

Toward Health Equity Oncology Grant[™]

2023 U.S. Funding Opportunity Announcement

Increasing Disinvested¹ Communities' Access to and Representation in Breast/Chest and Lung Oncology Clinical Trials: Collaborative Proposals Based in Oakland, the Gulf Coast (Louisiana, Mississippi, Alabama) or Washington D.C.

BACKGROUND

Gilead Corporate Giving | Gilead recognizes that patients and communities often face challenges in accessing the best possible care, and we know that passion for scientific discovery alone – and that Gilead alone – cannot solve these challenges. This is why, through our global corporate grant programs, we support patient advocates, healthcare professionals and nonprofit groups around the world that work tirelessly in local communities to improve people's lives day after day.

Gilead provides grants to support organizations partnering to advance the goals of our corporate giving mission: to improve healthcare access, eliminate the barriers to healthcare encountered by underserved populations and advance education among healthcare professionals, patients and community members.

TOWARD HEALTH EQUITY ONCOLOGY GRANT (THE Oncology Grant)

THE Oncology Grant was established as an annual initiative to catalyze innovative approaches to improve health equity across the cancer care continuum. THE Oncology Grant awards are given annually on World Cancer Day - February 4th. A Fall funding opportunity announcement describes the focus of the initiative for the coming year. THE Oncology Grant seeks to build on existing data, fund programs with a health equity approach and meaningful involvement of community, illuminate replicable models and identify sustainable outcomes.

2023 Grant Focus Area | Increasing Disinvested Communities' Access to and Representation in Breast/Chest and Lung Oncology Clinical Trials: Collaborative Proposals Based in Oakland, the Gulf Coast (Louisiana, Mississippi, Alabama) or Washington D.C.

¹ "Disinvested" refers to the purposeful withdrawal of resources - or intentional absence of resources - from a specific neighborhood or community.

Oncology clinical trials lack representative participation from disinvested communities². This gap in inclusion in clinical trials results in inapplicable data and inequitable treatment access³. These results are particularly striking in cancers where disinvested communities represent a large portion of diagnoses and their mortality rates are higher than other communities⁴. Community-based approaches with population-specific strategies are needed to improve disinvested communities' access to and representation in clinical trials².

The National Cancer Plan outlines multiple strategies as part of two goals to increase access to and representation in oncology clinical trials⁵. National Cancer Plan *Goal #4 Eliminate Inequities* and *Goal #6 Engage Every Person* calls on a multitude of stakeholders to apply specific strategies towards effective solutions. Additionally, the U.S. Food and Drug Administration (FDA) issued draft guidance to improve the enrollment of Black or African American, Hispanic/Latino, Indigenous and Native American, Asian, and Pacific Island people in clinical trials⁶. Gilead is committed to increasing access to and assuring diversity in clinical trials across its pipeline⁷.

Gilead seeks to fund 2-5 collaborative proposals aimed at increasing access to and engagement in clinical trials of Black or African American, Hispanic/Latino, Indigenous and Native American, Asian, and Pacific Island people in three geographies: Oakland, the Gulf Coast (Louisiana, Mississippi, Alabama) or Washington D.C.

Proposals will utilize a health equity lens and an understanding of the role of social determinants of health to evaluate their local or regional geography and propose collaborative solutions to bridge equity gaps in clinical trial access and representation.

Proposals should be joint, community-based approaches that include three or more organizations based in the selected geography. The collaborative should share objectives, funding, program implementation, data collection and reporting outcomes.

Priority will be given to proposals intentionally inclusive of LGBTQI communities, including the collection of sexual orientation and gender identity (SOGI) data. Proposals with structural

10.6004/jadpro.2022.13.8.2. Epub 2022 Nov 1. PMID: 36727023; PMCID: PMC9881739.

² Mutale F. Inclusion of Racial and Ethnic Minorities in Cancer Clinical Trials: 30 Years After the NIH Revitalization Act, Where Are We? J Adv Pract Oncol. 2022 Nov;13(8):755-757. doi:

³ National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Women in Science, Engineering, and Medicine; Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research; Bibbins-Domingo K, Helman A, editors. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. Washington (DC): National Academies Press (US); 2022 May 17. 2, Why Diverse Representation in Clinical Research Matters and the Current State of Representation within the Clinical Research Ecosystem. Available from: https://www.ncbi.nlm.nih.gov/books/NBK584396/ ⁴ Ajewole VB, Akindele O, Abajue U, Ndulue O, Marshall JJ, Mossi YT. Cancer Disparities and Black American Representation in Clinical Trials Leading to the Approval of Oral Chemotherapy Drugs in the United States Between 2009 and 2019. JCO Oncol Pract. 2021 May;17(5):e623-e628. doi: 10.1200/OP.20.01108. Erratum in: JCO Oncol Pract. 2021 Jul;17(7):459. PMID: 33974825; PMCID: PMC8120664.

⁵ https://nationalcancerplan.cancer.gov/national-cancer-plan.pdf

⁶ <u>https://www.fda.gov/news-events/press-announcements/fda-issues-draft-guidance-aimed-improving-oncology-clinical-trials-accelerated-approval</u>

⁷ <u>https://stories.gilead.com/articles/stacey-bledsoe-resolve-to-make-clinical-trials-available-to-everyone</u>

approaches proposing impact extending beyond the grant period will be prioritized. Successful applications will include <u>two or more</u> of the following evidence-based approaches⁸ for achieving the defined local outcomes:

- clinical trial access through integration into existing community-based health care locations and including decentralized clinical trial access and engagement⁹
- community and patient engagement about clinical trials including faith-based and multi-lingual approaches¹⁰
- community-based navigation services (including community health workers, promotores and/or health ministries) supporting clinical trial education, treatment options including enrolling in a clinical trial, care navigation, empowered patient decision-making, and financial, social and emotional wellness¹¹

ELIGIBILITY CRITERIA

Organization(s) must be U.S. based 501(c)3 with a clear mission of serving disinvested communities to improve oncology care.

Organizations must demonstrate:

- a record of sound financial stewardship
- ability to deliver impactful programming
- excellence in program development and implementation
- institutional infrastructure, including administrative capacities
- core content expertise and strong grounding in existing data
- knowledge of social change approaches
- a strong network and partnership capacity and ability to collaborate effectively

Collaborative submissions are required. One application is submitted by the designated lead organization based in the chosen geography. The application will include letters of support from collaborating organizations including agreements on staffing, budgets, decision making and reporting. Current or previous Gilead grantees should confirm with their grants manager eligibility to submit prior to submitting under this funding opportunity announcement.

¹⁰ Bodicoat DH, Routen AC, Willis A, Ekezie W, Gillies C, Lawson C, Yates T, Zaccardi F, Davies MJ, Khunti K. Promoting inclusion in clinical trials-a rapid review of the literature and

⁸ Vuong I, Wright J, Nolan MB, Eggen A, Bailey E, Strickland R, Traynor A, Downs T. Overcoming Barriers: Evidence-Based Strategies to Increase Enrollment of Underrepresented Populations in Cancer Therapeutic Clinical Trials-a Narrative Review. J Cancer Educ. 2020 Oct;35(5):841-849. doi: 10.1007/s13187-019-01650-y. PMID: 31713103.

⁹ Taiwo Adesoye, Matthew H.G. Katz, and Anaeze C. Offodile II Meeting Trial Participants Where They Are: Decentralized Clinical Trials as a Patient-Centered Paradigm for Enhancing Accrual and Diversity in Surgical and Multidisciplinary Trials in Oncology JCO Oncology Practice 2023 19:6, 317-321

recommendations for action. Trials. 2021 Dec 4;22(1):880. doi: 10.1186/s13063-021-05849-7. PMID: 34863265; PMCID: PMC8643184.

¹¹ Fouad MN, Acemgil A, Bae S, Forero A, Lisovicz N, Martin MY, Oates GR, Partridge EE, Vickers SM. Patient Navigation As a Model to Increase Participation of African Americans in Cancer Clinical Trials. J Oncol Pract. 2016 Jun;12(6):556-63. doi: 10.1200/JOP.2015.008946. Epub 2016 May 17. PMID: 27189356; PMCID: PMC4957258.

SELECTION CRITERIA

Successful proposals will clearly include:

- The collaborating organizations' health equity approach and staffing
- The collaborating organizations' capacity to fulfill requested project scope
- Staff expertise and experience in line with project scope
- Program logic and measurable outcomes
- An implementation strategy for fulfilling project scope
- A proposed organizational structure for the collaboration including how the program will operate and how decisions will be made
- A communication plan to share learnings from the grant-funded activities
- Appropriate and practical resources and budgets to support project goals

Programs will be independent of Gilead, controlled solely by the grantee organization.

EVALUATION AND REPORTING

Proposals will provide specific, measurable, and achievable goals. Gilead Oncology Corporate Giving has created a <u>Grantee Guide to Evaluation</u> including a Results-Based Accountability evaluation menu to support organization's program evaluation with potential impact measures. Proposals will describe applicant's capacity to implement the project and clear details on how data will be collected and analyzed.

Through grantee reporting data collection, Gilead hopes to create opportunities to learn from the successes and challenges faced by our partners and to assess ways to increase future programs' impact. Applicants may allocate up to 10% of the grant award outside of indirect cost to cover the costs of evaluation of the project.

GRANT AWARDS

Gilead will consider grant requests up to \$1,500,000 per collaborative application including evaluation and indirect rates, if applicable, with a timeline of 36-months starting March 1, 2024. Grant proposals will clearly articulate how the project will be sustained at the end of the project. Grant requests should be proportional to the scope, complexity, reach/impact of the program and program timeline while reflecting reasonable, good faith estimates of the true costs related to the proposed project. Organizations awarded collaborative grants will be convened as part of a grantee cohort to share lessons learned and receive evaluation support. Gilead will fund between 2-5 collaborative grants under this funding opportunity announcement.

FUNDING RESTRICTIONS

Gilead grant funding cannot support:

- Medications or purchasing of medications
- Direct medical expenses, including labs
- Existing deficits
- Basic biomedical research, Gilead-sponsored clinical research or clinical trials
- Projects that directly influence or advance Gilead's business, including purchase, utilization, prescribing, formulary position, pricing, reimbursement, referral, recommendation or payment for products

- Salaries of health care providers, patient organization representatives, government officials or physician group practices
- Events or programs that have already occurred
- Government lobbying activities
- Organizations that discriminate based on race, color, gender, religion, disability, sexual orientation, or gender identity or expression

Note: Gilead will not consider applications for funding of online marketing, the development of new or proprietary software, website or portal development. The funding may not be used to build capacity to directly provide, facilitate or expand medical care beyond the limited scope of the grant e.g., paying capital costs for treatment facilities, space refurbishment, medical equipment or supplies, medical expenses, medications, healthcare professional or allied healthcare professional compensation support, laboratory fees or other costs of providing medical care.

KEY DATES & DEADLINES

Funding opportunity announcement (FOA) released: August 31, 2023 Optional informational webinars:

Tuesday September 19, 2023 12 PM PT/3 PM ET <u>Registration Link</u> Thursday September 28, 2023 9 AM PT/12 PM ET <u>Registration Link</u> Virtual Site Visits: Week of October 9th Deadline to submit applications: 5 PM PT November 8, 2023 Funding decisions announced: February 4, 2024 Grant period begins: March 1, 2024

HOW TO APPLY

Organizations are required to submit their requests using the online application form, which can be accessed at <u>https://www.gilead.com/purpose/giving/funding-requests/apply-north-america</u>. Review the FOA and appendices before applying.

Select "Oncology Targeted Therapies" as the therapeutic area, "Community/Patient" as the grant type and "THE Oncology Grant" as the grant tag. This FOA includes suggested word limits for each section.

- Executive Summary: 200 (Briefly summarize this proposal.)
- Organizational Overview: 200 (Applicant overview, including collaborators.)
- Program Purpose/Description: 750
- Program Objectives: 300
- Program Activities: 500 (How will you achieve the objectives?)
- Expected Outcomes/Impact: 450 (What are the expected outcomes? How will they be measured? Propose measures using the Results-Based Accountability framework.)
- Sustainability: 300 (Your plan for sustainability after the proposed grant ends.)
- Additional Information: 300 (Any additional information that helps fulfill the eligibility or selection criteria?)
- Communication Plan: 250 (How will you outreach to the identified populations?)
- Dissemination Plan: 250 (How will you share your lessons learned?)

Collaborative proposals to include as supporting documents: letters of support from collaborators including agreements on staffing, budgets, decision making and reporting.

Applicants are strongly encouraged to schedule a virtual site visit with their collaborative team for the week of October 9th - kindly email shannon.weber2@gilead.com to schedule.

INQUIRIES

Submit questions about this announcement to shannon.weber2@gilead.com using the subject heading "THE Oncology Grant" and your organization's name or the intended name of the collaborative program.

DISCLAIMER STATEMENT

- An application is not a promise of funding.
- Gilead reserves the right to approve or deny any submitted application for any reason.
- The number of funding requests awarded will depend on the number of applications received.
- Recipients receiving support will be required to complete post program budget reconciliation, submit any data required for state/federal/country reporting purposes such as Open Payments (Sunshine Act), as well as provide program outcomes.
- Award of a grant in any one cycle does not imply that any subsequent grant for the same project or a similar project will be awarded without further application and approval.

ABOUT GILEAD

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis, COVID-19, and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.

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APPENDIX A - Indirect Cost Guidelines

Indirect costs are overhead expenses incurred by the applicant organization as a result of the project but that are not easily identified with the specific project. Generally, indirect costs are defined as administrative or other expenses that are not directly allocable to a particular activity or project; rather they are related to overall general infrastructure operations. Indirect costs are sometimes referred to as "overhead costs" and more recently by the U.S. government as "facilities and administrative costs." Examples include executive oversight, accounting, grants management, legal expenses, utilities, technology support and facility maintenance.

Gilead prefers, whenever possible, that specific allocable costs of an applicant organization's project should be requested and justified in the proposal as direct costs, including those for dedicated ongoing project management, facilities, and support (further definitions are provided below).

As a company we seek to fund the actual cost of the proposed project, and to support the efficiency and effectiveness needed for improving the care of patients. Gilead will consider supporting a consolidated indirect cost fee on a case-by-case basis (where allowed under local laws and regulations), provided it constitutes 10% or less of the total proposed project cost. Gilead has established basic definitions and guidance to be used by our grant applicants and prospective applicants (see below).

Through our philanthropy and grants programs, Gilead does not match the indirect-cost rates that the U.S. federal government may pay to its applicants and contractors. We recognize that this means that our applicants may need to engage in cost-sharing between projects, tap into unrestricted funds, or conduct other fundraising activities to cover unbudgeted operation costs.

Indirect Cost Definitions

- Facilities not acquired specifically and exclusively for the project (e.g., Foundation, Institute, or University headquarters)
- Utilities for facilities not acquired for and not directly attributable to the project
- Information technology equipment and support not directly attributable to the project
- Depreciation on equipment
- Insurance not directly attributable to a given project
- General administrative support not directly attributable to the project. Examples are as follows:
 - Executive administrators
 - $\circ \quad \text{General ledger accounting} \\$
 - o Grants accounting
 - General financial management
 - o Internal audit function
 - o IT support personnel
 - Facilities support personnel
 - Scientific support functions (not attributable to the project)
 - Environment health and safety personnel
 - o Human resources
 - Library & information support
 - Shared procurement resources
 - General logistics support
 - Material management
 - o Executive management
 - \circ $\;$ Other shared resources not directly attributable to the project
 - Institutional legal support
 - Research management costs