

#### **Best Practices for Management of Insomnia**

### I. Background

Eisai supports the global healthcare community's independent initiatives (e.g. Research needs assessments/environmental scans to improve patient outcomes in areas of unmet needs and aligned with Eisai's medical/scientific strategies).

Eisai's competitive grant program involves a publicly posted Request for Proposal (RFP) as that need arises that provides details regarding a general area of interest, timelines for review and approval and uses an independent review process to make final grant decisions. Organizations are invited to apply addressing the specific RFP.

For all grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, and selection of an expert consensus panel required to conduct of the independent initiative supported by the grant. Eisai must not be involved in any aspect of project development nor the conduct of the independent program.

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II. Eligibility		
Geographic Scope:	United States and Canada	
Applicant Eligibility Criteria	<ul> <li>The following may apply: medical, nursing, allied health, and/or pharmacy professional schools; healthcare institutions; professional associations, medical societies; medical education companies; and other organizations with a mission related to healthcare professional education and/or healthcare improvement.</li> <li>If the project involves multiple departments within an institution and/or between different institutions/organizations/associations, all institutions must have a relevant role and the requesting organization must have a key role in the project.</li> <li>The requesting organization must be accredited.</li> </ul>	
III. Requirements		
Date RFP Issued	October 1, 2021	
RFP Code	RFP-N-1	
Clinical Area	Insomnia	
General Area of Interest for this RFP	Projects considered for Eisai support will focus on convening an independent expert panel to discuss current issues related to the diagnosis and management of insomnia, with focus on the following: Discuss the current screening, diagnosis and treatment of insomnia and associated comorbidities.	



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- Review the evidence on the appropriate and adequate treatment of insomnia using pharmacological and nonpharmacological approaches.
- Address gaps in literature and existing treatment algorithms with expert consensus clinical recommendations representing best practices
- Provide appropriate treatment recommendations for clinical meaningful subtypes of patient with insomnia based on symptoms and comorbidities

Projects and/or educational activities should be developed with the intent to be easily accessible to healthcare professionals through effective learning formats that allow access to effective educational activities and materials.

Eisai is interested in supporting a comprehensive educational initiative that addresses the evidence-based educational needs and professional practice gaps that are evident to those in the field.

Eisai is interested in supporting an independent grant to a provider who can convene an independent Working Group of experts and patient advocates who are invested in discussing and identifying the "best practices" for the diagnosis, treatment and ongoing management and support of insomnia. We would expect the Working Group to develop educational resources and communication materials, including a manuscript for publication.

# Educational Needs and Professional Practice Gaps

Insomnia is a common disorder which adversely affects quality of life (QoL), work productivity, safety, and school performance. [Ford 2015; Kessler 2011; NSF 2015; Taddei-Allen 2020] More than one-third of adults experience insomnia, and the problem has grown throughout the COVID-19 pandemic. Insomnia has been identified as a significant risk factor for chronic diseases and is associated with increased mortality and morbidity in these populations. Untreated and poorly treated insomnia has also been linked to fatigue, workplace errors and accidents, which can have substantial public health impact.

Many factors increase the likelihood of insomnia, including but not limited to concurrent psychiatric comorbidities (ie, depression, anxiety, PTSD, etc.) and other medical conditions such as hypertension, COPD and OSA. In addition, certain subgroups may be more likely to experience a higher burden of insomnia. The condition is persistently underrecognized



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and undertreated. Continuing challenges include clinician underrecognition of the association between these disorders, a relative paucity of clinical evidence to inform treatment decisions, safety concerns with currently available agents, and insufficient consideration of current and emerging insomnia agents with varied mechanisms of action and their potential role in broader treatment plans.

The traditional pharmacologic armamentarium to treat insomnia is lacking because of adverse effects, next-day impairment, and/or the potential for addiction/withdrawal. Tricyclic antidepressants, melatonin receptor agonists, benzodiazepines, and nonbenzodiazepine hypnotics are the classes of medications that are available for the pharmacologic treatment of insomnia. Clinical practice guidelines on the management of sleeponset insomnia and sleep-maintenance insomnia in adults are available through the American Academy of Sleep Medicine. [Sateia 2017] There are newer agents, specifically orexin receptor antagonists, that have become available since the publication of the guidelines. These agents have a different mechanism and may provide better outcomes than other available treatments with respect to tolerability and next-day functioning. However, information about these newer therapies have not been integrated into current guidelines, which are several years old as of this RFP.

Education on the prevalence and significance of insomnia, guidance on how to manage patients with various comorbidities and appropriate treatment recommendations for psychiatry clinicians, PCPs, NPs and PAs who are on the front lines of care for patients with insomnia is crucial.

#### **Educational Design**

Eisai is interested in supporting a comprehensive educational initiative that is innovative, engaging, easily accessed, interactive, and that leverages current scientific data, clinical wisdom and builds on adult learning principles.

Special consideration will be given to innovative live and/or online formats (e.g., virtual educational series or podcasts). However, a manuscript published in a peer-reviewed journal is a desired output.

Knowledge and competency-based objective outcome measures according to Moore's Level 3 are required; competency-based Level 4 outcomes are highly preferred (if applicable to requests received).



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Target Audience	The intent of the RFP is to address the educational gaps of Primary care physicians, psychiatrists, and NP/PAs.
Expected Approximate Monetary Range of Grant Applications	Individual projects requesting up to \$200,000 will be considered.
Key Dates	<ul> <li>RFP Release date: October 1, 2021</li> <li>Grant Application due dates: November 30, 2021</li> <li>Deadline is 5 pm Eastern Standard Time</li> <li>Grants will be distributed following an executed Letter of Agreement (LOA)</li> </ul>
How to Submit	Please go to <a href="http://www.eisaigrants.com/">http://www.eisaigrants.com/</a> and sign-in. First-time users should click "create your password".  In the application: For the question "What type of request are you submitting?" select (Request for Proposal – RFP); (Needs Assessment – NA)  For the question "Are you replying to a Request for Proposal as part of the Eisai's Competitive Grant Program?" select "Yes"  Select the following Competitive Grant Program Name: (drop down)  Requirements for submission: Complete all required sections of the online application and upload your project proposal (see Appendix) in the General RFP Submission field.  If you encounter any technical difficulties with the website, please click the "Technical Questions" link at the bottom of the page.  IMPORTANT: Applications submitted after the due date will NOT be considered.
Questions	If you have questions regarding this RFP, please contact <a href="mailto:eisai_edugrants@eisai.com">eisai_edugrants@eisai.com</a> with the subject line "RFP Inquiry", or call 866-434-1286.
Review and Approval Process	Grant requests received in response to general RFP are reviewed by Eisai to make final grant decisions.



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Mechanism by which Applicants will be Notified	All applicants will be notified via email by dates noted above.  Applicants may be asked for additional clarification during the review period.
References	List any references that you relied upon to generate this RFP.
IV. Terms and Conditions	Please take note every RFP released by Eisai is governed by specific terms and conditions. These terms and conditions can be reviewed at <a href="https://www.eisaigrants.com/medical-education">https://www.eisaigrants.com/medical-education</a>



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## **General RFP Submission Requirements**

Project proposals should be single-spaced using <u>Calibri 12-point font and 1-inch margins</u>.

**Note**: there is a 15- page limit exclusive of references.

Please include the following:

Goals and Objectives	<ul> <li>Briefly state the overall goal of the project.</li> <li>List the objectives you plan to meet with your project, in terms of learning and expected outcomes.</li> </ul>
Needs Assessment for the Project	<ul> <li>Include a description of your organization's needs assessment for this proposed project which may include a quantitative baseline data summary, initial metrics, or a project starting point (please cite data on gap analyses or relevant patient-level data that informs the stated objectives) in your target area.</li> </ul>
Target Audience	<ul> <li>Describe the primary audience(s) targeted for this project.         Indicate who you believe will directly benefit from the project outcomes.     </li> <li>Describe the overall population size as well as the size of your sample population.</li> </ul>
Project Design and Methods	Describe the:  Planned project  Educational approach  How the planned methods address the established needs.
Innovation	<ul> <li>Explain what measures you have taken to assure that this project is original and does not duplicate other projects or materials already developed.</li> <li>Describe how this project builds on existing work, pilot projects, or ongoing projects developed either by your institution or other institutions.</li> </ul>
Evaluation and Outcomes	<ul> <li>In terms of the metrics used for the needs assessment,</li> <li>Describe how your organization will determine if the gap was addressed for the target group.</li> <li>Identify the sources of data your organization anticipates using to make the determination</li> </ul>



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	<ul> <li>Describe how your organization is expected to collect and analyze the data.</li> <li>Explain the method used to control for other factors outside this project (e.g. use of a control group or comparison with baseline data). Quantify the amount of change expected from this project in terms of the target audience.</li> <li>Describe how your organization will determine if the target audience was fully engaged in the project.</li> </ul>
Dissemination Plan	<ul> <li>Describe how the project may have benefit beyond the grant.</li> <li>Will the teaching materials be made available to others to use?</li> <li>Will there be tools or resources that are made publicly available beyond the initial project?</li> <li>Describe how the project outcomes might be broadly disseminated.</li> </ul>
Anticipated Project Timeline	Provide an anticipated timeline for your project including project start/end dates.
Organization Detail	Describe the attributes of the institutions/organizations that will support and facilitate the execution of the project, the leadership of the proposed project, and the specific role of each institution in the proposed project.
Budget Narrative	Please include a budget narrative that describes in greater detail the line items specified in the budget submitted within the application.  While estimating budget, please keep the following items in mind: Independent Medical Education Grants awarded by Eisai cannot be used to purchase therapeutic assets (prescription or non-prescription).
Additional Information	If there is additional information you feel Eisai should be aware of concerning the importance of this project, please summarize here.
References	If applicable, please provide a list of references you utilized to inform your thinking as you generated this grant proposal. This does not count in the page limit described at the beginning of the document.