

## Allergan – Request for Proposals Notification

**Issue Date:** September 9, 2016

**Therapeutic Area:** Alzheimer’s Disease

**Purpose:** Allergan is interested in providing grant support for independent continuing professional development and education of healthcare professionals in the United States who treat patients with Alzheimer’s Disease. This Request for Proposals Notification (RFP) provides public notice of the availability of funds in a general topic area for activities for which recognized scientific or educational needs exist and funding is available.

Allergan Medical Education is committed to supporting independent educational activities in specific therapeutic areas that foster increased understanding of scientific, clinical or healthcare issues, and that serve to improve patient care. All grants are awarded at Allergan’s sole discretion. Approval of grant funding is never related to or conditioned upon past prescriptions or purchases of Allergan products. Furthermore, Allergan does not offer or provide educational grants to encourage or to reward the prescription, purchase, ordering, or recommending of Allergan products.

### Intended Audience

- Primary Audience: PCPs
- Secondary Audiences: Neurologists and Psychiatrists

### Educational Design

- Online Activities

### Application Title: “RFP ALZ 04– Program Title”

- Your grant title must begin with the Request for Proposals ID number
- Refer to the submission instructions for further guidance on submitting your grant application

Submission Timeframe	September 10, 2016 – October 21, 2016
Proposal	Online Activities
Program Format	Online activities with enduring materials
Program Cost	≤\$150,000

### Eligibility Criteria

- Applicants must be US-based, registered on Allergan’s Grant Management website at [www.allerganmededgrants.com](http://www.allerganmededgrants.com), and in good standing and accredited to provide CME/CE by an official accrediting agency (e.g. ACCME, AOA, AAFP, AMA, ADA CERP, ANCC, ACPE, etc.).
- Our grant application system requires the registration of accredited providers and third parties before a grant application can be submitted.
- We recommend that your organization register in the system before the deadline if you are not currently registered.

### Educational Needs

Alzheimer’s Disease is a serious disease and a major public health issue that impacts approximately one in nine people aged 65 and older, and about 33 percent of people age 85 and older.<sup>1</sup> In addition, about 5 percent of people affected by Alzheimer’s Disease have early onset Alzheimer’s. These patients usually present in the fifth or sixth decade of life. Alzheimer’s is the most common form of dementia, accounting for about 60-80 percent of diagnosed dementias.<sup>2</sup>

Patients with Alzheimer's show a progressive dementia that worsens over time. In the early stages of disease, patients show symptoms of short-term memory loss. As the disease moves into the moderate and severe stages, patients suffer issues with language, self-care, changes in behavior, and finally, a loss in essential bodily functions, leading to death. The median time from diagnosis to death in a patient with Alzheimer's Disease is about three to twelve years.<sup>3</sup>

The pathogenesis of Alzheimer's Disease is not completely understood. There appear to be genetic components to the disease, and there are well-known genetic risk factors such as an allele of apolipoprotein E (APOE4). There are many other possible causes, such as the presence of extracellular beta amyloid and intracellular tau protein resulting in neurofibrillary tangles. Both plaques and tangles are features of Alzheimer's Disease, though their exact role in the development and progression of disease is not completely understood.<sup>4</sup>

Currently, there are 4 molecules that are FDA approved for the treatment of dementia of the Alzheimer's type: donepezil, rivastigmine, galantamine, and memantine.<sup>5</sup> Three of these drugs (donepezil, rivastigmine, galantamine) are acetylcholinesterase inhibitors and the other (memantine) is an NMDA receptor antagonist. None of these drugs are approved for the treatment of the underlying causes of Alzheimer's Disease and none of these drugs slow the underlying progression of disease. Frequently, these drugs are used in combination when patients are in the later stages of disease.<sup>6</sup>

Current developments in the search for new drugs to treat Alzheimer's Disease have looked at a number of different mechanisms including: suppression of inflammation in the brain, reduction in the creation of amyloid plaques, and prevention of the formation of neurofibrillary tangles. Unfortunately, as of late, most new therapies have failed to deliver on their potential for slowing the disease and/or reducing its symptoms.<sup>7</sup>

There is a major need in the medical community for a better understanding of Alzheimer's Disease including: how to diagnose Alzheimer's Disease and to diagnose it earlier in its course, how best to treat Alzheimer's Disease with the current drugs available, and how best to improve the quality of life for both patients with Alzheimer's Disease and their caretakers.<sup>8</sup>

We request that educational providers reach an independent decision as to whether there exists an educational need to improve the understanding, diagnosis, and treatment of Alzheimer's Disease. Requestors should be able to explain the latest disease state understandings and the state of unmet needs concerning current treatments for this disease.

Proposed and implemented educational activities must be fully compliant with all applicable accrediting organization and industry standards, guidelines, and requirements as they apply to the conduct of independent medical education. If an accredited provider chooses to submit an educational grant request in response to this RFP, a complete and independent needs assessment including identified barriers to patient care, must be provided with the grant application.

### **Outcomes Measurement**

Applications should include a detailed plan to provide quantitative evidence to show that the educational initiative had impact on healthcare provider knowledge, competence and or performance outcomes (Moore level 3 - 5).<sup>9</sup> The proposal should include pre- and post-educational assessments or a comparison to a control group who has not been exposed to the intervention. A description of the methodology used to evaluate the reach and quality of the activity should be provided.

### **Submission Instructions**

Submit applications through Allergan's Grant Management website at [www.allerganmededgrants.com](http://www.allerganmededgrants.com).

When submitting the application, please ensure the following are completed:

1. Select *Alzheimer's Disease – RFP ONLY* as the therapeutic area
2. Include the following, "RFP ALZ 04" in the program title of the grant application
6. Complete all sections of the grant application
7. Upload all documents requested by the system

### **Deadline for Submission of Application**

October 21, 2016

### **Decision Date and Notification**

You will receive an acknowledgement email once the Allergan Medical Education Department has reviewed your completed grant application approximately the **third week of November, 2016**. After your request has been completely reviewed by Allergan's Grant Review Committee, Allergan will provide you a written response regarding your request. If your request is approved, the response will be accompanied by a Letter of Agreement, which must be signed and returned to the Allergan Medical Education Department. Please do not consider any request approved until you have received written documentation from the Allergan Medical Education Department stating that your grant request has been approved.

### **Terms and Conditions**

We reserve the right to approve or deny any or all applications received as a result of this request or to cancel, in part or in its entirety, this RFP.

### **Transparency**

The Allergan grant approval process is in full accordance with the recommendations and the guidance of the Office of Inspector General (OIG), Pharmaceutical Research and Manufacturers of America (PhRMA), Advanced Medical Technology Association (AdvaMed), the Accreditation Council for Continuing Medical Education (ACCME), "National Physician Payment Transparency Program: OPEN PAYMENTS" commonly known as the "Sunshine Act," and internal Allergan Compliance policies.

Allergan, at its sole discretion, has the right to disclose the details of funded independent medical education activities, including those that may be required by federal, state, and/or local laws and regulations. This disclosure may include, but shall not be limited to, details of the activity and the grant amount.

### **References**

1. Alzheimer's Association. 2016 Alzheimer's Disease Facts and Figures. *Alzheimers & Dementia* 2016;12(4).
2. Alzheimer's Association. What is Alzheimer's? Retrieved Aug 6, 2016.
3. Todd, S, et. al. Survival in dementia and predictors of mortality: a review, *Int J Geriatr Psychiatry*. 2013 Nov;28(11):1109-24.
4. Alzheimer's Association. What is Alzheimer's? Retrieved Aug 6, 2016.
5. Namenda® [package insert]. Forest Laboratories, St. Louis, MO 2013., Aricept® [package insert] Eisai, Inc., Woodcliff Lake, NJ 2015.
6. Tjia, J, Use of medications of questionable benefit in advanced dementia. *JAMA Intern Med*. 2014 Nov;174(11):1763-71.
7. Amtul Z., Why therapies for Alzheimer's disease do not work: Do we have consensus over the path to follow? *Ageing Res Rev* 2016 Jan;25:70-84.
8. Alzheimer's Association. Early Detection. Retrieved Aug 6, 2016.

9. Moore DE, et al. Achieving desired results and improved outcomes: integrating planning and assessment throughout learning activities. *J Cont Educ Health Prof.* 2009; 29: 1-15.