

# Multidisciplinary Gene Therapy Education - Recombinant Adeno-Associated Virus (rAAV)

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 knowledge gaps as outlined in the specific RFP.

For all **independent medical education 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 of the independent education program.

### II. Eligibility

Geographic Scope:	Global
Applicant Eligibility Criteria	<ul> <li>The following may apply: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations and medical societies; medical education companies; and other entities with a mission related to healthcare professional education and/or healthcare improvement.</li> </ul>
	<ul> <li>If the project involves multiple departments within an institution and/or between different institutions / organizations / associations, then all institutions must have a relevant role and the requesting organization must have a key role in the project.</li> </ul>
	<ul> <li>For projects offering continuing education credit, the requesting organization must be accredited.</li> </ul>

#### **III. Requirements**

Date RFP Issued	October 18, 2021
Clinical Area	Gene Therapy – Rare Disease
General Area of Interest for this RFP:	<ul> <li>Through this RFP we seek to support educational initiatives that focus on one or both of the following:</li> <li>Improving the medical and scientific understanding of recombinant</li> </ul>
	adeno-associated virus (rAAV) gene therapy to help prepare multidisciplinary teams for the integration of rAAV gene therapy into the treatment armamentarium of eligible patients with a Rare Disease.
	<ul> <li>Advancing the preparedness of gene therapy centers with institutional and/or multidisciplinary team training to execute clinical and operational best practices (e.g., SOPs and workflows) to optimize the quality of care for patients who are eligible for available recombinant adeno-associated virus (rAAV) gene therapies.</li> </ul>





	<ul> <li>Proposals that include/address the following will be prioritized:</li> </ul>
	<ul> <li>Patient participation in the development of the initiative</li> </ul>
	<ul> <li>Diversity, equity and inclusion considerations</li> </ul>
	<ul> <li>Health literacy best practices</li> </ul>
	<ul> <li>Omnichannel approaches (an integrated approach between multiple channels of communication).</li> </ul>
	<ul> <li>Projects that address recombinant adeno-associated virus gene therapy in Rare Disease and that are therapeutic area and disease area agnostic (i.e., not related to a specific disease or group of diseases) will be prioritized.</li> </ul>
Target Audience:	Members of multidisciplinary care teams for rAAV gene therapy including but not limited to Pharmacists, Specialty Nurses, Genetic Counsellors, Medical Geneticists, and other Physicians.
Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to \$50,000 USD will be considered.  Pfizer anticipates supporting up to 3 projects.
Key Dates:	RFP release date: October 18, 2021
	Grant Application due date: December 21, 2021
	Anticipated Grant Award Notification Date: February 1, 2022
	<ul> <li>Grants will be distributed following a fully executed agreement.</li> </ul>
	o Anticipated Project Start Date: April 1, 2022
How to Submit:	Please go to <a href="https://www.cybergrants.com/pfizer/knowledge">www.cybergrants.com/pfizer/knowledge</a> and sign in. First-time users should click "Create your password".
	In the application:
	<ul> <li>For the question "What type of request are you submitting?" select Response to a Request for Proposal (RFP)</li> </ul>
	<ul> <li>For the question "Are you replying to a Request for Proposal as part of the Competitive Grant Program?" select Yes</li> </ul>
	<ul> <li>Select the following Competitive Grant Program Name: 2021 RD</li> <li>G Gene Therapy Education</li> </ul>
	<ul> <li>Select the following Primary Area of Interest: Gene Therapy</li> </ul>
	Requirements for submission:
	Complete all required sections of the online application and upload your





	<ul> <li>project proposal (see Appendix) in the General RFP Submission field.</li> <li>If you encounter any technical difficulties with the website, please click the "Technical Questions" link at the bottom of the page.</li> <li>IMPORTANT: Be advised applications submitted after the due date will not be reviewed by the committee.</li> </ul>
Questions:	<ul> <li>If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Amanda Stein (<u>amanda.j.stein@pfizer.com</u>), with the subject line "Gene Therapy Education".</li> </ul>
Grant Agreements:	<ul> <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">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>
Review and Approval Process	<ul> <li>Grant requests received in response to a general RFP are reviewed by Pfizer to make final grant decisions.</li> </ul>
Mechanism by which Applicants will be Notified:	<ul> <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 General RFP Submission Requirements

Project Proposals should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 12-page limit exclusive of references. Please include the following:

Goals and Objectives	<ul> <li>Briefly state the overall goal of the project.</li> <li>List the objectives you plan to meet with your project, in terms of learning and expected outcomes.</li> </ul>
Needs Assessment for the Project	<ul> <li>Include a description of your organization's needs assessment for this proposed project which may include a quantitative baseline data summary, initial metrics, 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.</li> </ul>
Target Audience	Describe the primary audience(s) targeted for this project. 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 the planned project, the educational approach, and the way the planned methods address the established need.
Innovation	<ul> <li>Explain what measures you have taken to assure that this project 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.</li> </ul>
Evaluation and Outcomes	<ul> <li>In terms of the metrics used for the needs assessment, describe how your organization will determine if the gap was addressed for the target group. Identify the sources of data your organization anticipates using to make the determination.</li> </ul>
	<ul> <li>Describe how your organization is expected to collect and analyze the data. Explain the method used to control for other factors outside this project (e.g., use of a control group or comparison with baseline data). Quantify the amount of change expected from this project in terms the target audience. Describe how your organization will determine if the target audience was fully engaged in the project.</li> </ul>





Dissemination Plan	<ul> <li>Describe how the project may have extended benefit beyond the grant. Will the teaching materials be made available to others to use? Will there be tools or resources that are made publicly available beyond the initial project. Describe how the project outcomes might be broadly disseminated.</li> </ul>
Anticipated Project Timeline	<ul> <li>Provide an anticipated timeline for your project including project start/end dates.</li> </ul>
Additional Information	If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here.
Organization Detail	<ul> <li>Describe the attributes of the institutions/organizations that will support and facilitate the execution of the project, the leadership of the proposed project, and the specific role of each institution in the proposed project.</li> </ul>
Budget Narrative	<ul> <li>Please include a budget narrative that describes in greater detail the line items specified in the budget submitted within the application</li> <li>While estimating your budget please keep the following items in mind:         <ul> <li>Independent Medical Education Grants awarded by GMG cannot be used to purchase therapeutic assets (prescription or non-prescription).</li> <li>Overhead rates up to 28% may be supported by Pfizer, however, the project budget including overhead must not exceed the grant maximum.</li> </ul> </li> </ul>



