

## The International Society for Infectious Diseases (ISID) & Pfizer Announce a Quality Improvement Grant RFP

# **ISID-Pfizer 2021 Grant Challenge**

## **Competitive Grant Program – using Expert Review Panel**

#### I. Background

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 external review panel (ERP) to make final grant decisions. Organizations are invited to submit an application addressing the specific gaps in practice as outlined in the specific 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 focused on the outpatient setting in low-income countries or under-resourced settings. 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. ISID recognizes that infectious diseases cross all geographic, financial, and political boundaries, and effective long-term solutions require international scientific exchange. www.isid.org.

## II. Eligibility

Geographic Scope:	<ul> <li>Low-income countries designated by the World Bank</li> <li>AND/OR</li> <li>Under resourced settings in middle-income countries as designated by the World Bank where limited capital and human resources create barriers to meeting outpatient antimicrobial prescribing needs of the population being served</li> <li>Lists of low-income and middle-income countries designated by the World Bank can be accessed at World Bank Country and Lending Groups – World Bank Data Help Desk</li> </ul>
Applicant Eligibility Criteria	<ul> <li>Only organizations are eligible to receive grants, not individuals or medical practice groups.</li> <li>The following may apply in this grant challenge: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations; government agencies; and other entities with a mission related to healthcare improvement.</li> <li>Collaborations within or between institutions (e.g., between departments and/or inter-professional) are encouraged. Please note, all partners must have a relevant role and the requesting organization must have a key role in the project.</li> <li>For programs offering education credit, the requesting organization must be the accredited grantee.</li> <li>Any grant requestor seeking funding through this grant challenge must be an existing antimicrobial stewardship program or center. No funding will be provided to establish a new center or hospital-based antimicrobial stewardship initiative.</li> <li>All organizations applying for this grant challenge must be located in the geographic scope of eligibility in a low or middle-income country (LMIC). If the applying organization is not located in an LMIC, the program will be disqualified.</li> </ul>

## **III. Requirements**

Date RFP Issued	• 17 May 2021
Clinical Area	Anti-Infective: Antimicrobial Stewardship (AMS) in the Outpatient Setting





Specific Area of Interest for this RFP:	Proposals should focus on antimicrobial therapy consumption, use patterns, and stewardship efforts in the <b>outpatient setting</b> , in low-income countries or under-resourced settings in middle-income countries. Antimicrobial stewardship programs confined to the clinical healthcare setting are not enough to effectively prevent the development and spread of antimicrobial resistance. Patient use behaviors, spurred by access to antimicrobial therapies in settings outside of traditional hospitals, are a neglected area that will benefit from novel antimicrobial stewardship programs.
	For the purpose of this grant challenge, outpatient setting is defined as any setting providing antimicrobial dispensation to patients who are not admitted to a hospital especially, but not only, in low-resource settings and in countries with a high proportion of unprescribed antibiotic sales where pharmacies and other private drug stores represent the primary access points for antimicrobials.
	<ul> <li>Proposals should outline innovative, quality improvement research, health services research, and/or educational research applications that identify and evaluate practices for successfully implementing antimicrobial stewardship initiatives in the outpatient setting.</li> </ul>
	<ul> <li>Proposals must provide a needs-assessment that accurately describes the current practices related to outpatient antimicrobial therapy consumption, and areas that could be improved with the application of the proposed antimicrobial stewardship program.</li> </ul>
	<ul> <li>Proposals should discuss how it will include a diverse group of healthcare and nonhealthcare professionals when identifying an antimicrobial stewardship challenge and proposing an intervention. Pharmacists, drug shop vendors, community leaders, students, patients, and families are valuable resources to first define, and then solve antimicrobial resistance challenges in the outpatient setting.</li> </ul>
	<ul> <li>Proposals must adhere to local laws and regulations regarding antimicrobial therapy prescribing, use, and treatment practices.</li> </ul>
	• Proposals must include a comprehensive <b>monitoring and evaluation</b> scheme that specifically details endpoints for program outcomes. All programs proposed must consider how enacted antimicrobial stewardship programs will change therapy consumption patterns and what effect this will have on patient health outcomes. Programs should focus on <i>correct</i> prescribing and dispensing practices and not compromise patient safety and positive health outcomes to reach unfounded reduction targets.
	<ul> <li>Proposals should describe how its programmatic intervention can be expanded to other regions to improve patient health outcomes.</li> </ul>
	• Sustainability of the initiative must be discussed in the proposal.
	Multi-disciplinary collaborations are encouraged when appropriate, but





	all partners must have a relevant role, which should be outlined.
	<ul> <li>It is expected that projects will be evidence-based (education and/or quality improvement) and the proposed research/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 principals of learning and behavior change for health professionals at <a href="https://www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange">www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange</a></li> </ul>
	<ul> <li>There is considerable 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.</li> </ul>
	<ul> <li>It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered.</li> </ul>
Target Audience:	Grant requestors should carefully consider the populations visiting outpatient facilities responsible for antimicrobial therapy dispensing to the general public and which population(s) will likely derive the greatest benefit from an antimicrobial stewardship program.
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. <sup>1-3</sup> If extrapolated to a global scale, the impact of antimicrobial resistance on patient health is incalculable.
	The outpatient setting is a key scenario for the implementation of antimicrobial stewardship (AMS) activities, considering that overconsumption of antibiotics occurs mainly outside hospitals. The misuse of antibiotics increases the risk of complications without any benefit to the patient and increases the pressure on bacteria to become resistant. Healthcare providers, patients and outpatient antimicrobial dispensers contribute to the development of antimicrobial resistance. The inappropriate use of antimicrobial therapies when they are not required, the premature stopping of prescribed regimens, consumption of poor-quality antimicrobials, and self- medicating behaviors are just some of the areas that can be addressed in antimicrobial stewardship programs that include both providers and patients. The outpatient setting is often overlooked when developing antimicrobial stewardship programs and should play a role in preventing the development of antimicrobial resistance.





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	Antimicrobial stewardship programs strive 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 health outcomes, and slow the development of antimicrobial resistance. <sup>5-7</sup>
Recommendations and Target Metrics:	All programs should focus on <b>outpatient healthcare settings</b> with the goal of improving <i>appropriate</i> antimicrobial therapy use behaviors. Metrics should be selected based on the proposed target community and must consider health outcomes for this population.
	Proposals will be reviewed according to the following criteria:
	<ul> <li>Portability – Ideally, the program outcome can impact communities, countries, and/or regions beyond where the intervention is being conducted.</li> </ul>
	<ul> <li>Innovation – New tools, methods, and plans to address stewardship challenges in the outpatient settings must represent novel additions to the field, unaddressed in previous work.</li> </ul>
	<ul> <li>Sustainability – Programs should be developed and executed by local researchers who can apply what they learned from the program in their country(s) after the program has ended.</li> </ul>
	<ul> <li>Probability – Programs with a high likelihood of generating impactful data/improving patient health outcomes will be prioritized.</li> </ul>
	<ul> <li>Safety – Any intervention must consider how it could negatively impact health outcomes and implement measures to mitigate these consequences.</li> </ul>
Barriers:	Barriers to successful outpatient antimicrobial stewardship program implementation include inadequate funding, overcrowded healthcare systems, lax legal and regulatory frameworks, non-uniform access to diagnostics, absence of electronic health record systems, limited knowledge and awareness especially with existence of multiple systems of medicines, issues with access to quality assured medicines, in-house pharmacies, and shortage of trained manpower.
Current National Efforts to Reduce Gaps:	<ul> <li>Global:</li> <li>World Health Organization's Antimicrobial Stewardship Course</li> <li>World Health Organization's Global Action Plan on Antimicrobial Resistance</li> <li>World Health Organization's Global Framework for Development &amp; Stewardship to Combat Antimicrobial Resistance</li> <li>International Society for Infectious Diseases' Guide to Infection Control in the Healthcare Setting – Antibiotic Resistance &amp; Antimicrobial Stewardship</li> <li>Tackling Drug-Resistant Infections Globally: Final Report and</li> </ul>





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	Regional:
	<ul> <li>The Africa CDC Framework for Antimicrobial Resistance Control, 2018–2023: <u>http://www.africacdc.org/resources/strategic-framework/strategic-framework/africa-cdc-amr-framework-eng/download</u></li> <li><u>Infection Control Africa Network</u></li> </ul>
Expected Approximate Monetary Range of Grant Applications:	<ul> <li>Proposals from eligible organizations requesting up to \$100,000 will be considered. The total available budget related to this RFP is \$1,000,000.</li> <li>The amount of the grant Pfizer will be prepared to fund will depend upon the external review panel's evaluation of the proposal and costs involved and will be stated clearly in the approval notification.</li> </ul>
Key Dates:	RFP release date: 17 May, 2021
	LOI due date: 18 June, 2021
	Please note the deadline is 23:59 Eastern Time (New York, GMT -5).
	Review of LOIs by External Review Panel: July 2021
	Anticipated LOI Notification Date: 26 July, 2021
	<ul> <li>Full Proposal Deadline: 23 August, 2021*</li> <li>*Only accepted LOIs will be invited to submit full proposals</li> <li>Please note the deadline is 23:59 Eastern Time (New York, GMT -5).</li> </ul>
	Review of Full Proposals by External Review Panel: September 2021
	Anticipated Full Proposal Notification Date: October, 2021
	<ul> <li>Grants distributed following execution of fully signed Letter of Agreement</li> </ul>
	Anticipated Project Start and End Dates: January 1, 2022 to December 31, 2024
How to Submit:	<ul> <li>Please go to <u>www.cybergrants.com/pfizer/loi</u> and sign in. First-time users should click "REGISTER NOW".</li> </ul>
	<ul> <li>Select the following Competitive Grant Program Name: [2021 G – ISID- Pfizer 2021 Grant Challenge].</li> </ul>
	Requirements for submission:
	Complete all required sections of the online application and upload the





	completed LOI template (see Appendix A).
	<ul> <li>If you encounter any technical difficulties with the website, please click the "Technical Questions" link at the bottom of the page.</li> </ul>
	<b>IMPORTANT:</b> Be advised that applications submitted through the wrong application type and/or submitted after the due date will not be considered.
Questions:	<ul> <li>If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Ai Ping Lee (<u>AiPing.Lee@pfizer.com</u>) with the subject line "ISID-Pfizer 2021 Grant Challenge – May 2021."</li> </ul>
Grant Agreements:	<ul> <li>If your grant proposal is approved, your organization will be required to enter into a written grant agreement with Pfizer. Please click <u>here</u> to view the core terms of the agreement.</li> <li>Pfizer has drafted the terms of these agreements to be balanced and reasonable and to further the goals of both parties. Please ensure that your organization (including your legal department) is able and willing to abide by the grant agreement with Pfizer before proceeding with submission of your application as such agreement will need to be accepted in its entirety.</li> </ul>
Review and Approval Process	<ul> <li>A specific grant program RFP uses an expert review panel (ERP) to make final grant decisions.</li> <li>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.</li> </ul>
Mechanism by which Applicants will be Notified:	<ul> <li>All applicants will be notified via email by the dates noted above.</li> <li>Applicants may be asked for additional clarification during the review period.</li> </ul>

#### **References:**

- 1. Antimicrobial stewardship across 47 South African hospitals: an implementation study: <a href="https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(16)30012-3/fulltext">https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(16)30012-3/fulltext</a>
- 2. Sustainable Access to Antimicrobials; A Missing Component to Antimicrobial Stewardship—A Tale of Two Countries: <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6246712/</u>
- 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: <u>https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death</u>.
- 5. Cox JA, Vlieghe E, Mendelson M, Wertheim H, Ndegwa L, Villegas MV, Gould I, Levy Hara G. Antibiotic stewardship in low- and middle-income countries: the same but different? Clin Microbiol





Infect. 2017 Nov;23(11):812-818. doi: 10.1016/j.cmi.2017.07.010. Epub 2017 Jul 14. Review. PubMed PMID: 28712667.

- 6. Antimicrob Resist Infect Control. 2019 Feb 12;8:35. doi:1186/s13756-019-0471-0. eCollection 2019. PubMed PMID: 30805182; PubMed Central PMCID: PMC6373132.
- 7. <u>Sanchez GV, Fleming-Dutra KE, Roberts RM, Hicks LA. Core Elements of Outpatient Antibiotic Stewardship.</u> MMWR Recomm Rep 2016; 65:1.
- 8. <u>Drekonja DM, Filice GA, Greer N, et al. Antimicrobial stewardship in outpatient settings: a systematic review.</u> Infect Control Hosp Epidemiol 2015; 36:142.
- 9. <u>Schroeck JL, Ruh CA, Sellick JA Jr, et al. Factors associated with antibiotic misuse in outpatient treatment for upper respiratory tract infections. Antimicrob Agents Chemother 2015; 59:3848.</u>
- 10. <u>Dobson EL, Klepser ME, Pogue JM, et al. Outpatient antibiotic stewardship: Interventions and opportunities. J</u> <u>Am Pharm Assoc (2003) 2017; 57:464.</u>
- 11. Cox JA, Vlieghe E, Mendelson M, Wertheim H, Ndegwa L, Villegas MV, Gould I, Levy Hara G. Antibiotic stewardship in low- and middle-income countries: the same but different? Clin Microbiol Infect. 2017 Nov;23(11):812-818. doi: 10.1016/j.cmi.2017.07.010. Epub 2017 Jul 14. PMID: 28712667.
- Arieti F, Göpel S, Sibani M, Carrara E, Pezzani MD, Murri R, Mutters NT, Lòpez-Cerero L, Voss A, Cauda R, Tacconelli E; ARCH working group. White Paper: Bridging the gap between surveillance data and antimicrobial stewardship in the outpatient sector-practical guidance from the JPIAMR ARCH and COMBACTE-MAGNET EPI-Net networks. J Antimicrob Chemother. 2020 Dec 6;75(Suppl 2):ii42-ii51. doi: 10.1093/jac/dkaa428. PMID: 33280045; PMCID: PMC7719405.





### 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	<ul> <li>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).</li> </ul>
	• List the <i>overall</i> 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 <i>your</i> 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. [Optional: The RFP includes a national 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 national basis, if appropriate.]
Target Audience	<ul> <li>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</li> </ul>
Project Design and Methods	<ul> <li>Describe the planned project and the way it addresses the established need.</li> </ul>
	If your methods include educational activities, please describe succinctly the topic(s) and format of those activities
Innovation	<ul> <li>Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.</li> </ul>
	<ul> <li>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.</li> </ul>





Evaluation and Outcomes	<ul> <li>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.</li> <li>Quantify the amount of change expected from this project in terms of your target audience.</li> </ul>
	Describe how the project outcomes will be broadly disseminated.
Anticipated Project Timeline	<ul> <li>Provide an anticipated timeline for your project including project start/end dates</li> </ul>
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	<ul> <li>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.</li> </ul>
Budget Detail	<ul> <li>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.</li> </ul>
	• The budget amount requested must be in U.S. dollars (USD).
	• While estimating your budget please keep the following items in mind:
	<ul> <li>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.</li> </ul>
	<ul> <li>The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.</li> </ul>
	<ul> <li>It should be noted that grants awarded through GMG cannot be used to purchase therapeutic agents (prescription or non- prescription).</li> </ul>
	<ul> <li>Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects</li> </ul>







