

Call for Grant Application (CGA)

To: Educational Providers
From: Zoe Chen, Medical Education Grant Officer, Lysosomal Storage Diseases
Date: 10/29/2024

Lilly is committed to supporting high-quality education that can lead to improvements in healthcare professionals' knowledge, competence, and/or performance in order to ultimately have a positive impact on patient care and outcomes. Lilly does not support Independent Medical Education, or any medical activities, for the purpose of encouraging off-label use of our products.

Grant proposals that include collaboration and/or partnerships with relevant professional organizations and societies are encouraged. Multi-supported proposals are encouraged.

PLEASE READ THIS DOCUMENT IN ITS ENTIRETY AND ENSURE THAT YOUR PROPOSAL INCLUDES ALL OF THE REQUESTED INFORMATION. INCOMPLETE PROPOSALS MAY NOT BE FORWARDED TO THE GRANT COMMITTEE FOR CONSIDERATION.

PLEASE DO NOT FORWARD CGA BEYOND INDIVIDUALS IN YOUR ORGANIZATION UNLESS YOU INTEND TO PARTNER WITH THEM FOR PROPOSAL SUBMISSION

A. Purpose: Lilly is currently seeking Continuing Education proposals to improve the care of patients with Lysosomal Storage Diseases (LSDs).

Evidence demonstrates the following healthcare gap that patients with rare genetic LSDs experience:

Patients with LSDs experience misdiagnosis and delays in diagnosis. The average diagnostic delay can range from 3-10 or more years depending on the disease. Timely and accurate diagnosis is key to halt disease progression, improve quality of life, optimize clinical management, and provide appropriate genetic counseling. ¹⁻⁵

B. Budget and Due Date: Lilly will consider funding 1 or more proposals with a total available budget of 500,000

Proposal due by: 1/15/2025

C. HCP Performance/Practice Gap(s)*: Evidence suggests that the above Patient Healthcare Gap(s) is due to the fact(s) that some HCPs ⁶⁻⁸:

- Delay and/or make errors in diagnosis of LSDs
- Fail to consistently adhere to guidelines for screening and/or diagnosis of LSDs
- Delay in the integration of new data, treatment, and/or guidelines for diagnosis of LSDs into practice
- Do not consistently or effectively use a multidisciplinary team approach when caring for patients with LSDs

The applicant must independently validate the healthcare practice gaps and provide references.

*References available upon request for standard HCP Performance/Practice Gaps

D. Root Causes: The applicant must provide clear, well researched insights into the root cause(s) (i.e., reasons underlying each Performance/Practice Gaps) that are preventing some HCPs from performing optimally and that will be addressed in the educational initiative. Methods used to identify root causes must be described and references provided.

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Potential root causes may include¹⁻¹²:

- Lack of skills and ability to implement and apply guidelines for diagnostic testing for LSDs including clinical, biochemical, radiological, and genetic testing
- Lack of knowledge of etiology, epidemiology, and pathophysiology of LSDs
- Lack of efficient and standardized workflows to incorporate genetic testing into diagnostic workflows
- Challenges in keeping up with rapidly evolving scientific advances, data, guidelines, and management options for LSDs
- Lack of optimal care coordination and communication with essential multi-disciplinary team members (including referral to disease specialists and genetic counselors)
- LSDs are rare genetic diseases not frequently encountered in medical practice, and they often receive inadequate clinical and social considerations compared to other disorders
- LSDs are characterized by non-specific multisystemic symptomatology that may make them difficult to distinguish from other disorders.
- Lack of patient/family awareness of these rare disease
- Lack of access to specialized healthcare, diagnostic facilities, and diagnostic tools
- Lack of consensus regarding the value and benefits of genetic testing
- HCP and patient/family concerns about the potential psychological burden of genetic testing

Preference will be given to proposals that:

- 1) Provide a high level of evidence for the Root Cause(s)
- 2) Have used well respected Root Cause Analysis methods
- 3) Focus on Root Causes related to deficiencies in competence/skills, strategies, attitudes, beliefs, available point of care tools and resources, and/or other abilities that prevent HCPs from performing optimally in practice (i.e., as opposed to proposals that focus primarily on deficiencies in underlying declarative and/or procedural knowledge.)

E. Target Audience: The intended audience includes the following HCPs involved in the care of patients with LSDs:

- General Neurologists**
- Genetic Counselors**
- Movement Disorder specialists**

The applicant must provide an evidence-based rationale for the target audience(s) explaining:

- How the target audience(s) is important in closing the gap and addressing the Root Cause(s)
- How the education will be customized to any unique learning needs of different HCPs – if necessary
- How the HCPs/Teams with the greatest needs will be targeted, recruited, and engaged.

Preference will be given to proposals that have a well-reasoned strategy for targeting and engaging those HCPs/Teams with the greatest need (i.e., versus proposals that seek to recruit less appropriate practitioners to maximize the number of participants).

F. Learning Objectives: Provide Learning Objectives that are the intended outcomes of the activity (i.e., what learners should be able to do better or differently upon completion of the activity)

- Learning Objectives should be SMART (**S**pecific, **M**easurable, **A**chievable, **R**ealistic and **T**imebound) and/or conform to the ABCD rubric (**A**udience, **B**ehavior, **C**onditions, **D**egree (**See references on Learning Objectives below**))
- Indicate the proportion of the total activity/curriculum time that will be allocated to each Learning Objective

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Preference will be given to proposals that emphasize LOs that describe and are aligned with the intended skills, strategies, and behaviors that address the Root Cause(s) (i.e., the competencies that are needed to improve patient care)

G. Content Topics, Instructional Methods/Tactics/Resources: Provide an outline of the content that you will include and describe and explain the activity type(s), format(s), learning experiences, instructional tactics, resources and/or materials that you are proposing for effective learner achievement of each Learning Objective.

Preference will be given to approaches that:

- Are based in the science of learning and research on physician learning (See examples of references below). Provide references to support that these types of interventions have been proven to enhance learning.
- Use evidence-based educational formats/modalities/techniques that have been demonstrated to lead to high completion rates, build skills that result in real-world practice improvements (e.g., high-levels of learner involvement, interactivity, demonstrations, practice & feedback, reflection, high relevance to practice, case-based, simulations, inclusion of practical resources/methods to help reinforce and apply learnings in practice, etc). *See references below*
- Include examples of outcomes achieved for activities with similar instructional approach and LOs.

H. Outcomes Plan: The proposal must use definitions outlined in the [Outcomes Standardization Project \(OSP\) Glossary](#). The Outcomes Plan for capturing metrics on the following items should be clearly stated in the proposal: At a minimum, **Expected # of Learners and Expected # of Completers**.

Describe the specific outcomes design, methods and measures that will be used to determine the extent to which learners have achieved each of the Learning Objectives – i.e., the intended outcomes.

A generic description of an outcomes model (e.g., Moore's Model, Kirkpatrick, etc.) is not sufficient.

- Provide the number and types of measures/questions/survey items/chart reviews, etc. that will be used to assess achievement of each Learning Objective
- Estimate the number of completers who will provide data/participate in each component of the Outcomes Plan
- Estimate the degree of improvement you expect for each Learning Objective.
- Provide the qualifications of those involved in the design and analysis of the outcomes.

Preference will be given to proposals that:

- Incorporate objective measures of competence, performance, and/or patient outcomes
- Measure long-term retention and application of new skills, etc. in practice
- Use validated measures that have been demonstrated to be reliable
- Provide statistical analyses (p values, effect sizes, and item statistics (e.g., discrimination index, difficulty for any Multiple Choice Questions) – (MCQs are not required, but if used should be psychometrically sound)

I. Content Accuracy: Lilly is committed to the highest standards for ensuring patient safety. Describe methods to ensure complete, accurate, evidence-based review of key safety data for any therapeutic entities discussed in the activity. Explain how content will be updated, if necessary, throughout the program period to ensure accuracy will be ensured.

J. Faculty Recruitment and Development: Provide information on the expected qualifications of contributors and describe the methods used to ensure recruitment of course directors and faculty who meet the qualifications. Explain any methods that will be used to ensure that faculty are fully

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trained in the program expectations and any skills that may be needed to ensure effective delivery of intended education.

K. Accreditation: Grant applicants must be, or partner with, an accredited provider. It is preferred that activities be certified (e.g., CME/CE) by the appropriate accrediting bodies and fully compliant with all ACCME Criteria and Standards for Integrity and Independence in Accredited Continuing Education.

L. Resolution of Conflict: The proposal should briefly describe methods for ensuring fair and balanced content and identification and resolution of any conflict of interest.

M. Communication and Publication Plan: Include a description of how the results of this educational intervention will be presented, published, and/or disseminated.

N. Mandatory Requirements:

- When submitting your proposal, you must include “CGA: [title of program]” in your grant submission.
- Please limit the length of your grant proposal to **20 pages or less** (not including references and budget).
- All responses to this CGA are to be submitted online through the Lilly Grant Office grant application system at <https://portal.lillygrantoffice.com> no later than close of business (5:00pm ET) on **1/15/2025**.

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References

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2. Rajkumar V, Dumpa V. Lysosomal Storage Disease. [Updated 2023 Jul 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK563270/>
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5. Uribe-Carretero E, Rey V, Fuentes JM et al. . Lysosomal Dysfunction: Connecting the Dots in the Landscape of Human Diseases. *Biology (Basel)*. 2024 Jan 7;13(1):34. doi: 10.3390/biology13010034. PMID: 38248465; PMCID: PMC10813815
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Examples of References on CE Effectiveness and Physician Learning

1. Cervero RM, Gaines JK. Effectiveness of Continuing Medical Education: Updated Synthesis of

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- Systematic Reviews. *Accredit Counc Contin Med Educ*. 2014;(July).
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