

Lundbeck Medical Education: Request for Independent Medical Education Grant Proposals

Submission / Review Timeline:	Accepting applications until 9 am CST on October 31, 2023; interview reviews and approvals will be ongoing during this time.
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Therapeutic Area	Agitation in Alzheimer’s Dementia
Summary	<p>In 2023, there are an estimated 6.7 million adults aged ≥65 living with Alzheimer’s disease in the US, with a projected increase to 12.7 million by 2050 (Alzheimer’s Association 2023). Alzheimer’s dementia exhibits a range of neuropsychiatric symptoms, including agitation, alongside cognitive symptoms (Geda 2013, Kales 2014, Kales 2015). Agitation is prevalent in both community-dwelling patients (45%) and nursing home residents (53%) in the United States (Fillit 2021, Halpern 2019). It affects patients across different disease severities, with occurrence rates of 56% in mild cases, 75% in moderate to severe cases, and 68% in severe cases of Alzheimer’s dementia within the US community (Halpern 2019).</p> <p>Patients displaying signs and symptoms of agitation in Alzheimer’s dementia have greater healthcare resource utilization and costs compared to those without the condition (Sanon Aigbogun 2020, Cloutier 2019, Jones 2021). Clinically, agitation is linked to accelerated disease progression, functional decline, reduced quality of life, increased risk of institutionalization, and earlier mortality (Halpern 2019, Koenig 2016, Peters 2015, Scarmeas 2007, Wilcock 2008, Banerjee 2006, Rockwood 2019). The presence of neuropsychiatric symptoms, including agitation, directly impacts caregiver burden, which escalates with the severity of agitation (Cerejeira 2012, Okura 2011, Grossberg 2020, Allegri 2006, Mohamed 2010). The combination of increased caregiver distress and agitation can lead to the institutionalization of patients with Alzheimer’s dementia (Cloutier 2019, Okura 2011).</p> <p>The consensus definition of agitation in cognitive disorders, developed by the International Psychogeriatric Association (IPA), categorizes agitation behaviors into three groups: Excess Motor Activity, Verbal Aggression, and Physical Aggression (Sano 2023). Caregivers often first encounter and address agitation-associated behaviors (Lindeza 2020), while detection of agitation is commonly based on caregiver reports (Stella 2015). Underdiagnosis of agitation in Alzheimer’s dementia may occur due to caregivers’ inadequate recognition of symptoms or hesitation to discuss these behaviors with healthcare providers (Gallego-Alberto 2022). Caregivers using tailored tools can potentially detect agitation early on, leading to improved management of these behaviors (Sano 2023).</p> <p>Agitation in Alzheimer’s dementia may result from a disruption of top-down executive control and an increase in bottom-up emotional drive, associated with tau pathology and neurodegeneration in key prefrontal and subcortical brain regions (Rosenberg 2015, Carrarini 2021; Guadagna 2012, Hu 2015, Tekin 2001, Trzepacz 2013). It can be linked to hyperactivity of the norepinephrine system (via alpha adrenoceptor activation), serotonin system deficits (serotonin receptor binding), and dysregulation of the dopamine system (dopamine receptor antagonism) (Jacobs 2021, Arnsten 2015, Evers 1998, Lanctôt 2001, Cox 2011, Lindenmayer 2000).</p>
Summary (cont.)	Treatment for agitation in Alzheimer’s dementia involves comprehensive planning and considering nonpharmacological and pharmacological options (Rabins 2007, Reus 2016). If agitation does not

	<p>pose significant danger or distress, non-pharmacological approaches to treatment are usually preferred as a first step in addressing agitation. In cases where nonpharmacological approaches fail or behaviors are dangerous/distressing, clinicians may prescribe typical or atypical antipsychotics, antidepressants, anxiolytics/sedatives-hypnotics, anticonvulsants, or other medications (Rabins 2007, Reus 2016, Cummings 2002, Antonsdottir 2015, Schneider 2006, Aigbogun 2020). Pharmacological treatments require a balance between efficacy and safety (Rabins 2007). Healthcare professionals managing agitation in Alzheimer's patients will benefit from education on evidence-based strategies, limitations of non-evidence-based treatments, and understanding the pharmacologic and clinical profiles of approved and emerging therapies.</p>
Unmet Needs	<ul style="list-style-type: none"> • Raise awareness about the prevalence and impact of agitation in individuals at every stage of Alzheimer's dementia. • Enhance understanding and promote education about the recognition of behaviors associated with agitation. • Educate on the pathophysiology of agitation in Alzheimer's dementia and explain the pharmacologic rationale for approved and emerging compounds. • Educate on approved and emerging treatments for agitation in Alzheimer's dementia.
The proposed education must:	<ul style="list-style-type: none"> • Thoroughly explain and confirm the unfulfilled requirements and/or areas for improvement by consulting at least three sources of information, such as conducting a literature review, analyzing population health data, conducting interviews with subject matter experts, or reviewing previous program outcomes. • Establish a coherent connection between the identified gaps, the proposed learning objectives, and the intended outcomes evaluation. • Offer ways for learners to actively engage, receive feedback, and reinforce the desired knowledge, skills, and/or behaviors. • Ensure effective communication of the education's intended impact, taking into account both the perspectives of healthcare professionals (HCPs) and patients.
Educational Format	<p>Prioritization will be given to accredited continuing education grant requests that include one or more of the following (live-in-person, live-virtual, on-demand, and/or digital and hybrid):</p> <ul style="list-style-type: none"> • Curriculum-based initiatives that can be measured individually and via paired and/or pooled analyses • Education must be designed to track HCP learner actions and progress throughout the initiative and include appropriate demographical data • Multidisciplinary educational interventions for HCPs and caregivers/care partners • Incorporate tools and resources for the HCP and/or caregiver/care partner
Educational Audience:	<p>Equally weighted priority between (1) primary care physicians, nurse practitioners, and physician assistants, and (2) psychiatrists and neurologists</p>
Interim and Final Outcomes Reporting	<p>Outcomes for approved grant requests with live education components must provide interim data within two weeks following the live event. Interim outcomes for online/digital education are due immediately following the first ninety (90) days post activity launch, and quarterly thereafter.</p>

	Final outcomes, financial reconciliation and transfer of value reporting for all approved grant activities 12 months or longer are due within 90 days after the program completion/expiry date . All recipients of RFP grant awards will be invited to present the final educational outcomes.
Program Cost:	All RFP responses must include a detailed, line-item budget
RFP/CGA Code	RFP-AAD-2301 - Please reference in front of program title
Website URL	Lundbeckincgrants.com

Funding Guide	<ul style="list-style-type: none"> • Multi or sole support. The budget should demonstrate fiscal responsibility and cost effectiveness. • Each budgetary item must be clearly delineated and be in line with fair market value (FMV) • Input from Lundbeck regarding selection of speaker(s) or the content of the program is not permissible. DO NOT INCLUDE SPEAKER NAMES • Lundbeck personnel cannot be utilized as speakers or consultants
Requirements	<p>The Program must be fully compliant with the criteria and/or standards of commercial support for ACCME, AAFP, AOA, ACPE, ANCC, AANP, or NCCPA. Furthermore, the program will be educational and non-promotional in nature and will be planned, designed and implemented in accordance with the U.S. Food and Drug Administration’s Guidance on Industry Supported Scientific and Educational Activities ("Policy Statement").</p> <p>The Policy Statement and the ACCME Standards require, among other things, that (i) Institution conduct the Program independently and without control or influence by Lundbeck over the Program's planning, content (including the selection of speakers or moderators), or execution; (ii) the Program be free of commercial bias for or against any product; (iii) Institution make meaningful disclosure of Lundbeck support of the Program and any prior relationship between Institution and Lundbeck, and the relationship, if any, between Lundbeck and the speakers selected by Institution; and (iv) Lundbeck not engage in, and Institution not permit any other sponsor to engage in, promotional activities in or near the Program room or advertise its products in any materials disseminated as part of the Program.</p> <p>In addition, Institution is required by the Policy Statement and the ACCME Standards to ensure that any product discussions at the Program be accurate, objective, balanced and scientifically rigorous. This includes a balanced discussion of each product and of treatment alternatives, that limitations on data be disclosed, that unapproved uses be identified as such, and that for live presentations there be opportunities for questioning or debate.</p>
Contact Information	Please email mededgrants@lundbeck.com or call 844-634-7867