

The International Society for Infectious Diseases (ISID) and Pfizer Global Medical Grants Announce:

Pfizer-ISID 2020 AFME Grant Challenge

Competitive Grant Program

I. Background

Pfizer Global Medical Grants (GMG) supports the global healthcare community's independent initiatives to improve patient outcomes in areas of unmet medical need. These areas include research, quality improvement measures, and expanded educational opportunities that align with Pfizer's medical and scientific strategies.

Pfizer's GMG competitive grant program begins with 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 external review panel (ERP) to make final grant decisions. Organizations are invited to submit an application addressing the specific gaps as outlined in the RFP.

For all quality improvement 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 must not be involved in any aspect of project development, nor the conduct or monitoring of the quality improvement program.

The International Society for Infectious Diseases (ISID), in collaboration with Pfizer Global Medical Grants, is initiating this RFP for research projects focused on the implementation and/or assessment of antimicrobial stewardship programs throughout Africa and the Middle East.

ISID is a non-profit organization composed of 80,000 professionals representing every country in the world. The mission of ISID is to support infectious disease practitioners in resource limited settings as they work to prevent, investigate, and manage infectious disease outbreaks. ISID encourages the collaborative efforts of health communities working locally, nationally, and globally for the best control and management of infectious diseases. We recognize that infectious diseases cross all geographic, financial, and political boundaries and that effective long-term solutions require international scientific exchange. www.isid.org.





II. Eligibility

| Geographic Scope: | Africa and the Middle East |
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| Applicant Eligibility Criteria | The following may apply: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations; public health organizations, environmental health organizations, government agencies; Research facilities and other entities with a mission related to healthcare improvement. |
| | More information on organizations eligible to apply directly for a grant can be found at http://www.pfizer.com/files/IGLC OrganizationEligibility effJuly2015.pdf. |
| | Collaborations within institutions (e.g., between departments and/or interprofessional), as well as between different institutions / organizations / associations, are strongly encouraged. Antimicrobial resistance challenges require input from multiple stakeholders where limited resources can be judiciously allocated through collaborative approaches. Please note all partners must have a relevant role and the requesting organization must have a key role in the project. Projects with direct organizing effort and health outcomes focusing on patient populations in Africa and the Middle East will be prioritized for funding consideration. |

III. Requirements

| Date RFP Issued | May 5, 2020 |
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| Clinical Area | Anti-infective: antimicrobial stewardship and infection prevention & control |
| Specific Area of Interest for this RFP: | To reduce the risk of antimicrobial resistance development and the spread of resistant bacteria, healthcare organizations must enact procedures to ensure the optimal use of antibiotics. By implementing antimicrobial stewardship programs, organizations can provide appropriate antibiotics to patients requiring antibiotic treatment. Additionally, these programs ensure the correct antibiotic is prescribed at the right time, dose, and duration. Collectively, these measures improve patient health outcomes and preserve the effectiveness of antimicrobial treatments. |
| | We are seeking innovative quality improvement research, health services research and/or educational research applications that identify and evaluate practices for successfully implementing key elements of antimicrobial stewardship programs. These programs can be implemented within large and small hospitals, academic medical centers, community hospitals, ambulatory care settings, and other healthcare facilities, such as nursing homes. Elements could include: |





tracking patterns of antibiotic prescribing; informing staff on antibiotic use and resistance; educating staff about optimal antibiotic use; regulating antibiotic use; clinical and/or health economic outcomes from stewardship initiatives; barriers to stewardship implementation, proper disposal techniques to reduce environmental antimicrobial resistance, etc. It is imperative local hospital/organizational leadership support the proposed program, which includes leadership's commitment to providing staffing, financial support, resources, and information-technology to ensure an effective stewardship-based study/education program. All resource allocations should be evidence-based.

In addition to infection prevention and control professionals, successful antimicrobial stewardship programs include physicians, nurses, public health professionals, pharmacists, students, patients, families, community leaders, environmental planners, government officials, engineers, and information technology professionals. The perspectives contributed by these disciplines allow proactive identification of barriers to program success and give intervention architects the opportunity to develop solutions that reduce these obstacles. ²

In response to this RFP, applications must:

- 1. Include a comprehensive "needs assessment" that accurately describes current, country-based gaps in resources, skills, or opportunities for antimicrobial stewardship and/or infection prevention and control practices within the defined community.
- 2. Include a diverse group of healthcare and nonhealthcare professionals when identifying an antimicrobial stewardship challenge and proposing an intervention. During this process, infection prevention and control professionals, physicians, nurses, public health professionals, pharmacists, students, patients, families, and community leaders serve as valuable resources to first define, and then solve a shared challenge.
- 3. Be based on scientific evidence, accepted practice guidelines, and local laws and regulations.
- 4. Include or refer to guidelines for the optimal use of hospital surveillance, infection control and antibiotic therapy for the treatment of infections, including the proper use of prophylactic antibiotic therapy.





5. Include a mechanism to oversee the antibiotic stewardship program, naming responsible parties and departments.

6. Include a mechanism to monitor the effectiveness of the antibiotic stewardship program to track progress and prevent unintended negative consequences.

7. Have defined outcomes and measurable data collection throughout the program to demonstrate the impact of the initiative on usual practices, patient outcomes and/or how the intervention fits within existing health services. Antimicrobial stewardship programs must focus on the prudent use of antimicrobial treatments, which may or may not lead to decreased antimicrobial consumption. By simply reducing the number of antimicrobial treatments dispensed, patients requiring these interventions may be harmed. Thus, all programs with patient health components must *improve the correct use* of antimicrobial treatments, not simply reduce the total amount.

Initiatives that solely focus on knowledge improvement (e.g., journal clubs, grand round programs, lectures) will not be eligible for consideration.

We are seeking applications that span a broad range of implementation levels. Applicants are encouraged to submit quality improvement research, health services research and/or educational research proposals that either establish new stewardship mechanisms and/or evaluate the effectiveness of existing antimicrobial stewardship initiatives. If research evaluates an existing program, programs must focus their assessment on the application of the program, how it changed barriers to appropriate care, significant changes in clinical outcomes, solutions implemented to overcome challenges, and measurable outcomes with supporting statistical analysis where appropriate.

Additionally, applicants should consider how their intervention, and the results generated as a result of its implementation, may be disseminated to other institutions. Antimicrobial stewardship challenges are shared by many institutions, thus sharing effective practices improves health across communities.

If applicants focus on information technology and use of electronic healthcare records (i.e., utilizing computerized order entry and electronic surveillance), applicants should describe how such solutions





may be disseminated and adopted by other organizations and how data will be shared and/or integrated into existing systems.

It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered. Information on how to submit requests for support of clinical research projects can be found at www.Pfizer.com/iir.

Target Audience of Project Results:

Small and large hospitals, academic medical centers, community hospitals, and ambulatory care settings and other healthcare facilities, e.g. nursing homes.

Disease Burden Overview:

The overuse and misuse of antibiotics have increased multi-drug resistant pathogens globally. The World Health Organization's Global Antimicrobial Surveillance System (GLASS) identified over 500,000 resistant infections in just 22 countries during the first release of surveillance data.³ If extrapolated to a global scale, the impact of antimicrobial resistance on patient health is incalculable. This is highlighted in the fact that lower respiratory infections and tuberculosis are among the top 10 global causes of death.⁴

Isolation of resistant clinical isolates requires more aggressive treatment approaches including the use of multiple antibiotics in some cases. This puts patients at risk for adverse events and/or treatment complications, including the acquisition of *Clostridioides difficile*, kidney or liver damage, hearing loss, hemolytic anemia, and other complications. The misuse of antibiotics increases the risk of complications without any benefit to the patient and increases the pressure on bacteria to become resistant.

Health care practitioners contribute to the development of antimicrobial resistance by continuing antibiotic treatments when they are no longer necessary, using broad-spectrum antibiotics without clinical or microbiologic indication, or continuing broad-spectrum antibiotics unnecessarily after sensitivity results are received. 5-7 Other actions contributing to the development of antimicrobial resistance include using the wrong antibiotic for an infection, prescribing the wrong dose, or continuing prophylactic antibiotics after it is no longer recommended. Beyond these actions, healthcare professionals have an obligation to their patients to inform them of the proper antibiotic regimen and the importance of taking antibiotics as prescribed.

An antimicrobial stewardship program strives to reduce the misuse of antimicrobial therapies, thereby reducing the pressure to develop antibiotic





resistance. Antimicrobial stewardship programs have been shown to improve prescribing practices, reduce healthcare-related costs, improve patient outcomes, and slow the development of antimicrobial resistance. 8-10

Recommendations and Target Metrics:

Gaps Between Actual and Target, Possible Reasons for Gaps:

Barriers:

Current Efforts to Reduce Gaps:

Proposals will be reviewed according to the following critieria:

- Innovation Does the work address a knowledge gap not yet anwsered in the proposed country or region?.
- Data/knowledge transfer How can other hospitals/clinics/institutions benefit from the data, methodology and/or results?
- Probability Is there a high likelihood of generating actionable data within the project period?
- Sustainability Does the support go primarily to researchers living within the region and the proposed project benefits the regional patient population?
- Patient Safety Do proposals take into account potential impacts on patient safety and present ways to mitigate potential adverse effects?

Global:

- World Health Organization's Antimicrobial Stewardship Course
- World Health Organization's Global Action Plan on Antimicrobial Resistance
- World Health Organization's Global Framework for Development & Stewardship to Combat Antimicrobial Resistance
- International Society for Infectious Diseases' Guide to Infection Control in the Healthcare Setting – Antibiotic Resistance & Antimicrobial Stewardship
- Antibiotic stewardship interventions in hospitals in low-and middle-income countries: a systematic review
- Antimicrobial stewardship programmes in health-care facilities in lowand middle-income countries: A WHO practical toolkit
- O'Neill J: Tackling Drug-Resistant Infections Globally: Final Report and Recommendations May 2016

Regional

Africa:

- The Africa CDC Framework for Antimicrobial Resistance Control, 2018–2023
- Infection Control Africa Network
- Impact of Antimicrobial Stewardship Strategies on Antibiotic
 Appropriateness and Prescribing Behaviours in Selected Countries in the Middle East: Systematic Review
- Antimicrobial Stewardship for the Gulf, Middle East and North Africa:





| | National |
|--|---|
| | South Africa: Guidelines on Implementation of the Antimicrobial Strategy in South Africa: One Health Approach & Governance Prevention and Containment of Antimicrobial Resistance – FIDSSA: National Action Plan for Antimicrobial Resistance - Nigeria Kenya - Alliance for the Prudent Use of Antibiotics Centers for Disease Control and Prevention's Core Elements of Hospital Antibiotic Stewardship Programs American Academy of Pediatrics (AAP): Red Book – Antimicrobial stewardship |
| Expected Approximate Monetary Range of Grant Applications: | Individual projects requesting up to \$100,000 will be considered. The total available budget related to this RFP is \$1,000,000. Final determination of project funding will depend upon the external review panel's evaluation of the proposal and costs involved. Approved funding amounts will be stated clearly in the applicant notification. |
| Key Dates: | RFP release date: May 5, 2020 LOI due date: August 4, 2020 Please note the deadline is 11:59PM Eastern Time (New York, GMT -5). Review of LOIs by External Review Panel: Week of September 14, 2020 Anticipated LOI Notification Date: September 28, 2020 Full Proposal Deadline: November 2, 2020 *Only accepted LOIs will be invited to submit full proposals Please note the deadline is 11:59PM Eastern Time (New York, GMT -5). Review of Full Proposals by External Review Panel: Mid-November 2020 Anticipated Full Proposal Notification Date: December 2020 Note: Final approval is subject to FCPA compliance checks. Grants distributed following execution of fully signed Letter of Agreement Period of Performance: 18 to 24 months |





| How to Submit: | Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click "REGISTER NOW". Select the following Competitive Grant Program Name: 2020 HOS R Pfizer-ISID AFME Grant Challenge |
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| | Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix). |
| | All applications must be submitted in English. |
| | If you encounter any technical difficulties with the website, please click the "Need Support?" link at the bottom of the page. |
| | IMPORTANT: Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee. |
| Questions: | If you have questions regarding this RFP, please direct them in writing to Pfizer Global Medical Grant Officer, Angelo Carter (angelo.carter@pfizer.com) and/or John Ramatowski (john.ramatowski@isid.org) at ISID with the subject line: "2020 HOS R Pfizer-ISID AFME Grant Challenge" |
| 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 or to make a summary presentation during the review period. |





References:

- Antimicrobial stewardship across 47 South African hospitals: an implementation study: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(16)30012-3/fulltext
- 2. Sustainable Access to Antimicrobials; A Missing Component to Antimicrobial Stewardship—A Tale of Two Countries:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6246712/
- 3. World Health Organization, 2018. *High Levels Of Antibiotic Resistance Found Worldwide, New Data Shows*. [online] Available at: https://www.who.int/mediacentre/news/releases/2018/antibiotic-resistance-found/en/.
- 4. World Health Organization, 2018. *The Top 10 Causes Of Death*. [online] Geneva: World Health Organization. Available at: https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death.
- Sharland M, Gandra S, Huttner B, Moja L, Pulcini C, Zeng M, Mendelson M, Cappello B, Cooke G, Magrini N; EML Expert Committee and Antibiotic Working Group. Encouraging AWaRe-ness and discouraging inappropriate antibiotic use-the new 2019 Essential Medicines List becomes a global antibiotic stewardship tool. Lancet Infect Dis. 2019 Dec;19(12):1278-1280. doi: 10.1016/S1473-3099(19)30532-8. PubMed PMID: 31782385.
- Laxminarayan R, Van Boeckel T, Frost I, Kariuki S, Khan EA, Limmathurotsakul D, Larsson DGJ, Levy-Hara G, Mendelson M, Outterson K, Peacock SJ, Zhu YG. The Lancet Infectious Diseases Commission on antimicrobial resistance: 6 years later. Lancet Infect Dis. 2020 Feb 11. pii: S1473-3099(20)30003-7. doi: 10.1016/S1473-3099(20)30003-7. [Epub ahead of print] Review. Erratum in: Lancet Infect Dis. 2020 Feb 25;:. PubMed PMID: 32059790.
- 7. Mendelson M, Morris AM, Thursky K, Pulcini C. How to start an antimicrobial stewardship programme in a hospital. Clin Microbiol Infect. 2019 Aug 22. pii: S1198-743X(19)30448-3. doi: 10.1016/j.cmi.2019.08.007. [Epub ahead of print] Review. PubMed PMID: 31445209.
- 8. Pulcini C, Binda F, Lamkang AS, Trett A, Charani E, Goff DA, Harbarth S, Hinrichsen SL, Levy-Hara G, Mendelson M, Nathwani D, Gunturu R, Singh S, Srinivasan A, Thamlikitkul V, Thursky K, Vlieghe E, Wertheim H, Zeng M, Gandra S, Laxminarayan R. Developing core elements and checklist items for global hospital antimicrobial stewardship programmes: a consensus approach. Clin Microbiol Infect. 2019 Jan;25(1):20-25. doi: 10.1016/j.cmi.2018.03.033. Epub 2018 Apr 3. PubMed PMID: 29625170.
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- 10. Antimicrob Resist Infect Control. 2019 Feb 12;8:35. doi:1186/s13756-019-0471-0. eCollection 2019. PubMed PMID: 30805182; PubMed Central PMCID: PMC6373132.





IV. Terms and Conditions

Please take note every Request for Proposal (RFP) released by Pfizer Independent Grants for Learning & Change (IGLC), as well as a RFP released jointly with a Partner(s), is governed by specific terms and conditions. Click here to review these terms and conditions.





Appendix A

Letter of Intent Requirements

The Letter of Intent (LOI) will be accepted via the online application. When answering the LOI questions in the application please keep the following in mind:

| 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). |
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| | 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. |
| Needs Assessment for Proposed 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. The RFP includes an assessment of the need for the project. Please do not repeat this information within the LOI (you may reference the RFP, if necessary). Only include information that impacts your specific project, linking regional or local needs to those identified on the global basis, if appropriate. |
| 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 | 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. Letters of support from partner organizations will be required at the Full Proposal stage only and should not be included with the LOI. |
| Budget Detail | A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable. |
| | The budget amount requested must be in U.S. dollars (USD). |
| | While estimating your budget please keep the following items in mind: |
| | Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment. |
| | The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP. |
| | It should be noted that grants awarded through GMG cannot be used to purchase therapeutic agents (prescription or non- prescription). |
| | Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects |



