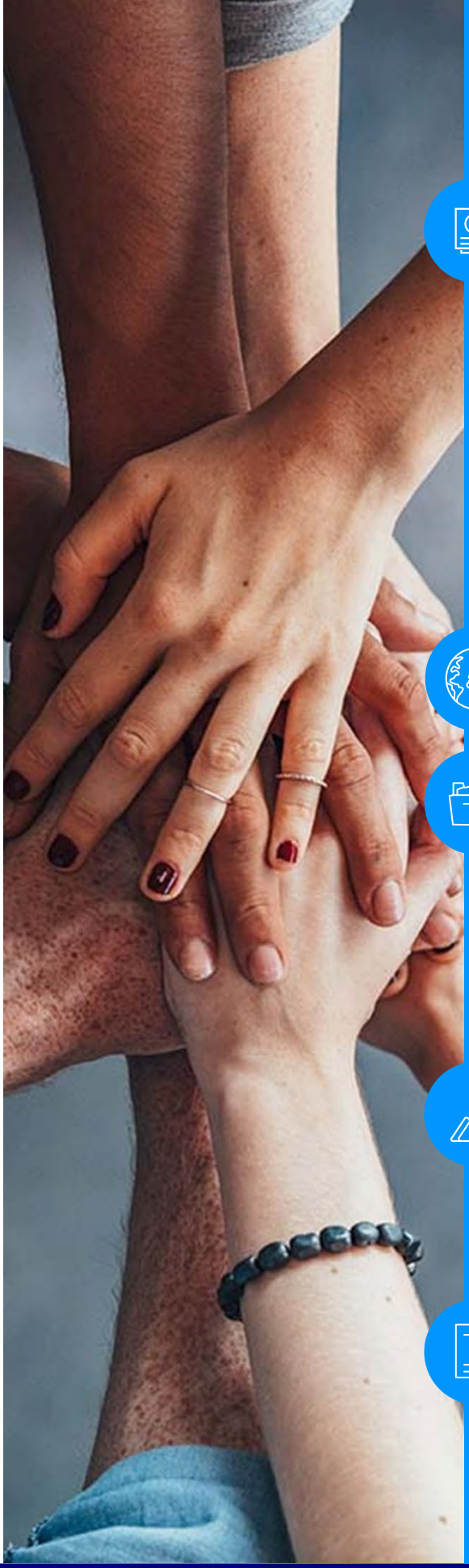

Pfizer Request for Proposals (RFP)

Exploring the Use of Artificial Intelligence (AI) Applications in ALK+ NSCLC

Competitive Grant Program – using Expert Review Panel (ERP)

Overview

The intent of this RFP is to support initiatives that will improve the quality of care or quality of healthcare services for patients with ALK+ Non-Small Cell Lung Cancer (NSCLC) through the incorporation of AI applications and clinical tools.

At Pfizer it's our mission to be the premier, innovative biopharmaceutical company, making breakthroughs that change patients' lives. Good health is vital to all of us and finding sustainable solutions to the most pressing health care challenges of our world cannot wait. That's why we at Pfizer are committed to applying science and our global resources to improve health and well-being at every stage of life. We strive to provide access to safe, effective and affordable medicines and related health care services to the people who need them.

Geographic Scope/Location of Project

Italy

Project Types and Area of Interest

Organizations are invited to submit proposals for either General Research or Quality Improvement projects that will implement innovative AI-based approaches to improve the quality of care for ALK+ NSCLC patients. Projects should aim to improve patient care at any point from diagnosis to clinical experience including addressing the physical, social, or emotional side effects of therapies. Projects may include optimization of the collection and evaluation of patient-reported outcomes (PROs).

Key Milestones

- Application submission deadline: May 02, 2025.
- Anticipated decision notification date: July 01, 2025.
- Anticipated project start date: December, 2025.

Funding Range and Project Length

- Individual projects requesting up to €90,000 will be considered. The total available budget related to this RFP is €180,000.
- Projects should start in 2025 with a project duration of up to 2 years.

I. Eligibility

Geographic Scope/Location of Project:

- Italy

Applicant Eligibility Criteria

- 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 patients.
- 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).
- 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.
- The applicant must be the Project Lead/Principal Investigator (PI) or an authorized designee of such individual (e.g., Project Lead/PI's grant/research coordinator).
- The Project Lead/PI must be an employee or contractor of the requesting organization.
- Requesting organization must be legally able to receive award funding directly from Pfizer International LLC. 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 International LLC may be subject to rescission.

II. Requirements

Date RFP Issued

- February 10, 2025

Clinical Area

- Oncology – Lung: ALK+ NSCLC

General Area of Interest for this RFP:

IMPORTANT: Projects that will be considered for Pfizer support may fall into 1 of 2 different grant types:

1) Investigator-Sponsored/General Research designed to develop and study the effectiveness of a new AI-based tool or strategy in a pilot group of ALK+ NSCLC patients; or

2) Quality Improvement (QI) projects aimed at translating existing and already validated AI-based tools or strategies into everyday clinical practice for the benefit of all ALK+ NSCLC patients coming through that organization or institution

Areas of interest include:

- Improve histological and molecular biomarker testing practices in NSCLC.
- Development of standard workflows for biomarker testing.
- Optimal management of the most common pharmacological side effects.
- Initiatives to improve patients' quality of life and enhance the collection and utilization of PROs.
- Implementing tools for sharing experiences between groups of patients and between patients and

caregivers to optimize their diagnostic and/or therapeutic awareness and opportunities.

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.

Target Audience

Medical Oncologist, Pneumologist, Radiotherapist, Surgeon

Disease Burden Overview

ALK+ NSCLC represents 5-8% among all the NSCLC cases. The prognosis of ALK+ patients has been improved upon the clinical introduction of therapeutic agents targeting oncogene mutations. Thus, access to the standard of care including early biomarker testing and targeted treatment is pivotal to achieving optimal patient outcomes.

Although national and international guidelines recommend a comprehensive molecular diagnostic approach from the initial phase, routine implementation of guideline-concordant biomarker testing for patients with NSCLC has proven challenging and has not been fully incorporated into clinical practice.

Recommendations and Target Metrics

ALK+ NSCLC is characterized by high disease related symptoms, with a specific tropism for CNS metastasis. Available anti-cancer therapies are characterized by a particular safety profile impacting a patients' quality of life. Metrics to be evaluated might include: improving in testing rate, QoL evaluation, PROs based upon PROs collected during clinical trials, patient's preferences, effective communication among HCPs, patients and caregivers, therapy adherence, safety report incidence, reasons for treatment discontinuation, etc.

Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to €90,000 will be considered. The estimated total available budget related to this RFP is €180,000.
- Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.
- 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 grant agreement.

Key Dates:

- RFP Release Date: **February 10, 2025**
- Full Proposal Due Date: **May 02, 2025**
  - Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Review of Full Proposals by ERP: **June 16, 2025**
- Anticipated Full Proposal Notification Date: **July 01, 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.

How to Submit

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

For Investigator Sponsored/General Research projects:

Please go to https://www.cybergrants.com/pfizer/Research and sign in.

For Quality Improvement projects:

Please go to www.cybergrants.com/pfizer/QI and sign in.

All the following sub-instructions are the same for Sponsored/General Research projects and Quality improvement projects:
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" or the “Start a New Quality Improvement Application” button.
• In the application:
• For the question “Competitive Grant?” select Yes
• Select the following Competitive Grant Program Name: 2025 ONC IT: ALK+ NSCLC Research-QI
• Select the following Primary Area of Interest: Oncology – Lung Cancer – ALK+ NSCLC
• 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 “[2025 ONC IT: ALK+ NSCLC Research-QI February 10].”

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

- A specific grant program RFP uses an 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.

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.

About Quality Improvement Projects

Quality improvement (QI) projects are systematic, data-guided, sustainable activities designed to bring about immediate, positive changes in the delivery of healthcare in particular settings[1,2]. Quality improvement seeks to standardize structure and processes to reduce variation, achieve predictable results, and improve outcomes for patients, healthcare systems, and organizations. Structure includes things like technology, culture, leadership, and physical capital. Process includes knowledge capital (e.g., standard operating procedures) or human capital (e.g., education and training)[3].

QI projects systematically apply what is already known into the local practice, intended to quickly improve patient care within a specific setting. The goal of QI projects is to close a gap in performance at a specific health care system. The "performance" is a standard in health care that is not efficiently/appropriately/consistently being done[4]. For these reasons, QI focuses on translating existing knowledge into programs or practices to immediately improve the quality of services to individuals and populations within a local institution or setting[5]. The risk of participation in QI is the same as the risk of receiving standard clinical care6 since the standard of care remains the same for all patients.

In contrast, research projects use a systematic approach to discover something that is unknown. Research projects add new knowledge to what was previously unknown in literature through testing of a hypothesis or a scientific question[4]. Research aims to generate knowledge with broad applications, often through controlled studies. The subjects may or may not benefit directly from the knowledge gained. Research studies aim to evaluate an innovation, study something new, or analyze a process not yet rigorously studied[6].

1) Baily MA, *et al*., Hastings Cent Rep, 2006. 2) Lynn J, *et al*., Ann Intern Med, 2007. 3) Centers for Medicare & Medicaid Services, Page Last Modified: 09/10/2024. 4) Jackson C, Research Quality Manager, Office of Research and Scholarship University of Maryland, Baltimore School of Nursing. 5) Columbia University Institutional Review Board Guidance for the Classification of Quality Improvement Activities Versus Research with human Subjects, 2023. 6) Newhouse *et al*., J Nurs Adm, 2006.

Appendix

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

- For general research project, 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.
- For QI project: 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).
- For QI project: 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

- For general research 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.
- 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. 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

- For general research project: 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.
- For QI projects: 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

- For general research project: 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.
- 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.
- A general research 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 EUR.
- 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 overhead 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.