Pfizer Research Call for Collaborator(s)

Global Call for Collaborators – Pfizer RSV OA Research

Competitive CFC Research Program – Pfizer Internal Review Process

Overview

This competitive call for collaborator(s) (CFC(s)) seeks to identify investigators with innovative research proposals who are interested in partnering with Pfizer and potentially other likeminded investigators on co-developing research studies focused on the respiratory syncytial virus (RSV) vaccine (Pfizer – Abrysvo) in adults (RSV). Proposals selected from this CFC(s) will work in collaboration with the Pfizer medical team to co-develop a research project and final study protocol. In all studies, the investigator will be the regulatory sponsor of the study.

Geographic Scope/Location of Project

Global

Project Types and Area of Interest

Respiratory syncytial virus (RSV) is a common cause of lower respiratory tract disease (LRTD) among adults and can lead to serious morbidity and mortality, especially among older adults and adults with underlying comorbidities, such as immunocomprising conditions.

The intent of this CFC is to identify investigators with research ideas who want to partner and co-develop research studies with Pfizer. Projects may also potentially involve other investigators if multiple proposals share similar objectives and methodological approaches. In these instances, Pfizer, along with the investigators, may pursue a single research study with multiple sites if all parties agree. This CFC will be a two-step process. The first step will be for investigators to submit a Letter of Intent (LOI) providing a high-level synopsis of the proposed project. In the second step, LOIs will be selected for further development into a potential research collaboration with Pfizer.

Key Milestones

- Application submission deadline: **March 31, 2025**
- Anticipated decision notification date: **May 6, 2025**
- Anticipated project start date: **Target end of July 2025**

Maximum Funding Range and Study Duration

Our intent is to support 1 to 3 studies. Study design for a single site, up to **$500,000 USD**, for a length of **12 months**.

Pfizer

I. Eligibility

Geographic Scope/Location of Project/Study:

- Global

Applicant Eligibility Criteria

- The institution and Principal Investigator (PI) must be based in one of the eligible countries.
- Only organizations are eligible to receive funds and in-kind support, not individuals or medical practice groups (i.e., an independent group of physicians not affiliated with a hospital, academic institution, or professional society).
- If the project involves multiple departments within an institution and/or between different institutions / organizations / associations, all institutions must have a relevant role and the requesting organization must have a key role in the project.
- The PI must have a medical or postdoctoral degree (MD, PhD, or equivalent), an advanced nursing degree (BSN with a MS/PhD), or a degree in Pharmacy, Physiotherapy, or Social Work.
- The applicant must be the PI or an authorized designee of such individual (e.g., PI's research coordinator).
- The PI must be an employee or contractor of the requesting organization.
- If selected, the PI and their organization are willing and able to engage in a Research Collaboration with Pfizer; see definition of 'Research Collaboration' further down for details.
    - For all Research Collaborations (RCs), the selected principle investigator is responsible for the design, implementation, sponsorship, and conduct of the initiative supported by the RC, including compliance with any regulatory requirements.

      Pfizer may be involved in the design of the study protocol and project development, as well as the conduct or monitoring of the research program. Preference will be given to PIs that are open to collaborative agreements with other institutions with similar research interests.
- Requesting organization 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. Funding awarded to organizations that are subsequently found to be unable to accept funding directly from Pfizer Inc. may be cancelled.

II. Requirements

Date CFC Issued

- **February 27, 2025**

Clinical Area

- **Infectious Disease - Respiratory Syncytial Virus (RSV)**

General Area of Interest for this CFC:

Projects that will be considered for Pfizer support will focus on the immune response of **severely immunocompromised adults** to Abrysvo vaccine.

Under this LOI submission, applicants must utilize the CFC template found in Cybergrants to submit a **high-level synopsis** of the proposed research study (maximum of 3 pages). The research study must focus on one (or more) of the following:

Respiratory syncytial virus (RSV) is a common cause of lower respiratory tract disease (LRTD) among adults and can lead to serious morbidity and mortality, especially among older adults and adults with underlying comorbidities, such as immunocompromising conditions. Pfizer's Abrysvo vaccine is now approved and recommended among older adults in the US and several countries globally. While Abrysvo has been shown to be effective, immunogenic, and efficacious among older adults and adults with comorbidities including immunocompromising conditions, Pfizer wishes to expand available data among severely immunocompromised persons. An overview of previous immunogenicity results for immunocompromised adults for Arbysvo is available at: **PowerPoint Presentation**.

In your proposal, please include the following:

1. Describe post-vaccination immune response to Pfizer's Abrysvo vaccine among severely immunocompromised adults ≥ 18 years of age. Examples of severely immunocompromising conditions include but not limited to hematopoietic stem cell transplant, B-cell depletion therapy, and lung transplant.
2. Provide a definition of severely immunocompromised and include a justification of this definition. Briefly outline the experimental design and approach.
3. The specific severely immunocompromised populations proposed to study.
4. The planned mechanism of recruitment or access to the targeted immunocompromised populations or related data to enable conduct of the study.
5. Type and proposed recruitment approach to any comparison group(s) to be used.
6. The timing of serology sampling.
7. The type of serology proposed to be conducted by your site.
8. The process to store residual serum for testing by Pfizer.

The following research studies are out-of-scope and will not be considered:

- Topics duplicative to on-going or planned trials
- Studies among pediatric populations (<18 years old)

Based upon the LOI review:

- Applicants will be selected and requested to submit a full proposal application under a Pfizer Research Collaboration. Selection of an LOI for further development does not obligate the investigator to enter into a research collaboration agreement with Pfizer if mutually agreed upon terms cannot be met.
- In circumstances where multiple proposals are sufficiently aligned to explore multisite collaborations, LOI details will not be shared across applicants without their express permission.
- No research idea will be shared outside of Pfizer.

Pfizer Policy on Submission of Research Proposal:

- Any information or materials submitted to Pfizer by applicant related to a submission are non-confidential and will not contain any markings claiming confidentiality. Applicant acknowledges that Pfizer will not treat such information or materials as confidential or assume any obligation to keep them confidential. Applicant acknowledges that Pfizer may conduct ongoing or future research substantially similar or identical to any concepts submitted.
- Pfizer refers applications to a number of colleagues working for or on behalf of Pfizer to determine if a proposal is of interest and will be supported. While Pfizer will use any information or material submitted only for internal purposes and has no intention of publicly disseminating anything submitted in

connection with a proposal, Pfizer assumes no obligation to keep any information or material submitted confidential. You agree that any information or material you submit to Pfizer during the application stage, or subsequently, is non-confidential and will not contain any markings claiming confidentiality and you acknowledge that Pfizer will not treat such information or material as confidential or assume any obligation of confidentiality.

- It is Pfizer policy to consider research proposals from person outside Pfizer upon the following condition.
    a. That the submission is not made in confidence and is not accompanied by any reservation or condition whatever which imposes upon Pfizer any obligation or restriction with regards to its use.
    b. That the submitter's rights shall be only those given under the patent law as and/or under any written contract to which the submitter and Pfizer may mutually agree.
    c. That the submitter is the originator of the information and materials or has been authorized by the originator to provide information and materials on their behalf.
- By submitting your proposal, you agree to the following:

    I acknowledge that I have read the above statement "Pfizer Policy on Submission of a Research proposal", which sets forth Pfizer's policy on the submission of proposals and ideas by persons from outside Pfizer. I agree that I am not submitting any confidential information in making this submission, and I agree to be bound by the terms and conditions set forth in the policy statement. I acknowledge that Pfizer may conduct ongoing or future research identical to my proposal or ideas. In consideration for your examining my proposal and idea, to the fullest extent allowed, I release your company from any and all liability for use of all or any portion thereof, other than infringing uses of my proposal or ideas that are protected by patent.

Expected Approximate Monetary Range of Funding Support:

- Individual single-site projects requesting up to **$500,000 USD** will be considered.
- Award amounts include direct costs, institutional overhead costs, and indirect costs. For overhead costs above Pfizer's allowable limit of 28%, a strong justification will need to be included.

Key Dates:

CFC Release Date: **Feb 27, 2025**

LOI Due Date: **March 31, 2025**

- **Note: Cybergrant Application Portal will be available for application submissions starting March 14, 2025**

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

Anticipated Notification of Selected Proposal Date: **May 6, 2025**

Full proposal submission (under a Research Collaboration) Due Date: **June 1, 2025**

- Only selected LOIs will be invited to submit full research protocol.
- Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).

Sign contract and finalized research protocol by: **Target July 1, 2025**

- Support will be distributed following a fully executed agreement and submission of Final Research Protocol, documentation of IRB/IEC approval, regulatory approval (if applicable), exemption or waiver.

Anticipated project duration (LOI selection to final study report): **12 months**

How to Submit:

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

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

- Click the "Start a New CFC LOI" button.
- In the application:
  - Select the following Competitive CFC Program Name: **2025 VAC Global RSV OA CFC RES**
- Select the following Primary Area of Interest: **VAV - RSV (Respiratory Syncytial Virus) – RC**
  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 CFC, please direct them in writing to the Grant Officer, Sue Lee (sue.lee@pfizer.com), with the subject line **"Global Call for Collaborators –2025 VAC Global RSV OA CFC RES, Feb 2025"**

Research Collaboration Agreements:

- Selection of an LOI for further development does not obligate Pfizer to enter into a research collaboration agreement if mutually agreed upon terms cannot be reached.
- If your proposal is selected and you choose to proceed with a research collaboration with Pfizer, your institution will be required to enter into a written research collaboration agreement with Pfizer.
- This CFC is supported by Pfizer Inc. and, if approved, payment will be sent from the United States.
- Except where prohibited by applicable law and, in any case, subject to review by Pfizer, payment of funding may only be paid to the collaborator organization.

Review and Approval Process

- There will be a two-step review process. The first step will be a Letter of Intent (LOI) submission to provide a high-level synopsis of the proposed project; applicants must utilize the CFC template to submit completed application via Cybergrants portal. In the second step, LOIs will be selected for further development into a research collaboration with Pfizer.
- Proposals received in response to the CFC are reviewed by Pfizer to make final selection decisions.
- Proposals selected for co-development under a Pfizer research collaboration will be notified of decision.
- In circumstances where multiple proposals are sufficiently aligned to explore multisite collaborations, LOI details will not be shared across investigators without their express permission.

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.

About Pfizer Global Medical Grants & Partnerships

Pfizer Global Medical Grants & Partnerships (GMGP) 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 GMGP CFC research program involves a publicly posted general Call for Collaborator(s) (CFC(s)) 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 decisions. Organizations are invited to submit an application addressing the research gaps as outlined in the specific CFC.

About Pfizer Research Collaboration

Research Collaboration (RC) allows Pfizer to partner with investigators and organizations (Collaborators) to generate innovative research of potential scientific value to patients, physicians, and the greater scientific community. Collaborators may be academic institutions, research networks, cooperative groups, government agencies or other entities.

Pfizer's evaluation of a proposed RC is based on scientific merit, strategic fit and the Collaborator's qualifications and ability to perform the research. All RC submissions undergo both a scientific as well as a standard due diligence review. As a result, Pfizer may engage in preliminary due diligence activities which may involve the exchange of confidential information, review of processes, systems, training etc. relating to the research infrastructure and study conduct.

Note that RC engagements are not structured (or contracted) as industry-sponsored research nor as investigator-sponsored research (ISR), also commonly referred to as Investigator-Initiated Research (IIR) or Investigator-Initiated Trial (IIT). RCs are hybrid undertakings where Collaborator assumes regulatory sponsorship, safety reporting duties and responsibility for its research personnel, sites and subcontractors, and Pfizer contributes intellectual input along with various forms of research support. In return for its input and support, Pfizer expects certain monitoring and audit rights to ensure data quality and integrity, as well as the ability to use data and inventions generated from the RC.

By acknowledging these terms and agreeing to Pfizer's RC submission policy, it does not place either party under any obligation to finalize and sign any additional agreement, nor to provide funding or other support of any kind. Prior to execution of a definitive Research Collaboration Agreement, either party may determine not to proceed with the RC at any time and for any or no reason.

Following Pfizer's internal scientific and diligence reviews, if there is mutual agreement to proceed with the RC, Pfizer will prepare a form of Research Collaboration Agreement. Collaborators should be prepared to dedicate resources to review and negotiate this unique collaboration agreement which will include, among others, provisions detailing monitoring and audit rights, data quality and transfer requirements, indemnification, record-keeping, publications, and insurance.

By submitting a proposal, you certify, on your own behalf as well as on behalf of your organization, that, if approved, (i) the proposed RC has not been and will not be conditioned on or related, in any way, to: (a) any pre-existing or future business relationship with Pfizer; or (b) any business or other decision made or may be made, relating to Pfizer or its products (including coverage or Aug-23 formulary status decisions); (ii) the Collaborator agrees to the confidentiality terms described on **Exhibit A**; and (iii) the Collaborator will use good faith efforts to negotiate the Research Collaboration Agreement as described above and summarized on **Exhibit B**.