



## Request for Proposals (RFP)

### **ADOPTION OF BIOSIMILARS IN ONCOLOGY**

#### **National Comprehensive Cancer Network® and Pfizer Global Medical Grants**

##### **I. Introduction**

The National Comprehensive Cancer Network® (NCCN) and Pfizer Global Medical Grants (Pfizer) are collaborating to offer a new grant opportunity seeking proposals in support of the adoption of biosimilars in oncology.

The intent of this RFP is to encourage NCCN Member Institutions and non-NCCN Member Institutions to submit proposals describing concepts and ideas that develop and validate enduring approaches that improve the safe and efficient adoption of biosimilars in oncology. Proposals that directly measure increases in biosimilar use or improve safety, value and efficiency in oncology practices will be prioritized. The sustainability and broad applicability of the approach will be key factors in evaluating funded projects.

The National Comprehensive Cancer Network® (NCCN®) is a not-for-profit [alliance of 30 leading cancer centers](#) devoted to patient care, research, and education. NCCN is dedicated to improving and facilitating quality, effective, efficient, and accessible cancer care so patients can live better lives. Through the leadership and expertise of clinical professionals at [NCCN Member Institutions](#), NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. By defining and advancing high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers around the world.

The mission of Pfizer Global Medical Grants is to accelerate the translation of science into quality patient care through independent grants, partnerships, and collaborations. Pfizer Global Medical Grants 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. For all 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.

This RFP is being issued by both organizations. NCCN is the lead organization for review and evaluation of proposals. A review committee, led by NCCN, will make decisions on which proposals will receive funding. **Grant funding and general oversight of the funded projects will be provided directly from Pfizer.** Collectively, \$1.5 Million USD is available for award.

## II. Background

The intent of the RFP is to encourage organizations to submit letters of intent (LOIs) describing concepts and ideas that improve the safe and efficient adoption or utilization of biosimilars in oncology. Emphasis is placed on adding value to the oncology care model through safe and effective use of biosimilars as well as the sustainability and broad applicability across university and community-based practices.

The creation of a sustainable and competitive marketplace for originator biologics and biosimilars has the potential to improve patient access to biologics, increase treatment options, and generate savings and efficiencies for health care systems.<sup>1,2,3</sup>

Based on a recent RAND corporation study that assumes a biosimilar market share of 50% and biosimilar prices that are 50% of the reference product, a savings of \$150 billion in direct spending on biologic drugs could be realized between 2017 and 2026.<sup>4</sup>

The FDA has created several guidance documents to support the development of therapeutic protein biosimilars. Comparative analytics and other quality-related considerations are detailed.

<https://www.fda.gov/vaccines-blood-biologics/general-biologics-guidances/biosimilars-guidances>

A biological product is biosimilar to a “reference product” based upon data derived from:

1. Analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;
2. Animal studies (including the assessment of toxicity);
3. A clinical study or studies (including the assessment of immunogenicity and PK or PD) that are sufficient to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product.<sup>5,6,7</sup>

Based on these analytics, the FDA may grant approval “for a biological product that is administered more than once to an individual, [if] the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.”<sup>7</sup>

Extrapolation is a scientific and regulatory principle that refers to the approval of a biosimilar for use in an indication held by the reference product but not directly studied in a comparative clinical trial with a biosimilar. Extrapolation of efficacy and safety data from one indication to another may be considered if biosimilarity to the reference product has been shown by a comprehensive comparability program including safety, efficacy, and immunogenicity, and there is sufficient scientific justification for extrapolation. Extrapolation is not automatic and is considered only after biosimilarity is established based on the totality of evidence.<sup>1,8,9</sup>

Using this mechanism, numerous therapeutic agents, generally antibodies or supportive agents such as growth factors, are approved and on the market. The expectation is that biosimilars will become increasingly available. However, the safe and efficient adoption of biosimilars in oncology has been challenging. Skepticism regarding the use of biosimilars has been well documented.<sup>8,9</sup> The idea of extrapolating the results of a single pivotal non-inferiority clinical trial to other clinical scenarios has been questioned. Nevertheless, there is great hope that patient access to biologics and treatment options for patients will increase. Additionally, there is anticipation that there will be a significant financial savings with the increasing adoption of biosimilars in oncology.<sup>2,3,5,9,10</sup>

Mechanisms that improve the adoption of biosimilar use in oncology have not been validated. Models that increase the safe and efficient utilization of biosimilars are needed thereby adding value to the oncology care model.<sup>9</sup> Any impact that a tool might have on biosimilar use must be evaluated through objective measures and be sustainable and broadly applicable.

### **III. The following factors will be evaluated in prioritizing applications:**

1. **Significance** in developing tools to improve the safe and efficient use of biosimilars in oncology
2. **Investigator's** experience and the affiliated project team including mentor if applicable
3. **Innovation** in improving the value to oncology care being added by using biosimilars in oncology
4. **Approach** in measuring the impact, applicability and the sustainability of the tool(s) being studied
5. **Environment** and resources consistent with the needs of the study

Criterion scores are intended to convey how each assigned reviewer weighed the strengths and weaknesses of each of these five factors.

### **IV. Scope**

NCCN and Pfizer encourage proposals studying any of the following (not inclusive):

1. Quality of care and best practices around the appropriate use of biosimilars
2. Quality of care and best practices around the perceptions of biosimilars
3. Quality/Process improvement projects that impact efficiency and resource utilization
4. Educational tools for providers, nurses, pharmacists, administrative units
5. Pharmacy and Therapeutic Committee processes
6. Pharmacy practices that improve the safety or use of biosimilars
7. Electronic medical records and integration of biosimilars
8. Tools impacting prescribing behaviors
9. Clinical pathway and consensus guidelines development
10. Challenges related to payer mandates/insurance issues
11. Optimization and integration of processes
12. Value/Quality/Cost for patients, clinicians and institutions

LOIs addressing topics in addition to those listed above will be considered. A plan for long-term sustainability should be included within the submission.

This RFP is open to investigators from all US institutions and organizations. Collaboration between institutions is strongly encouraged in order to foster the interactive sharing of knowledge and expertise, and to utilize the combined strengths of members.

**V. Letters of Intent/Proposals**

This RFP model employs a 2-stage process: Stage 1 is the submission of a 3-page LOI. If an LOI is selected, the applicant will be invited to Stage 2 to submit a full program proposal into Pfizer’s web-based system (see Section VII).

Researchers seeking funding for clinical research projects will not be considered under this RFP.

The NCCN Request for Proposals Development Team (RFPDT) has been formed to oversee this process and will utilize a formalized review procedure to accept LOIs and subsequently select the proposals of highest scientific merit. The NCCN PRPC has overseen the development of the RFP and will perform the peer review of applications.

**VI. Requirements**

<b>Date RFP Issued:</b>	<b>July 1, 2020</b>
<b>Clinical Area:</b>	Oncology
<b>Applicant Eligibility Criteria:</b>	<ul style="list-style-type: none"> <li>● Restricted to US institutions</li> <li>● Academic and Community Centers (Principal Investigators {PIs} from Academic Centers are encouraged to include a co-investigator from the community)</li> <li>● Patient Advocacy Groups</li> <li>● Open to any type of care delivery system with the exception small, physician-owned group practices</li> <li>● Health care professional organizations and other organizations with a mission related to health care improvement</li> </ul>
<b>Expected Approximate Monetary Range of Grant Applications:</b>	<p>Individual projects requesting up to \$250,000 (direct and indirect costs) will be considered; smaller, lower-cost projects are strongly encouraged.</p> <p>The maximum indirect (overhead) rate is 28% and must be included in the total grant request amount.</p> <p>The total funding available for this RFP is \$1.5 million.</p> <p>Applicants are required to disclose additional sources of funding for this project and demonstrate that funding does not overlap.</p>

<p><b>Estimated Key Dates:</b></p>	<p>LOI Deadline: <b>September 9, 2020</b> Please note the deadline is 11:59pm Eastern Time (New York, GMT -5).</p> <p>Anticipated LOI Notification Date: <b>October 28, 2020</b> Full Proposal Deadline: <b>*December 9, 2020</b> *Only accepted LOIs will be invited to submit full proposals. Please note the deadline is 11:59pm Eastern Time (New York, GMT -5).</p> <p>Anticipated Full Proposal Notification Date: <b>February 10, 2021</b></p> <p>Grants distributed following execution of fully signed Letter of Agreement</p> <p>Period of Performance: <b>12 months with the possibility of one 12 month no cost extension (requires approval)</b></p>
<p><b>How to Submit:</b></p>	<p>Please go to <a href="http://www.cybergrants.com/pfizer/loi">www.cybergrants.com/pfizer/loi</a> and sign in. First-time users should click "REGISTER NOW".</p> <p>Select the following Competitive Grant Program Name: <b>2020 Oncology NCCN Pfizer Biosimilars Project</b></p> <p>Select the following Area of Interest: <b>Oncology - Biosimilars</b></p> <p>Requirements for submission: Complete all required sections of the online application referring to the guide included in the Appendix</p> <p>If you encounter any technical difficulties with the website, please click the "Need Support?" link at the bottom of the page.</p> <p><b>IMPORTANT:</b> Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.</p>
<p><b>Questions:</b></p>	<p>If you have questions regarding this RFP, please direct them in writing to Nicole Kamienski, NCCN Research Study Associate at <a href="mailto:Kamienski@nccn.org">Kamienski@nccn.org</a> or Pfizer's Grant Officer, Jacqueline Waldrop at <a href="mailto:Jacqueline.Waldrop@pfizer.com">Jacqueline.Waldrop@pfizer.com</a> with the subject line "NCCN Pfizer Biosimilars Project"</p>
<p><b>Mechanism by which Applicants will be Notified:</b></p>	<p>All applicants will be notified via email by the anticipated dates noted above.</p> <p>Applicants may be asked for additional clarification or to make a summary presentation during the review period.</p>

**VII. Terms and Conditions**

1. This RFP does not commit Pfizer or its partners to award a grant or a grant of any particular size if one is awarded, nor to pay any costs incurred in the preparation of a response to this request.
2. Pfizer reserves the right to accept or reject any or all applications received as a result of this request, or to cancel this RFP in part or in its entirety, if it determines it is in the best interest of Pfizer to do so.
3. For compliance reasons and in fairness to all applicants, all communications about the RFP must come exclusively to Pfizer at the email address included in the RFP. Applicants should not contact other departments within Pfizer regarding this RFP. Failure to comply will disqualify applicants.

This RFP does not provide permission and license for the use (including the creation of derivative products) of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for commercial use. Grant recipients will need to maintain a separate end-user or other license agreement directly with NCCN for use of the NCCN Guidelines.

**VIII. Letter of Intent Submission Requirements**

**The LOI will be accepted via the online application. When answering the LOI questions in the application please keep the following in mind:**

<p><b>Goals and Objectives</b></p>	<p>Briefly state the overall goal of the project. Describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s).</p> <p>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.</p>
<p><b>Assessment of Need for the Project and Preliminary Data</b></p>	<p>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.</p>
<p><b>Target Audience</b></p>	<p>Describe the primary audience(s) targeted for this project. 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.</p>

<p><b>Project Design and Methods</b></p>	<p>Describe the planned project and the way it addresses the established need.</p> <p>If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.</p>
<p><b>Innovation</b></p>	<p>Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.</p> <p>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.</p>
<p><b>Evaluation and Outcomes</b></p>	<p>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.</p> <p>Quantify the amount of change expected from this project in terms of your target audience.</p> <p>Describe how the project outcomes will be broadly disseminated.</p>
<p><b>Anticipated Project Timeline</b></p>	<p>Provide an anticipated timeline for your project including project start/end dates.</p>
<p><b>Additional Information</b></p>	<p>If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here.</p>
<p><b>Organization Detail (Environment and Mentors)</b></p>	<p>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.</p>
<p><b>Budget Detail</b></p>	<p>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.</p> <p>The budget amount requested must be in U.S. dollars (USD).</p> <p>While estimating your budget please keep the following items in mind:</p> <p style="padding-left: 40px;">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,</p>

	<p>IRB/IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment.</p> <p>The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.</p> <p>It should be noted that grants awarded through GMG cannot be used to purchase therapeutic agents (prescription or non-prescription).</p> <p>Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.</p>
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## **IX. References**

1. [Understanding the Role of Comparative Clinical Studies in the Development of Oncology Biosimilars](#). Stebbing J, Mainwaring PN, Curigliano G, Pegram M, Latymer M, Bair AH, Rugo HS. J Clin Oncol. 2020 Apr 1;38(10):1070-1080.
2. [Barriers to the Access of Bevacizumab in Patients with Solid Tumors and the Potential Impact of Biosimilars: A Physician Survey](#). Monk BJ, Lammers PE, Cartwright T, Jacobs I. Pharmaceuticals (Basel). 2017 Jan 28;10(1).
3. [An Efficient Development Paradigm for Biosimilars](#). Webster CJ, Wong AC, Woollett GR. BioDrugs. 2019 Dec;33(6):603-611.
4. <https://www.rand.org/pubs/perspectives/PE264.html>. Mulcahy, Andrew W., Jakub P. Hlavka, and Spencer R. Case. Biosimilar Cost Savings in the United States: Initial Experience and Future Potential. Santa Monica, CA: RAND Corporation, 2017
5. <https://www.pfizer.com/science/research-development/biosimilars> accessed April 16, 2020
6. [The rise of oncology biosimilars: from process to promise](#). Verrill M, Declerck P, Loibl S, Lee J, Cortes J. Future Oncol. 2019 Oct;15(28):3255-3265.
7. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/scientific-considerations-demonstrating-biosimilarity-reference-product>
8. <https://pubmed.ncbi.nlm.nih.gov/29428205/> Gámez-Belmonte R et al. Biosimilars: Concepts and controversies. Pharmacol Res. (2018)
9. [Recognizing and addressing challenges to the adoption of trastuzumab biosimilars and HER2-targeted therapies](#). Whalen J. Am J Manag Care. 2020 Mar;26(2 Suppl):S23-S31
10. [Pharmacist perspectives and considerations for implementation of therapeutic oncology biosimilars in practice](#). Cuellar S, McBride A, Medina P. Am J Health Syst Pharm. 2019 Oct 15;76(21):1725-1738.