American College of Emergency Physicians (ACEP) &
Pfizer/Bristol-Myers Squibb Alliance

Quality Improvement - Request for Proposals (RFP)

Improving the Outpatient Management of Emergency Department Patients with Venous Thromboembolism (VTE) in Rural Areas and Underserved Communities

Competitive Grant Program – using Expert Review Panel

I. Background

Overview

This Quality Improvement program will fund projects that promote the safe outpatient management of patients diagnosed with low-risk venous thromboembolism (VTE) in the Emergency Department setting. We seek to support project focused on clinical program development that overcomes barriers to safe, evidence-based management, disposition, and follow up of this patient population. Funded projects will describe the proposed clinical initiative's efficacy with outcome measures that demonstrate improved outpatient management of VTE patients, patient safety, physician satisfaction, and/or patient satisfaction. This program seeks to foster a collaborative approach model and gives strong consideration to proposals that pair urban/academic sites with community/rural sites.

About American College of Emergency Physicians (ACEP)

ACEP represents more than 38,000 emergency physicians, emergency medicine residents and medical students. ACEP promotes the highest quality of emergency care and is the leading advocate for emergency physicians and their patients, and the public. Learn more at https://www.acep.org/.

About Pfizer/Bristol-Myers Squibb Alliance

Pfizer and Bristol-Myers Squibb (BMS) are collaborating to provide grant support for Quality Improvement programs in the areas of atrial fibrillation and venous thromboembolism. We are committed to supporting innovative projects that promote the safe outpatient management of patients diagnosed with low-risk venous thromboembolism (VTE) in the Emergency Department setting.

Pfizer Global Medical Grants (GMG) supports the global healthcare community's independent initiatives (e.g., research, quality improvement or education) to improve patient outcomes in areas of unmet medical need that are aligned with Pfizer's medical and/or scientific strategies. Pfizer's GMG competitive grant program involves a publicly posted **Request for Proposal (RFP)** that provides detail regarding a specific area of interest, sets timelines for review and approval, and uses an **expert review panel (ERP)** to make final grant decisions. Organizations are invited to submit an application addressing the specific gaps in clinical practice or care as outlined in the specific RFP.

For all independent medical education grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, and conduct of the independent initiative supported by the grant. Pfizer and BMS must not be involved in any aspect of project development, nor the conduct of the independent education program.

II. Eligibility

Geographic Scope:

- United States

Applicant Eligibility Criteria

- The following may apply: Emergency Departments (ED) located in the United States. All EDs regardless of location, patient population, annual visit volume, hospital affiliation, and resource allocation are encouraged to apply.
- Only organizations are eligible to receive grants, not individuals or medical practice groups (i.e., an independent group of physicians not affiliated with a hospital, academic institution, or professional society).
- Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions / organizations / associations, are encouraged. Please note all partners must have a relevant role and the requesting organization must have a key role in the project.
- The applicant must be the Project Lead/Principal Investigator (PI) or an authorized designee of such individual (e.g., Project Lead/PI's grant/research coordinator).
- The Project Lead/PI must be an employee or contractor of the requesting organization.
- Requesting organizations must be legally able to receive award funding directly from Pfizer Inc. We strongly recommend that applicants confirm this with their organization or institution prior to submitting an application. Grants awarded to organizations that are subsequently found to be

unable to accept funding directly from Pfizer Inc. may be subject to rescission.

For projects offering continuing education credit, the requesting organization must be accredited.

III. Requirements

Date RFP Issued

- July 2, 2024

Clinical Area

- Venous Thromboembolism (VTE)

Project Types and Area of Interest

- The intent of this RFP is to encourage health care institutions to submit projects that promote the safe outpatient management, of patients diagnosed with low-risk venous thromboembolism (VTE) in the Emergency Department in rural areas/underserved communities.
- Potential applicants are encouraged to pinpoint and tackle obstacles and deficiencies concerning Venous Thromboembolism (VTE) care in outpatient settings. We are seeking studies that address the following, but not limited to:
    - Barriers to obtaining evidence-based medications for outpatient management.
    - Barriers to ensuring follow-up after outpatient care.
    - Barriers to appropriately identifying low-risk patients for outpatient management.

Specific Area of Interest for this RFP:

- It is our intent to support projects that focus on improving Venous Thromboembolism (VTE) outpatient care in rural areas/underserved communities.
- Multi-disciplinary collaborations are encouraged when appropriate, but all partners must have a relevant role.
- Inter-institutional collaborations between urban/teaching institutions and smaller/local/rural hospitals will be prioritized with the intention to address and improve quality of care and health equity in underserved communities.
- It is expected that projects will be evidence-based (quality improvement) and the proposed evaluation will follow generally accepted scientific principles. **During review the intended outcome of the project is given careful consideration and, if appropriate based on the project goal, projects with the maximum likelihood to directly impact patient care will be given high priority.** Projects including an educational element can find more information on principles of learning and behavior change for health professionals here.
- There is a considerable amount of interest in receiving responses from projects that utilize system- based changes. Although educational efforts for grantees and patients may be entirely appropriate components in responses to this RFP, projects that include an overt description of system changes will be given high priority.

Note: It is not our intent to support clinical research projects, including those that evaluate the efficacy of therapeutic or diagnostic agents. Information on how to submit requests for support of these types of clinical research projects can be found at https://www.cybergrants.com/pfizer/Research.

Impact and Outcomes

Applications need to include a detailed outcomes plan with description and timelines of the expected quality improvements and how they will be evaluated; examples might include but not limited to:

- Expected behavioral/practice changes in the care provided to patients with VTE; standardization of processes, diagnosis, inpatient/outpatient management, education
- Measurement of the program's impact; baseline, process and outcome metrics
- Sustainability of the implementation; policies/processes development
- Potential replicability and dissemination
- Potential collaborations with other sites, medical societies, academia, etc.
- Innovative approaches and/or new technologies/AI/web-based
- Interim/final reports expected to be presented to the Expert Review Panel
- Publication plan and timelines should be included

Target Audience

- Emergency Physicians, cross functional ED team members, other healthcare professionals in the hospital setting (e.g., Internal Medicine, Hematologist, Pharmacists, etc.)

Disease Burden Overview

- Every emergency physician is acquainted with VTE and has to address the differential diagnosis, the evaluation and the planning for patients presenting with VTE. This disease group impacts every emergency physician. VTE is not uncommon in the adult population. VTE affects 1-2 million Americans every year, with roughly the same incidence as stroke, and is the third most common cause of cardiovascular mortality in the United States. Up to 900,000 people in the United States are affected by VTE each year. An estimated 60,000-100,000 Americans die of VTE each year and many others have long-term complications from a VTE. Most VTEs are diagnosed in an Emergency Department.

References

1. *Beckman MG, et al. Am J Prev Med. 2010; 38-S495-S501.*
2. *Heit JA. Arterioscler Thromb Vasc Biol. 2008;28:370-372.*
3. *Oger E. Thromb Haemost. 2000;83:657-660.*
4. *Barnes GD, et al. J Vasc Surg. 2010;51(6):1467- 1473.*
5. *Heit JA, et al. J Thromb Thrombolysis. 2016;41(1):3-14.*
6. *Smith SB, et al. Chest. 2016;150(1):35-45.*
7. *Jimenez S, et al. Medicine (Baltimore). 2017;96(48):e8796.*
8. *Kabrhel C, et al. Chest. 2016;150(2):384-393.)*

Gaps Between Actual and Target, Possible Reasons for Gaps

- Studies have demonstrated the outpatient management of low-risk VTE is safe and preferable to a large proportion of patients, however there are significant barriers that limit emergency physicians' ability to discharge patients with reliable follow-up. These barriers include:
    - reliable access to anticoagulant evidence-based medications
    - reliable access to follow-up
    - knowledge about patient selection for outpatient management

References:

9. Kabrhel C, et al. J Am Coll Emerg Physicians Open. 2021;2(6):e12588.

10. Aujesky D et al. Lancet. 2011;378(9785):41-48.

11. Zondag W, et al. Eur Respir J. 2013;42(1):134-144.

12. Roy PM et al. J Thromb Haemost. 2017;15(4):685-694.

13. Peacock FW et al. Acad Emerg Med. 2018;25(9):995-1003.

14. Barco S et al. European Heart Journal. Published online May 23, 2019:ehz367.

15. Kabrhel C et al. Acad Emerg Med. 2019;26(6):657-669.

16. Singer AJ, et al. Acad Emerg Med. 2016;23(11):1280-1286.

17. Kline JA, et al. Circ Cardiovasc Qual Outcomes. 2021;14(7):e007600.

18. van der Wall SJ, et al. Curr Opin Pulm Med. 2018;24(5):425-431.

19. Vinson DR, et al. Ann Intern Med. 2018;169(12):855-865)

Barriers

- Reliable access to evidence-based medications is limited by patient finances, insurance, the need for prior authorizations, and difficulties in navigating free/reduced drug programs.
- Reliable access to follow-up is limited by difficulty in obtaining appointments, lack of health insurance coverage, loosely integrated systems and lack of specialists that can perform follow-up, especially in under-served areas.
- Knowledge about patient selection is a barrier as some emergency physicians may be unfamiliar with risk stratification, identifying low-risk VTE patients, the definitions of a low-risk patient, drug-drug interactions, and contraindications to anticoagulants, and other barriers to outpatient management.

References:

20. Kline JA, et al. Adher. 2016;10:561-569.

21. Vinson DR, et al. Acad Emerg Med. 2021;28(3):377-378.

15. Kabrhel C, et al. Acad Emerg Med. 2019;26(6):657-669.

22. Simon LE, et al. West J Emerg Med. 2018;19(6):938-946.

23. Kabrhel C, et al. Hosp Pract. 2017;45(3):123-129. (1995).

24. Hayes BD, et al. Am J Emerg Med. 2012;30(9):2011-2014.)

25. Tsai J, et al. PLoS ONE 10(4): e0123842

26. Schaefer JK, et al. Blood Adv. 2017 Dec 7;1(26):2536-2540

27. Lowery A, et al. Int J Spine Surg. 2021 Jun;15(3):562-569.

Current National Efforts to Reduce Gaps

- ACEP has published point-of-care tools that provide guidance on the outpatient management of low-risk PE and DVT. ACEP has published clinical policies on the topics of Acute Venous Thromboembolic Disease (see references).

Reference:

28. Kabrhel C, et al. J Am Coll Emerg Physicians Open. 2021;2(6):e12588.

29. Wolf SJ, et al. Ann Emerg Med. 2018;71:e59-e109.)

30. https://poctools.acep.org/POCTool/Low-riskPE/2b7ac2d5-45ee-429f-9e60-42e3c77dfc94/

31. https://poctools.acep.org/POCTool/Low-riskDVT/fdc2865c-250d-4c45-b2ab-c154b319792f/

32. https://www.acep.org/patient-care/clinical-policies/acute-venous-thromboembolic-disease

Expected Approximate Monetary Range of Grant Applications:

- **Projects can request up to $200,000 USD. The estimated total available budget related to this RFP is $600,000 USD.**
- Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.
- The amount of the grant Pfizer will be prepared to fund for any project will depend upon the expert review panel's evaluation of the proposal and costs involved and will be stated clearly in the grant agreement.

Key Dates:

- RFP Release Date: **July 2, 2024**
- Full Proposal Due Date: **September 8, 2024**

Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).

- Review of Full Proposals by ERP: **October 3, 2024**
- Anticipated Full Proposal Notification Date: **October 15, 2024**
- Grants will be distributed following a fully executed agreement and submission of Final Protocol, documentation of IRB/IEC approval, regulatory approval (if applicable), exemption or waiver.

How to Submit:

Note: please read this section carefully since applications submitted not following these instructions will not be accepted and will be canceled.

- Please go to www.cybergrants.com/pfizer/QI and sign in. First-time users should click "Create your password". *[Note: there are individual portals for each grant application type. Please be sure to use the URL above.]*

- Click the "Start a New Quality Improvement Application" button.

- In the application:
    - For the question “Competitive Grant?” select Yes
    - Select the following Competitive Grant Program Name: 2024 IM US ACEP Outpatient Management of ED Patients with VTE QI
    - Select the following Primary Area of Interest: CVM – Anti-coagulation (AFIB, VTE) - QI
- Requirements for submission:

  Complete all required sections of the online application and upload your project proposal (see Appendix) in the Full Proposal Submission field.
- If you encounter any technical difficulties with the website, please click the “Technical Questions” link at the bottom of the page.

IMPORTANT: Be advised applications submitted after the due date will not be reviewed.

Questions:

- If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Miguel Briceno (miguelangel.briceno@pfizer.com), with the subject line “2024 IM US ACEP Outpatient Management of ED Patients with VTE QI”

Grant Agreements:

- If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click here to view the core terms of the agreement.
- Under Pfizer's competitive grant program, modifications to grant agreements will not be reviewed unless a genuine conflict exists as between applicable law and the terms of the relevant grant agreement. Applicant is encouraged to share the core terms with counsel for approval prior to submitting an application.
- Except where prohibited by applicable law and, in any case, subject to review by Pfizer Legal, payment of grant funding may only be paid to the grantee organization.

Review and Approval Process

- Pfizer and ACEP will initially review all proposals to determine if applicants meet eligibility criteria and the proposed projects are in the scope.
- This specific grant program RFP will use an expert review panel (ERP) to make final grant decisions.
- The panels are comprised of professionals from the medical community with advanced degrees and expertise in particular clinical areas, or specific needs of a geographic region/learner group, or expertise in research, continuing professional development or quality improvement.

Mechanism by which Applicants will be Notified:

- All applicants will be notified via email by the dates noted above.
- Applicants may be asked for additional clarification during the review period.

Appendix

Specific RFP Submission Requirements

Applications will be accepted via the online portal listed in the How to Submit section. Project Proposals/Protocols should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 15-page limit exclusive of references. When uploading your Full Proposal please ensure it addresses the following sections:

Goals and Objectives

- Briefly state the overall goal of the project. Also describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s).
- List the overall objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.

Assessment of Need for the Project

- Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), 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. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information.

Target Audience

- Describe the primary audience(s) targeted for this project. Also indicate whom you believe will directly benefit from the project outcomes. Describe the overall population size as well as the size of your sample population

Project Design and Methods

- Describe the planned project and the way it addresses the established need.
- If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.

Innovation

- Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.
- Describe how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.

Evaluation and Outcomes

- Detailed description and plan of the expected quality improvements/outcomes and how they will be evaluated.
- In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Describe how you expect to collect and analyze the data.
- Quantify the amount of change expected from this project in terms of your target audience.
- Describe how the project outcomes will be broadly disseminated.

Anticipated Project Timeline

- Provide an anticipated timeline for your project including project start/end dates.

Additional Information

- If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here.

Organization Detail

- Describe the attributes of the institutions / organizations / associations that will support and facilitate the execution of the project and the leadership of the proposed project. Articulate the specific role of each partner in the proposed project.

Budget Detail

- The budget amount requested must be in U.S. dollars (USD).
- While estimating your budget please keep the following items in mind:
  - General organizational running costs such as legal fees, insurance, heating, and lighting etc. should be included in an Institutional Overhead (if required). These costs are not specific to a grant request and therefore, should not appear as line items in budgets. However, costs that are specific to the study (e.g., some countries require insurance to be taken out on a per-study basis for clinical research) would be acceptable to be included as line items.
    - The inclusion of overhead costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
  - Pfizer does not provide funding for capital purchases (infrastructure expenses such as equipment, purchases of software or software licenses, technology or bricks and mortar). Equipment hire/leasing is acceptable and may be included in the project budget.
  - It should be noted that grants awarded through GMG cannot be used to purchase Pfizer therapeutic agents (prescription or non-prescription).
- Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects. Please click here for details.