Gilead Sciences Medical Affairs Request for Proposals:
NOVA (Novel Research to Advance HIV Prevention) 2024 Program

Through the Medical Affairs Phase 4 Investigator-Sponsored Research (ISR) and Collaborative Programs, Gilead supports the research efforts of academic institutions, clinical investigators, community-based organizations, and research networks to evaluate the best approaches for HIV prevention and implementation strategies in populations who may benefit from PrEP. Gilead supports these research efforts based on the validity of the scientific question proposed to be addressed, and when the results will fill a data gap of interest and not duplicate previous studies/data conclusions already available.

F/TDF for PrEP was first approved in 2012 in the United States, followed by F/TAF in 2019,* providing an additional option to fill additional unmet needs in those who can benefit from daily oral PrEP. Despite the availability of a daily oral PrEP option globally, uptake and persistence remain low in many areas and barriers persist. Per the CDC, only 30% of the 1.2 million individuals who can benefit from PrEP have been prescribed PrEP, far short of the 50% goal by 2025.[1] PrEP use is disproportionately low among priority populations, including Black/Latino men who have sex with men (MSM), Black cisgender women, transgender individuals, and those living in the US South.[2] The WHO first recommended F/TDF for PrEP in 2015.[3] As of 2021, 144 countries around the world have adopted the WHO recommendations in their national guidelines.[4] While the rate of PrEP uptake has increased steadily in some populations and geographies, absolute numbers remain low. At the end of 2021, there were only an estimated 1.6 million PrEP users worldwide, far short of the UNAIDS goal of 10 million by 2025.[5]

Innovative strategies to help improve steps in the PrEP continuum, including awareness, uptake, and persistence, and expansion of PrEP services to novel, non-traditional settings and by non-traditional providers are needed to achieve the CDC's and UNAIDS 2025 HIV prevention targets.

**The indication excludes individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.*

Through the NOVA 2024 RFP process, Gilead will evaluate and potentially support research proposals that address the following areas of interest where data gaps exist and seek to answer the following open research questions:

1. **Real-world use of F/TAF in priority populations, including safety, adherence, and persistence**
    a. What is the feasibility, acceptability, and impact on seroconversion of rapid-start F/TAF for PrEP in various clinical settings in key populations (Black/Latino MSM, transgender and gender non-binary individuals, migrant populations and border communities, and those who exchange sex for commodities)?
    b. What is the real-world safety, adherence, and persistence of F/TAF in people who inject/use drugs (PWID/PWUD)?

2. **Implementation strategies to improve PrEP awareness, uptake, and ongoing access/linkage/retention for PWBP to prevention care**
    a. What is the feasibility, acceptability, uptake, and ongoing access/persistence of oral PrEP delivered through non-traditional settings outside of primary care and HIV/ ID clinics?
    b. What is the feasibility and acceptability of innovative digital approaches (e.g. social media, geolocated apps, gamification) to improve PrEP awareness and uptake, and identify PWBP not engaged through a traditional healthcare system? *(Note: telePrEP and chatbot proposals excluded. Research support will only be provided to test established digital tools in answering this research question, not the development of such tools.)*
    c. What interventions are effective to improve PrEP awareness, uptake, and ongoing access/persistence in priority populations (e.g. transgender & gender nonbinary individuals, Black and Latino MSM, Black cisgender women, those who exchange sex for commodities, border communities, and migrant populations)?
    d. What is the impact of peer navigation on PrEP uptake in non-MSM populations and non-LGBTQ care settings?

e. What is the feasibility and impact (HIV and STI rates, sexual health conversation starter) of using doxy-PEP as a gateway to providing PrEP?

Please note: *For proposals using F/TAF in the intervention, F/TAF should currently have regulatory approval for HIV PrEP or have regulatory approval for HIV PrEP at the time of study initiation in the country the study will be conducted in as well as in the population the study will be on. Additionally, as the study sponsor, the principal investigator will be responsible for compliance with all laws and regulations applicable to research sponsors, including satisfying local requirements and obtaining all necessary regulatory approvals prior to beginning the study.*

Proposals should include (where appropriate) descriptions of:

- Incorporation of community and/or user/participant involvement in study planning and study design/protocols;
- Clear scientific objectives and endpoints, based on sound scientific hypotheses;
- Appropriate, defined, and specific data collection/evaluation methods;
- Scalability and sustainability of the program after funding completion (when applicable);
- Generalizability to other settings; and
- Feasibility of completion of the project within 18 months, followed by rapid data dissemination and presentation of results.

Key Dates & Program Specifics:

Stage 1: Letter of Intent (LOI: a concise overview of proposed project and total estimated budget)

- **February 12, 2024**: LOI submission window opens
- **March 22, 2024**: LOI submission window closes

LOIs must be submitted via the online GOPTICS portal (https://gileadmedaffairs.appiancloud.com/suite/portal/login.jsp)

Any questions about the NOVA RFP 2024 program or application process can be submitted to your local Gilead Medical Scientist or NOVA@gilead.com.

Stage 2: Full Application Submission (complete proposal with detailed budget)

All those who have submitted an LOI will be informed of the outcome of the LOI review by May 6, 2024. Certain applicants will be invited to submit a full application, including a detailed budget. The timelines for submission and review of full applications are as follows:

- **May 31, 2024**: Deadline for receipt of full application
- **By end of July, 2024**: Notice of full application outcome

Full applications must be completed in GOPTICS following approval to submit (https://gileadmedaffairs.appiancloud.com/suite/portal/login.jsp)

Investigators who meet criteria for a standard Gilead ISR (https://www.gilead.com/science-and-medicine/research/investigator-sponsored-research) are encouraged to apply.

The program provides awards for proposals completed in up to 18 months. Awards shall be for research purposes only; ***routine medical care or other costs associated with routine medical care will not be considered for funding.***

Budget Considerations

Gilead plans to award a total of approximately $5,000,000 in funds for research proposals under the NOVA RFP 2024 Program, dependent upon availability of funds and receipt of meritorious applications. Any proposal greater than $500,000 should be discussed with your Gilead Medical Scientist prior to submission.

Review Process

Letters of Intent (LOI) will be rigorously reviewed by a Gilead internal committee. Each complete LOI that meets program requirements will be assigned to multiple primary and secondary reviewers. Each reviewer will review and score the LOI and will evaluate how well the proposal addresses the RFP, the potential impact of the study, the strength of the objectives/study design, sustainability/scalability of the proposal/intervention, and the site's and study team's ability to recruit the proposed study population and execute on study objectives. Scoring is based on the modified NIH Scoring Tool. High scoring LOIs will be discussed by a multidisciplinary committee. Investigators with the top LOI submissions will be offered the opportunity to submit a full application, which will be similarly reviewed.

No Guarantee of Funding

Gilead reserves the right to approve or decline any application at its sole discretion. Submission of an LOI or a full application does not guarantee funding. Applications are reviewed by an internal review committee.

No Inducement or Reward

Gilead approval of awards does not take into account the past, present, or future volume or value of any business or referrals between the parties. Awards are not being given, directly or indirectly, as an inducement or reward with respect to the past or potential future purchase, utilization, recommendation or formulary placement of any Gilead product. Further, except for the use of the Gilead product in an approved award/research, the awardee is not required to purchase, order, recommend or prescribe to any patients any products manufactured by or available through Gilead.

About Gilead Sciences

Gilead Sciences, Inc. is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California.

Footnote: DESCOVY is indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating DESCOVY for HIV-1 PrEP.

References:

1. CDC Fact Sheet: https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html#:~:text=CDC%20data%20show%20that%20about,only%20about%2013%25%20in%202017
2. AIDSVu Public Data Resource - https://aidsvu.org/prep/. Accessed August 17th, 2023
3. Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection, 2nd edition. Recommendations for a Public Health Approach. Geneva: World Health Organization; 2016. https://www.who.int/publications/i/item/9789241549684. Accessed November 15, 2023
4. https://www.who.int/groups/global-prep-network/global-state-of-prep#:~:text=Adoption%20of%20WHO%20PrEP%20recommendations,in%20the%20next%202%20years. Accessed November 15, 2023.
5. Joint United Nations Programme on HIV/AIDS (UNAIDS) IN DANGER: UNAIDS Global AIDS Update 2022. Geneva: UNAIDS; 2022.