Request for Proposal (RFP)

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

To: Quality Improvement Teams
From: Lilly Grant Office
Date: 9/5/23

This Proposed Quality Improvement or Performance Improvement Initiative seeks to augment current clinical practice, leading to measurable improvements in the timely and accurate clinical and neuropathological diagnosis of early symptomatic Alzheimer's disease (inclusive of AD with Mild Cognitive Impairment [MCI], and AD with mild dementia). The field of Alzheimer's disease has been moving toward including evidence of pathology in the diagnostic framework, which can potentially lead to a more timely diagnosis and resultant benefits on holistic patient care and healthcare costs over time.[1-6]

Background:

A QI grant is a grant which Lilly funds to support independent projects with systematic and continuous actions that lead to measurable improvements in the delivery of care that improve the health status of targeted patient groups within specific health systems.

Lilly is committed to supporting QI efforts that foster the translation of scientific evidence into evidence-based clinical practice using QI theory, process and models to ultimately provide patients and providers with new ideas and insights on how to more effectively and efficiently receive and deliver optimal care. Lilly seeks to support a QI program that has the potential for widespread transferability and dissemination to other healthcare organizations.

For all independent quality improvement grants, the grant requestor (and ultimately the grantee) is responsible for the design, implementation, and supervision of the independent initiative. Lilly must not be involved in any aspect of project development nor the conduct of the quality improvement program. Lilly does not support initiatives or any medical activities for the purpose of encouraging off-label use of our products.

<table>
<tr><td>Clinical Area</td><td>Alzheimer's disease (AD)</td></tr>
<tr><td>Clinical Practice Gaps and Supporting Evidence</td><td>Lilly is requesting proposals for Quality Improvement or Performance Improvement (QI/PI) initiatives that seek to augment current clinical practice in healthcare institutions leading to measurable improvements in the timely and accurate clinical and neuropathological diagnosis of early symptomatic Alzheimer's disease (inclusive of AD with MCI, and AD with mild dementia).

<table>
<tr><th>Clinical Practice Gaps</th><th>Root Causes and Barriers</th></tr>
<tr><td>Patients with AD can experience lengthy delays from the time of initial reporting of cognitive and/or functional complaints to receiving an accurate, directly communicated diagnosis from a healthcare professional.[7-9] Delayed diagnosis prevents timely consideration of potential</td><td>1. Healthcare institutions lack standardized protocols, tools, and resources for efficient and seamless integration of clinical and neuropathological assessments into patient visits, including when and how to refer to additional health care professionals.[9-15]
2. Barriers to utilization of clinical assessments and diagnostic tools, in addition to limited treatment options</td></tr>
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	treatments/interventions and may contribute to increased healthcare costs.[4-6] | impact the ability for patients to receive a timely diagnosis.[4,13]
	The QI/PI Initiative should demonstrate measurable improvements in the timely and accurate clinical and neuropathological diagnosis of early symptomatic Alzheimer's disease (inclusive of AD with MCI, and AD with mild dementia) through Quality Improvement methods.
Project Design	It is Lilly's intent to support a QI/PI initiative that will lead to improvements in the timely and accurate clinical and neuropathological diagnosis of early symptomatic Alzheimer's disease (inclusive of AD with MCI, and AD with mild dementia). **All proposals should clearly describe and estimate the magnitude of expected improvements in the timely and accurate clinical and neuropathological diagnosis of AD as a result of the QI intervention**. It is expected that standard Quality Improvement methods will be used as recommended by major organizations such as the Institute for Healthcare Improvement, the CDC, the Agency for Healthcare Quality, the AAFP etc. (see examples of QI resource sites below). These methods include: data that quantify current practice gaps using evidence-based measures, identification of the root causes underlying the gap(s), an intervention(s) and implementation plan to close the gap, and re-evaluation of measures to document changes and improvements in care, processes, and outcomes. Continuing Education activities or credits may be incorporated as part of the intervention if appropriate. (See QI reference 8) If your proposal includes CME/CE, programs must be accredited by the appropriate accrediting bodies and fully compliant with all ACCME criteria and Standards for Integrity and Independence in Accredited Continuing Education. The following measures for baseline and final evaluation may include but are not limited to: proportion of patients that receive a timely and accurate diagnosis of Alzheimer's disease, use of appropriate clinical and biomarker assessments/tools, timely referrals where appropriate, time from cognitive complaints to confirmed and communicated diagnosis, and patient and care partner support. Other considerations will be clinical feasibility, applicability to a variety of healthcare settings, strength of process and outcomes assessments, and methodologic rigor. **IMPORTANT:** It is not the intent of this RFP to support clinical research projects. Research projects, such as those evaluating novel therapeutic or diagnostic agents, will not be considered.
Geographic Scope	United States
Eligible Applicants	Preference will be given to: applicants who are – or partner with - large integrated health delivery systems, ACO's, hospital systems or insurers who can use healthcare data to measure current gaps and outcomes, and who have a vested interest in improving the care of their patients with early

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	symptomatic Alzheimer's disease (inclusive of AD with MCI, and AD with mild dementia).
Qualifications/Eligibility	Please provide information on the Quality Improvement qualifications and experience of the project leader and collaborators. Please include any certifications (i.e. Black Belt, Science of Improvement training), recognitions (ex: Baldridge award) and the number and type of quality improvement projects you or your organization have successfully executed in the past. Provide a robust example of a past completed QI project. Explain any methods that will be used to ensure those expected to participate are fully trained in the program expectations and any skills that may be needed to ensure effective execution of the project. If you are not in direct control of the data used for measurement, please provide letters of commitment to fully participate and supply data to support the project. Preference will be given to applicants who have the potential and interest in disseminating successful QI/PI interventions to other institutions, as well as integrating health equity improvements across underserved patients into their plan. Lilly encourages applicants to collaborate with similar healthcare organizations that treat patients with Alzheimer's disease to demonstrate the potential for widespread dissemination.
Communication/ Publication Plan	Include a description of how the results of this quality improvement intervention will be presented, published, or disseminated.
Conflict Resolution	The proposal should briefly describe methods for ensuring fair and balanced content and identification and resolution of conflict of interest.
Timing	Ideally, program will launch in Q1 2024 with a project length as determined by the design of the program. Interim report/read out is expected quarterly or as requested by the supporter and long term sustained results should be reported as appropriate to the setting and the initiative. Please explain the rationale for suggested start/end dates, duration of the program and timeline for reporting any long-term results.
Budget Guidance	Please complete the attached budget template. Lilly will consider funding up to two proposals with expected budgets of approximately $600,000 to $800,000 each. Individual grants of varying budget will be accepted, evaluated, and may be distributed among more than one provider. The grant amount Lilly will be prepared to fund will depend upon the evaluation of the proposal and costs involved, and this amount will be stated clearly in the Letter of Agreement. Institutional overhead and indirect costs ("overhead") may be included within the Quality Improvement grant request. However, any included overhead should be kept to a minimum, may not exceed 30% of the total grant request, and may not cause the amount requested to exceed the budget limit set forth in the RFP. NOTE: Lilly Grant Office funding may not be used for entertainment, capital, gifts (monetary or otherwise), or personal travel.

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	The attached Grant Request Budget and Reconciliation template will categorize the financial components of the QI programs in a consistent way. This template is not yet required by the Lilly Grant Office, but we request that you use this template to represent the budget for your RFP submission. It should be submitted in our portal following the normal upload process. Should a grant be awarded as a result of this RFP, certain payments may be subject to reporting by Lilly pursuant to the U.S. Physician Payment Sunshine Act ("Open Payments") - a subpart of the Patient Protection and Affordable Care Act of 2010.
Submission Instructions	**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 10/24/23** **NOTE: When submitting your proposal, please be sure to include "QI RFP: [title of program]" in your grant submission.**

Recipients of this RFP are required to treat the RFP and its contents, and any information derived there from, as CONFIDENTIAL and PROPRIETARY information.

We look forward to your response.

Linda Battiato
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Specific References for this RFP:

1. Dubois B, Villain N, Frisoni GB. Clinical diagnosis of Alzheimer's disease: recommendations of the International Working Group. Lancet Neurol. 2021;20(6):484-496.
2. Jack CR, Bennett DA, Blennow K, et al. NIA-AA Research Framework: Toward a biological definition of Alzheimer's disease. Alzheimers Dement. 2018;14(4):535-562.
3. Hampel H, Au R, Mattke S, et al. Designing the next-generation clinical pathway for Alzheimer's disease. Nat. Aging. 2022;2:692-703.
4. Dubois B, Padovani A, Scheltens P, et al. Timely diagnosis for Alzheimer's disease: A literature review on benefits and challenges. J Alzheimers Dis. 2016;49:617-631.
5. Galvin JE, Aisen P, Langbaum JB, et al. Early stages of Alzheimer's disease: Evolving the care team for optimal patient management. Front. Neurol. 2021;11:592302.
6. Barnett JH, Lewis L, Blackwell AD, Taylor M. Early intervention in Alzheimer's disease: a health economic study of the effects of diagnostic timing. BMC Neurol. 2014;14:101.
7. Rasmussen J, Langerman H. Alzheimer's disease–why we need early diagnosis. Degen Neurol Neuromusc Dis. 2019;9:123-130.
8. Alzheimer's Association. 2022 Alzheimer's Disease Facts and Figures. Alzheimer's Dement 2022.
9. Judge D, Roberts J, Khandker R, et al. Physician perceptions about the barriers to prompt diagnosis of mild cognitive impairment and Alzheimer's disease. Int J Alzheimers Dis. 2019;3637954.
10. Judge D, Roberts J, Khandker R, et al. Physician practice patterns associated with diagnostic evaluation of patients with suspected mild cognitive impairment and Alzheimer's disease. Int J Alzheimers Dis. 2019;4942562.
11. Maserejian N, Krzywy H, Eaton S, Galvin J. Cognitive measures lacking in EHR prior to dementia or Alzheimer's disease diagnosis. Alzheimers Dement. 2021;17(7):1231-1243.
12. Shao Y, Zeng QT, Chen, KK et al. Detection of probable dementia cases in undiagnosed patients using structured and unstructured electronic health records. BMC Med Inform Decis Mak. 2019;19:128.
13. Bernstein Sideman A, Al-Rousan T, Tsoy E, et al. Facilitators and barriers to dementia assessment and diagnosis: perspectives from dementia experts within a global health context. Front Neurol. 2022;13:769360.

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14. Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question: understanding time lags in translational research. J R Soc Med. 2011;104(12):510-520.
15. Ebell MH, Shaughnessy AF, Slawson DC. Why Are We So Slow to Adopt Some Evidence-Based Practices? Am Fam Physician. 2018;98(12):709-710.

Quality Improvement Resources and Bilbliography:

1. Ihi.org; Science of Improvement | IHI - Institute for Healthcare Improvement Quality Improvement Essentials Toolkit | IHI - Institute for Healthcare Improvement
2. Ahrq.govHome | Agency for Healthcare Research and Quality (ahrq.gov)
3. SQUIRE | HOME PAGE (squire-statement.org)
4. Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): Revised Publication Guidelines from a Detailed Consensus Process. Perm J. 2015 Fall;19(4):65-70. doi: 10.7812/TPP/15-141. PMID: 26517437; PMCID: PMC4625997.
5. Goodman D, Ogrinc G, Davies L, et al. Explanation and elaboration of the SQUIRE (Standards for Quality Improvement Reporting Excellence) Guidelines, V.2.0: examples of SQUIRE elements in the healthcare improvement literature. BMJ Qual Saf. 2016;25(12):e7.
6. Davies L, Batalden P, Davidoff F, Stevens D, Ogrinc G. The SQUIRE Guidelines: an evaluation from the field, 5 years post release. BMJ Qual Saf. 2015;24(12):769-775.
7. Davidoff F, Batalden P, Stevens D, Ogrinc G, Mooney S; SQUIRE Development Group. Publication guidelines for quality improvement in health care: evolution of the SQUIRE project. Qual Saf Health Care. 2008 Oct;17 Suppl 1(Suppl_1):i3-9. doi: 10.1136/qshc.2008.029066. PMID: 18836063; PMCID: PMC2773518.
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