

## Allergan – Request for Proposals Notification

**Issue Date:** August 12, 2016

**Therapeutic Area:** Schizophrenia and Bipolar I Disorder

**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 schizophrenia and bipolar I disorder. 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

- Psychiatrists

### Educational Design

- Live and/or Online Activities
- Enduring materials inclusive of accredited online material and/or print supplement

### Application Title: “RFP SCZ/BPD 03– 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	August 13, 2016 – September 23, 2016
Proposal	Live and/or Online Activities
Program Format	Live and/or online activities with enduring materials
Program Cost	≤\$250,000

### 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

Schizophrenia is a serious and chronic mental disorder afflicting 0.3% – 0.7% of the population.<sup>1</sup> In affected individuals, the symptoms generally surface between ages 16 and 30,<sup>2</sup> and can be further specified as positive or negative, both of which have a substantial harmful effect on quality of life. Positive symptoms (psychotic behaviors) of schizophrenia include delusions, hallucinations, and unusual thoughts or movements, while negative symptoms (alterations to normal behavior) include avolition and “flatness” of emotion in facial expressions and tone of voice.<sup>2</sup> Current treatments available to patients are limited in their scope to treat both classes of

symptoms,<sup>3</sup> but potential solutions are emerging as the scientific community's understanding of the disease evolves. The mutable nature of this disease state understanding, along with the present state of unsatisfactory treatment of symptoms and issues such as caregiver burden, emphasize an increasing need of awareness regarding schizophrenia.

The etiology of schizophrenia is largely attributed to an imbalance of the neurotransmitter dopamine, excessive binding of which results in the trademark symptoms of the disease.<sup>3</sup> Receptors for dopamine exist in several classes (denoted by different numbers); recent findings suggest a shift in focus to the D<sub>2</sub> and D<sub>3</sub> receptors and their potential roles in schizophrenia. D<sub>3</sub> receptors are selectively distributed, with a high density in the mesolimbic system, associated with emotion and memory, and in the ventral striatum,<sup>4</sup> a crucial region in the pathology of mental disorders. The selective targeting of the D<sub>2</sub>/D<sub>3</sub> receptors has thus been an active area of research, to identify prospective targets for antipsychotic drugs that can better treat patients of schizophrenia and other disorders.

Negative symptoms of schizophrenia are one therapeutic target for clinical development.<sup>5</sup> Current treatments enjoy qualified success in reducing positive symptoms such as delusions and hallucination, but do not exhibit the same proficiency in combating negative symptoms such as avolition and alogia. Even patients in clinical periods of stability continue to suffer from these symptoms,<sup>6</sup> suggesting that current treatments are insufficient in returning patients to a standard quality of life. Based on the rationale surrounding D<sub>2</sub>/D<sub>3</sub> receptors, newer agents are emerging that are partial agonists for both receptors, rather than antagonists, and this approach may yield improved results.

Bipolar disorder, known colloquially as manic depression, is a psychiatric illness for which the exact etiology is unknown. Currently, it affects over 3 million persons in the United States and accounts for one fourth of all mood disorders,<sup>7</sup> though these estimates are conservative at best, as there are often problems with diagnosis and identification of symptoms in patients suffering from the disease. Manic episodes, characteristic of bipolar I disorder, are defined as abnormal or persistent periods of elevated or irritable moods resulting in reckless behavior and/or impairment of work and social functioning.<sup>8</sup> The lifetime risk of suicide in bipolar individuals is at least 15 times that of the general populace.<sup>8</sup> Taking into context the risks and impairment conferred by this condition, along with its prevalence among mood disorders, it is vital that healthcare providers are regularly updated on the most recent findings and latest advancements in the treatment of bipolar disorder.

Individuals with these mental disorders are not only burdened in their own ability to function, but also pose an enormous burden to their caregivers, who are at risk of developing shared psychotic disorder, defined as delusions resulting from close contact with someone with an illness such as schizophrenia.<sup>9</sup> Research suggests that reducing patients' symptomology will ease caregiver distress and prompt relatives to lessen their use of psychotropic medication.<sup>10</sup>

Based on the gaps documented in the literature, funding is available to support independent certified educational activities developed by accredited providers that address practice gaps in the management of patients with schizophrenia and bipolar I disorder in the format of a live and/or online activity, and an enduring material.

We request that providers reach an independent decision as to whether there exists an educational need to improve understanding and treatment of schizophrenia and bipolar I disorder. Requesters should be able to explain the latest disease state understandings and the state of unmet needs concerning current treatments.

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>11</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 *Schizophrenia/Bipolar Mania – RFP ONLY* as the therapeutic area
2. Include the following, "RFP SCZ/BPD 03" 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**

September 23, 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 October, 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

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3. Meltzer, Herbert Y., et al. "Chapter 16. Schizophrenia." *CURRENT Diagnosis & Treatment: Psychiatry, 2e*. Eds. Michael H. Ebert, et al. New York, NY: McGraw-Hill, 2008. AccessMedicine. Web. 22 Jun. 2016.
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7. Loosen, Peter T., and Richard C. Shelton. "Chapter 18. Mood Disorders." *CURRENT Diagnosis & Treatment: Psychiatry, 2e*. Eds. Michael H. Ebert, et al. New York, NY: McGraw-Hill, 2008. AccessMedicine. Web. 22 Jun. 2016.
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10. Schene AH, van Wijngaarden B, Koeter MWJ: Family caregiving in schizophrenia: domains and distress. *Schizophrenia Bulletin*. 1998, 24:609-618.
11. 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.