



Pfizer Announces a **Research Grant RFP**

# **2021/2022 Global Cachexia ASPIRE\***

**Competitive Grant Program- using Expert Review Panel**

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 research, practice or care 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.

\*ASPIRE: Advancing Science and Patient care through Innovative Research and Education

## Competitive Grant Program Eligibility

<b>Geographic Scope</b>	<ul style="list-style-type: none"> <li>• Global</li> </ul>
<b>Applicant Eligibility Criteria</b>	<p>To be eligible:</p> <ul style="list-style-type: none"> <li>• Only organizations are eligible to receive grants, not individuals or medical practice groups.</li> <li>• The applicant (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.</li> <li>• Applicant must be affiliated with a host institution.</li> <li>• Both early career and experienced investigators are encouraged to apply and consideration will be given to all proposals meeting the selection criteria.</li> </ul>

## Requirements

<b>Date RFP Issued</b>	<ul style="list-style-type: none"> <li>• October 4, 2021</li> </ul>
<b>Clinical Area</b>	<ul style="list-style-type: none"> <li>• Cachexia/GDF-15</li> </ul>
<b>Area of Interest Focus</b>	<p><b>The following types of research will be considered in-scope:</b></p> <ul style="list-style-type: none"> <li>• Basic science, pre-clinical research, and clinical research that aligns with the in-scope research topics.</li> <li>• Animal experimentation related to human biology.</li> <li>• Translational studies.</li> </ul> <p>In-scope research includes:</p> <p><b>Evidence generation in Understanding Cachexia/Unintentional Weight Loss in Cancer or Heart Failure:</b></p> <ol style="list-style-type: none"> <li>a. Predictors and vulnerabilities for the development of cachexia (i.e., cancer, HF)</li> <li>b. Early diagnoses of cachexia based on underlying mechanisms and/or biomarkers</li> <li>c. Impact of cachexia on treatment/management outcomes of specific diseases (i.e., cancer, heart failure)</li> <li>d. Impact of cachexia (i.e., cancer, heart failure) on physical activity, performance, or functional measures</li> <li>e. Understanding the impact of reversing and/or maintaining weight gain in patients with cachexia (cancer, heart failure)</li> <li>f. Understanding the impact of cachexia on the ability (or inability) to receive cancer treatment (e.g. surgery, chemotherapy, other anticancer treatments etc.)</li> </ol>

- g. Understanding the impact of managing cancer cachexia in patients presenting with obesity at diagnosis
- h. Understanding the impact on outcomes of diagnosing cachexia earlier vs later
- i. Understanding sex-specific differences in cachexia
- j. Assessment of the current management of cachexia/unintentional weight loss in cancer, palliative care and/or heart failure
- k. Understanding the cachexia palliative care patient journey (academic center vs community)
- l. Understanding if/how cachexia differentially impacts underserved populations
- m. Understanding the impact of multimodal, non-therapeutic interventions on cachexia/UWL

**Role of GDF-15/GFRAL Pathway in Disease:**

- a. Cancer
  - Role in unintentional weight loss and cachexia associated with cancer
  - Direct role of GDF-15/GFRAL in cancer (i.e. anti-tumor genesis, metastasis, immunotherapy, etc)
- b. Heart Failure
  - Direct role of GDF-15/GFRAL in HF
  - Understanding the causal relationship/mechanistic link between GDF15 pathway and HF clinical associations (fatigue, survival, poor outcomes, etc)
- c. Relevance and Impact of GDF-15/GFRAL in normal aging

**GDF-15/GFRAL Biology:**

- a. Ligand-receptor interactions
- b. Interactions between GFRAL+ neurons and the traditional hypothalamic feeding center
- c. Impact of Inflammation/Immuno-inflammatory response on GDF-15 signaling
- d. Role of GDF-15/GFRAL pathway on peripheral organ metabolism and/or tissue wasting
- e. Neuroendocrine role of GDF-15/GFRAL

**Natural History (longitudinal) studies specifically related to cachexia/weight loss and/or heart failure:**

- a. The quantitative relationship of GDF-15 levels/concentration and body weight changes in cancer and heart failure over time
- b. Understanding how treatments for cancer or heart failure impact GDF-15 levels in the setting of cachexia/ unintentional weight loss

	<p>Out of scope research includes:</p> <ul style="list-style-type: none"> <li>• Studies involving investigational products</li> <li>• Any clinical or pre-clinical study involving the use of therapeutics, including GDF-15RA/GFRAL agents</li> <li>• Studies requesting use of Pfizer investigational drugs/pure compound</li> <li>• Retrospective database analysis of a specific drug</li> <li>• Highly invasive studies and studies that may have an ethical concern</li> <li>• Replication of existing studies (i.e., lack of innovation)</li> <li>• Pharmacoeconomic analyses</li> </ul>
<p><b>Expected Approximate Monetary Range of Grant Applications</b></p>	<ul style="list-style-type: none"> <li>• Individual projects requesting up to USD \$250,000 will be considered. Pfizer anticipates a total fund of USD \$750,000.</li> <li>• Research is expected to be completed and submitted for presentation/publication within 3 years of study start. Smaller, high-quality, innovative grant requests with anticipated results within 12-18 months will be enthusiastically considered</li> <li>• 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 approval notification.</li> </ul>
<p><b>Key Dates</b></p>	<ul style="list-style-type: none"> <li>• RFP release date: October 4, 2021</li> <li>• Full Proposal Due Date: *January 7, 2022 <i>*[Please note the deadline is 23:59 Eastern Time (New York, GMT -5).]</i></li> <li>• Review of Full Proposals by ERP: April 2022</li> <li>• Anticipated Full Proposal Notification Date: May 2022 <i>Processing time may take longer for organizations outside of the U.S</i></li> </ul>
<p><b>How to Apply</b></p>	<ul style="list-style-type: none"> <li>• Please go to <a href="http://www.cybergrants.com/pfizer/Research">www.cybergrants.com/pfizer/Research</a> and sign in. First-time users should click "Create your password". <i>[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.]</i></li> <li>• Click the “Start a New Research Grant Application” button.</li> </ul> <p>Requirements for submission:</p> <ul style="list-style-type: none"> <li>• For the question “Competitive Grant?” select Yes</li> <li>• Select the following Competitive Grant Program Name: <b>2021/2022 IM G: Cachexia ASPIRE</b></li> <li>• Complete all required sections of the online application. See <b>Appendix A</b> for additional details</li> <li>• If you encounter any technical difficulties with the website, please click</li> </ul>

	the “Technical Questions” link at the bottom of the page.
<b>Questions:</b>	<ul style="list-style-type: none"> <li>If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Jessica Romano (jessica.romano@pfizer.com), with the subject line “2021/2022 Global Cachexia ASPIRE.”</li> <li>Please click <a href="#">here</a> to view Frequently Asked Questions regarding the Competitive Grant Program.</li> </ul>
<b>Grant Agreements:</b>	<ul style="list-style-type: none"> <li>If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click <a href="#">here</a> to view the core terms of the agreement.</li> <li>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.</li> </ul>
<b>Review and Approval Process</b>	<ul style="list-style-type: none"> <li>Grant requests received in response to a specific RFP are reviewed by an expert review panel (ERP) to make final grant decisions.</li> <li>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.</li> <li>The members of the ERP are as follows: <ul style="list-style-type: none"> <li>Daniel Marks, MD, PhD (Chair) <i>Oregon Health &amp; Science University, Portland, OR</i></li> <li>Stephan von Haehling, MD, PhD <i>University Medical Centre Göttingen, Germany</i></li> <li>Aminah Jatoi, MD <i>Mayo Clinic, Rochester, MN</i></li> <li>Josep M. Argiles, PhD <i>University of Barcelona, Barcelona, Spain</i></li> <li>Florian Strasser, MD <i>Cancer Fatigue Clinic, Onkologie-SH &amp; Cantonal Hospital St.Gallen, Switzerland</i></li> <li>Marcus Dasilva Goncalves, MD, PhD <i>Weill Cornell Medical College, New York, NY</i></li> <li>Carla Prado, PhD, RD <i>University of Alberta, Edmonton, AB, Canada</i></li> </ul> </li> </ul>
<b>Mechanism by which Applicants will be Notified:</b>	<ul style="list-style-type: none"> <li>All applicants will be notified via email by the dates noted above.</li> <li>Applicants may be asked for additional clarification during the review period.</li> </ul>



## Appendix A

### Full Proposal/Protocol

Applications will be accepted via the online portal. Full Proposal/Protocol documents should be no longer than 6 pages in length (5 pages, plus 1 aims page; 12-point font and 1-inch margins) excluding Organization Detail and References. When uploading your Full Proposal/Protocol please ensure it addresses the following:

<b>Goals and Objectives</b>	<ul style="list-style-type: none"> <li>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</li> </ul>
<b>Assessment of Need for the Project</b>	<ul style="list-style-type: none"> <li>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</li> </ul>
<b>Target Audience</b>	<ul style="list-style-type: none"> <li>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</li> <li>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</li> </ul>
<b>Project Design and Methods</b>	<ul style="list-style-type: none"> <li>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</li> </ul>
<b>Innovation</b>	<ul style="list-style-type: none"> <li>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</li> <li>Note, the Principal Investigator should not be receiving, and will not receive, funding from other pharmaceutical companies for the submitted research proposal. No other industry-sponsored projects may cover the same work scope as the proposal covering the ASPIRE program. However, an ASPIRE research grant may be related to other funding from foundations or government agencies as long as there is no direct overlap. It is the responsibility of the applicant to justify the novelty of the proposal and provide evidence that the proposal does not overlap with any current or pending funding.</li> </ul>
<b>Evaluation and Outcomes</b>	<ul style="list-style-type: none"> <li>Specify type and frequency of safety, efficacy, and/or outcome measures. Also indicate the method(s) used to assess measures</li> </ul>

	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<b>Anticipated Project Timeline</b>	<ul style="list-style-type: none"> <li>• Provide an anticipated timeline for your project including project start/end dates</li> </ul>
<b>Additional Information</b>	<ul style="list-style-type: none"> <li>• If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here</li> <li>• Please describe how your proposal and/or your team seek to promote diversity, equity, and inclusion in this study.</li> <li>• Early-career applicants: Letter(s) of support from mentor(s) and collaborators describing how the award will advance the applicant's career.</li> </ul>
<b>Organization Detail</b>	<ul style="list-style-type: none"> <li>• 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</li> </ul>
<b>Budget Detail</b>	<ul style="list-style-type: none"> <li>• <b>The budget amount requested must be in U.S. dollars (USD).</b></li> <li>• While estimating your budget please keep the following items in mind: <ul style="list-style-type: none"> <li>○ Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment.</li> <li>○ Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.</li> <li>○ The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.</li> <li>○ It should be noted that grants awarded through GMG cannot be used to purchase therapeutic agents (prescription or non-prescription).</li> </ul> </li> </ul>
<b>References</b>	<ul style="list-style-type: none"> <li>• Bibliography of relevant references.</li> </ul>