Pfizer's Support of Independent Research

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Introduction

Pfizer supports the global healthcare community's independent initiatives to improve patient outcomes in areas of unmet medical need that are aligned with Pfizer's medical and/or scientific strategies.

The GrantSeeker (Requester), and ultimately the Grantee (Requesting Organization), is responsible for the design, implementation, sponsorship, and conduct of the independent initiative supported by the grant, including compliance with any regulatory requirements.

Investigator Sponsored Research

Pfizer supports Investigator Sponsored Research (ISR) projects that advance medical and scientific knowledge about our therapies.

An ISR is a type of grant that supports an independent research study where the investigator or organization is the sponsor of the study and where Pfizer provides financial and/or non-financial support for the development or refinement of specific and defined medical knowledge **related to a Pfizer asset**. This global program is open to all researchers who are interested in conducting their own research. This grant type is used as support for pre-clinical and clinical studies (including interventional and non-interventional), that involve a Pfizer asset (e.g., commercial drug, investigational drug, pure compound*).
**Pfizer has an extensive pure substance library that encompasses our publicly known compounds.*

General Research

Pfizer also supports general research projects focused on the development or refinement of specific and defined medical knowledge **unrelated to a Pfizer asset**.

This grant type is used to support research that does not include the study of a Pfizer asset, including health services research unrelated to a Pfizer asset, registry development and/or queries unrelated to a Pfizer asset, and outcomes research unrelated to a Pfizer asset. This includes observational studies, such as epidemiology studies and certain outcomes research studies where the primary focus is the scientific understanding of disease as well as other types of independent research on disease states.

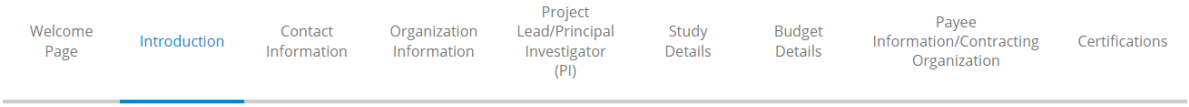
IMPORTANT: Pfizer has implemented application windows for unsolicited requests. Please click here to view the Application and Batched Review Cycles.

General Submission Requirements

- All fields must be completed in English and any uploaded documents must be in English
- If approved, the requesting organization will be the contracting organization to which the grant will be paid
- Pfizer cannot provide grants to individuals, individually owned private physician practices or informal groups which are not legal entities
- To submit your request to Pfizer you must answer all questions in the online application system available at http://www.cybergrants.com/pfizer/Research

Overview of Research Grant Application

The research grant application is divided into the following sections.



Introduction

The GrantSeeker (requester) will be asked to agree to the following:

Pfizer Policy on Submission of a Research Proposal

Pfizer refers grant 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 grant, 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 grant 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 persons outside Pfizer upon the following conditions: 1. 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 regard to its use. 2. That the submitter's rights shall be only those given under the patent laws and/or under any written contract to which the submitter and Pfizer may mutually agree. 3. 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.

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.

Financial Disclosure by Pfizer

In the interest of transparency relating to its financial relationships with investigators and study sites, Pfizer may publicly disclose the funding associated with a Research Agreement. Such reports by Pfizer may differentiate between payments made to institutions and payments made to individuals. For more information, please click on the following link which will take you to Pfizer Responsibility-Grants & Payments on the Pfizer website. In addition, Pfizer reserves the right to announce the details of successful grant application(s) by whatever means insures transparency, such as on the Pfizer website, in presentations, and/or in other public media. All approved proposals, as well as all resulting materials (e.g., status updates, outcomes reports, etc.) may be posted on the GMG website and/or any other Pfizer document or site.

Contract Agreement Terms:

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. Pfizer has recently revised its grant agreement templates based on feedback from both internal and external stakeholders. 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.

Please provide the name and email address of the individual at your Organization that is authorized to sign the contract if this grant is approved. Pfizer only requires one signature.

Information required:

- Authorized Signatory Name
- Authorized Signatory Email

Contact Information

GrantSeeker (requester) must enter or select contact details to associate a named contact with the grant application. If not the requester, the Primary Investigator's details should also be added as a contact.

Information required:

- Salutation (Title)
- First name
- Last name
- Title/position
- e-mail address
- contact number

Organization Information

In this section the GrantSeeker is asked to review their Registration Profile information and provide eligibility confirmation. If the organization name or Tax ID is incorrect, contact globalmedicalgrants&partnerships@pfizer.com.

The Organization associated with the request application will be considered the contracting
Information required:

- Confirmation that organization is NOT a group practice or an individually owned private physician practice
- Legal entity name
- Tax ID number
- Organization type
- Country
- Address & Zip/postal code

Project Lead/Principal Investigator

Any relevant CV/bio-sketch information should be entered in the online fields. If the study involves a Co-Investigator that information should be entered here as well. Please note that a CV/bio-sketch cannot be uploaded to the research grant application.

The information you provide will be used for the purpose of evaluating the application. Please do not include any personally identifiable information unrelated to the grant request such as personal email, home address, personal phone number or marital status.

Note: the PI must serve as the Primary Safety Contact.

The PI will be asked to certify information entered is accurate and complete.

Information required:

- PI First Name
- PI Middle Name
- PI Last Name
- PI Email
- Confirmation of licensure
- PI Work Address
- PI Current Position Title
- PI Primary Degree
- Institution and Location of Primary Degree
- Completion Date of Primary Degree
- Field of Study
- PI Secondary Degree
- Institution and Location of Secondary Degree
- Completion Date of Secondary Degree
- Field of Study of Secondary Degree
- PI Positions and Honors
- PI Contributions to Science
- Additional PI Information regarding Research Support and/or Scholastic Performance
- If relevant, Co-Investigator name, primary degree, email

Study Details

Information required:

- Confirmation if any study objective involves assessing some clinical effect or outcome related to a Pfizer medicinal product (e.g., efficacy or safety)?
- Project type – selected according to Project Classification Decision Matrix
- Grant request type – Funding only, Funding & Drug^, Funding, Drug & Compound^, Funding & Compound^, Drug only^, Compound only^
- If Project type = ISR – confirmation of Pfizer drug of interest
- Primary Area of Interest
    - If Area of Interest = Vaccines, see additional Vaccines section below[1]
- Secondary Area of Interest
- Confirmation if applying to a Competitive Grant Program Request for Proposal (RFP)
    - Name of RFP
- Confirmation if same project previously submitted
- Study title
- Abstract summary
- Protocol/Full Proposal upload
- External ID number (if assigned by requesting organization)
- Estimated Study start date
- Estimated Study end date
- Confirmation if project related to Opioids/Pain
    - If yes, Opioid/Pain attestation
- Confirmation if project offers CME credit
- Research setting
- Primary country site
    - If multi-site, multi-select available
- Confirmation if study involves genetics/genomics
- Primary & Secondary End Points
- Total subject enrolment
- If ISR Clinical/Pre-Clinical selected following information collected:
    - Study type – Clinical/Pre-Clinical
        - If Clinical – sub-type, Epidemiology/Interventional/Observational/Outcomes Research/Retrospective
            If Interventional – confirmation if Blinded
            If Retrospective – design type: Single Select: Case-controlled, Co-hort, Other
- Age group of study population
- Ethnicity of study population
- Length of enrolment
- Date of Estimated First Patient Enrollment
- Estimated CTA Submission Date
- Question: Does your study involve genetics or genomics?
- Question: Does your study involve Pfizer Expanded Access (also referred to as Compassionate Use/Named Patient Programs) patients?
- Question: Does your study involve Pharmacokinetic (PK) or Pharmacodynamic (PD) sample analysis?
    - If yes, see PK/PD section below*
- Study Phase – I-IV
- Study Design – Cross-over, Double Blind, Open Label, Single Blind, N/A
- Confirmation of randomization

- Total subject enrolment
- Number of arms
    - For each arm – treatment plan, Pfizer drug, non-Pfizer drug, #subjects
        - If Pre-Clinical - In vitro/In vivo/Both In-vitro & In vivo
            - For In vitro – human tissue collection confirmation
                - Type of human tissue collected
            - For In vivo – animal type
            - For In Vitro & In vivo – animal type & human tissue confirmation & type

Planned Results

Information required:

- Target date to provide results to Pfizer
- Question: Plan to publish?
    - If Yes, Publication type, date of first anticipated publication, notes box
    - If No, Reason for not publishing

Drug/Compound Questions^

Information provided:

- *Drug/Compound Disclosure Statement*
  Pfizer will strive to provide drug as requested within the grant submission. However, provision of drug for grant requests cannot negatively impact the drug development process or the product needs for ongoing or endorsed internal clinical trials. As such, in some instances, Pfizer may offer to provide alternative drug presentation based on study design.

- Vendor Services Statement: Pfizer drugs may be provided in the form of bulk supply in a large container/carton to ONE site and WILL NOT include institutional, investigator or study information. As the study sponsor, your Institution is responsible for any re-labelling or special packaging of the Pfizer product needed to make it appropriate for use in the Study, and the management of the distribution of Pfizer product to your participating sites, as applicable.
    - Question: Will you be using a vendor for the packaging, labeling and/or distribution of drug for this study?
        - If Yes, Vendor Services Note: Please ensure cost for these activities is included in the study budget
        - If No, In-House Services Affirmation: You have indicated that you will not be using a vendor for the packaging, labeling, and distribution of drug for this study. If there are any costs associated with these services you should include them in the Other Fees section of your budget. Please confirm that your organization has the capability to perform these services in-house. If your organization cannot perform these services then you must obtain the services of a vendor and change the answer to the Vendor Services question.

If Funding & Drug, Funding, Drug & Compound or Drug only selected, information required:

- Number of Pfizer Drugs Requested – 1-6
- Question – are all Pfizer drugs commercially available in the country the study is being conducted?
- For each Pfizer drug requested
    - Select Pfizer drug from drop down list
    - Question: Is this drug commercially available in the country the study is being conducted?
    - If yes, question: Will you be using drug for its labelled indication in this study?
    - Strength, Formulation, Quantity details

- Question: Does your study design require placebo? Note: Pfizer may not have developed placebo for the drug requested

If Drug requested:

- Information provided:

PK/PD Sampling Questions

Information provided:

Pfizer Proprietary Assays
To ensure consistency, accuracy, and precision of PK/PD results across all clinical studies (including ISR trials), PK or PD sample analysis involving Pfizer compounds may be conducted at Pfizer-approved bioanalytical laboratories (CROs) using Pfizer proprietary assays. The Pfizer-approved CROs have developed and validated the assays with oversight by the Pfizer Clinical Assay Group. Pfizer will not provide investigator/sponsors (requesters) with Pfizer drug substances for the development of or with the details of any proprietary bioanalytical assays for use at their own facilities. These requirements do not apply to non-Pfizer compounds (e.g., co-administered drugs, comparator drugs) for which readily available assay methods may exist.

Contracting with the CRO using Pfizer's proprietary assay
The requester will be responsible for contracting the PK/PD sample analysis work with the Pfizer approved contract bioanalytical laboratory and obtaining the data. If Pfizer approves the PK/PD analysis (PK/PD study design and funding) then the Pfizer Clinical Assay Group will issue an authorization letter to the contract bioanalytical laboratory allowing the use of the Pfizer proprietary assay that is study specific. The contract process may then begin between the requester and contract bioanalytical laboratory.

Bioanalytical Study Report included
No method details of the proprietary assay will be provided but the contract bioanalytical laboratory will provide a bioanalytical study report containing the concentration data, bioanalytical plan, and assay performance of the batch runs including the statistics of the calibration standards and quality control samples. Please contact Pfizer if any assay information is needed for a publication.

PK/PD Sample Handling Instructions
The Pfizer Clinical Assay Group will provide the sample handling, processing, and storage (e.g., temperature and validated long term stability period) instructions for the PK/PD sample collection to ensure that samples are collected in accordance with the proprietary assay. If the matrix is plasma then the instructions will include the anticoagulant.

PK/PD Sample Kits/Tube Labels and Shipments
The requester is responsible for ensuring that the appropriate PK/PD sample collection kits (e.g., collection and storage tubes) and tube labels (e.g., Protocol#, Investigator Name, Subject ID, Matrix, Analyte, Nominal Visit/Time Point) are used. In addition, the sample shipment(s) sent to the contract lab is to be scheduled so that the samples are analyzed within the validated stability period for the analyte in matrix. All shipments require that PK/PD samples are shipped on dry ice (unless it is a special case), so for international shipments please use a shipping courier that will monitor the samples and replenish the dry ice.

Information required:

- PK/PD Agreement - Requester must agree to the terms above in order to request PK/PD Analyte Samples

- Confirmation of number of analytes involved in study
    - For each analyte: names of analyte, types of matrix to be collected
- Estimated number of subjects participating in PK/PD part of study
- Nominal visits and time points
- Number of samples to be analyzed
- Co-administered drugs, if applicable

Vaccine Specific Questions[1]

Information required:

- Question: Does this study collect specimens for shipment to Pfizer Laboratories for assay testing?
    - If Yes, Assay(s) Requested – UAD1, UAD2, OPA, IgG

Budget Details

Information provided:

Independent medical grants must not be used to support infrastructure expenses (e.g. equipment, technology, bricks and mortar). Examples of equipment include, but are not limited to: Computers, iPhones, tablets, appliances, machinery, camera equipment, sensors etc. Equipment rental is acceptable and may be included in the project budget.

Pfizer does not directly pay invoices for independent medical grants. Please ensure costs for any study related invoices (i.e. IRB/EC fees) which are to be paid by requesting organization, are included in the project budget.

In-House Services: Question: Do you plan on using in-house services (in lieu of, or in addition to, third party vendors) to assist in the execution of this project/activity? For example, graphics, marketing materials, audio/visual, etc. If your request is approved and you have answered yes to this question you must provide copies of all internal invoices/charges at the time of completing the reconciliation.

Information required:

- Currency code
- Confirmation budget does not include capital expense items
- Direct Labor Costs
    - Populate worksheet with total labor costs, hourly rate & percentage effort, per role (if relevant)
        - Primary Investigator
        - Sub PI
        - Coordinator
        - Study Nurse
        - Data Manager/Entry
        - Medical Writer
        - Statistician
        - Pharmacist
        - Administrative
        - Project Manager
        - Lab Technician
        - Regulatory

        - Post Doc
        - Fellow
        - Patient/Caregiver Consultant
        - Other
- Direct Study/Project Costs
    - Populate worksheet with relevant budget line-item totals for the following items:
        - Publication costs
        - Supplies/consumables
        - Materials/Communications
        - Program/Content Developer
        - Procedures/Tests/Assessments
        - Travel
        - Statistics/Biostatistics
        - Study Start Up Costs
        - Monitoring
        - Other Fees
        - Meeting Logistics
        - Study Participant Stipend
        - One Time Fees
        - Participant Reimbursement

Other Details

Information required:

- If amount entered on Other Fees line, further details required to provide description of funding required
- Institutional Overhead Percentage to be charged, if applicable
- Requested Amount from Pfizer – should match the total budget
- Confirmation of Other Sources of Support
    - If Yes, Specify Support and Source
- Budget narrative, as applicable
- W-9 Form upload (for organizations based in US) W-9 Form can be downloaded from the IRS website

Payee Information/Contracting Organization

Information provided:

Payments can be made to an AFFILIATED foundation (not-for-profit organization). Under no circumstances will Pfizer make payments to Partners/Collaborators; only to the requesting organization or an affiliated foundation. Payments will not be sent to P.O. Boxes.

Information required:

- Question: Do you require payment to be made to an Affiliated Foundation?
- Confirmation of existing payee information/contracting organization as associated with grantseeker profile

Certifications

Information provided:

Requesters will be asked to agree to the following Compliance Certification:

Please read the following certification carefully. You must certify the following before you can submit your request to Pfizer for consideration. Please certify your agreement by clicking "I agree".

You certify that you are an active employee of the requesting organization, with the responsibility and authorization to apply for financial support from Pfizer.

You certify that you have no knowledge that Pfizer has had involvement in the creation or development of this project.

You certify that, if approved, the source of all support from commercial interests must be disclosed in all publications and presentations. When commercial support is "in-kind" the nature of the support must be disclosed to learners.
You certify that, if approved, you will provide Interim Reports every six months throughout the lifecycle of the project, as well as a Final Report at the conclusion of your project. You also agree to provide monthly patient enrollment reports for clinical studies involving human subjects.

You certify that, if approved, in the performance of all activities related to an independent medical grant, you and all participants must comply with all applicable Global Trade Control Laws. “Global Trade Control Laws” include, but are not limited to, U.S. Export Administration Regulations; the International Traffic in Arms Regulations; EU export controls on dual-use goods and technology; Financial Sanctions Laws and Restrictive Measures imposed within the framework of the CFSP - Treaty on European Union; and the economic sanctions rules and regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control.

You certify that, if approved, the grant 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 formulary status decisions).

Further you certify that you are authorized to submit an application and provide information in an application on behalf of the requesting organization and any partner organization(s), and you affirm that all responses and information provided in this application are truthful, accurate and complete. Your certification also represents that neither you nor your organization's directors, trustees, and/or anyone who will be involved in the project(s) that will be funded by this grant are on the OIG debarment list.

Please note, if the request is approved you will be required to sign a contract which includes additional terms and conditions as they relate to the execution of the request.

For all ISR studies using a Pfizer Product and/or Device:
For Investigator Sponsored Research (ISR) studies where the product under study is sourced directly by Pfizer or obtained from supplies on the market and used as per standard of care: the Grant Seeker is required to submit AE/SAEs to Pfizer.

Reporting Timeline: Pfizer requires the Grant Seeker to notify Pfizer within 24 hours of first awareness or secure email exchange any Adverse Event (AE) [serious and non-serious, as applicable] that occurs during the reporting period in a study subject assigned to receive the Pfizer product. In addition, studies using a Pfizer device or Pfizer product packaged with a device, reportable events include not only AEs but also Device Incidents Malfunctions.

Reporting Forms: Principal investigator will report qualified adverse events using the applicable Pfizer ISR/CRC Adverse Event Report Form or approved local regulatory form (i.e. FDA MEDWATCH, CIOMS, etc.) with the AE/SAE Fax Cover Sheet provided by Pfizer. Grant Seeker may use the institution AE report form provided it is preapproved by Pfizer Safety Leads. SAEs/AEs should be reported as soon as they are determined to meet the definition, even if complete information is not yet available.

Reporting Period: Reportable Events subject to this provision are those that occur from after the first dose of the Pfizer product through at least 28 calendar days after discontinuation of the Pfizer product or longer as specified by the protocol. In addition, any AE/SAEs which occur after active reporting period and are considered related to study drug(s) by investigator should be reported to Pfizer.

Follow-up Information: Institution and/or Grant Seeker will assist Pfizer in investigating any SAE/AE and will provide any follow-up information requested by Pfizer.

Regulatory Reporting: Reporting a SAE/AE to Pfizer does not relieve the institution and/or principal investigator of the responsibility for reporting it to the FDA or local regulatory authority, as required.

Final protocol: Safety language in the Final Protocol developed by the Grant seeker should always be cross-checked, by the Grant seeker/study team, with the safety language written in contract to make sure these two documents are aligned.

Special consideration for Multiple-site studies: For multi-site studies, lead institutions often use one single point of contact or data coordinating center. This process may be acceptable by Pfizer provided the following terms are met and will be described in the contract with the sponsor:

a. Study may be multi-national.
b. All investigators from each site must report to a single, well established data coordinating center.
c. Pfizer must only receive AE/SAEs from this single and well-established data coordinating center.
d. In such scenario, Pfizer receipt date is the date on which the information is provided to the data coordinating center. Given such, the data coordinating center must document its receipt date on the approved adverse event report form.
e. This single data coordinating center must be responsible for independently initiating and performing all follow-up activities with each individual investigator for missing and/or incomplete medical information for every AE/SAE.
f. Single data coordinating center must agree to accept Pfizer queries/request for additional information about the AE/SAEs and follow up with the investigator until resolution.
g. SAE information provided to Pfizer must not contain any Privacy information.
h. Everything must be exchanged in English.

Principal Investigator agrees to the Pfizer Policy terms listed above and downloaded the relevant documents from within the application.