Pfizer Announces a Research Grant RFP

Pre-clinical and Translational Research in Multiple Myeloma

Competitive Grant Program - internal Pfizer review process

I. Background

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 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.

II. Eligibility

Geographic Scope:	Italy
Applicant Eligibility Criteria	• The institution and principal investigator (PI) must be based in Italy • Only organizations are eligible to receive grants, not individuals or medical practice groups. • The applicant (PI) must have a medical or postdoctoral degree (MD, PhD, or equivalent). • Applicant must be affiliated with a host institution • Both early career and experienced investigators are encouraged to apply.

III. Requirements

Date RFP Issued	• February 16, 2022
Clinical Area	• Multiple Myeloma (MM)

General Area of Interest for this RFP:	Projects that will be considered for Pfizer support will focus on:
	• Exploring the predictive impact of biological mechanisms in response/refractoriness to and relapse after anti-BCMA (B-cell maturation antigen) treatment, in particular
	  • Mechanisms of resistance and scientific rationale for potential sequencing of therapies (e.g., role of soluble BCMA [sBCMA] in resistance/relapse; downregulation of membrane bound BCMA; T-cell exhaustion)
	  • The correlation between soluble BCMA (sBCMA) and BCMA expression on myeloma cells (including assessment of gamma secretase activity)
	  • Mechanistic understanding of the impact of previous anti-myeloma agents (e.g., immunomodulatory drugs (IMiDs) –, anti-CD38, proteasome inhibitors, dexamethasone) and dynamic biological evolution of MM disease, in particular related on elranatamab - mediated T-cell activation and anti-myeloma activity
	  • Exploring *in vitro* or *in vivo* novel combination with elranatamab (PF-06863135) with focus on drugs that are not currently standard of care (SOC) in MM
	  • How changes in bone marrow microenvironment triggered by

	pathological plasma cells can impact on immunotherapy outcomes and how to use this evidence to enhance anti-BCMA efficacy • Comparative analysis of bone marrow aspirate transcriptomes between responders and non-responders to SOC treatment and elranatamab • Advanced proteoma and proteogenoma analysis to elucidate functional MM biology with particular focus on anti-BCMA pathway • Exploring immunological microenvironment and anti-BCMA pathway in the elderly population e.g. aging-associated molecular changes. Their potential impact on disease response to anti-BCMA, development biological rationale for tailored treatment strategy and tolerability of elranatamab • Preclinical predictive model and evaluation of biological heterogeneity for minimization of toxicity, with particular focus on cytokine release syndrome (CRS) • Expanding development, use and application of computational analysis, artificial intelligence, machine learning in MM setting, with particular focus on anti BCMA pathway NOTE: A limited amount of the Pfizer asset elranatamab (PF-06863135) is available and can be requested through this RFP for non-clinical studies.
Expected Approximate Monetary Range of Grant Applications:	• Individual projects requesting up to 100,000 EUR will be considered. However, for large-scale and/or innovative translational methodology projects of particular relevance, Pfizer may consider requests for higher budgets and the details of this should be clearly outlined in the proposal. • The estimated total available budget related to this RFP is 300,000 EUR.
Key Dates:	• RFP release date: February 16, 2022 • Grant Application due date: May 25, 2022 (Extension, original due date : May 18 2022). Please note the deadline is 23:59 Eastern Standard Time (e.g. New York, GMT -5). • Anticipated Grant Award Notification Date: July 2022 (Extension, original date : June 2022). • Grants will be distributed following a fully executed agreement. • Anticipated Project Start and End Dates: December 2022 to December 2024.

How to Submit:	• 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 (e.g., knowledge, LOI, research full proposal, and QI full proposal). Please be sure to use the URL above.]* • Click the "Start A New Research Grant Application" button. • In the application: o For the question "Competitive Grant?" select Yes o Select the following Competitive Grant Program Name: 2022 Onc IT: Pre-clinical and Translational Research in Multiple Myeloma o Select the following Primary Area of Interest: Oncology – Hematology – Multiple Myeloma • 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, Ai Ping Lee (AiPing.Lee@pfizer.com), with the subject line 'Pre-clinical and Translational Research in Multiple Myeloma" February 2022.' • 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. • 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.
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.

Appendix A

General RFP Submission Requirements

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. Please include the following:

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. All publications must follow ICH guidelines
Anticipated Project Timeline	• Provide an anticipated timeline for your project including project start/end dates o 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 Euros (EUR) • While estimating your budget please keep the following items in mind: o General organizational running costs 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. o The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP. o 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
References	• Bibliography of relevant references.