Call for Grant Application (CGA)

Lilly USA, LLC
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.

To: Educational Providers
From: Linda Battiato Medical Education Grant Officer, Neuroscience
Date: 9/20/24

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 ability of global Health Care Professionals (HCPs) to optimally support and improve brain health and Alzheimer's disease care.

A healthy brain is critical for living a longer and fuller life. Several organizations are advocating for increased awareness around brain health. AAN has a vision of making a brain health visit standard of care across the lifespan. Though brain health encompasses multiple dimensions, cognitive health is a key aspect, especially considering the aging global population at an increased risk for mild cognitive impairment (MCI) and dementia, including Alzheimer's Disease (AD), the most common cause of dementia in older adults. [1-8] AD is now understood as a continuum comprised of multiple stages spanning from cognitively unimpaired individuals with abnormal pathology to severe dementia. Because of their central role in patient care and management throughout the lifespan, HCPs such as primary care providers (PCPs), general neurologists, and geriatricians may care for patients across all stages of the AD continuum and are in a strategic position to identify and manage risk factors and early signs of cognitive decline. By integrating knowledge of emerging data on brain health and Alzheimer's disease into clinical practice, conducting brain health assessments, educating on risk factor modification, detecting early cognitive signs & symptoms using validated tests, and offering appropriate management and referrals, HCPs can contribute significantly to preserving brain health and improving overall well-being

Evidence demonstrates the following healthcare gap:

Patients may not optimally benefit from recommended strategies to optimize brain health and identify early cognitive changes and thus are at increased risk for cognitive decline and decreased Quality of Life. [1-15]

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B. Budget and Due Date: The total available budget related to this CGA is approximately **$500,000.** Multiple Individual grants of varying budget will be considered and evaluated and may be distributed among more than one provider. The grant amount Lilly will fund will depend upon the evaluation of the proposal and costs involved, and this amount will be stated clearly in a formal Letter of Agreement.

Proposal due by: 10/16/24

C. HCP Performance/Practice Gap(s)*: Evidence suggests that the above Patient Healthcare Gap is due to the fact(s) that some HCPs [16-18]

- ❑ Delay the integration of new data and recommendations on brain health and cognitive assessment into practice
- ❑ May not distinguish between normal aging and early cognitive decline
- ❑ Do not incorporate conversations about brain health into routine healthcare
- ❑ May not identify and manage modifiable risk factors for dementia

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. Root causes may include [1,2,9,16-25]

- Challenges in keeping up with rapidly evolving scientific advances, data, and guidelines for brain health including recommendations for delaying cognitive decline through risk factor modification and promotion of healthy brain practices
- Lack of skills and ability to integrate and apply knowledge of the following into clinical practice:
  - AD risk factors include the APOE-ε4 allele, obesity, diabetes, hypertension, smoking, and dyslipidemia.
  - AD is a continuum with neuropathological changes preceding symptoms by several decades
  - Neuropathological changes can be detected by biomarkers, which are associated with cognitive decline.
  - Cognitively unimpaired individuals with abnormal pathology are at risk for developing symptoms due to Alzheimer's disease
  - The difference between Alzheimer's disease (which is based on neuropathologic change) and Alzheimer's dementia (which is based on neuropathologic change and cognitive/functional decline
- Variable utilization of cognitive assessments and understanding to distinguish Mild Cognitive Impairment from normal aging, and early from later stages of AD
- HCP discomfort discussing cognitive concerns with patients
- Lack of patient awareness of strategies to improve brain health
- Patient/family hesitation to initiate brain health conversations
- Skepticism about brain health research and therapeutic nihilism
- Lack of practical tools, processes, and strategies for HCPs to initiate and integrate conversations about brain health, cognitive preservation, and cognitive decline into routine healthcare.
- Lack of reimbursement/financial incentives to provide brain health services and challenges with billing/coding for cognitive services including consults, follow ups, in-clinic cognitive testing, computerized cognitive testing, study interpretation, management of modifiable risk factors, etc.

Preference will be given to proposals that:

1) Provide a high level of evidence for the Root Cause(s)

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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 globally:
Primary
Primary Care Practitioners/General Practitioners including Nurse Practitioners and Physician Assistants, General Neurologists, Geriatricians
Secondary: Psychiatrists, OB-GYNs

Preference will be given to proposals that include translations for HCPs in key geographies outside of the US including Germany and Japan

*HCPs located in the United Kingdom **may not be directly targeted (i.e., via email or a UK hosted website)** in the targeted HCP reach.*

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).**

D. 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

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)**

E. 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.

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- 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.

F. 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)

G. 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.

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

I. Accreditation: Grant applicants must be, or partner with, an accredited provider.

Programs and activities must 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.

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

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

L. 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 10/16/24

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Patient Healthcare Gap and Root cause References

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Examples of References on CE Effectiveness and Physician Learning

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