



Pfizer Announces
Biosimilars Research in Solid Tumors
Investigator Sponsored Research (ISR) Competitive Grant Program

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.



II. Eligibility

Geographic Scope:	Countries where Pfizer's trastuzumab and bevacizumab biosimilars have received regulatory approval
Applicant Eligibility Criteria	<ul style="list-style-type: none"> • The institution and principal investigator (PI) must be based in one of the eligible countries noted above. • Only organizations are eligible to receive grants, not individuals or medical practice groups. • The applicant (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. • Applicant must be affiliated with a host institution

III. Requirements

Date RFP Issued	September 10, 2019
Clinical Area	Oncology - Biosimilars: trastuzumab-qyyp or bevacizumab-bvzr
General Area of Interest for this RFP:	<p>Proposals for interventional, non-interventional, basic science, or other studies that include but not limited to:</p> <ul style="list-style-type: none"> • Demonstrate the value or economic benefit of the biosimilar • Incorporate Real World Data and/or Patient Reported Outcomes • Evaluate the integration of the biosimilar with a standard-of-care regimen in an approved indication not previously evaluated • Explore rational treatment combinations with other Pfizer medicines <p>Out of Scope:</p> <ul style="list-style-type: none"> • Head-to-Head Comparative clinical trials of the biosimilar versus the originator drug • Studies in a country in which the biosimilar has not received regulatory approval • Country in which commercial supply of the biosimilar is not available (there may be very limited exceptions) • Pediatric Trials

<p>Expected Approximate Monetary Range of Grant Applications:</p>	<ul style="list-style-type: none"> • The estimated total available budget related to this RFP in 2019 is \$500,000. Additional funding available for study payments in 2020 and 2021. • Grant monetary size may vary and there is no stated maximum. • Approximately 4-6 are studies are expected to be supported
<p>Key Dates:</p>	<ul style="list-style-type: none"> • RFP release date: September 10, 2019 • Grant Application due date: October 15, 2019 Please note the deadline is midnight Eastern Standard Time (e.g. New York, GMT -5) • Anticipated Grant Award Notification Date: October 30, 2019 • Grants will be distributed in milestone payments following a fully executed agreement • Anticipated Project Start and End Dates: January 2020 to December 2021
<p>How to Submit:</p>	<ul style="list-style-type: none"> • Please go to www.cybergrants.com/pfizer/Research and sign in. First-time users should click “Create your password”. • In the application: <ul style="list-style-type: none"> ○ For the question “Are you replying to a Request for Proposal as part of the Competitive Grant Program?” select Yes ○ Select the following Competitive Grant Program Name: 2019 Oncology G – Biosimilars Research in Solid Tumors ○ Select the following Primary Area of Interest: Oncology – Biosimilars ○ Primary asset name: trastuzumab-qyyp or bevacizumab-bvzr • Requirements for submission: Complete all required sections of the online application and upload your Full 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. <p>IMPORTANT: Be advised applications submitted after the due date will not be reviewed as part of this competitive grants program.</p>
<p>Questions:</p>	<ul style="list-style-type: none"> • If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Jackie Waldrop (Jacqueline.Waldrop@pfizer.com), with the subject line “Biosimilars Research in Solid Tumors.” • Please click here to view Frequently Asked Questions regarding the

	Competitive Grant Program
Review and Approval Process	<ul style="list-style-type: none">• 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:	<ul style="list-style-type: none">• All applicants will be notified via email by the dates noted above.• Applicants may be asked for additional clarification during the review period.

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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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. All publications must follow ICH guidelines
Anticipated Project Timeline	<ul style="list-style-type: none"> • Provide an anticipated timeline for your project including project start/end dates
Additional Information	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none">• 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
References	<ul style="list-style-type: none">• Bibliography of relevant references.