

Review and Analysis of Retrospective, Local Source, Serotype Distribution for Invasive Pneumococcal Disease in Latin America

Competitive Grant Program - internal Pfizer review process

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 general Request for Proposal (RFP) that provides detail regarding a general area of interest, sets timelines for review and approval, and uses an internal Pfizer review process to make final grant decisions. Organizations are invited to submit an application addressing the research gaps as outlined in the specific RFP.

For all Investigator Sponsored Research (ISRs) and general research grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, sponsorship, and conduct of the independent initiative supported by the grant, including compliance with any regulatory requirements. Pfizer must not be involved in any aspect of study protocol or project development, nor the conduct or monitoring of the research program. An ISR grant request cannot be submitted for a study that has already commenced and was not originally supported by Pfizer.

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II. Eligibility

Geographic Scope:	Latin America
Applicant Eligibility Criteria	 The institution and principal investigator (PI) must be based in a country within the defined geographic scope.
	 Only organizations are eligible to receive grants, not individuals or medical practice groups.
	 The applicant (PI) must have a Medical or Doctoral degree (MD, PhD, or equivalent) or Master degree in a medical area, or a degree in Pharmacy.
	 Applicant must be affiliated with the requesting organization.

III. Requirements

Date RFP Issued	• July 18, 2022
Clinical Area	Pneumococcal Conjugate Vaccine
General Area of Interest for this RFP:	• Projects that will be considered for Pfizer support will focus on the review and analysis of retrospective data from a local source of invasive pneumococcal disease serotype distribution, whether in children or adults, from one of any of three time periods: before, during, or following the implementation of a pneumococcal conjugate vaccine immunization program.
	 Local surveillance data from countries within Latin America Region that are under-represented in the international, peer-reviewed medical literature will be given priority.
	 Invasive Pneumococcal Disease (IPD) clinical presentations to be considered include sepsis / bacteremia, meningitis, or bacteremic pneumonia, as well as other presentations of IPD such as empyema, peritonitis, osteoarticular infection / septic arthritis, or endocarditis.
	 Clinical sources should have been obtained from blood or cerebrospinal fluid (CSF), or from any other normally sterile site (such as pleural fluid, peritoneal fluid, joint fluid, or pericardial fluid).
	 Projects submitted should be based on (1) serotyping data already available from records or (2) data that will be obtained by serotyping of laboratory samples currently under cold storage.
	 The submission should include a brief description of the intended statistical analysis of serotyped isolates based on, for example,





	stratification by age, gender, clinical source of the specimen, clinical presentation or patient diagnosis, and/or antibiotic resistance.
	The serotyping data already available from records can include:
	 National- or subnational-level publications (including local language publications).
	 Publicly available surveillance reports at the national- or subnational- level, which includes hospitals, public health organizations, or academic settings (such as universities or educational institutions).
	 With respect to serotyping of laboratory samples currently under cold storage:
	 Serotyping method could be performed using conventional (Quellung) or molecular (PCR or whole genome sequencing) methods.
	 The proposal should include costs for serotyping (including reagents) or costs of contracting with a third-party laboratory with corresponding transportation of samples.
	References:
	 Man MY, Shum HP, Yu JSY, Wu A, Yan WW. Burden of pneumococcal disease: 8-year retrospective analysis from a single centre in Hong Kong. Hong Kong Med. 2020;26(5):372-81 Soto-Nogueron A, Carnalla-Barajas MN, Solorzano-Santos F, et al. Streptococcus pneumoniae as cause of infection in infants less than 60 days of age: serotypes and antimicrobial susceptibility. Int J Infect Dis. 2016; 42:69-73.
	• Hawkins P, Mercado E, Chochua S, et al. Key features of invasive pneumococcal isolates recovered in Lima, Peru determined through whole genome sequencing." Int J Med Microbiol 2017; 307 (7):415-421.
Expected Approximate Monetary Range of Grant Applications:	• Individual projects requesting up to \$60,000 will be considered. For projects requiring third-party lab services for serotyping and the corresponding transportation of samples, up to an additional \$30,000 (total \$90,000) will be considered. The estimated total available budget for this RFP is \$600,000 .
Key Dates:	• RFP release date: July 18, 2022
	Grant Application due date: August 29, 2022
	Please note the deadline is 23:59 Eastern Standard Time (e.g. New





	York, GMT -5).
	Anticipated Grant Award Notification Date: October 2022
	 Project End date: 6 months upon contract execution
	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:	• Please go <u>www.cybergrants.com/pfizer/Research</u> and sign in. First-time users should click "Create your password". [Note: there are individual portals for each grant application type (e.g., knowledge, LOI, research full proposal, and QI full proposal). Please be sure to use the URL above.]
	Click the "Start A New Research Grant Application" button.
	In the application:
	 For the question "Competitive Grant?" select Yes
	 Select the following Competitive Grant Program Name: 2022 VAC LATAM: Review and Analysis of Retrospective, Local Source, Serotype Distribution for Invasive Pneumococcal Disease for Latin America
	 Select the following Primary Area of Interest: Vaccine Preventable Disease-Pneumococcal
	Requirements for submission:
	Complete all required sections of the online application and upload your project proposal (see Appendix) in the Proposal/Protocol 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 (<u>MiguelAngel.Briceno@pfizer.com</u>), with the subject line " <i>Review and Analysis of Retrospective, Local Source, Serotype Distribution for Invasive Pneumococcal Disease</i> ".
	 Please click <u>here</u> to view Frequently Asked Questions regarding the Competitive Grant Program
Grant Agreements:	 If your grant is approved, your institution 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. Pfizer has drafted the terms of these agreements to be balanced and reasonable and to further the goals of both parties. Negotiating grant agreements requires significant resources, so please ensure that your institution (including your legal department) is able and willing to abide





	by these terms before proceeding with submission of your application as they will need to be accepted in their entirety.
Review and Approval Process	 Grant requests received in response to a general RFP are reviewed by Pfizer to make final grant decisions.
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.





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Appendix A General RFP Submission Requirements

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. Please include the following:

Goals and Objectives	 Provide the main goal of the study and the study population (if applicable). Provide a detailed definition that is directly linked to the primary objective
Assessment of Need for the Project	• This should reflect your study rationale. Provide a brief description of the medical/scientific question and the rationale of how this trial or study addresses the question
Target Audience	 Describe the primary audience(s) targeted for this project. For Investigator Sponsored Clinical Trials, please specify the age, gender and other demographic information for trial population
	 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 concisely the research design and methods for achieving the stated goals. For a clinical interventional study, include inclusion/exclusion criteria, treatment plan and statistical plan
Innovation	• Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects. 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	 Specify type and frequency of safety, efficacy, and/or outcome measures. Also indicate the method(s) used to assess measures
	 Provide a publication plan describing intended submission of abstracts to (a) congress(es) or intended submission of (a) publication(s) to peer- reviewed journals.
Anticipated Project Timeline	 Provide an anticipated timeline for your project including project start/end dates
	 An ISR grant request cannot be submitted for a study that has already commenced and was not originally supported by Pfizer.
Additional Information	 If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here
	 Early-career applicants: Letter(s) of support from mentor(s) and





	collaborators describing how the award will advance the applicant's career.
Organization Detail	• This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used [laboratory, animal, clinical and "other"]. If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project
Budget Detail	While estimating your budget please keep the following items in mind:
	 General organizational running costs such as insurances, heating, lighting, rent, building maintenance may be included. 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 project budget.
	 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 Pfizer therapeutic agents (prescription or non- prescription).
	 Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects. Please <u>click here</u> for details.
References	Bibliography of relevant references.



