

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. Gilead evaluates proposals based on the need addressed by the proposed scientific question, validity of study methodology, timing of when results will fill a data gap of interest, and lack of redundancy with previous studies/data conclusions already available. Letters of intent (LOIs) will be used to determine who will be invited to submit a full application.

Investigational bicitegravir/lenacapavir (BIC/LEN), a single-tablet-regimen (STR), represents the latest example of Gilead's commitment to scientific innovation. Initially investigated in virologically suppressed adults receiving complex regimens (e.g. high pill burden regimens, boosted regimens, or requiring twice daily dosing), BIC/LEN may be a potential new option for virologically suppressed adults as treatment needs may evolve, as evident by the ARTISTRY development program, pending regulatory approval.^{1,2}

BIC/LEN combines the integrase strand transfer inhibitor (INSTI) bicitegravir with lenacapavir, a capsid inhibitor. If safety and efficacy are approved by regulatory agencies, this combination would form a new, once-daily STR with the potential to deliver sustained virologic suppression and maintain a high barrier to resistance in VS PWH without Hepatitis B.^{1,2} Certain populations, including older adults, individuals with comorbidities such as declining renal function, and those transitioning from other antiretroviral regimens, may face unique clinical considerations that are not fully characterized in existing clinical trials. Additional real world and targeted clinical evidence in these populations is therefore needed to better understand the safety, efficacy, and patient reported outcomes of BIC/LEN and to help inform clinical decision making.

Gilead will evaluate and potentially support research proposals which address one or more of the following research topics:

1. Evaluate the safety, efficacy and patient-reported outcomes of BIC/LEN in virally suppressed people with HIV who are switching to BIC/LEN, including characterization of switch regimens.
2. Assess the safety, efficacy, and patient-reported outcomes of BIC/LEN in virally suppressed aging* people with HIV, including characterization of switch regimens and concomitant medications, and additional age-related measures. **Those with age >50 years, >60 years, and/or >75 years*
3. Assess the safety, efficacy, and patient-reported outcomes of BIC/LEN in virally suppressed people with HIV with declining renal function (CrCL 15-30 mL/min and 30-50 mL/min).
4. Evaluate tools and/or strategies to ensure label-compliant LEN-loading as part of the BIC/LEN regimen, among virally suppressed people with HIV who are switching to BIC/LEN.

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

Application Criteria

- **Initiation of studies through this RFP will be contingent upon regulatory approval of BIC/LEN for the population being studied.**
- Gilead will provide study drug for fully approved studies
- Investigators with proposals that meet the criteria for a standard Gilead [IIR](#) are encouraged to apply.
- Both investigator-initiated research study proposals and collaborative research study proposals (developed in conjunction with Gilead) will be considered.
- We recommend that submitted proposals:
 - Can generally be completed within 18-24 months after contract execution, unless a longer timeline is warranted based on study complexity or design
 - Have a well-defined research question with supporting sound scientific hypothesis, objectives and endpoints
 - Capture and describe outcomes with significant sample sizes (for example, through study proposals involving additional study sites/institutions) to enhance scientific robustness.
 - Collect appropriate metrics using defined and specific data collection methods
 - Have a plan to present results in scientific forums and to publish results in a peer reviewed journal
 - Highlight generalizability to other practice settings
 - Have an appropriate budget for the study design

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.

Submission Deadlines and Application Process

Letter of Intent (LOI) Submission Window

- **April 6, 2026:** Submission window opens
- **May 4, 2026 (23:59 PST):** Submission window closes

To be considered for funding under the RESONATE RFP Program, applicants must submit a LOI that contains a concise overview of the proposed project and includes the total estimated budget. LOIs must be submitted via the [Gilead Optics online portal](#) in the RESONATE LOI section in order to be considered for this program.

LOIs are not binding documents on either party. The purpose of the LOI is to provide a brief summary of the proposed study to enable Gilead to determine on a preliminary basis whether the proposed study and related budget are aligned with the criteria, timeline and scope of this RFP.

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

Key Dates & Program Specifics:

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 May 8, 2026:** Notice of LOI outcome, with invitations for full application submission
- **By May 29, 2026 (23:59 PST):** Deadline for receipt of full application
- **By June 30, 2026:** 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 \$4,000,000 in funds for these research proposals, dependent upon availability of funds and receipt of meritorious applications. Proposed overhead costs should not exceed 30% of total budget.

Gilead's approval of awards will depend on the availability of funds and receipt of meritorious and complete proposals. Awards shall be granted solely on the merit of the research and alignment with the criteria of this program.

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.

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 research topics, 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 approved research, there is no requirement to purchase, order, recommend, prescribe or continue to 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.

BIC/LEN refers to Gilead's investigational bicitegravir 75mg/lenacapavir 50mg daily oral tablet for virally suppressed adults with HIV that are at least 18 years old. BIC/LEN is not approved by any regulatory agency and its approval is not guaranteed. Safety and efficacy of this investigational drug has not been established.

References

1. Orkin C, Ruane PJ, Hedgcock M, et al. Switch to single-tablet bicitegravir-lenacapavir from a complex HIV regimen (ARTISTRY-1): a randomized, open-label, phase 3 clinical trial. *Lancet*. 2026; published online Feb 25. DOI: 10.1016/S0140-6736(26)00307-7.
2. Meissner M et al. Phase III Efficacy and Safety of Switch From B/F/TAF to Single-Tablet BIC/LEN in ARTISTRY-2. CROI 2026, Denver. Poster 513.