

Gilead Sciences, Inc. Medical Affairs Request for Novel HIV Research Applications Utilizing B/F/TAF

Through Medical Affairs, Gilead supports the research efforts of academic institutions, clinical investigators, and research networks to help improve initiation and long-term management of antiretroviral therapy (ART) for HIV-infected patients.

Gilead supports these research efforts where it has a legitimate scientific purpose. Gilead's decision to support will be based on the validity of the scientific question proposed to be addressed and only when the data that will be generated by the research proposal will complement the existing body of evidence and not repeat previous research studies.

Gilead is now making a specific call for proposals in the disease area of HIV. This Request for Applications is in addition to the already existing Investigator Sponsored Research Program, which supports investigator-sponsored research conducted by clinicians and researchers on Gilead's marketed products or within therapeutic areas of interest to the company (<https://www.gilead.com/science-and-medicine/research/investigator-sponsored-research>).

With this RFA, Gilead intends to support investigator research focused on: (i) addressing the challenges associated with rapid initiation of treatment upon a positive HIV infection diagnosis, for the reasons explained below; and (ii) treatment in populations that to date have been under represented in clinical studies. Targeting reduction of new HIV infections through earlier initiation of ART and inclusion of special populations with evaluation of the potential barriers, and methods to overcome those barriers, will be positive steps towards achieving the UNAIDS 90:90:90 goal.

Please discuss other research topics not listed above with your local Medical Scientist.

Through the Medical Affairs Investigator Sponsored Research process, Gilead will evaluate and support programs which address the following two objectives:

- Rapid ART initiation¹ with B/F/TAF
- Use of B/F/TAF, in special HIV-infected populations that traditionally have been excluded from or under recruited in the clinical trial participation

1. Rapid ART Initiation with B/F/TAF

The benefits of earlier ART have been demonstrated in 2 trials, START and TEMPRANO. The results of those trials are also supportive of rapid initiation. Advantages of rapid initiation include: i) reducing the number of individuals who fail to engage in care between the time of HIV diagnosis and antiretroviral initiation, ii) decrease in the number of patients who are lost to follow-up; and iii) decreasing ongoing HIV transmission by reducing the time to suppression and population viral load (compared to later initiation of therapy). The success of rapid ART initiation strategies, based on the studies, has led to adoption of rapid initiation in San Francisco and New York.

The goal of this objective is to evaluate rapid ART initiation programs (e.g. <7 days from HIV diagnosis to ART initiation), including: randomized clinical trials, implementation science projects, studies of feasibility, participant acceptance of rapid start, modeling, and assessment of retention and viral suppression. Research studies may include, but are not

¹ Defined by the World Health Organization as "Rapid initiation is defined as within seven days from the day of HIV diagnosis" WHO. Guidelines for the managing advanced HIV disease and rapid initiation of antiretroviral therapy. July 2017. - <http://www.who.int/hiv/pub/guidelines/advanced-HIV-disease/en>

limited to, the following elements:

- Occur within a defined population. A population may be defined by a clinic, a health system, a geographic location, demographics, or other clearly defined characteristics
- Define and evaluate novel methods of improving linkage from testing to care and the reduction in time to ART initiation
- Evaluate the percent of patients who are linked and retained in care and who achieve virologic suppression within the study time frame
- Evaluate individuals who do not initiate rapid ART and the reasons for exclusion/refusal (individual, structural, institutional)
- Define and evaluate HIV treatment outcomes, including maintenance of HIV suppression, tolerability and persistence on therapy

2. Special Populations

The goal of this objective is to generate new or confirmatory clinical data on B/F/TAF efficacy and safety in special population patients including but not limited to:

- Patients who are ≥ 60 years old
- Women
- Black
- Asian
- Latino
- Transgender
- Malignancy
- Patients with potential drug-drug interactions
- Patients with multiple co-morbidities
- HIV/HCV

Items to consider in development of the proposal submission:

- The proposal should have clear scientific objectives based on scientific hypotheses
- Potential scalability and sustainability of the program once funding is complete; generalizability to other practice settings
- Defined and specific data collection methods
- Collect appropriate metrics
- Can be completed within 3 years
- For U.S. based investigators, special consideration will be given to projects in the Southern U.S. (Texas, Oklahoma, Louisiana, Mississippi, Alabama, Tennessee Kentucky, Virginia, Washington, D.C., Maryland, Delaware, North Carolina, South Carolina, Georgia, Florida, Arkansas, see Gilead COMPASS initiative- <http://www.gilead.com/responsibility/compass>)
- Proposals with the potential for rapid data dissemination and presentation of results will be prioritized
- Plan to publish results in peer reviewed journals and to present results in scientific forums and to other organizations

Key Dates & Program Specifics:

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

15 March 2019: LOI submission window opens

10 May 2019: LOI submission window closes

The LOI should use the format attached to this document and should be submitted to: bftaf-rfa@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.

21 June 2019: Notice of LOI outcome, with invitations for full application submission

2 August 2019: Deadline for receipt of full application

Early to mid September 2019: Notice of full application 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 completed in up to 3 years. 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 6-10 awards will be granted. Any proposal greater than \$500,000 should be discussed with your Gilead Medical Scientist prior to submission.

Proposals which request B/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 to <https://www.gilead.com/science-and-medicine/research/investigator-sponsored-research>. Questions about the announcement or application process should be submitted to your local Medical Scientist.

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

Review Process:

LOI will be rigorously reviewed by an internal (Gilead) committee. Each LOI, that meets program requirements and is complete, 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 RFA, 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 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.