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

Date	June 8, 2022
RFE Requestor Information	Name: Sylvia Nashed, PharmD, RPh Title: Director, IME Phone: 609-302-3320 E-mail: Sylvia.Nashed@bms.com
RFE Code	RFE-22-CV-104
Therapeutic Area	Cardiovascular (CV)
Area of Interest	Venous Thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE)
Educational Design	The Bristol Myers Squibb/Pfizer Alliance is interested in supporting a comprehensive, innovative, and engaging audio-based learning platform. Proposals that include any of the following will be given higher priority: • Podcast or YouTube series featured on multiple platforms, including easily accessible applications, such as Apple, Google, Spotify, Audible, etc • Component of the series targeting patient education • Incorporation of the patient voice/journey and demonstration of the clinician-patient interaction • Educational series to cover multiple topics across the spectrum of VTE management, including but not limited to, diagnosis, evidence-based guidelines, extended management/secondary prevention, VTE in Cancer The successful proposal should include: • Clear and concise statement of the goal, learning objectives, and expected outcomes of the educational initiative • Learning plan that incorporates innovative techniques designed to engage learners, promotes application of education into practice, and incorporates a patient-centered approach to care • Tools that provide HCP learners the opportunity to facilitate change to improve patient outcomes • Measurement of outcomes, inclusive of learner progression throughout the activity, extent to which the activity closed the identified practice gaps, and patient impact

Intended Audience (may include, but not limited to)	Primary Target Audience: Primary Care Physicians, Internists, Oncologists, Family Medicine Physicians, Emergency Medicine Physicians, Allied Healthcare Professionals (ie, NPs, PAs, pharmacists), involved in the care of patients with VTE Secondary Target Audience: VTE Specialists, Cardiologists
Budget/Budget Range	The maximum amount of funding available for this RFE is $150,000. Single or multi-supported initiatives will be considered.
Accreditation	ACCME, ANCC, ACPE, AAPA, and others as appropriate
Geographic Coverage	United States
Deadline for Submission	July 11, 2022 by 5 PM EST

Background

Venous thromboembolism (VTE) is a consequence of clot formation in the blood circulation and is more commonly seen as a deep vein thrombosis (DVT) or a pulmonary embolism (PE), resulting in possible death.[1] The incidence of symptomatic VTE occurrence is estimated at 1.32 per 1,000 patients.[2] VTE is often associated with certain identifiable risk factors, with some of the most common risk factors being clotting disorders, recent surgery, obesity, smoking, and cancer. At least 70% of VTE deaths occur more than 1 month after diagnosis, and about 33% of patients with DVT/PE will have a recurrence within 10 years.[3] VTE is also a life-threatening complication in nearly a fifth of all cancer patients.[4-5] Those with active malignancies have the highest VTE recurrence risk that varies between 2- to 9-fold.[6] In addition, VTE is the second most common cause of death among cancer patients with a risk of 24.6 events per 1,000 per year as compared to the previous 1.32 per 1,000 for patients without cancer who have VTE.[7-9] As such, it is crucial for HCPs to recognize VTE in its early stages to effectively use evidence-based therapies to prevent serious complications, and to establish prophylactic care plans or establish extended VTE management plans to prevent recurrent episodes and decrease mortality.

VTE is observed more in prostate, breast, and colon cancer.[10] However, this results from the higher prevalence of these cancer types, despite having a lower thrombotic risk.[10] Specific types of cancers, including pancreatic, stomach, and metastatic, place patients at very high risk for thromboembolic events.[10] The correlation between specific cancer gene mutations, including JAK2 mutation by integration activation, can lead to development of VTE.[11] VTE risk can also be dependent on cancer-specific therapies. Examples of cancer therapies associated with VTE risk include platinum-based therapy, hormonal therapy, Anti-VEGF therapy, BCR-ABL TKI, immunomodulatory agents, and protease inhibitors.[12] Surgery can increase postoperative VTE risk and related death in cancer by 2-fold and increase PE risk, specifically, by 4-fold.[13]

The current management landscape of VTE includes warfarin, other vitamin K antagonists, low molecular weight heparin, direct oral anticoagulants (DOACs), and unfractionated heparin.[14] The 2019 European Society of Cardiology (ESC) guidelines, the American Society of Hematology (ASH) 2020 guidelines, and the 2021 Second Update of the CHEST Guidelines for VTE suggest using DOACs as the first choice for anticoagulation in eligible VTE patients.[15-17] In cancer-related VTE patients, category 1 recommendations include DOACS or LMWH (preferred for patient with gastric or gastroesophageal

lesions).[18] Despite available treatment options, adequate management of VTE that prevents recurrence requires continuity of care when patients transition to and from hospitals, long-term care facilities, and outpatient settings.[19] Such healthcare models call for a multidisciplinary approach that involves primary care physicians (PCPs), nurse practitioners (NPs), physician assistants (PAs), and pharmacists, to optimally manage patients with or at risk for recurrence of VTE. The multidisciplinary team plays a vital role in timely specialty practice referrals, educating and monitoring patients, and ensuring they receive and adhere to anticoagulant therapy as recommended. The multidisciplinary VTE treatment approach may take place in many different environments, anywhere from the PCPs' office to the emergency room.

Due to the busy nature of the multidisciplinary team (MDT), an audio-based educational series would be beneficial to further improve understanding of the clinical presentation of VTE, proper management of VTE (including special populations, such as those with cancer), application of evidence-based guidelines for initial and extended VTE treatment,[15-17] secondary prevention, and how efficacy, safety, duration, and appropriate dosing of current treatment options may reduce the morbidity, mortality, and burden associated with VTE.

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 professional practice gaps by providing education on appropriate management of VTE in patients:

- Need for proactive identification/diagnosis and management of VTE patients
- Need to understand efficacy and safety profiles for currently available treatment options, and their appropriate dosage regimens
- Need to understand and apply current, evidence-based guidelines on managing VTE (including VTE in cancer), as they evolve and new data becomes available
- Need to understand appropriate duration of treatment/rationale for extended treatment and secondary prevention of VTE (while considering patient risk/benefit profile), and to inform and educate patients on importance of adhering to the recommended treatment duration
- Need to counsel patients on the high risk of VTE, and treat, follow-up and/or refer patients who are diagnosed with VTE as appropriate

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 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.[20] 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:

1. ISTH Steering Committee for World Thrombosis Day. Thrombosis: A major contributor to the global disease burden. J Thromb Haemost 2014:12:1580-1590. [PubMed: 25302663]
2. Martinez C, Cohen AT, Bamber l, Rietbrock S. Epidemiology of first and recurrent venous thromboembolism: A population-based cohort study in patients without active cancer. Thromb Haemost 2014;112:255-263. [PubMed: 24695909]5
3. Data and statistics on venous thromboembolism. Centers for Disease Control and Prevention. https://www.cdc.gov/ncbddd/dvt/data.html. Published February 7, 2020. Accessed August 3, 2021.
4. Gao S, Escalante C. Venous thromboembolism and malignancy. Expert Rev Anticancer Ther. 2004;4(2):303-320.
5. Khorana AA. Cancer and thrombosis: implications of published guidelines for clinical practice.
6. Áinle FN, Kevane B. Which patients are at high risk of recurrent venous thromboembolism (deep vein thrombosis and pulmonary embolism)? Blood Adv. 2020;4(21):5595-5606.
7. Martinez C, Cohen AT, Bamber l, Rietbrock S. Epidemiology of first and recurrent venous thromboembolism: A population-based cohort study in patients without active cancer. Thromb Haemost. 2014;112:255-263.
8. Khorana AA, Francis CW, Culakova E, et al. Thromboembolism is a leading cause of death in cancer patients receiving outpatient chemotherapy. J Thromb Haemost. 2007;5:632-634.
9. Bloom JW, Vanderschoot JP, Oostindier MJ, Osanto S, et al. Incidence of venous thrombosis in a large cohort of 66,329 cancer patients: results of a record linkage study. J Thromb Haemost 4: 3:2006;529-535.
10. Mosarla RC, Vaduganathan M, Qamar A, et al. Anticoagulation Strategies in Patients with Cancer. J Am Coll Cardiol. 2019;1336-49.
11. Edelmann B, Gupta N, Schnoder TM, et al. JAK2-V617F promotes venous thrombosis through beta1/beta2 integrin activation. J Clin Invest. 2018;128:4359-71.
12. Moslehi JJ. Cardiovascular toxic effects of targeted cancer therapies. N Engl J Med. 2016;375:1457-67.
13. Cancer-Associated Venous thromboembolic Disease. Version 2.2021. National Comprehensive Cancer Network. https://www.nccn.org/professionals/physician_gls/pdf/vte.pdf. Published August 2021. Accessed November 10, 2021.
14. Kearon C, Akl EA, Ornelas J, et al. Antithrombotic Therapy for VTE Disease: CHEST Guideline and Expert Panel Report [published correction appears in Chest. 2016 Oct;150(4):988]. Chest. 2016;149(2):315-352. doi:10.1016/j.chest.2015.11.026

15. N Konstantinides SV, Meyer G, Becattini C, et al. 2019 ESC Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS). Eur Heart J. 2020;41(4):543-603. doi:10.1093/eurheartj/ehz405
16. Brandow AM, Carroll CP, Creary S, et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. Blood Adv. 2020;4(12):2656-2701. doi:10.1182/bloodadvances.2020001851
17. Stevens SM, Woller SC, Baumann Kreuziger L, et al. Antithrombotic therapy for VTE disease: second update of the chest guideline and expert panel report – executive summary. Chest. Published online August 2021:S0012369221015075.
18. National Comprehensive Cancer Network. Cancer-Associated Venous Thromboembolic Disease (Version 1.2022). https://www.nccn.org/professionals/physician_gls/pdf/vte.pdf. Accessed May 25, 2022.
19. The Joint Commission. Transitions of care: The need for a more effective approach to continuing patient care. www.jointcommission.org/-/media/deprecated-unorganized/importedassets/tjc/systemfolders/topicslibrary/hot_topics_transitions_of_carepdf .pdf?db=web&hash=CEFB254D5EC36E4 FFE30ABB20A5550E0. Accessed August 4, 2020.
20. Cervero RM, Gaines JK. The impact of CME on physician performance and patient health outcomes: An updated synthesis of systematic reviews. *Journal of Continuing Education in the Health Professions.* 2015;35(2):131-138.