Bristol Myers Squibb & Johnson & Johnson
Innovative Medicine Alliance
Independent Medical Education
Request for Educational Support (RFE)

Date	January 13, 2025
RFE Requestor Information	Name: Briana Botros, PharmD, RPh, BCPS Title: Associate Director, Medical Education E-mail: Briana.Botros@bms.com Name: Kenneth Todd Moore, DBE, MS, FAHA, FCP Title: Scientific Director, Cardiovascular Disease E-mail: Tmoore17@its.jnj.com
RFE Code	RFE-25-THR-101
Therapeutic Area	Cardiovascular
Area of Interest	**Thrombosis in ACS, AF, and SSP**
Educational Design	Bristol Myers Squibb and Johnson & Johnson alliance is interested in supporting a comprehensive, innovative, and interactive initiative: **An interactive live satellite symposium at the following congresses:** • **European Society of Cardiology (ESC) meeting in Madrid, Spain (August 29-September 1, 2025)** Program design includes: • Live – Interactive in-person and virtual satellite symposium • On-demand - Web-based enduring activity leveraging the medical content from the live meeting • Online resource tools • Health Equity component acknowledging the differences in disease burden across diverse racial/ethnic/sex populations (encouraged, but not required) The activity should measure improvement of learners' knowledge, confidence, performance and competency 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.
Intended Audience (may include, but not limited to)	Cardiologists, Interventional Cardiologists, Electrophysiologists, and Cardiac Surgeons, Primary Care Practitioners (Physicians, NPs, PAs), and other healthcare practitioners (HCP) who are involved in the care of ACS, AF, and SSP

Budget/Budget Range	The maximum amount of funding available for this RFE is $325,000 for each individual grant submission
Accreditation	ACCME
Geographic Coverage	EU5 and United States
Deadline for Submission	February 18, 2025 by 12 PM EST via the BMS portal

Background:

Thrombosis is a significant global health concern, contributing to 1 in 4 deaths worldwide. It serves as the common underlying mechanism for venous thromboembolism (VTE), as well as the majority of myocardial infarctions and strokes, making it a leading cause of both morbidly and mortality.[1]

Among the deaths caused by cardiovascular diseases (CVDs), ischemic heart disease (IHD) is the most common, resulting in more than 9 million deaths around the world in 2016 according to World Health Organization (WHO).[2] Among IHDs, acute coronary syndrome (ACS) is the leading cause of death around the world and is the leading cause of disease burden in high-income countries.[2] The standard of care for ACS includes antiplatelets, anticoagulants, betablockers, statins, and angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARB). Despite advances in treatment, patients remain at high risk of recurrent (MACE) within 1 year following ACS.[3] Due to the indiscriminate global burden of ACS, rapid prevention and treatment strategies are still required to decrease this disease problem.

Between 2010 and 2019, the global prevalence of atrial fibrillation (AF) has increased from 33.5 million to 59 million individuals living with AF.[4] In the US alone, it is estimated that at least 6 to 16 million people will have AF by 2050,[5] and 10% (672,000) of the total AF prevalence is comprised of undiagnosed AF.[6] AF patients have an average 4 to 6 times increased risk of stroke. In those over 80 years of age, 25% of all strokes are directly caused by AF.[7] Not all patients with AF present with symptoms; approximately 20% of stroke patients discover they have AF as their first sign of AF.[8] In addition to diagnosis, with > 85% of patients with CHADS2-VASc ≥ 2 across registries, only 2/3 of patients received appropriate OAC therapy.[9] It's estimated that about 20% of patients receive inappropriate dosing of direct oral anticoagulants (DOACs) to reduce the risk of bleeding, however, this also can result in reduced efficacy and thrombotic protection.[10] Therefore, proper AF detection and inadequate treatment remain barriers in the setting of primary prevention of stroke in AF.

According to the Global Burden of Disease (GBD) estimates, there were around 12.2 million incident cases of stroke, 143 million disability-adjusted life-years (DALYs) lost, and 6.6 million deaths globally, making stroke the second leading cause of death and third leading cause of disability worldwide.[11] In the United States, 1 in 6 deaths (17.5%) from cardiovascular disease was due to stroke.[12] About 87% of all strokes are ischemic strokes and nearly 1 in 4 are people who have already had a previous stroke, leading to long-term disability.[13] In addition, the risk of having a first stroke is nearly twice as high for non-Hispanic Black adults as for White adults, with the highest stroke mortality residing in the Non-Hispanic Black and Pacific Islander adult patient populations.[12-13] Lifestyle modifications and risk reduction has remained a mainstay of therapy, including management of blood pressure and cholesterol, healthy diet, physical activity, and smoking cessation. Pharmacologic therapy plays a crucial role in the treatment of ischemic stroke, including initiation of dual antiplatelet therapy (DAPT) or

anticoagulant therapy depending on the stroke etiology. However, despite adhering to guideline-indicated therapy, ischemic stroke patients remain at high risk of secondary or recurrent stroke, which is associated with worse disability and mortality than primary strokes.[14-15] Therefore, low adherence to DAPT and underuse of anticoagulants due to increased risk of bleeding remains a barrier to optimal care.[16-17]

Investigational new approaches targeting anticoagulation are promising and differentiate their mechanisms by attenuating thrombosis without significantly increasing bleeding. These strategies for targeting FXI/FXIa across all thrombotic indications include antisense oligonucleotides, monoclonal antibodies, and small molecules. FXIa inhibitor small molecules and monoclonal antibodies (MABs) are currently under investigation in phase 2 and phase 3 trials for ACS, SSP, and AF. FXIa inhibitor small molecules are synthetic compounds that are designed to block the active site of FXIa. FXIa inhibitor small molecules are orally administered, with a rapid onset within hours, shorter half-life, and minimal renal elimination.[18-19] FXI inhibitor MABs act by preventing FXI to FXIa or by binding to FXIa and preventing its activity.[17] MABs are administered parenterally, have a rapid onset and long duration of action, and are metabolized via proteolysis by the reticuloendothelial system. [19-20] In conclusion, educating healthcare providers about investigational anticoagulation strategies is critical in the future management of thrombosis.

Education Needs and Professional Practice Gaps:

The BMS & J&JIM Alliance has identified, through insights from educational needs assessments, literature search, learning outcomes, and other methods, the need to address the following existing professional practice gaps:

- Review the prevalence and unmet patient need of thrombosis treatment, focusing on ACS, AF, and SSP
- Evaluate the current efficacy and safety profile for the standard of care for the treatment of ACS, AF, and SSP and implications of inadequate treatment
- Identify emerging anticoagulant strategies, including data from investigational clinical trials, and potential place in therapy for ACS, AF, and SSP

The educational program will ensure timely and effective communication of the latest science, clinical trial data, evidence-based guidelines, barriers to care, and practice gaps related to thrombosis management.

Specific Area of Interest

BMS & J&JIM 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 professional 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.[21] 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 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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