



**Pfizer Announces**  
***Improving the Management of Patients with Uncontrolled Acromegaly***  
***Competitive Grant Program- using External Review Panel***

**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 Request for Proposal (RFP) that provides detail regarding a specific area of interest, sets timelines for review and approval, and uses an external 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.

## II. Eligibility

<b>Geographic Scope:</b>	Europe, Australia, Japan and New Zealand
<b>Applicant Eligibility Criteria</b>	<ul style="list-style-type: none"> <li>• Only organizations are eligible to receive grants, not individuals or medical practice groups.</li> <li>• The following may apply: medical, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations; government agencies; and other entities with a mission related to healthcare improvement. More information on organizations eligible to apply directly for a grant can be found at <a href="http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf">http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf</a>.</li> <li>• 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.</li> <li>• For programs offering credit, the requesting organization must be the accredited grantee.</li> </ul>

## III. Requirements

<b>Date RFP Issued</b>	<ul style="list-style-type: none"> <li>• 8<sup>th</sup> April 2019</li> </ul>
<b>Clinical Area</b>	<ul style="list-style-type: none"> <li>• Endocrinology</li> </ul>
<b>Specific Area of Interest for this RFP:</b>	<ul style="list-style-type: none"> <li>• It is our intent to support projects that focus on addressing challenges relating to the management of adults with uncontrolled acromegaly.</li> <li>• Multi-disciplinary collaborations, are encouraged when appropriate, but all partners must have a relevant role.</li> <li>• It is expected that projects will be evidence-based (education and/or quality improvement) 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. Projects including an educational element can find more information on principals of learning and behavior change for health professionals at <a href="http://www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf">www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf</a>.</li> <li>• There is a considerable amount of interest in receiving responses from</li> </ul>

	<p>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.</p> <ul style="list-style-type: none"> <li>• <i>It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered.</i> Information on how to submit requests for support of clinical research projects can be found at <a href="http://www.Pfizer.com/iir">www.Pfizer.com/iir</a>.</li> </ul>
<p><b>Target Audience:</b></p>	<ul style="list-style-type: none"> <li>• Healthcare providers caring for acromegaly patients in wider Europe, Australia, Japan and New Zealand; including (but not limited to) endocrinologists, neurosurgeons, specialist nurses, oncologists and psychologists.</li> </ul>
<p><b>Disease Burden Overview:</b></p>	<p>Acromegaly is a rare disease with a worldwide prevalence of between 40 and 70 cases per million<sup>1</sup>. With an estimated incidence of three to four cases per million population per year, physicians are unlikely to have a case of acromegaly presented to them with any regular frequency. Lack of awareness and experience with the disease can potentially lead to a delay in diagnosis or suboptimal treatment<sup>1,2</sup>.</p> <p>The average delay of diagnosis has been reported to be 7–10 years in most studies, although more recent studies have shown a reduction in this time to 2.5 years<sup>1</sup>.</p> <p>The signs and symptoms that patients with acromegaly cope with on a daily basis vary and can be extreme in nature, such as the characteristic dysmorphic syndrome, where the extremities are broadened and the facial features become disproportioned<sup>2</sup>. In fact, because the symptoms of headaches or weight gain are non-specific, patients often overlook them thinking that they may be related to something else and patients have no knowledge of acromegaly, which perhaps contributes further to the delay in diagnosis<sup>3</sup>. As well as changes in their appearance, patients may suffer from further physical and clinical difficulties with a range of associated vascular, metabolic and pulmonary comorbidities. Furthermore, poor control of disease activity has been associated with a 2- to 3-fold increase in mortality<sup>4</sup>. Living with this burden can put huge stresses on the patient, potentially leading to them losing their profession, loved ones and becoming financially unstable due to the pain and disability associated with the disease<sup>3</sup>. With the impact that the disease has on a patient’s life, earlier diagnosis and appropriate treatment is crucial in order to normalise the mortality rate and reduce the symptoms and associated comorbidities.</p> <p>Acromegaly has further been associated with substantial impairment in quality of life (QoL), which has been attributed to the symptoms of the disease, comorbidities and to the burden of treatment<sup>3</sup>.</p>

**Recommendations and Target Metrics:**

Once a patient is diagnosed and an effective treatment plan is actioned, continued monitoring of the patient forms an integral part of their management<sup>5</sup>.

- As loss to follow-up is common, an active search of these patients may allow the resumption of treatment in a significant proportion of cases. A study demonstrated that patient follow-up conducted via mail and phone allowed treatment to be restarted in over 40% of patients who had initially been lost to follow-up<sup>6</sup>. Through knowledge and empowerment, patients feel more 'in control' of their disease<sup>3</sup>.
- Frequently monitoring a patient with acromegaly is important in maintaining follow-up of care and assessment of their disease<sup>5,7</sup>. While the recommendations highlight assessment of biochemical measures and tumour size<sup>8,9</sup> with 'cure' or 'control' defined by GH and IGF-I control, the optimal management of acromegaly goes beyond this to include the comprehensive management of the symptoms and comorbidities typically associated with the disease<sup>5,10</sup>. Taking the patient as a whole into consideration may help define management pathways that better reflect the personalised and predictive approach that patients expect as standard of care<sup>11</sup>

**Gaps Between Actual and Target, Possible Reasons for Gaps:**

As acromegaly is a chronic disease, patients can become demotivated should treatment not meet their personal goals; up to 1 in 5 patients became lost to follow-up<sup>7,6</sup>. In a study specifically designed to investigate patient loss to follow-up in acromegaly and its consequences, the main reason cited for abandoning follow-up was not being informed that it was necessary. Of those patients who were lost to follow-up, details from their last recorded visit revealed 30% were uncontrolled, 33% were receiving medical therapy and 53% had residual tumour<sup>7</sup>.

Furthermore, despite a number of available treatment options, the proportion of patients who achieve disease 'control', in terms of achievement of IGF-I level normalisation, is not optimal and varies across the treatment options<sup>5,12-20</sup>. The response to treatment and the definitions of poor, partial and full response remain varied and no true definition exists<sup>21</sup>. Deformities, altered QoL and comorbidities may still exist even if a patient meets the guideline definition of control and discrepancies between clinical findings, GH, and total IGF-I levels are frequently encountered in clinical practice<sup>2,22</sup>. The definition of 'normal' values, or 'control', remains a challenge and adequately suppressed GH/IGF-I levels may not reflect control for the patient<sup>23</sup>.

According to a recent survey, patient perceptions regarding the healthcare community appear to be strongly influenced by their experiences during the diagnostic process, which in acromegaly can be a contracted process<sup>3</sup>. These perceptions may influence attitudes toward subsequent treatment, including the extent to which patients

discuss lifestyle issues with their physicians<sup>3</sup>. It is important that patients are asked more about how acromegaly impacts them in terms of their day-to-day activities. The survey found that patients with a good partnership with their physicians were more willing to discuss the disease's impact on their lives<sup>3</sup>.

**Barriers:**

It is important that the proposed project seeks to identify the particular barriers within the identified setting. A few example barriers to the appropriate management of uncontrolled acromegaly patients include:

- Lack of awareness and experience with the disease on the part of healthcare teams can potentially lead to suboptimal treatment<sup>1,2</sup>.
- Since many patients are diagnosed late in disease evolution, they present with a range of comorbid conditions, such as cardiovascular disease, diabetes, hypertension, and sleep apnea. It is important that patients are screened carefully at diagnosis (and thereafter), for common associated complications, and that biochemical control does not become the only treatment goal. Mortality and morbidities in acromegaly can be reduced if patients are treated using a multimodal approach with comprehensive comorbidity management<sup>24</sup>.

	<ul style="list-style-type: none"> <li>- Treatments are often sub-optimal with different treatments having different degrees of efficacy<sup>5,12-20</sup></li> <li>- Historically, the focus in acromegaly has been on biochemical and tumour control rather than holistic management of the patient<sup>3</sup>.</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 \$120,000 will be considered. The total available budget related to this RFP is \$240,000.</li> <li>• The amount of the grant Pfizer will be prepared to fund for any project will depend upon the external 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: 8<sup>th</sup> April 2019</li> <li>• Full proposal due date: 17<sup>th</sup> June 2019 Please note the deadline is midnight Eastern Time (New York, GMT -5).</li> <li>• Review of proposals by External Review Panel: August 2019</li> <li>• Anticipated Notification Date: On or before 31<sup>st</sup> August 2019</li> <li>• Grants distributed following execution of fully signed Letter of Agreement</li> <li>• Anticipated Project Start and End Dates: October 2019 to October 2021</li> </ul>
<p><b>How to Submit:</b></p>	<ul style="list-style-type: none"> <li>• Please go to <a href="http://www.cybergrants.com/pfizer/QI">www.cybergrants.com/pfizer/QI</a> and sign in. First-time users should click "REGISTER NOW".</li> <li>• Select the following Competitive Grant Program Name: Management of uncontrolled acromegaly 2019</li> <li>• Requirements for submission: Complete all required sections of the online application and upload the completed full proposal template (see Appendix).</li> <li>• If you encounter any technical difficulties with the website, please click the "Technical Questions" link at the bottom of the page.</li> </ul> <p><b>IMPORTANT:</b> Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.</p>
<p><b>Questions:</b></p>	<ul style="list-style-type: none"> <li>• If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Jo Harbron (jo.harbron@pfizer.com), with the subject line "Acromegaly RFP 2019."</li> </ul>
<p><b>Review and Approval</b></p>	<ul style="list-style-type: none"> <li>• A specific grant program RFP uses an external review panel (ERP) to make final grant decisions.</li> </ul>

<b>Process</b>	<ul style="list-style-type: none"><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></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 or to make a summary presentation during the review period.</li></ul>

## References:

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8. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab* 2014;99:3933–3951
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11. Puig Domingo M. Treatment of acromegaly in the era of personalized and predictive medicine. *Clin Endocrinol (Oxf)* 2015;83:3–14.
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14. Lee CC, Vance ML, Xu Z, et al. Stereotactic radiosurgery for acromegaly. *J Clin Endocrinol Metab* 2014;99:1273–1281. Losa M, Gioia L, Picozzi P, et al. The role of stereotactic radiotherapy in patients with growth hormone-secreting pituitary adenoma. *Clin Endocrinol Metab* 2008;93:2546–2552.
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20. van der Lely AJ, Hutson RK, Trainer PJ, et al. Longterm treatment of acromegaly with pegvisomant, a growth hormone receptor antagonist. *Lancet* 2001;358:1754–1759.
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## IV. Terms and Conditions

Please take note every Request for Proposal (RFP) released by Pfizer Independent Grants for Learning & Change (IGLC), as well as a RFP released jointly with a Partner(s), is governed by specific terms and conditions. Click [here](#) to review these terms and conditions.

## Appendix A

Please answer all questions listed in the online application portal. In addition, please upload a full proposal document following the guidance below. Proposals must be single-spaced, using Calibri 12-point font and 1-inch margins. Note that the main section of the proposal has a 15-page limit (excluding letters of commitment) and the organization detail has a 3-page limit. Please limit the number of attachments uploaded into the system. There is no reason to submit the organization detail (section F) as a separate document from the main section (section D) of the proposal. All proposals must follow the outline detailed below.

<b>Goals and Objectives</b>	<ul style="list-style-type: none"> <li>Describe the overall goal for this project. Describe how this goal aligns with the focus of the RFP, the goals of the applicant organizations and the proposed project. List the key objectives and how they are intended to address the established need for this project.</li> </ul>
<b>Assessment of Need for the Project</b>	<ul style="list-style-type: none"> <li>Describe the need for this project in your target area. Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis if appropriate. Describe the need for your project in terms of “what is” versus “what should be”.</li> <li>Please include quantitative baseline data summary, initial metrics (e.g., quality measures), or project starting point (please cite data on gap analyses or relevant patient-level data that describes the problem) 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.</li> </ul>
<b>Target Audience</b>	<ul style="list-style-type: none"> <li>Describe the level of commitment from the potential participants including your plan for recruitment as necessary.</li> <li>Demonstrate the scope of your target audience has a potential to impact the goal established in this proposal.</li> <li>Describe who will directly benefit from the project outcomes. Include in this description whom, beyond the primary target, would potentially benefit from the project in terms of this being a model for others to replicate or expand.</li> </ul>
<b>Project Design and Methods</b>	<ul style="list-style-type: none"> <li>Include a description of the overall strategy, methodology and analysis linking them to the goal of the project.</li> <li>Describe the way the project planned addresses the established need and produces the desired results.</li> <li>Indicate how you will determine if the target audience was fully engaged in the project.</li> </ul>

	<ul style="list-style-type: none"> <li>• Include a description of the measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.</li> <li>• If appropriate, show 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>• If your project includes the development of tools note if they be available publically at no cost.</li> </ul>
<p><b>Innovation</b></p>	<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 or materials already developed.</li> <li>• 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> </ul>
<p><b>Evaluation and Outcomes</b></p>	<ul style="list-style-type: none"> <li>• In terms of the metrics used to assess the need for this project, describe how you will determine if the practice gap was addressed for the target group.</li> <li>• Identify the sources of data that you anticipate using to make the determination.</li> <li>• Describe how you expect to collect and analyze the data.</li> <li>• Describe how you will determine if the results evaluated are directly related to the intervention described in this proposal</li> <li>• Quantify the amount of change expected from this project in terms of your target audience (e.g., a 10% increase over baseline or a decrease in utilization from baseline between 20-40%)</li> <li>• Describe how you plan for the project outcomes to be broadly disseminated.</li> </ul>
<p><b>Anticipated Project Timeline</b></p>	<ul style="list-style-type: none"> <li>• Provide an anticipated timeline for your project including project start/end dates</li> </ul>
<p><b>Detailed Workplan and Deliverables Schedule</b></p>	<ul style="list-style-type: none"> <li>• Include a narrative (which counts toward the 15-page limit) describing the work plan and outlining how the project will be implemented over the time period. Using a table format (no page limit), list the deliverables and a schedule for completion of each deliverable.</li> </ul>
<p><b>Additional Information</b></p>	<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> </ul>

<b>Letter(s) of Commitment</b>	<ul style="list-style-type: none"><li>• Letter(s) should be provided from all appropriate organisations documenting their support and commitment to the project. Letters should be issued from an institutional authority or authorities and collaborators guaranteeing access, resources and personnel (as the case may be) for proposed project.</li><li>• <b>Important: For projects in England</b> A Letter of Support from the Academic Health Science Network (AHSN) for the region is expected but not mandatory. For projects from other parts of the UK (Wales, Scotland, NI) letters of support from local/regional stakeholders are important however we have not mandated a particular organization, examples might include local/regional health board, NHS Trust</li></ul>
<b>Organization Detail (not to exceed 3 pages)</b>	<ul style="list-style-type: none"><li>• <b>Organizational Capability:</b> Describe the attributes of the institution(s)/organization(s)/association(s) that will support and facilitate the execution of the project.</li><li>• <b>Leadership and Staff Capacity:</b> Include the name of the person(s) responsible for this project (PI/ project lead (PL) and/or project manager). The project manager, whether a current staff member or someone to be hired, is essential to the work outlined in your proposal. Demonstrate the PI/PL and project manager’s availability, commitment, and capability to plan, implement, and evaluate the proposed project; describe how the project manager will oversee the project activities, including ensuring that tasks are accomplished as planned.</li><li>• List other key staff members proposed on the project (e.g., healthcare provider champion, medical advisor, statisticians, IT lead, etc.), if relevant, including their roles and expertise. Please list out key staff for each institution/organization/association the specific role that they will undertake to meet the goals of this project.</li><li>• When listing staff, please include staff first name, last name, professional credentials, and Country of Residence.</li><li>• c. <b>NOTE Regarding Proposed Speakers:</b> Pfizer IGLC shall not provide funding of CME when Pfizer has knowledge at the time of the decision to fund CME that a proposed CME faculty member has conducted a promotional speaking engagement on similar topic(s) on behalf of Pfizer in the past 12 months.</li><li>• <b>Detailed Budget (Refer to/Complete Budget Template; no page limit for the Excel file or the narrative):</b></li><li>• Upload a detailed budget, using the Excel template provided.</li><li>• (Click here for Budget Template;)</li></ul>

- Applicants are expected to customize the budget for their proposal, adding additional details and deliverables as appropriate.
- Provide a written narrative in the budget description field that contains an explanation of each cost element proposed. Budget narratives should include a justification for all personnel, indicating the percentage of time allocated to the project. The budget should demonstrate appropriate and reasonable costs for project expenses.
- Some examples of what awarded funds may not be used for are listed below:
  - Office equipment (e.g., furniture, computers)
  - Registration and travel costs for professional development meetings or courses not related to this project
  - Health care subsidies for individuals
  - Construction or renovation of facilities
  - Therapeutic agents (prescription or non-prescription)
  - Food and/or beverages for learners and/or participants in any capacity
  - Lobbying