Call for Grant Application (CGA)

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

To: Educational Providers
From: Zoe Chen, Medical Education Grant Officer, Neuroscience
Date: June 19, 2025

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 innovative Continuing Education proposals (+enduring content) to improve ability of Health Care Professionals (HCPs) to optimally support cognitive health and clinical care across the continuum of normal aging through Alzheimer's disease (AD).

AD is now recognized as a continuum that progresses through several stages, beginning with individuals who are cognitively unimpaired with evidence of AD pathology, and extending to those with severe dementia due to AD. Up to 20 years before the clinical symptoms of AD emerge, pathophysiological hallmarks of the disease appear, including the accumulation of amyloid plaques (composed of aggregated forms of amyloid beta) and neurofibrillary tangles (formed within neurons and composed of abnormally phosphorylated tau). Recently, the diagnosis of AD has moved towards a clinical–biological approach supported by robust cerebrospinal fluid (CSF) and position emission tomography (PET) biomarkers that provide evidence of pathology[1]. With the approval of novel blood biomarker tests, which offer a more cost-effective and less burdensome approach to detecting AD pathology, education is essential to support clinical decision making and promote timely, accurate diagnosis and optimal care for patients with AD[17]. HCPs including primary care providers (PCPs) and general neurologists may care for patients across all stages of the AD continuum, with PCPs uniquely positioned as the first point of contact to identify modifiable risk factors and detect early cognitive changes in mid-life adults.

Evidence demonstrates the following healthcare gaps[8]:

- Patients are not diagnosed with AD in a timely and accurate manner due in part to underutilization of PET imaging and CSF biomarker testing

Preference will be given to proposals that:

- Foster deep learner engagement through proven evidence-based instructional tactics that optimize skill development (e.g. active learning, demonstrations, interactive formats, workshops, etc.)
- Require active *involvement from learners, <u>including effective practice opportunities to apply and use new concepts/skills.</u>*

B. Budget and Due Date: 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

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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: 7/21/2025

C. HCP Performance/Practice Gap(s)*: Evidence suggests that the above Patient Healthcare Gap(s) is due to the fact(s) that some HCPs[9-11]

- ❑ May not distinguish normal aging and early cognitive decline due to AD
- ❑ May not understand the use of dynamic biomarkers to detect pathological changes in disease
- ❑ Do not recognize the value and utility of blood biomarker tests to aid in detecting amyloid pathology in the early stages of disease, nor do they recognize how to identify the appropriate patient for testing
- ❑ May not be aware of new data for the use of blood biomarker tests in clinical practice
- ❑ Fail to interpret and communicate blood biomarker test results (i.e., positive, indeterminate, negative), and identify individuals who should be referred to specialists for further evaluation

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 those that will be addressed in the educational initiative. Methods used to identify root causes must be described and references provided.

- Challenges in keeping up with rapidly evolving scientific advances and research on blood biomarker testing and interpretation of results from the tests[1]
- Challenges in consistent integration and implementation of blood biomarker testing into clinical practice and into standard diagnostic process for AD[8,10]
- Lack of education on blood biomarker test characteristics[10]
- Lack of consensus guidelines describing the use of blood biomarker tests[1,8,11]
- Variable access to and utilization of blood biomarker tests[12,13]
- Lack of confidence in the accuracy of blood biomarker test results[1,14]
- Lack of consistent recommendations for assessing cognitive impairment in primary care setting[10]
- Lack of practical tools, processes, and strategies for HCPs to initiate and integrate conversations about cognitive health, cognitive preservation, and cognitive decline into routine healthcare[15,16]

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 US HCPs:

- ❑ **Primary Care Physicians/General Practitioners (MD/DO/NP/PA)**
- ❑ **General Neurologists**

Note: HCPs located in the United Kingdom (UK) 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)

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- 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

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:

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

K. Accreditation: *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.*

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 ensure the **Program Foundation & Accountability template** is included at the beginning of submitted proposals.
- Please limit the length of your grant proposal to **20 pages or less** (not including Program Foundation & Accountability template, references, budget).
- All responses to this CGA are to be submitted online through the Lilly Grant Office grant application system no later than close of business (5:00pm ET) on the date stated in **section B** above.

Patient Healthcare Gap References

1. Schöll M, Verberk IMW, Del Campo M, et al. Challenges in the practical implementation of blood biomarkers for Alzheimer's disease. Lancet Healthy Longev. 2024;5(10):100630. doi:10.1016/j.lanhl.2024.07.013
2. Palmqvist S, Tideman P, Mattsson-Carlgren N, et al. Blood Biomarkers to Detect Alzheimer Disease in Primary Care and Secondary Care. JAMA. 2024;332(15):1245-1257. doi:10.1001/jama.2024.13855
3. Rissman RA, Donohue MC, Langford O, et al. Longitudinal Phospho-tau217 Predicts Amyloid Positron Emission Tomography in Asymptomatic Alzheimer's Disease. J Prev Alzheimers Dis. 2024;11(4):823-830. doi:10.14283/jpad.2024.134
4. Sperling RA, Donohue MC, Rissman RA, et al. Amyloid and Tau Prediction of Cognitive and Functional Decline in Unimpaired Older Individuals: Longitudinal Data from the A4 and LEARN Studies. J Prev Alzheimers Dis. 2024;11(4):802-813. doi:10.14283/jpad.2024.122

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5. Sperling RA, Donohue MC, Rissman RA, et al. Amyloid and Tau Prediction of Cognitive and Functional Decline in Unimpaired Older Individuals: Longitudinal Data from the A4 and LEARN Studies. J Prev Alzheimers Dis. 2024;11(4):802-813. doi:10.14283/jpad.2024.122
6. Atri A, Dickerson BC, Clevenger C, et al. Alzheimer's Association clinical practice guideline for the Diagnostic Evaluation, Testing, Counseling, and Disclosure of Suspected Alzheimer's Disease and Related Disorders (DETeCD-ADRD): Executive summary of recommendations for primary care. Alzheimers Dement. Published online December 23, 2024. doi:10.1002/alz.14333
7. M. Schöll, A. Vrillon, T. Ikeuchi, F.C. Quevenco, L. Iaccarino, S.Z. Vasileva-Metodiev, S.C. Burnham, J. Hendrix, S. Epelbaum, H. Zetterberg, S. Palmqvist, Cutting through the noise: A narrative review of Alzheimer's disease plasma biomarkers for routine clinical use, The Journal of Prevention of Alzheimer's Disease, 2025,100056, ISSN 2274-5807, https://doi.org/10.1016/j.tjpad.2024.100056.
8. Angioni, D., Delrieu, J., Hansson, O. et al. Blood Biomarkers from Research Use to Clinical Practice: What Must Be Done? A Report from the EU/US CTAD Task Force. J Prev Alzheimers Dis 9, 569–579 (2022). https://doi.org/10.14283/jpad.2022.85
9. Dubois, B., von Arnim, C.A.F., Burnie, N. et al. Biomarkers in Alzheimer's disease: role in early and differential diagnosis and recognition of atypical variants. Alz Res Therapy 15, 175 (2023). https://doi.org/10.1186/s13195-023-01314-6
10. Mielke MM, Anderson M, Ashford JW, et al. Considerations for widespread implementation of blood-based biomarkers of Alzheimer's disease. Alzheimers Dement. 2024;20(11):8209-8215. doi:10.1002/alz.14150
11. Mielke MM, Anderson M, Ashford JW, et al. Recommendations for clinical implementation of blood-based biomarkers for Alzheimer's disease. Alzheimers Dement. 2024;20(11):8216-8224. doi:10.1002/alz.14184
12. Arias JJ, Phillips KA, Karlawish J. Developing an Economic and Policy Research Agenda for Blood Biomarkers of Neurodegenerative Diseases. JAMA Health Forum. 2021;2(7):e211428. doi:10.1001/jamahealthforum.2021.1428
13. Eleanor Hayes-Larson, Sarah F Ackley, Indira C Turney, Renaud La Joie, Elizabeth Rose Mayeda, M Maria Glymour, for the Alzheimer's Disease Neuroimaging Initiative, Considerations for Use of Blood-Based Biomarkers in Epidemiologic Dementia Research, American Journal of Epidemiology, Volume 193, Issue 3, March 2024, Pages 527–535, https://doi.org/10.1093/aje/kwad197
14. VandeVrede L, Rabinovici GD. Blood-Based Biomarkers for Alzheimer Disease—Ready for Primary Care? JAMA Neurol. 2024;81(10):1030–1031. doi:10.1001/jamaneurol.2024.2801
15. Borson S, Small GW, O'Brien Q, et al. Understanding barriers to and facilitators of clinician-patient conversations about brain health and cognitive concerns in primary care: A systematic review and practical considerations for the clinician. BMC Prim Care. 2023;24(233).
16. Hill NL, Bratlee-Whitaker E, Jang H, et al. Patient-provider communication about cognition and the role of memory concerns: a descriptive study. BMC Geriatr. 2023;23(1):342. doi:10.1186/s12877-023-04053-3
17. U.S. Food and Drug Administration. FDA clears first blood test used in diagnosing Alzheimer's disease. FDA. Published May 16, 2025. Accessed May 16, 2025. https://www.fda.gov/news-events/press-announcements/fda-clears-first-blood-test-used-diagnosing-alzheimers-disease

Examples of References on CE Effectiveness and Physician Learning

1. Cervero RM, Gaines JK. Effectiveness of Continuing Medical Education: Updated Synthesis of Systematic Reviews. *Accredit Counc Contin Med Educ*. 2014;(July).
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
4. Davis D, O'Brien MAT, Freemantle N, Wolf FM, Mazmanian P, Taylor-Vaisey A. Impact of formal

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continuing medical education: Do conferences, workshops, rounds, and other traditional continuing education activities change physician behavior or health care outcomes? *J Am Med Assoc*. 1999;282(9):867-874. doi:10.1001/jama.282.9.867
5. Mansouri M, Lockyer J. A meta-analysis of continuing medical education effectiveness. *J Contin Educ Health Prof*. Published online 2007. doi:10.1002/chp.88
6. Bransford, J. D., Brown, A. CRR (eds). How People Learn Brain, Mind, Experience, and School. *Comm Dev Sci Learn Comm Dev Sci Learn Com Behav Soc Sci Educ*. Published online 1999.
7. Dirksen J. *Design for How People Learn*. New Riders, Berkley, CA; 2012
8. Mayer RE. Applying the science of learning to medical education. *Med Educ*. 2010;44(6):543-549. doi:10.1111/j.1365-2923.2010.03624.
9. Moore DE, Green JS, Gallis HA. Achieving desired results and improved outcomes: Integrating planning and assessment throughout learning activities. *J Contin Educ Health Prof*. 2009;29(1):1-15. doi:10.1002/chp.2000
10. Ericsson KA. Deliberate practice and the acquisition and maintenance of expert performance in medicine and related domains. In: *Academic Medicine*. ; 2004. doi:10.1097/00001888-200410001-00022
11. Branch WT, Paranjape A. Feedback and Reflection: Teaching Methods for Clinical Settings. *Acad Med*. 2002;77(12):1185-1188. doi:10.1097/00001888-200212000-00005
12. Ende J. Feedback in clinical medical education - PubMed. *JAMA*. 1983;250(6):1185-1188
13. Schon DA. *Educating the Reflective Practitioner. Toward a New Design for Teaching and Learning in the Professions.* The Jossey-Bass Higher Education Series; 1987.
14. Ratelle JT, Wittich CM, Yu RC, Newman JS, Jenkins SM, Beckman TJ. Relationships between reflection and behavior change in CME. *J Contin Educ Health Prof*. Published online 2017. doi:10.1097/CEH.0000000000000162
15. Moore DE. How physicians learn and how to design learning experiences for them: an approach based on an interpretive review of the literature. In: *Continuing Education in the Health Professions: Improving Healthcare Through Lifelong Learning*. ; 2008.
16. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8011054/

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
3. *Heinich, R., Molenda, M., Russell, J., & Smaldino, S. (2001). Instructional media and technologies for learning (7th ed).Englewood Cliffs, NJ: Prentice Hall.*