GILEAD
Creating Possible

RESONATE RFP Program
Research to Advance HIV Treatment Outcomes

Gilead supports the research efforts of academic institutions, clinical investigators, and research networks that focus on improving outcomes across the treatment care cascade for people with HIV.

Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF*) is a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg, who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen with no known or suspected substitutions associated with resistance to bictegravir or tenofovir. The single tablet regimen addresses the treatment needs of most treatment-naïve and virologically suppressed people with HIV and offers a high barrier to resistance and few interactions with other drugs.

Lenacapavir (LEN) is a novel first-in-class capsid inhibitor, which in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

Gilead is making a specific request for research study proposals in the disease area of HIV treatment, as further scientific data are needed on B/F/TAF and LEN to support medical management and decisions of clinicians and people with HIV.

Through the RESONATE RFP Program, Gilead will evaluate and potentially support research proposals which address one or more of the following open research questions:

1. Real world data on B/F/TAF *

- Among treatment experienced people with HIV switching to B/F/TAF from other ART regimens, we are seeking research proposals that address the following questions:
    - What are the patient reported outcomes post switch to B/F/TAF, including but not limited to treatment satisfaction, neuro-psychological and mental health outcomes?
    - What are the clinical, virologic and persistency outcomes post switch to B/F/TAF, including health care resource utilization outcomes associated with switch?

  These could be single arm or comparative studies, assessing outcomes among those who switch compared to those who do not switch, or to those who switch to other common regimens.

- Among treatment naïve people with HIV rapidly initiating (same-day) B/F/TAF, or among people who discontinue treatment or interrupt treatment for > 60 days and are viremic when rapidly re-starting therapy with B/F/TAF:

    - What are the clinical, virologic and persistency outcomes following immediate start/restart with B/F/TAF compared to those who do not initiate immediately?

- What is the patient reported outcomes following immediate start/restart with B/F/TAF compared to those who do not initiate immediately, including but not limited to treatment satisfaction, neuro-psychological and mental health outcomes?
- How does engagement in care among those who start/restart HIV treatment immediately compare to those who do not?

* Research that addresses these questions in the following sub-groups of interest will be given particular consideration: people with HIV with sub-optimal adherence, pre-existing resistance, comorbidities/poly medications, substance use disorders, mental health challenges, who are older than 50 or 65 years (including frail or infirmed), with advanced HIV disease in geographies with high HIV disease burden, immigrants/migrants, racial and ethnic minorities, homeless/marginally housed, formerly incarcerated, transgender women, and youth

2. **Data on the burden of HIV and novel implementation strategies to improve person centered care, increase access, sustain engagement, and optimize ART in communities disproportionately impacted by HIV.**

- What are the impacts of social determinants of health on HIV treatment access and virologic outcomes among underserved communities?
- How do innovative access, engagement, and implementation science programs address these barriers?
- What are effective interventions to limit stigma experienced by people with HIV in healthcare settings that improve access and sustained consistent engagement in HIV care?
- What is the effectiveness of implemented patient care models focused (including those supporting communication between people with HIV and HCPs) on expansion of HIV services into novel settings at increasing sustained engagement in HIV care?

3. **Drivers and barriers for implementation of LEN for heavily treatment experienced people with HIV**

- Are there facilitators/best practices to implementing LEN for heavily treatment experienced people with HIV, and how can these be maximized?
- What is the patient and provider experience when receiving treatment with LEN?
- What actions or currently available tools could facilitate adherence to the optimized background regimen (OBR) for heavily treatment experienced people with HIV receiving LEN?
- What opportunities exist to overcome challenges to implementing LEN for heavily treatment experienced people with HIV?

4. **Effectiveness, safety, and adherence/persistence of LEN for heavily treatment experienced people with HIV in real world settings**

LOIs in this topic area should address at least one of the following open research questions:

- What is the real-world effectiveness and safety of LEN + OBR in heavily treatment experienced people with HIV? What is the real-world adherence/persistence of LEN and the OBR among heavily treatment experienced people with HIV?
- How does adherence/persistence of LEN compare to adherence/persistence of other treatment options for heavily treatment experienced people with HIV (i.e., ibalizumab, fostemsavir, enfuvirtide)?

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

Application Criteria

- Investigators with proposals that meet the criteria for a standard Gilead ISR are encouraged to apply.
- Both investigator-sponsored research study proposals and collaborative research study proposals (developed in conjunction with Gilead) will be considered.
- To enhance scientific robustness, we encourage applicants to submit LEN study proposals that capture and describe outcomes beyond single patient cases (for example, through study proposals involving additional study sites/institutions).
- Proposals will only be reviewed from countries where B/F/TAF or LEN have regulatory approval and are available. Questions about availability of B/F/TAF or LEN in specific regions can be directed to RESONATE@gilead.com
- Proposals that request study drug support in addition to funding will be considered.
- We recommend that submitted proposals:
    - Can be completed within 18 months after contract execution
    - Have a well-defined research question with supporting hypothesis and objectives
    - Collect appropriate metrics using defined and specific data collection methods
    - Have a plan to present results in scientific forums and to other organizations, and to publish results in a peer reviewed journal
    - Note potential scalability and sustainability of the program once funding is complete (when applicable)
    - Highlight generalizability to other practice settings
- 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.

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.

Submission Deadlines and Application Process

Letter of Intent (LOI) Submission Window

To be considered for funding under the RESONATE RFP Program, applicants must submit a LOI that is no longer than two pages, contains a concise overview of the proposed project and includes the total estimated budget.

Gilead will evaluate and rank LOIs received on a monthly basis until funds are exhausted. It is strongly recommended to submit earlier rather than later so that proposals can be evaluated while funding is still available.

- **July 8, 2024**: Submission window opens
- **August 5, September 9, October 14, November 18 (23:59 PST)**: Submission deadlines for monthly LOI review
- **November 18, 2024 (23:59 PST)**: Submission window closes

LOIs must be submitted via the Gilead Optics online portal in the RESONATE LOI section in order to be considered for this program.

Questions about the RFP or the application process can be submitted to your local Gilead Medical Scientist or RESONATE@gilead.com

A review of the LOIs will result in invitations for selected LOI applicants to submit a full application with detailed budget. Below are the timelines for full submissions.

- **By December 10, 2024**: Notice of LOI outcome, with invitations for full application submission
- **By January 10, 2025 (23:59 PST)**: Deadline for receipt of full application
- **By February 28th, 2025**: Notice of full application outcome

Applications must be completed in Gilead Optics following invitations to submit full proposals.

Budget Considerations

Gilead plans to award up to $7,000,000 in funds for these research proposals, dependent upon availability of funds and receipt of meritorious applications. Gilead anticipates that up to 15 awards will be granted. Any proposal greater than $500,000 should be discussed with your Gilead Medical Scientist prior to submission. Proposed overhead costs should not exceed 30% of total budget.

Review Process

LOIs will be rigorously reviewed by an internal Gilead committee. Each LOI that meets program requirements and is complete, will be assigned to multiple reviewers. Each reviewer will evaluate and rank how well the proposal addresses one or more of the open research questions, the potential impact of the study, the strength of the objectives/study design and sustainability/scalability of the methods under study. Applicants with the top LOI submissions will be offered the opportunity to submit a full proposal, 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.

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. Furthermore, 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.

**B/F/TAF refers to Gilead's Biktarvy® (either bictegravir 50 mg / emtricitabine 200 mg / tenofovir alafenamide 25 mg tablets for adult and pediatric patients weighing ≥25kg or bictegravir 30 mg / emtricitabine 120 mg / tenofovir alafenamide 15 mg tablets for pediatric patients weighing ≥14 kg to <25 kg). The use of B/F/TAF in patients with a history of treatment failure is investigational and the safety and efficacy of this use has not been determined. Please always refer to your local/regional label for B/F/TAF.*