to identify and address the data gaps for mRCC related to axitinib in combination with IO treatments. This may include:

- First Line (1L) axitinib and Immuno-oncology (IO) combinations with supporting evidence
- Efficacy/AE management/PRO (Patient report outcomes) for axitinib combinations with IO
- Real World Data (RWD) studies

Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to $50,000 will be considered. The estimated total available budget related to this RFP is $450,000. Drug/compound requests are not in scope of this RFP. This RFP will only support requests for monetary funding for research studies. Drug supply requests cannot be part of these applications.
- Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.

Key Dates:

- RFP release date: **October 10, 2024**
- Grant Application due date: **February 17, 2025**
- Anticipated Grant Award Notification Date: **April 30, 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.
- Anticipated Project Start and End Dates: **August 2025** to **August 2027**

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”.
- 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 CN The Value of Axitinib combinations with Immuno-oncology in Patients with mRCC RES
  - Select the following Primary Area of Interest: Oncology-Genitourinary-RES.
- 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, Juan Liu (GMGChina@pfizer.com), with the subject line “2024 ONC CN The Value of Axitinib combination with Immuno-oncology in Patients with Metastatic Renal Cell Carcinoma RES October 10, 2024”
- 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.

Review and Approval Process

- Grant requests received in response to a general RFP are reviewed by Pfizer 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 15-page limit exclusive of references. 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

- The budget amount requested must be in Chinese YUAN(CNY).
- 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 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 click here for details.