

**Bristol Myers Squibb/Pfizer Alliance**  
**Independent Medical Education/Global Medical Grants**  
**Request for Educational Support (RFE)**

<b>Date</b>	June 18, 2024
<b>RFE Requestor Information</b>	Name: Sylvia Nashed, PharmD, RPh Title: Director, Medical Education E-mail: Sylvia.Nashed@bms.com
<b>RFE Code</b>	RFE-24-CV-102
<b>Therapeutic Area</b>	Cardiovascular (CV)
<b>Area of Interest</b>	<p>Undiagnosed Nonvalvular Atrial Fibrillation (NVAF)</p> <p>It is our intent to support a comprehensive, innovative educational initiative that:</p> <ul style="list-style-type: none"> <li>• Increases awareness of prevalence, burden, and potential consequences of undiagnosed NVAF, especially in patients with increased risk factors, such as CHADSVASC score <math>\geq 2</math>, age <math>\geq 65</math> years, heart failure (left ventricular dysfunction), hypertension, diabetes, prior stroke or embolism, and vascular disease (peripheral vascular disease, prior MI, or aortic plaque)</li> <li>• Increases the awareness of the association of AF with other CV co-morbidities, such as heart failure, obstructive sleep apnea, etc.</li> <li>• Reviews gaps in the healthcare system that can cause an individual with AF to remain undiagnosed, including health care disparities</li> <li>• Familiarizes learners with the different screening tools that can help detect NVAF and education on options/considerations regarding subsequent diagnosis and providing guideline-recommended management</li> <li>• Reviews management and treatment of those subsequently diagnosed NVAF patients</li> </ul>
<b>Educational Design</b>	The Bristol Myers Squibb/Pfizer Alliance is interested in supporting a comprehensive educational initiative; various formats and designs will be considered, with priority given to those that are most innovative, engaging, and provide resources/tools that will further aid HCPs in their clinical decision making, as well as patient education resources. Proposed initiatives should include the following:

	<ul style="list-style-type: none"> <li>• Provides learnings and tools to help improve detection and subsequent diagnosis of undiagnosed NVAF and help potentially reduce the risk of stroke by leading patients to guideline-recommended management</li> <li>• The activity(ies) should measure improvement of learners’ knowledge, confidence, competence, and performance and should achieve at least a Moore’s Level 4 impact. Activities that achieve Moore’s Levels 5 and 6 outcomes are highly favored and recommended when possible.</li> <li>• Leverage evidence-based content</li> </ul> <p>The successful proposal should include:</p> <ul style="list-style-type: none"> <li>• Clear and concise statement of the goal, learning objectives, and expected outcomes of the educational initiative</li> <li>• Learning plan that incorporates innovative techniques designed to engage learners, promotes application of education into practice, and incorporates a patient-centered approach to care</li> <li>• Tools that provide HCP learners the opportunity to facilitate change to improve patient outcomes and address healthcare inequities</li> <li>• Measurement of outcomes, inclusive of learner progression throughout the activity, extent to which the activity closed the identified practice gaps, and patient impact</li> </ul>
<b>Intended Audience (may include, but not limited to)</b>	Primary Care Clinicians, Nurse Practitioners, Nurses, Physician Assistants, Pharmacists, and/or other clinicians who help care for patients with CV disease
<b>Budget/Budget Range</b>	The maximum amount of funding available for this RFE is \$100,000-120,000.  Single or multi-supported initiatives will be considered.
<b>Accreditation</b>	ACCME, ANCC, AAPA, ACPE, and others as appropriate
<b>Geographic Coverage</b>	United States
<b>Deadline for Submission</b>	July 17 <sup>th</sup> , 2024 by 5 PM EST

**Background**

Atrial fibrillation (AF) remains one of the major causes of stroke and a leading cardiovascular morbidity. Nonvalvular atrial fibrillation (NVAF) has been defined as atrial fibrillation in the absence of moderate-to-severe mitral stenosis or a mechanical heart valve.<sup>1</sup> According to data from the Framingham Heart Study, the prevalence rate of AF is estimated to have increased 3-fold over the last 50 years.<sup>2</sup> The lifetime risk for developing AF has risen to about 1 in 3 in white individuals and 1 in 5 for black individuals.<sup>3</sup> In the US alone, it is estimated that at least 6 to 16 million people will have AF by 2050,<sup>4</sup>

and 23% of the total AF prevalence is comprised of undiagnosed AF.<sup>5</sup> The prevalence of atrial fibrillation is higher in white patients compared to black and Hispanic patients, but adverse atrial fibrillation outcomes are higher in non-white patients. An analysis of 15,000 patients with a mean follow-up of 20 years found that the rate of stroke associated with atrial fibrillation is twice as high in Black patients compared to White patients.<sup>6</sup> The prevalence of undiagnosed NVAf (and therefore lack of treatment and monitoring by a healthcare professional ) is disturbing, as AF patients have an average 4 to 6 times increased risk of stroke.<sup>7</sup> In those over 80 years of age, 25% of all strokes are directly caused by AF.<sup>7</sup>

Not all patients with AF present with symptoms; approximately 20% of stroke patients discover they have AF as their first sign of AF.<sup>8</sup> Therefore, detection of AF is important to help identify or detect and subsequently diagnose patients meeting criteria for guideline-recommended management; potentially helping reduce the risk of thromboembolic events, including stroke.

Literature reviews have summarized that there are two main approaches for AF screening:<sup>9</sup>

- Opportunistic screening during routine medical consultation
- Systematic screening done in a wider range of people than those who present for routine medical consultations, including:
  - Targeted screening for those at higher risk for AF
  - Population screening for a particular population not previously diagnosed with AF

While the proliferation of technology continues to provide new ways to assess heart rhythm, clinicians can assess patients' results easily with simple, non-invasive devices, including pulse palpation to identify those who could potentially benefit from guideline-recommended management. Both opportunistic and systematic screenings can be effective to identify new individuals with NVAf at a similar rate.<sup>10</sup> In fact, one-time and multiple times or extended-screening AF studies have shown the percentage of AF patients who are newly diagnosed by screening ranges from 19% to 43%, and 25% respectively.<sup>10-14</sup> Screenings are also potentially beneficial in that they may identify previously diagnosed yet untreated to guidelines patients, as shown in the initial publication of the STROKESTOP study.

In addition to clinician screening, wearable technologies have allowed for an abundant variety of consumer-targeted-tools through which an individual can monitor their heart rhythm, such as sensors used in applications for smartphones, wrist bands, and watches, automated BP monitors, and photoplethysmography devices, potentially detecting undiagnosed atrial fibrillation. However, the sensitivity and specificity of these tools vary greatly.<sup>15</sup> As the use of consumer wearables continues to increase, clinicians must evaluate how to manage the influx of patient-initiated heart rhythm notifications into their daily practice.

The ACC/AHA/ACCP/HRS issued an updated guideline (2023) for the diagnosis and optimal management of AF. Jose Joglar, MD, FACC, FAHA, FHRS, who was the chair for the guideline development, explained that this recent guideline update has important changes, as the previous classification was largely based only on arrhythmia duration and tended to emphasize specific therapeutic interventions rather than a more holistic and multidisciplinary management approach. The new proposed classification uses 4 stages to recognize AF as a disease continuum that requires a variety of strategies at different stages, from prevention, lifestyle and risk factor modification, screening, and therapy. There has also been new and consistent evidence on the importance of early and continued management of patients with AF with a focus on maintaining sinus rhythm and minimizing AF burden. The guideline also includes updated recommendations for AF detected via implantable devices and wearables.<sup>16</sup>

Healthy People 2023 defines social determinants of health (SDOH) as conditions in the places where people live, learn, work, and play that affect a wide range of health risks and outcomes. Five key areas include healthcare and education access and quality, social and community context, economic stability, and neighborhood and built environment.<sup>16</sup> In the US, high income and wealth are associated with improved healthcare access, HCPs decision-making, and clinical outcomes in patients with NVAF. Conversely, lower income at both the individual and household levels has been related to higher rates of CV risk factors, adverse cardiac events, and death. Results from the Atherosclerosis Risk in Communities (ARIC) study found that AF incidence was higher among participants with lower household income than in participants with higher household income.<sup>17</sup> In another study conducted to evaluate the disparities and temporal trends in the use of DOACs in patients with ischemic stroke and atrial fibrillation, results indicated existing race-ethnicity and sex disparities in the use of these medications, with significantly greater use of warfarin in Black people and underutilization of anticoagulation in women.<sup>18</sup>

As primary care physicians and allied healthcare professionals are often the first point of contact for patients, it is crucial that they are aware of the association between NVAF and increased stroke risk, the importance and application of NVAF detection in practice, and subsequent guideline-recommended management of patients diagnosed with NVAF can reduce their risk of stroke. As advancements and innovations in screening and treatment options become available, all patients with NVAF should receive the standard of care to achieve equity in health outcomes. Achievement in health equity will require a multidisciplinary and a patient-centric approach to care. Therefore, education to help improve HCPs' ability to screen, identify, diagnose, and manage patients with NVAF, while also addressing existing SDOH in their patient population is needed to help reduce the substantial clinical and non-clinical complications associated with NVAF for patients and their families.

#### **Educational Needs and Professional Practice Gaps:**

BMS and Pfizer Alliance has identified, through insights from educational needs assessments, literature search, learning outcomes, and other methods, the need to address the following existing unmet medical and healthcare practice gaps:

- Recognize the implications of undiagnosed NVAF (ie, NVAF present, but not detected, diagnosed and managed to guidelines) —missed opportunities to prevent preventable strokes with potential result of stroke, systemic embolism, (~20% of patients presenting with stroke are found to have AF for the first time),<sup>14,19</sup> or exacerbation of HF<sup>20</sup>
- Apply current best practices for promoting disease management and delivering quality care to patients with NVAF based on the most recent guideline updates from ACC/AHA/ACCP/HRS
- Identify the different types of NVAF detection (including pulse palpation, medical-grade devices, and consumer wearable devices) and how these tools can be utilized in non-cardiology settings
- Counsel and follow-up with individuals who are at increased risk for or detected/diagnosed with NVAF, to help ensure guideline-recommended management and adherence to prescribed treatment
- Collaborate among clinicians to help improve patient care, ensure guideline-recommended management, address SDOH and potentially benefit patients, their families, and their communities

BMS and the Pfizer Alliance is seeking grant applications for development and implementation of a well-designed, innovative, interactive, and educational program that addresses the above educational needs

and unmet medical and healthcare practice gaps. Based on a series of systematic reviews conducted by Dr. Cervero to assess the impact of CME, activities that are more interactive, apply multiple methods and multiple exposures, and are focused on outcomes that are considered important by physicians, lead to more positive outcomes.<sup>21</sup> Proposals that incorporate such findings into the design and development of the educational activity will be given higher priority.

The content and/or the format of the CME/CE activity and its related materials must be current and designed in such a way that it addresses the educational needs of the intended audiences as described in this RFE.

*Grant Proposals should include, but not be limited to, the following information:*

- **Executive Summary:** The Executive Summary should consist of 1-2 pages and highlight the key areas as described below.
- **Needs Assessment/Gaps/Barriers:** Needs assessment should be referenced and demonstrate an understanding of the specific gaps and barriers of the target audiences. The needs assessment must be independently developed and validated by the educational provider through triangulation.
- **Target Audience and Audience Generation:** Target audience for educational program must be identified within the proposal. In addition, please describe methods for reaching target audience(s) and any unique recruitment methods that will be utilized. The anticipated or estimated participant reach should also be included, with a breakdown for each modality included in the proposal, as applicable (e.g., number of participants for the live activity, the live webcast, and enduring activity).
- **Learning Objectives:** The learning objectives must be written in terms of what the learner will achieve as a result of attending. The objectives must be clearly defined, measurable, attainable, and address the identified gaps and barriers.
- **Program Evaluation and Outcomes Reporting:** Description of the approach to evaluate the quality of the educational program. Describe methods used for determining the impact of the educational program on closing identified healthcare gaps.
  - Please refer to “Guidance for Outcomes Report” (on the BMS grants website) for a detailed explanation of preferred outcomes reporting methods and timelines.
  - Remember that knowledge, performance and competency-based outcome measures according to Moore’s Levels 4 & 5 are required. Level 6 outcomes are highly favored and recommended when possible.
- **Educational Design and Methods:** Describe the approach used to address knowledge, competence, and performance gaps that underlie identified unmet medical & healthcare gaps. The proposal should include strategies that ensure reinforcement of learning through use of multiple educational interventions and include practice resources and tools, as applicable.
- **Communication and Publication Plan:** Provide a description of how the provider will communicate the progress and outcomes of the educational program to the supporter. It is highly recommended to describe how the results of the activity will be presented, published, or

disseminated.

- **Innovation:** Describe how this project is innovative and engages the learners to improve knowledge, competence and/or performance. Further describe how this project might build on existing work, pilot projects or ongoing projects developed either by your institution or other institutions related to this topic.
- **Budget:** Detailed budget with rationale of expenses, including breakdown of costs, content cost per activity, out-of-pocket cost per activity, and management cost per activity.

**Note:** The accredited provider and, if applicable, the medical education partner (MEP) or other third party executing the activities, are expected to comply with current ethical codes and regulations. They must have a conflict-of-interest policy in place to identify and resolve all conflicts of interest from all contributors and staff involved in developing the content of the activity prior to delivery of the program, and must have a separate company providing/accrediting independent medical education if they are also performing promotional activities.

*If your organization wishes to submit an educational grant request, please use the online application available on the Bristol Myers Squibb Independent Medical Education website.*

<http://www.bms.com/responsibility/grantsandgiving>

#### **References:**

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6. Magnani JW, Norby FL, Agarwal SK, et al. Racial Differences in Atrial Fibrillation-Related Cardiovascular Disease and Mortality: The Atherosclerosis Risk in Communities (ARIC) Study. JAMA Cardiology. 2016;1(4):433-441
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Association Task Force on Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. 2014;64(21):e1-e76.

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14. Svennberg E, Engdahl J, Al-Khalili F, Friberg L, Frykman V, Rosenqvist M. Mass screening for untreated atrial fibrillation: the STROKESTOP Study. *Circulation*. 2015;131:2176–2184.
15. Hindricks G, Potpara T, Dagres N, et al. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for CardioThoracic Surgery (EACTS). *European Heart Journal*. 2021;42(5):373-498.
16. Renoux C, Patenaude V, Suissa S. Incidence, mortality, and sex differences of non-valvular atrial fibrillation: A population-based study. *J Am Heart Assoc*. 2014; doi:10.1161/JAHA.114.001402.
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