# The Japanese Society for Pediatric Endocrinology and Pfizer Quality Improvement RFP *Quality Improvement in Pediatric Endocrinology Fields*

Competitive Grant Program – using Expert Review Panel

#### Overview

The object of this RFP by The Japanese Society for Pediatric Endocrinology and Pfizer is to improve medical quality in pediatric endocrinology fields.

It is expected for Quality improvement projects to encourage behavioral changes among HCPs involved in pediatric endocrinology and improve prognosis and treatment outcomes for patients and their families.

# **Geographic Scope**

Japan

# **Project Types and Area of Interest**

The following projects aiming at enhancing the treatment of pediatric endocrine disorders, described in "Project targets" below, become the targets of support.

- Utilization of growth curve
- Cooperation with school health and child health
- Promotion of Health care transition
- Mental care related to pediatric endocrine disorders
- Promotion of measures and responses during times of disaster
- Promotion of proper diagnosis and treatment (the spread of specialized knowledge on pediatric endocrine disorders)

#### **Key Milestones**

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• Application submission deadline: July 18, 2023

Extended Due Date: August 1, 2023

- Anticipated decision notification date: September 30, 2023
- Anticipated project start date: January 1, 2024

# **Funding Range and Project Length**

The total available budget related to this RFP is 10,000,000 JPY. Ceiling for on project

- 1. Large-scale project: up to 3,000,000 JPY
- 2. Small-scale project: up to 1,000,000 JPY

Anticipated Project Start and End Dates: 1-3 years (January 2024 – December 2026)



# I. Eligibility

#### Geographic Scope:

• Japan

#### Applicant Eligibility Criteria

- Only organizations are eligible to receive grants, not individuals or medical practice groups.
- The following may apply: medical, dental, 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.
- 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.
- For projects offering continuing education credit, the requesting organization must be accredited.

# **II. Requirements**

#### Date RFP Issued

• March 8, 2023

#### **Clinical Area**

Pediatric Endocrine Disorders

#### Specific Area of Interest for this RFP:

- The following projects aiming at enhancing the treatment of pediatric endocrine disorders, described in "Project targets" below, become the targets of support.
  - o Utilization of growth curve
  - o Cooperation with school health and child health
  - o Promotion of Health care transition
  - o Mental care related to pediatric endocrine disorders
  - o Promotion of measures and responses during times of disaster
  - Promotion of proper diagnosis and treatment (the spread of specialized knowledge on pediatric endocrine disorders)

It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered. In addition, it is not also our intent to support guideline development (e.g., clinical treatment guidelines) from the viewpoint of COI.

#### **Target Audience**

 Healthcare professionals (physicians, dentists, nurses, pharmacists, etc.), and school nurses, public health nurses and teachers, etc., involved with infants' health checkups and school medical checkups.

#### **Disease Burden Overview**

• For children, endocrine abnormality is a problem that is directly involved with their growth, development and maturation. A delay in diagnosis and inappropriate treatment may cause



disadvantages that a child would suffer throughout patient's lifetime. Advanced expertise is being sought in the treatment of pediatric endocrine disorders, and medical professionals are required to correctly understand the complicated mechanism of action of hormones, and the structure of molecular bases [1]. As a result of advancements in learning and changes in the environment surrounding medical care in recent years, the field of pediatric endocrinology has deepened even further, as described below [2].

- 1. Results of genetic research have borne fruit in discovering new diseases and elucidating disease conditions.
- 2. Development of treatment methods by translational research and other means has made rapid strides, and effective drugs can now be used, even for the treatment of ultra-rare diseases.
- 3. Formulation of guidelines for standard diagnosis and treatment, as well as development of tools for patients' use have been progressing.
- 4. For childhood-onset endocrine disorders, transition to adulthood medical treatment as well as lifetime management are becoming the focus of attention.

The following are examples of existing reports related to medical education efforts.

- <u>Commentary: Launch of a quality improvement network for evidence-based management of uncommon pediatric endocrine disorders: Turner syndrome as a prototype</u> J Clin Endocrinol Metab. 2015;100(4):1234-6.
- <u>A quality improvement project to address the challenges surrounding zoledronic acid use in children</u> J Bone Miner Metab. 2021;39(4):693-699.
- <u>Improved screening for cystic fibrosis-related diabetes by an integrated care team using an algorithm</u> Pediatr Pulmonol. 2014;49(10):971-7.
- <u>Creating a sustainable pediatric diabetes transition program</u> J Pediatr Nurs. 2021 7;S0882-5963(21)00159-7.
- <u>Health-system-based interventions to improve care in pediatric and adolescent type 1 diabetes</u> Curr Diab Rep. 2015;15(11):91.
- <u>The impact of adrenal tumor multidisciplinary team meetings on clinical outcomes</u> Endocrine. 2020;69(3):519-525.

# **Recommendations and Target Metrics**

Related Guidelines and Recommendations

- Evaluation of the physique of Japanese children
- Guidelines for transition of pediatric to adult growth hormone (GH) treatment in GH deficiency
- Guideline for GH treatment in SGA short children
- Guideline for estrogen replacement therapy in Turner syndrome
- Guidance on the initial response to disorder of sex development
- Guidance on responses to disorder of sex development (childhood)
- Guidelines for diagnosis and treatment of 21-hydroxylase deficiency (2014 revision)
- Guidelines for diagnosis and treatment of 21-hydroxylase deficiency (2014 revision) (the recommended version)
- Guidelines for Mass Screening of Congenital Hypothyroidism (2014 revision)
- Guidelines for Mass Screening of Congenital Hypothyroidism (2014 revision), recommended version, Q&A
- Guidelines for the treatment of childhood-onset Graves' disease in Japan, 2016
- Guidelines for the treatment of childhood-onset Graves' disease in Japan, 2016, recommended version, Q&A



- Clinical Practice Guideline for Osteogenesis imperfecta
- Guidance on diagnosis of vitamin D-deficient rickets and hypocalcaemia
- Clinical practice guidelines for congenital hyperinsulinism
- An endocrinology follow-up guide for childhood cancer survivors (CCS)
- Guidelines for diagnosis and treatment of childhood obesity, 2017
- Consensus Guidelines for Childhood and Adolescent Diabetes
- Consensus Guidelines for Prader-Willi syndrome (PWS)

#### **Barriers**

• All endocrine disorders seen during childhood have a tremendous influence on child's growth, development, and maturation. It is therefore desired that pediatric endocrinology specialists take the initiative to become actively involved with diagnosis and treatment. As an example, we will show below, the current challenges regarding (1) Cooperation with school health and child health, (2) Health care transition, and (3) Measures and responses during times of disaster.

(1) Schools carry out health examinations each year, based on the School Health and Safety Act, and measure children's height and weight to grasp their status of growth. However, it is not necessarily easy to make full use of these precious measurement data. The Ministry of Education, Culture, Sports, Science and Technology calls for the periodic utilization of growth curves and other data [3].

(2) The prognosis of childhood-onset diseases improves, but many patients enter adolescence and adulthood while carrying those diseases. To make sure that such patients can continue to receive appropriate medical treatment, even after moving on to their adulthood and throughout their lifetime, there is a call for provision of seamless medical care. A system must be prepared before a patient reaches adult age. Not only a mere transfer of clinical departments, but also transitional-period medical care that serves as a bridge to connect pediatric medical treatment and adult medical treatment, is required [4].

(3) The Great East Japan Earthquake and the Kumamoto Earthquake ended up becoming a largescale disaster that greatly impacted pediatric medical care. Responses to disasters by the Disaster Medical Assistance Team (DMAT) and Disaster Liaison for Pediatric and Perinatal Medicine are steadily being established. Responses during disaster to pediatric endocrine disorder patients who require continuous medical attention by medical specialists are our future challenge [5].

# Expected Approximate Monetary Range of Grant Applications:

- The estimated total available budget related to this RFP is 10,000,000 JPY.
- Ceiling for on project
  - 1. Large-scale project: up to 3,000,000 JPY
  - 2. Small-scale project\* up to 1,000,000 JPY
- 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
- \* Applicable project is focused on a region by single institution like a pilot project.

# Key Dates:

- RFP Release Date: 3/8/2023
- Due Date: 7/18/2023 Extended Due Date: August 1, 2023
  - Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Anticipated Full Proposal Notification Date: 9/30/2023



• Grants will be distributed following a fully executed agreement and submission of Final Protocol, documentation of IRB/IEC approval, regulatory approval (if applicable), exemption or waiver.

# How to Submit:

Note: Please read this section carefully since applications submitted not following these instructions will not be accepted and will be cancelled

- Please go to <u>www.cybergrants.com/pfizer/QI</u> and sign in. First-time users should click "Create your password". [Note: there are individual portals for each grant application type. Please be sure to use the URL above.]
- Click the "Start a New Quality Improvement Application" button.
- In the application:
  - For the question "Competitive Grant?" select Yes
- Select the following Competitive Grant Program Name: 2023 RD JP: Quality Improvement in Pediatric Endocrinology Fields
- Select the following Primary Area of Interest: Endocrine
- Requirements for submission:
   Complete all required sections of the online application and upload your project proposal (see Appendix) in the Full Proposal Submission 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 Pfizer MEG-J office (meg.japan@pfizer.com), with the subject line "2023 RD JP: Quality Improvement in Pediatric Endocrinology fields."

#### **Grant Agreements:**

- If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click <u>here</u> 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.
- Payment will only be made to requesting Institution.

# **Review and Approval Process**

- A specific grant program RFP uses an expert review panel (ERP) to make final grant decisions.
- 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

#### 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.

#### References



• Bibliography of relevant references.

# About The Japanese Society for Pediatric Endocrinology and Pfizer Global Medical Grants

The Japanese Society for Pediatric Endocrinology, or JSPE, was established in 1967 with the goals of ensuring the progress and spread of pediatric endocrinology and contributing to the welfare for children. The JSPE has over 1,400 members consisting of clinicians, researchers and medical staff with expertise in pediatric endocrinology and diabetes.

To achieve these goals, the JSPE carries out the following business operations.

(1) Holding academic meetings

(2) Holding study, lecture and other meetings for the purpose of research, investigation and

dissemination of knowledge

- (3) Publishing academic journal and other publications
- (4) Fostering of clinicians, researchers and educators in the field of pediatric endocrinology
- (5) Supporting the medical practice and research of pediatric endocrinology
- (6) Promoting international exchanges
- (7) Awarding outstanding achievements that meet the objectives of the JSPE
- (8) Other business operations necessary for attaining the objectives of the JSPE

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 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.



#### **Specific RFP Submission Requirements**

Applications will be accepted via the online portal listed in the How to Submit section. Project Proposals/Protocols should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 15-page limitexclusive of references. When uploading your Full Proposal please ensure it addresses the following sections:

# **Goals and Objectives**

- Briefly state the overall goal of the project. Also describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s).
- List the overall objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.

#### Assessment of Need for the Project

• Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), 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. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information.

# **Target Audience**

 Describe the primary audience(s) targeted for this project. 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 the planned project and the way it addresses the established need.
- If your methods include educational activities, please describe succinctly the topic(s) and format of those
  activities

#### Innovation

- Explain what measures you have taken to assure that this project idea 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 related to this project.

# **Evaluation and Outcomes**

- In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Describe how you expect to collect and analyze the data.
- Quantify the amount of change expected from this project in terms of your target audience.
- Describe how the project outcomes will be broadly disseminated.

#### Anticipated Project Timeline

• Provide an anticipated timeline for your project including project start/end dates.



# **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**

Describe the attributes of the institutions / organizations / associations that will support and facilitate the
execution of the project and the leadership of the proposed project. Articulate the specific role of each
partner in the proposed project.

#### **Budget Detail**

- Please include a budget narrative that describes in greater detail the line items specified in the budget submitted within the application
- While estimating your budget please keep the following items in mind:
  - Independent Medical Education Grants awarded by GMG cannot be used to purchase therapeutic assets (prescription or non-prescription).
  - Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects. Please <u>click here</u> for details.

