To: Educational Providers

From: Linda Battiato, Medical Education Grant Officer, Alzheimer's Disease

Date: 3/13/24

Note: This grant request was jointly developed through a collaboration between the Lilly Grant Office IME department ("Lilly") and the Fujirebio Diagnostics, Inc department of Scientific Affairs ("Fujirebio"). Should you decide to respond, you will be required to submit two separate applications: one to Lilly and one to Fujirebio. There may be some differences in information required by each company, as more specifically provided below.

Lilly and Fujirebio are 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 and Fujirebio do 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 <u>UNLESS</u> YOU INTEND TO PARTNER WITH THEM FOR PROPOSAL SUBMISSION

A. Purpose:

Lilly and Fujirebio are currently seeking continuing education proposals to improve the care of patients with early symptomatic Alzheimer's disease mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild dementia due to AD by improving the ability of health care providers (HCPs) to integrate fluid biomarkers into the AD diagnostic algorithm to provide a timely and accurate diagnosis. Evidence demonstrates the following healthcare gap:

Patients with early symptomatic Alzheimer's disease often experience delayed or inaccurate diagnosis, contributing to suboptimal management and poorer outcomes. ¹⁻⁶ New and emerging treatments that slow the progression of disease in early symptomatic patients introduce new urgency into the need for timely and accurate diagnosis. ⁷⁻¹²

B. Budget and Due Date: Lilly and Fujirebio will consider funding 1 proposal with a total available budget of \$250,000 split equally between Lilly and Fujirebio

Proposal due by: 4/12/24

Ideally programs will launch by early Q3 2024

C.HCP Performance/Practice Gap(s): Evidence suggests that the above Patient Healthcare Gap(s) is due to the fact(s) that some HCPs ^{1-6,13-16}

- Delay and/or make errors in clinical and neuropathological diagnosis of early symptomatic AD
- □ Fail to consistently adhere to recommendations for the use of fluid biomarkers for patients with early symptomatic AD
- □ Do not feel a sense of urgency to diagnose early symptomatic AD
- ☐ May not integrate knowledge about scientific and clinical advances in AD fluid biomarkers and AD treatment into practice

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

- **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. Potential root causes may include 13-20.
 - Lack of awareness regarding:
 - The emerging evidence highlighting the use of fluid biomarkers to detect AD pathology and facilitate diagnosis in patients presenting with cognitive impairment
 - The advantages and limitations linked to the use of AD biomarkers, as well as the sensitivity and accuracy of various methods and assays used for the assessment of patients with early symptomatic AD
 - Lack of skills and confidence to appropriately integrate fluid biomarker assessments into the AD diagnostic pathway
 - Challenges in keeping up with advances in AD treatment and limited awareness of the importance of timely and accurate diagnosis to appropriately identify patients for new and emerging disease modifying therapies (DMTs) for AD

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 AD including:
 - □ Dementia specialists, Neurologists, Geriatricians, Geriatric Psychiatrists and neuropsychologists

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).

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 (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)

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
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- 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 and Fujirebio are 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: 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:

- Please limit the length of your grant proposal to <u>20 pages or less</u> (not including references and budget).
- All responses to this RFP must be submitted no later than close of business (5:00 PM ET) on 4/12/24

Please submit the same proposal to Lilly and Fujirebio

Submission to Lilly

- All responses to this RFP are to be submitted online through the Lilly Grant Office grant application system at https://portal.lillygrantoffice.com
- When submitting your proposal, you must include "RFP: [title of program]" in your grant submission.

Submission to Fujirebio

- All responses to this RFP are to be submitted via email to Dr. Francesca De Simone, PhD (<u>DeSimoneF@fdi.com</u>) and to Diana Dickson (dicksond@fdi.com)
- When submitting your proposal, you must include "RFP: [title of program]" in your grant submission.

Questions and Communication

All questions and communication must be submitted to both the Lilly Grant Office at lillygrantoffice@lilly.com AND Fujirebio at DeSimoneF@fdi.com

References

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Examples of References on CE Effectiveness and Physician Learning

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