

Request for Proposal (RFP)/ Call for Grants



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

To: Educational Providers
From: Linda Battiato, Medical Education Grant Officer, Neuroscience
Date: 2/28/24

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 RFP 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 suspected or diagnosed Alzheimer's disease (AD). As data accrue around differential risk/benefit of new amyloid targeting therapies (ATT) for patients with and without genetic risk for AD, additional information related to genetic risk factors for Alzheimer's disease across diverse global ethnic and racial populations, selection of appropriate patients for testing, interpretation and communication of results, and implications for patients with known risk will be needed.^{1,2} Evidence demonstrates the following healthcare gaps that people with suspected or diagnosed Alzheimer's disease experience:

- Knowledge of genetic risk may be helpful in evaluating appropriate patients for treatment with ATT, but there is little consensus to guide selection of the appropriate patient for genetic screening, and these tests are not routinely utilized in clinical practice.¹⁻³ Emerging data suggests that genetic risk may be related to the likelihood of experience of ARIA in patients treated with ATT and may also predict response to treatment.⁴⁻¹⁰ Knowledge of APOE ε4 status (genotype and/or proteotype) may help guide HCP-patient discussion regarding potential risks and benefits of novel ATT.¹⁻¹² Without genetic testing of appropriate patients, physicians and patients may not have the necessary information to enable treatment planning and appropriately assess and monitor risk during treatment.
- Patients may not receive appropriate information and education about results of genetic testing. Patients may not be counseled appropriately, or sufficiently, about what the presence or absence of genetic risk factors may mean for their prognosis and course.¹⁻⁴

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

Proposal due by: 4/3/24

- HCP Performance/Practice Gap(s):** Evidence suggests that the above Patient Healthcare Gap(s) is due to the fact(s) that some HCPs^{1,2, 11-16}:
- Delay integration of new data and guidelines for genetic testing into practice for patients with known or suspected AD
- Delay and/or make errors in patient selection for ATTs
- Do not engage in Shared Decision-Making (SDM) to develop individualized treatment plans for AD treatment inclusive of genetic risk considerations and patient/care partner goals, values, and preferences

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

C. 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 include¹⁻¹⁶:

- Challenges in keeping up with rapidly evolving scientific data and guidelines, including data regarding the impact of APOE genotype and/or proteotype on the risk of experiencing AEs from ATT treatment
- Lack of skills and experience in implementing appropriate genetic testing for patients with known or suspected AD into clinical practice and communicating the rationale for testing to patients and their care partners
- Lack of confidence and skills regarding how to interpret genetic test results and how to communicate results to patients and their care partners
- Lack of knowledge regarding how and when they may need to engage genetics counseling services per local laws/regulations
- Lack of skills, tools and processes for individualized patient and care partner education and SDM regarding risks and benefits of treatment with ATTs

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.)

D. Target Audience: The intended audience includes the following HCPs on a global level involved in the care of patients with **Alzheimer's Disease**

- Specialists including: Dementia specialists, neurologists, geriatricians, geriatric psychiatrists
- NPs (working in AD specialty settings)
- PAs (working in AD specialty settings)

Preference will be given to proposals that include translations for HCPs in key geographies outside of the US.

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.

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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).

- E. 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 (Specific, Measurable, Achievable, Realistic and Timebound) and/or conform to the ABCD rubric (Audience, Behavior, Conditions, Degree (**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)

- F. 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.

- G. 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

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- 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)

H. 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.

I. 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.

J. 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.

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

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

M. Mandatory Requirements:

- When submitting your proposal, you must include "RFP: [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 RFP 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 4/3/24

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RFP References

1. Blasco, D., Roberts, J.S. Implications of Emerging Uses of Genetic Testing for Alzheimer's Disease. *J Prev Alzheimers Dis* **10**, 359–361 (2023)
2. Ritchie M, Sajjadi SA, Grill JD. Apolipoprotein E Genetic Testing in a New Age of Alzheimer Disease Clinical Practice. *Neurol Clin Pract*. 2024 Apr;14(2)
3. Ramanan VK, Armstrong MJ, Choudhury P, Coerver KA, Hamilton RH, Klein BC, Wolk DA, Wessels SR, Jones LK Jr; AAN Quality Committee. Anti-amyloid Monoclonal Antibody Therapy for Alzheimer Disease: Emerging Issues in Neurology. *Neurology*. 2023 Nov 7;101(19):842-85
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5. Doran SJ, Sawyer RP. Risk factors in developing amyloid related imaging abnormalities (ARIA) and clinical implications. *Front Neurosci*. 2024 Jan 19
6. Withington CG, Turner RS. Amyloid-Related Imaging Abnormalities With Anti-amyloid Antibodies for the Treatment of Dementia Due to Alzheimer's Disease. *Front Neurol*. 2022 Mar 23;13
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8. Van Dyck,, Swanson, C, Aiesn, P, et al Lecanemab in early AD. *NEJM* 2023; 388:9-2-21
9. Evans CD, Sparks JD, Andersen SW, et al. APOE ε4's impact on response to amyloid therapies in early symptomatic Alzheimer's disease: Analyses from multiple clinical trials. *Alzheimer's 9. Dement*. 2023; 19: 5407–5417.
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16. van der Flier, W.M., Kunneman, M., Bouwman, F.H., Petersen, R.C. and Smets, E.M.A. (2017), Diagnostic dilemmas in Alzheimer's disease: Room for shared decision making. Alzheimer's & Dementia: Translational Research & Clinical Interventions, 3: 301-304.

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Examples of References on CE Effectiveness and Physician Learning

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2. Marinopoulos, S.S.; Dorman T., Ratanawongsa, N., Wilson, L. M., Ashar, B., Magaziner, J.L., Miller, R. G., Thomas, P. A., Propowicz, G.P., Qayum, R., Bass EB. Effectiveness of continuing medical education. *Evid Report/technology Assess Agency Healthc Res Qual Rockville, MD*. 2007;149.
3. Nissen SE. Reforming the continuing medical education system. *JAMA - J Am Med Assoc*. 2015;313(18):1813-1814. doi:10.1001/jama.2015.4138
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References on Learning Objectives

1. Chatterjee D, Corral J. How to Write Well-Defined Learning Objectives. *J Educ Perioper Med.* 2017 Oct 1;19(4):E610. PMID: 29766034; PMCID: PMC5944406.
2. Liu, P.L. & Lohr, L. (2004). Do You Know How to Write Learning Objectives? -- An Action Research. In R. Ferdig, C. Crawford, R. Carlsen, N. Davis, J. Price, R. Weber & D. Willis (Eds.), *Proceedings of SITE 2004--Society for Information Technology & Teacher Education International Conference* (pp. 979-981). Atlanta, GA, USA: Association for the Advancement of Computing in Education (AACE). Retrieved March 8, 2023
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