Gilead Sciences Medical Affairs Request for Proposals:
NOVA (NOVel HIV Prevention Research Utilizing F/TAF) Program

Gilead Sciences is committed to advancing progress towards the UN Sustainable Development Goals and 90-90-90 targets by reducing new HIV infections, which requires a holistic approach through comprehensive HIV Prevention strategies including Treatment as Prevention (TasP; U=U), Pre-Exposure Prophylaxis (PrEP), and Post-Exposure Prophylaxis (PEP). Through Medical Affairs Investigator-Sponsored Research (ISR) Program, Gilead supports the research efforts of academic institutions, clinical investigators, community organizations, and research networks to improve clinical understanding of HIV prevention strategies and evaluate the best approaches for HIV prevention and implementation in the most vulnerable populations. 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 in clinical research and not duplicate previous studies.

This specific Request for Proposals (RFP) is calling out for research proposals that seek to reduce disparities in global HIV incidence by focusing on three objectives: (i) evaluating PrEP strategies with F/TAF and addressing challenges associated with HIV prevention program implementation and individual adherence through innovative strategies; (ii) prioritizing vulnerable populations and previously underrepresented populations in registrational trials; and (iii) prioritizing regions with high HIV incidence and low access to prevention services.

This RFP will target three specific objectives:

1. **Innovative HIV Prevention Evaluation and Implementation with F/TAF**

   Oral PrEP in conjunction with safer sex practices is highly effective at reducing the risk of HIV-1 infection; however, there are many barriers to integrating PrEP into routine care and with enabling equitable access (e.g., resource challenges, lack of staff/provider education and awareness, patient and provider stigma and bias, social concerns about identifying PrEP-eligible individuals).

   Further challenges exist at the individual patient level, ranging from lack of perceived risk precluding PrEP initiation, to maintaining adherence to PrEP regimens while at risk for HIV-1 infection.

   The focus of this objective is to evaluate innovative strategies that include F/TAF for PrEP to improve program implementation and individuals' PrEP adherence and persistence through methods including: randomized clinical trials, implementation and feasibility studies, acceptability and adherence studies, and modeling. Funded projects may include the following:

   - Testing novel methods of PrEP implementation via telemedicine and technology-driven solutions including PrEP online
   - HIV screening and PrEP implementation in non-traditional settings (e.g., schools, corrections, mobile units, emergency departments, urgent care settings, family planning clinics, Native American reservations, substance use treatment facilities)
   - Engaging Pharmacists, Nurses, and other non-MD/DO providers in managing PrEP care
   - Evaluating new strategies for individual adherence maintenance and clinical monitoring of adherence
   - Evaluating strategies to improve PrEP persistence and re-engagement in PrEP care of at risk individuals, especially in populations with lower rates of retention in care such as adolescents and women
   - Evaluating approaches for same-day or rapid-start PrEP initiation
   - Assessing HIV testing and linkage to care strategies as well as STI prevention strategies in the context of PrEP
   - Using social media and peer related strategies to connect people at risk to PrEP care
   - Qualitative research strategies to describe social attitudes, behaviors, and knowledge of HIV prevention among communities and populations described in Objective 2
   - Evaluating interactions between F/TAF and feminizing or masculinizing hormones in

transgender individuals

2. Specific Populations

The focus of this objective is to evaluate data supporting best practices for the use of F/TAF for HIV-1 prevention in specific populations who may be vulnerable to infection and/or have been underrepresented in previous research. Populations of interest include but are not limited to the following:

- In the US: people of African descent, Latinx populations, Native Americans, Asian/Pacific Islander
- Cisgender women
- Adolescents
- Transgender women and men
- People who engage in transactional sex
- Individuals with heightened vulnerability, including people who are unstably housed, have substance use disorders, or have mental health conditions
- Older adults

3. Specific Regions

The focus of this objective is to evaluate data from strategies for equitable access to prevention care through PrEP implementation and expansion of prevention services in regions with high or growing HIV-1 prevalence/incidence and lower levels of regional investment in prevention services. Regions of interest include but are not limited to the following:

- United States:
  - Southern states (Texas, Oklahoma, Louisiana, Mississippi, Alabama, Tennessee, Kentucky, Virginia, West Virginia, Washington, D.C., Maryland, Delaware, North Carolina, South Carolina, Georgia, Florida, Arkansas)
  - Appalachia
  - Other jurisdictions with high HIV incidence, high rates of injection drug use, or other outbreak indicators
- Canada
- Africa
- Asia

Please note: *The use of F/TAF for the prevention of HIV is investigational and has not been approved by the FDA or other regulatory authorities. Approval and initiation of implementation studies through this RFP will be contingent upon FDA approval of F/TAF for PrEP for the intended population. 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.*

Consider the following while developing the proposal:

- Scientific objectives must be clear and based on scientific hypotheses
- Data collection/evaluation methods must be appropriate, defined, and specific
- Scalability and sustainability of the program after funding completion
- Generalizability to other settings
- Feasibility of completion of the project within 3 years, followed by rapid data dissemination and presentation of results

Key Dates & Program Specifics:

Letter of Intent (LOI: 2-page concise overview of proposed project and budget)

- **July 15, 2019**: LOI submission window opens
- **August 23, 2019**: LOI submission window closes

The LOI should be entered into the provided template, downloadable below, and submitted to: NOVA@gilead.com

Full Application Submission

A review of the LOIs will result in invitations for selected LOI applicants to submit a full application. The timelines below will be followed for those full submissions.

- **September 27, 2019**: Notice of LOI outcome, either approved for full application submission or declined
- **October 28, 2019**: Deadline for receipt of full application
- **Mid to late December, 2019**: Notice of full application initial outcome

Investigators who meet criteria for a standard Gilead ISR (https://www.gilead.com/science-and-medicine/research/investigator-sponsored-research) are encouraged to apply. There are no geographic limitations to applications.

The program provides awards for proposals with a three year maximum duration. Awards shall be for research purposes only; ***requests that include routine medical care or other costs associated with routine medical care will not be considered*.**

Budget Considerations

Gilead plans to award a total of approximately $5,000,000 in funds for these research proposals, dependent upon availability of funds and receipt of meritorious applications. Gilead anticipates that approximately 10 awards will be granted. Any proposal greater than $500,000 should be discussed with your Gilead Medical Scientist prior to submission.

Proposals which request F/TAF study medication will also be considered, but supply will be dependent on the status of local approval for supply of the particular study medication.

Full Application

Once notice of approval to submit a full application has been received, a full application should be submitted according to the instructions at https://www.gilead.com/science-and-medicine/research/investigator-sponsored-research. Questions about the announcement or application process can be submitted to your local Medical Scientist or to NOVA@gilead.com.

Gilead reserves the right to approve or decline any application. Applications are reviewed by an internal review committee.

Review Process

Letters of Intent (LOI) will be rigorously reviewed by an internal (Gilead) committee. Gilead retains the right to accept or deny any proposal and will attempt to ensure accepted submissions fulfill a data need and represent geographical distribution as applicable. Each complete LOI that meets program requirements will be evaluated based on how well the proposal addresses the RFP, the potential impact of the study, the strength of the objectives/study design and sustainability/scalability of the methods under study. 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

proposal, which will be similarly reviewed.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California.