

Pfizer Independent Grants for Learning & Change
Request for Proposals (RFP)
Improving the Clinical Management of Uncontrolled Acromegaly

I. Background

The mission of Pfizer Independent Grants for Learning & Change (IGLC) is to partner with the global healthcare community to improve patient outcomes in areas of mutual interest through support of measurable learning and change strategies. “Independent” means that the projects funded by Pfizer are the full responsibility of the recipient organization. Pfizer has no influence over any aspect of the projects and only asks for reports about the results and the impact of the projects in order to share them publicly.

The intent of this document is to encourage organizations with a focus in healthcare professional education and/or quality improvement to submit a proposal in response to a Request for Proposal (RFP) that is related to education in a specific disease state, therapeutic area, or broader area of educational need.

When a RFP is issued, it is posted on the Pfizer IGLC website (www.pfizer.com/independentgrants) in the Request for Proposals section and is sent via e-mail to all registered users in our grants system. Some RFPs may also be posted on the websites of other relevant organizations, as deemed appropriate.

Please note that applications must be submitted in English

II. Eligibility

Geographic Scope:	<input checked="" type="checkbox"/> International (specify country/countries) Wider Europe, Australia, Japan and New Zealand
Applicant Eligibility Criteria:	<p>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.</p> <p>More information on organizations eligible to apply directly for a grant can be found at http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf.</p> <p>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.</p> <p>For programs offering credit, the requesting organization must be the accredited grantee.</p>

III. Requirements

Date RFP Issued:	1 st March 2018
Clinical Area:	Endocrinology
Specific Area of Interest for this RFP:	<p>It is our intent to support projects that focus on addressing challenges relating to the clinical management of adults with uncontrolled acromegaly.</p> <p>Multi-disciplinary collaborations, are encouraged when appropriate, but all partners must have a relevant role.</p> <p>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 www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf.</p> <p>Please note that this RFP seeks to fund initiatives that have the potential to improve healthcare systems and directly impact patient outcomes. Although educational efforts for grantees and patients may be entirely appropriate components in responses to this RFP, projects that include an overt description of healthcare system changes will be given the most priority.</p> <p><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 www.Pfizer.com/iir.</p>
Target Audience:	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.

Disease Burden Overview:	<p>Acromegaly is a rare disease with a worldwide prevalence of between 40 and 70 cases per million¹. 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^{1,2}. 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 years¹.</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 disproportioned². 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 diagnosis³. 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 mortality⁴. 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 disease³. 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 treatment³.</p>
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Recommendations and Target Metrics:	<p>Once a patient is diagnosed and an effective treatment plan is actioned, continued monitoring of the patient forms an integral part of their management⁵.</p> <p>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-up⁶. Through knowledge and empowerment, patients feel more 'in control' of their disease³.</p> <p>Frequently monitoring a patient with acromegaly is important in maintaining follow-up of care and assessment of their disease^{5,7}. While the recommendations highlight assessment of biochemical measures and tumour size^{8,9} 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^{5,10}. 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 care¹¹</p>
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<p>Gaps Between Actual and Target, Possible Reasons for Gaps:</p>	<p>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^{7,6}. 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 tumour⁷.</p> <p>Furthermore, despite a number of 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^{5,12-20}. The response to treatment and the definitions of poor, partial and full response remain varied and no true definition exists²¹. 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^{2,22}. The definition of 'normal' values, or 'control', remains a challenge and adequately suppressed GH/IGF-I levels may not reflect control for the patient²³.</p> <p>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 process³. These perceptions may influence attitudes toward subsequent treatment, including the extent to which patients discuss lifestyle issues with their physicians³. 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 lives³.</p>
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<p>Barriers:</p>	<p>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:</p> <ul style="list-style-type: none"> - Lack of awareness and experience with the disease on the part of healthcare teams can potentially lead to suboptimal treatment^{1,2}. - 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 management²⁴. - Treatments are often sub-optimal with different treatments having different degrees of efficacy^{5,12-20} - Historically, the focus in acromegaly has been on biochemical and tumour control rather than holistic management of the patient³.
<p>Expected Approximate Monetary Range of Grant Applications:</p>	<p>Individual projects requesting up to \$120,000 will be considered.</p> <p>The amount of the grant Pfizer will be prepared to fund for any project will depend upon the review panel's evaluation of the proposal and costs involved, and will be stated clearly in the approval notification.</p>
<p>Key Dates:</p>	<p>RFP release date: 1st March 2018</p> <p>Full Proposal Deadline: 31st May 2018 Please note the deadline is midnight Eastern Time (New York, GMT -5).</p> <p>Review of Full Proposals by External Review Panel: June 2018</p> <p>Anticipated Full Proposal Notification Date: On or before 15th July 2018</p> <p>Grants distributed following execution of fully signed Letter of Agreement</p> <p>Period of Performance: October 2018 to October 2019</p>

How to Submit:

Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click “REGISTER NOW”.

Select the following Area of Interest: “Clinical Management of Uncontrolled Acromegaly”

Complete all required sections of the online application and upload your completed application (see Appendix for application guidance).

Be advised the system is designed for a two-stage submission process: 1) Letter of Intent and 2) Full Proposal. However, for this RFP, we are not using a Letter of Intent. Instead, the only stage will be submission of the Full Proposal.

In the “Required Uploads” section, please follow the table below:

For Field Name:	Please upload:
Letter of Intent	Full Proposal (see application template in Appendix)
LOI Additional Required Uploads	Completed budget template which is available at the following link: https://www.cybergrants.com/pfizer/docs/BudgetTemplate2017.xls

Given that this programme is utilising a one-stage submission process, please remember to consider the following when drafting your proposal:

- Consider carefully whether your proposal is aligned to the scope of the RFP. If your proposal is outside of scope of the RFP, it cannot be funded.
- Review your project design and methods. Are you adequately and appropriately explaining what you plan to do to an audience who may not be familiar with your previous work?
- Be sure to conduct a needs assessment to ensure that your proposal is relevant in your targeted geography.
- Compare your methods to your expected results. Will your methods help you achieve your goals? Are your methods aligned with your desired outcomes? What systems-based changes will your proposal help to deliver?
- Review your evaluation plan. Is your plan for evaluating the success of your project appropriate and valid?
- Ensure that your budget is comprehensive and fully itemised

For helpful resources, visit:

https://www.pfizer.com/responsibility/grants_contributions/resource_center

If you encounter any technical difficulties with the website, please click the “Need Support?” link at the bottom of the page.

IMPORTANT: Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.

Questions:	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 2018."
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 or to make a summary presentation during the review period.

References:

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2. Chanson P, Salenave S, Kamenicky P. Acromegaly. *Handb Clin Neurol* 2014;124:197–219.
3. Gurel MH, Bruening PR, Rhodes C, et al. Patient perspectives on the impact of acromegaly: results from individual and group interviews. *Patient Prefer Adherence* 2014;8:53–62.
4. Clemmons DR, Chihara K, Freda PU, et al. Optimizing control of acromegaly: integrating a growth hormone receptor antagonist into the treatment algorithm. *J Clin Endocrinol Metab* 2003;88:4759–4767.
5. Silverstein JM. Need for improved monitoring in patients with acromegaly. *Endocr Connect* 2015;4:R59–R67.
6. Kasuki L, Marques NM, Braga La Nuez MJ, et al. Acromegalic patients lost to follow-up: a pilot study. *Pituitary* 2013;16:245–250.
7. Delemer B, Chanson P, Foubert L, et al. Patients lost to follow-up in acromegaly: results of the ACROSPECT study. *Eur J Endocrinol* 2014;170:791–797.
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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10. Vilar L, Valenzuela A, Ribeiro-Oliveira A, et al. Multiple facets in the control of acromegaly. *Pituitary* 2014;17(Suppl 1):S11–S17.
11. Puig Domingo M. Treatment of acromegaly in the era of personalized and predictive medicine. *Clin Endocrinol (Oxf)* 2015;83:3–14.
12. Vik-Mo EO, Øksnes M, Pedersen P-H, et al. Gamma knife stereotactic radiosurgery for acromegaly. *Eur J Endocrinol* 2007;157:255–263
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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.
15. Pollock BE, Jacob JT, Brown PD. Radiosurgery of growth hormone-producing pituitary adenomas: factors associated with biochemical remission. *J Neurosurg* 2007;106:833–838.

16. Jagannathan J, Sheehan JP, Pouratian N, et al. Gamma knife radiosurgery for acromegaly: outcomes after failed transsphenoidal surgery. *Neurosurgery* 2008;62:1262–1269
17. Carmichael JD, Bonert VS, Miriam Nuño M, et al. Acromegaly clinical trial methodology impact on reported biochemical efficacy rates of somatostatin receptor ligand treatments: a meta-analysis. *J Clin Endocrinol Metab* 2014;99:1825–1833..
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19. Freda PU, Gordon MB, Kelepouris N, et al. Longterm treatment with pegvisomant as monotherapy in patients with acromegaly: experience from ACROSTUDY. *Endocr Pract* 2015;21:264–274.
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: Full Proposal Submission Guidance

Proposals should be single-spaced, using Calibri 12-point font and 1-inch margins. Note that the main section (section C, below) of the proposal has a 10-page limit and the organization detail (section E, below) has a 3-page limit. **Please limit the number of attachments uploaded in the system.** There is no reason to submit the organization detail (section E) as a separate document from the main section (section C) of the proposal. **All proposals must follow the outline detailed below.**

Proposal requirements - include the following sections:

A. Cover Page (do not exceed 1 page):

1. **Title:** *Please include the project title, Grant ID number and main collaborators.*
2. **Abstract:** *Please include an abstract summary of your proposal including the overall goal, target population, methods and assessment. Please limit this to 250 words.*

B. Table of Contents (no page limit)

C. Main Section of the proposal (not to exceed 10 pages):

1. **Overall Goal & Objectives:** *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.*
2. **Current Assessment of need in target area**
 - a. *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”.*
 - b. *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.*
3. **Target Audience:** *Describe the primary audience(s) targeted for this project.*
 - a. *Describe the level of commitment from the potential participants including your plan for recruitment as necessary.*
 - b. *Demonstrate the scope of your target audience has a potential to impact the goal established in this proposal.*
 - c. *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.*

4. **Project Design and Methods:** Describe your project design and methods.
- a. Include a description of the overall strategy, methodology and analysis linking them to the goal of the project.
 - b. Describe the way the project planned addresses the established need and produces the desired results.
 - c. Indicate how you will determine if the target audience was fully engaged in the project.
 - d. 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.
 - e. 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.
 - f. If your project includes the development of tools note if they will be made available publically at no cost.

5. **Evaluation Design**

- a. 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.
 - Identify the sources of data that you anticipate using to make the determination.
 - Describe how you expect to collect and analyze the data.
 - Describe how you will determine if the results evaluated are directly related to the intervention described in this proposal
- b. 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%)
- c. Describe how you plan for the project outcomes to be broadly disseminated.

6. **Detailed Workplan and Deliverables Schedule:** Include a narrative (which counts toward the 10-page limit) describing the workplan and outlining how the project will be implemented over the 2-year maximum period. Using a table format (no page limit), list the deliverables and a schedule for completion of each deliverable.

D. References (no page limit)

E. Organizational Detail (not to exceed 3 pages)

1. **Organizational Capability:** Describe the attributes of the institution(s)/organization(s)/association(s) that will support and facilitate the execution of the project.
2. **Leadership and Staff Capacity:** 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.
 - a. 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.
 - b. When listing staff, please include staff first name, last name, professional credentials, and Country of Residence.
 - c. NOTE Regarding Proposed Speakers: Pfizer 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.

F. Detailed Budget (Refer to/Complete **Budget Template**; no page limit for the Excel file or the narrative):

1. Upload a detailed budget, using the Excel template provided. Applicants are expected to customize the budget for their proposal, adding additional details and deliverables as appropriate.
2. Provide a **written narrative** that contains a detailed 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.
3. Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.
 - **Institutional Overhead Costs:** Costs to the institution for the support of your project. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance.
4. 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*

G. Staff Biosketches (no page limit):

Applicants must provide brief biosketches of all individuals listed in section F in an appendix. NIH Biosketches are an acceptable format but not required.

H. Letter(s) of Commitment (no page limit):

Letter(s) must be provided from all organizations listed in section E 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.

Submission: Proposals should be submitted online via the Pfizer Independent Grants for Learning & Change website www.pfizer.com/independentgrants

Proposals should be single-spaced using Calibri 12-point font and 1-inch margins. Please adhere to the page limits listed for each section. There is no page limit for the reference section. Tables and Figures should be included in the main section of your proposal and do count to the page count. Only sample forms or other full page documents can be included as an appendix. Please consult with the Grant Officer before submitting such additional documents.

All required sections (aside from the budget) should be combined in one document (MS Word or Adobe PDF). There is no need to submit the organization detail or references in a document separate from the main section of the full proposal. Budgets should be submitted in a separate excel file.