



**Competitive Research Grant Program -
Improving Duration of Therapy and Outcomes in
NSCLC Patients Receiving Targeted Therapy**

Request for Proposals (RFP)

1. Background and Program Summary

The Lung Cancer Research Foundation and Pfizer Global Medical Grants are collaborating to offer a new research grant opportunity focused on understanding ways to improve clinical practices for side effect management for non-small cell lung cancer (NSCLC) patients receiving targeted therapies.

About the Lung Cancer Research Foundation:

The Lung Cancer Research Foundation (LCRF) is the leading nonprofit organization focused on funding innovative, high-reward research with the potential to extend survival and improve quality of life for people with lung cancer. The foundation's mission is to improve lung cancer outcomes by funding research for the prevention, diagnosis, treatment and cure of lung cancer. Through its scientific grant program, LCRF has funded 362 research grants totaling \$33 million since inception.

In this initiative, LCRF will support grantees and foster collaboration by hosting meetings/forums that bring together researchers, project leaders, and other key stakeholders throughout the award period. The organization will leverage its expertise in bringing together thought leaders in the field and highlighting the many ways in which research has made an impact on lung cancer treatment advancements. LCRF will also be responsible for overseeing and facilitating the pre- and post-award processes.

About Pfizer:

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 works with a partner organization or an external review panel to make final grant decisions. Organizations are invited to submit an application addressing the specific gaps in research, practice or care as outlined in the 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.

About This Initiative:

With the rapid development of new targeted therapies for the treatment of lung cancer, effective management of side effects and adverse events (AEs) has become increasingly important to ensure patients' adherence and compliance and lead to the most potentially effective duration of therapy. As new generations and classes of tyrosine kinase inhibitors continue to enter the market, more sophisticated approaches and increased vigilance are needed to effectively manage their toxicities and enable patients to benefit from these new treatments.

Some of the most common AEs in patients treated with EGFR inhibitors include diarrhea, skin toxicity, nausea, and/or other gastrointestinal or cutaneous effects.¹⁻² Patients whose tumors harbor other genetic alterations in genes such as ALK may be treated with drugs that elicit a different toxicity profile including hyperlipidemia, central nervous system effects, weight increase, edema, peripheral neuropathy, and/or gastrointestinal effects.³⁻⁵ The effective identification, diagnosis, and treatment of these toxicities is a significant clinical need. Moreover, low treatment adherence due to drug toxicities may diminish the overall effectiveness of a patient's treatment and has been linked to poorer overall outcomes.⁶ Improved approaches to side effect and AE management have the potential for significant impact on lung cancer treatment and are increasingly needed in a quickly evolving landscape of new targeted therapies.

To meet these needs, this collaborative funding mechanism is designed to support innovative health services research proposals that leverage multidisciplinary approaches to improve the management of targeted therapy toxicities. Proposals on a variety of topics including the following are encouraged:

- Patterns of real-world versus pre-approval patient side-effect experiences
- Defining and understanding tolerability (including late toxicities and patient reported outcomes)
- Role of diverse, multi-disciplinary teams (including pharmacists, dieticians, caregivers, etc.) and coordination of care in managing and monitoring therapy
- Real-time symptom monitoring
- Implementation science approaches to improving care delivery

Projects incorporating mixed-practice settings through collaborations such as in the NCI's Community Oncology Research Program, the SIMPRO Research Center, and other quality-of-care alliances are also encouraged. Through this initiative, **Pfizer and LCRF will support up to three innovative health services research projects focused on the improved management of treatment toxicities from targeted therapies in NSCLC patients. Specifically, up to \$350,000 will be provided over a period of two years to investigators at US-based institutions.** Additional eligibility details and application instructions may be found below.

2. Eligibility Criteria

Project scope:

Approaches to management of toxicities in NSCLC patients treated with tyrosine kinase inhibitors, including but not limited to ALK, ROS1, and/or EGFR inhibitors, fall within the scope of this project. Approaches focused on side effects of immunotherapies, however, are not eligible.

Investigator eligibility:

All investigators at or above the level of postdoctoral fellow (or equivalent) who hold a tenure or non-tenure track faculty appointment at a US-based, non-profit academic or research institution are eligible to apply. Applicants from non-US institutions are not eligible to apply for this funding opportunity.

3. Application Instructions

Proposals for funding consideration must be submitted via a two-step process consisting of a letter of intent (LOI) followed by a full proposal. Upon submission and review of the LOIs, investigators whose proposals are deemed most relevant to the area of interest and demonstrate an exceptional level of scientific merit will be invited to submit full proposals. Complete details of the LOI components may be found in the Appendix.

All LOIs and subsequent full applications will be accepted via Pfizer's online grants management system at <https://www.cybergrants.com/pfizer/loi>. You will be asked to sign in. First-time users should click "REGISTER NOW". Select the following Competitive Grant Program Name: **LCRF- Managing Side Effects of Targeted Therapies**. Complete all required sections of the online application. See Appendix for additional details. If you encounter any technical difficulties with the website, please click the "Technical Questions" link at the bottom of the page.

4. Timeline

- RFP release date: April 29, 2019
- LOI deadline: June 24, 2019
- Full applications invited: August 1, 2019
- Application deadline: September 19, 2019
- Notification of award: November 12, 2019
- Project start: December 2019 / January 2020

5. Budget Requirements

The maximum award amount is \$350,000 for a period of two years. Additional budget requirements and considerations include the following:

Permitted	Not Permitted
<ul style="list-style-type: none"> • Overhead/indirect/F&A costs not exceeding 15% of the total* • Publication expenses 	<ul style="list-style-type: none"> • Direct patient care costs reimbursable by other sources • Capital equipment • Travel expenses • Food/beverages

** Note: This indirect cost rate is specific for this initiative. Any standard Pfizer or LCRF allowable indirect rates are not applicable.*

6. Open Science and Data Sharing

LCRF and Pfizer are committed to promoting open science by helping to increase access to investigators' findings and improving collaboration and data sharing among the lung cancer research community. Accordingly, it is a condition of funding that all peer-reviewed articles supported in whole or in part by this award must be made available in the PubMed Central online archive no later than twelve months after publication. In addition, grantees must indicate explicitly in all reports, publications, and other research communications whether the data, methods used in the analysis, and materials used to conduct the research will be made available to any researcher for purposes of reproducing the results or replicating the procedure. At the time of application, all investigators must indicate if they will or will not make their data, analytic methods, and study materials available to other researchers.

7. Evaluation of Applications

LOIs and full proposals will be reviewed by a panel of experts convened by LCRF and Pfizer. This multidisciplinary panel will consist of experts in health services research and other disciplines who will be asked to provide their assessment of the likelihood for the project to exert a sustained, powerful influence in the specific area of interest. Criteria that will be considered include scientific rationale and level of innovation, potential impact and expected outcomes of the project, and the capacity to carry out the work (including appropriateness of amount requested).

LOIs will be evaluated on the above criteria and will be required to include the following sections (see Appendix for additional detail):

- Goals and Objectives
- Assessment of Need for the Project
- Target Audience
- Project Design and Methods
- Innovation
- Evaluation and Outcomes
- Anticipated Project Timeline
- Additional Information
- Organization Detail

Feedback: Regrettably, due to the high volume of submissions, specific feedback will not be provided at the LOI stage. Summary feedback will be provided on full proposals.

8. Award Notification and Announcement

All applicants will be notified of their award status via email by the date specified in the Timeline section above, and awards will be publicly announced subsequently at an LCRF event, via press release, the LCRF and Pfizer websites, social media, and/or other means.

9. Post-award Reporting Requirements

During the funding period, all investigators are required to submit progress reports every six months.

In addition, investigators may be asked to participate in person LCRF-hosted investigator meetings at the end of year one of the grant term and/or upon its completion.

10. Inquiries

For questions, please contact the LCRF office at grants@lcrf.org. You may also contact Jacqueline Waldrop, Grant Officer, Pfizer Inc. via email at Jacqueline.Waldrop@Pfizer.com.

11. Terms and Conditions

- a. This RFP does not commit Pfizer or its partners to award a grant or a grant of any particular size if one is awarded, nor to pay any costs incurred in the preparation of a response to this request.
- b. Pfizer and LCRF jointly reserve the right to accept or reject any or all applications received as a result of this request, or to cancel this RFP in part or in its entirety, if it determines it is in the best interest of Pfizer and LCRF to do so.

12. References

1. Ding, Pei Ni, Sarah J. Lord, Val GebSKI, Matthew Links, Victoria Bray, Richard J. Gralla, James Chih-Hsin Yang, and Chee KhooN Lee. "Risk of Treatment-Related Toxicities from EGFR Tyrosine Kinase Inhibitors: A Meta-Analysis of Clinical Trials of Gefitinib, Erlotinib, and Afatinib in Advanced EGFR-Mutated Non-Small Cell Lung Cancer." *Journal of Thoracic Oncology* 12, no. 4 (April 1, 2017): 633–43. <https://doi.org/10.1016/j.jtho.2016.11.2236>.
2. Bauer, Todd M., Enriqueta Felip, Benjamin J. Solomon, Holger Thurm, Gerson Peltz, Marc D. Chioda, and Alice T. Shaw. "Clinical Management of Adverse Events Associated with Lorlatinib." *The Oncologist*, March 19, 2019, [theoncologist.2018-0380](https://doi.org/10.1634/theoncologist.2018-0380). <https://doi.org/10.1634/theoncologist.2018-0380>.
3. Rothenstein, J. M., and N. Letarte. "Managing Treatment-Related Adverse Events Associated with Alk Inhibitors." *Current Oncology (Toronto, Ont.)* 21, no. 1 (February 2014): 19–26. <https://doi.org/10.3747/co.21.1740>.
4. Sullivan, Ivana, and David Planchard. "ALK Inhibitors in Non-Small Cell Lung Cancer: The Latest Evidence and Developments." *Therapeutic Advances in Medical Oncology* 8, no. 1 (January 2016): 32–47. <https://doi.org/10.1177/1758834015617355>.
5. Zhu, Qian, Hao Hu, De-Sheng Weng, Xiao-Fei Zhang, Chang-Long Chen, Zi-Qi Zhou, Yan Tang, and Jian-Chuan Xia. "Pooled Safety Analyses of ALK-TKI Inhibitor in ALK-Positive

NSCLC.” *BMC Cancer* 17, no. 1 (June 12, 2017): 412. <https://doi.org/10.1186/s12885-017-3405-3>.

6. Borghaei, Hossein, Yeun Mi Yim, Annie Guerin, Irina Pivneva, Sherry Shi, Mayank Gandhi, and Raluca Ionescu-Iltu. “Severe Adverse Events Impact Overall Survival and Costs in Elderly Patients with Advanced Non-Small Cell Lung Cancer on Second-Line Therapy.” *Lung Cancer (Amsterdam, Netherlands)* 119 (2018): 112–19. <https://doi.org/10.1016/j.lungcan.2018.02.011>.

Appendix: LOI Submission Guidance

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	<ul style="list-style-type: none">• Provide the main goal of the study and the study population. Provide a detailed definition that is directly linked to the primary objective
Assessment of Need for the Project	<ul style="list-style-type: none">• This should reflect your study rationale. Provide a brief description of the medical question and the rationale of how this project addresses the question
Target Audience	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Describe concisely the research design and methods for achieving the stated goals.
Innovation	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Define what constitutes success of your project and what you will do to measure this. Specify type and frequency of any outcome measures and indicate the method(s) used to assess these measures
Anticipated Project Timeline	<ul style="list-style-type: none">• Provide an anticipated timeline for your project including project start/end dates
Additional Information	<ul style="list-style-type: none">• If there is any additional information you feel Pfizer and LCRF should be aware of concerning the importance of this project, please summarize here
Organization Detail	<ul style="list-style-type: none">• 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