



## **(Implementation of twice-yearly Lenacapavir to address unmet needs in HIV prevention) Global 2026 Request for Proposals**

Through the Medical Affairs Investigator-Sponsored Research (ISR) and Collaborative Research Programs, Gilead supports the research studies of academic institutions, clinical investigators, community-based organizations, and research networks. Gilead supports these research studies based on the need addressed by the proposed scientific questions, validity of study methodology, timing of when results will fill an evidence need 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.

**Background:** Widening economic inequalities are threatening decades of progress in the HIV response. UNAIDS modeling finds that if the current resource constrained environment continues, there could be a staggering 6 million additional new HIV infections and 4 million additional AIDS-related deaths globally by 2030.<sup>1</sup> Health inequities may amplify the harmful impact of barriers to HIV prevention and care, including inadequate perception of risk; harmful trends in drug use; increases in HIV-related stigma, homophobia and transphobia; challenges faced by migrant and mobile populations; and suboptimal access to HIV prevention, testing, and treatment.

Highly effective HIV prevention, including pre-exposure prophylaxis (PrEP), can reduce the risk of HIV acquisition from sex by up to 99% when taken as prescribed.<sup>2</sup> However, gaps in HIV prevention programs stubbornly remain, with 1.3 million new infections occurring in 2024, almost unchanged from the year before.<sup>1</sup> HIV continues to pose a significant burden in sub-Saharan Africa, with countries in Eastern and Southern Africa accounting for an estimated 490,000 new infections – nearly 40% of the global cases in 2024.<sup>3</sup> Regionally, adolescent girls and young women (AGYW) represent approximately 28% of new infections,<sup>3</sup> and in some settings incidence rates peak among women aged 25-34 years.<sup>4</sup> The impact of the HIV epidemic among vulnerable populations is also seen in some areas of Southeast Asia, where the overwhelming majority of new infections occur among men who have sex with men (MSM) and transgender women (TGW).<sup>5</sup> In addition to the higher incidence of HIV in these regions, risks are further exacerbated by factors such as extreme poverty, fragile health systems, gender inequities, co-occurrence of infectious agents (e.g., malaria, tuberculosis (TB), hepatitis), employment insecurity, and exposure to conflict zones.<sup>6,7,8,9</sup>

Despite the availability of multiple PrEP options and substantial efforts to expand PrEP access amongst key populations in sub-Saharan Africa (e.g., 63% and 26% PrEP coverage among female sex workers and MSM, respectively<sup>10</sup>), uptake and persistence remain low in many areas and among populations who could benefit. In 2024, only 3.9 million people received PrEP, a mere 18.4% of the 2025 global target.<sup>1</sup> Similarly, comprehensive prevention services for key populations only reached half of those with unmet need, underscoring the need to further enhance PrEP access and use to reach 2030 goals for ending HIV as a public health threat.<sup>1</sup> Offering a variety of PrEP options with their delivery tailored to the local context could help reduce unmet need and enhance PrEP acceptability, adoption, and persistence in those who need or want PrEP.

Recently, lenacapavir (LEN), a twice-yearly injectable HIV-1 capsid inhibitor, became an additional HIV prevention option to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35kg. With regulatory approvals this year from U.S. FDA (18 June), EMA including EU-M4ALL (26 August),<sup>11,12</sup> South Africa (27 October), and Zambia (7 November), the addition of LEN as a PrEP option has the potential to reduce unmet individual, societal, and public health needs to end the HIV epidemic. The efficacy and safety of LEN PrEP was established in cisgender adolescent girls and young women in the PURPOSE 1 trial<sup>13</sup> and in cisgender men, transgender women, transgender men, and gender non-binary people ≥ 16 years of age who have sex with male partners in the PURPOSE 2 trial.<sup>14</sup> The recently launched World Health Organization (WHO) guidelines for LEN PrEP highlighted the need for research on different strategies to integrate,

implement, and evaluate the public health impact of adding this twice-yearly injectable option to existing PrEP options.<sup>15</sup> This is especially true in the context of alternative delivery settings and reaching more providers, both of which are key strategies identified by WHO to prevent HIV transmission.<sup>15</sup>

With the INCLUSION Global 2026 RFP program, Gilead will evaluate and potentially support research study proposals that address at least one of the following **open research topics/questions**:

1. Evaluate the implementation outcomes (e.g., feasibility, acceptability, adherence, persistence) of new clinical tools, resources, and delivery strategies using LEN PrEP within regionally appropriate care settings, for example:
  - Delivery within existing government public health systems;
  - Integration into new clinical settings (e.g., antenatal care);
  - Specific communities [e.g., Individuals who need or want PrEP (INWP) with unmet need (who are not yet using PrEP); TB-affected populations; adolescents and young adults (AYA)]
2. Delayed PrEP initiation is associated with increased HIV-1 acquisition.<sup>16</sup> Can LEN PrEP be used as a potential modality for same day/rapid PrEP initiation?
3. What is real-life effectiveness in terms of persistence, adherence, satisfaction, Quality of Life (QOL), safety, among PrEP-naïve and those who switch?
4. Relative to existing PrEP programs, what is the effectiveness of integrating LEN PrEP on adherence, persistence, reported satisfaction, health care resource utilization (HCRU) / clinic burden, and costs, among PrEP-naïve and those who switch?
5. How does real-life use of LEN PrEP impact experiences, perceptions, preferences, and satisfaction with PrEP modalities, access to care, and administration setting, including willingness to initiate PrEP and stay on PrEP for those who need or want PrEP?

#### **Eligible Countries:**

We will only accept applications from the following countries at this time:

- Eswatini, Kenya, Lesotho, Malawi, Mozambique, Nigeria, the Philippines, South Africa, Uganda, Zambia, Zimbabwe.

#### **Please note:**

- ***Only proposals where study site(s), participants, and the principal investigator are located in at least one of the 11 countries of interest will be considered. (In the case of multiple principal investigators, at least one principal investigator must be based in a country of interest.)***
- ***Initiation of studies through this RFP will be contingent upon country-specific regulatory approval and availability of LEN PrEP via local public health systems.***
- ***Priority will be given to submissions led by existing, local entities that demonstrate strong technical expertise, commitment to providing access to HIV prevention services, and experience conducting implementation research.***

#### **Lenacapavir supply:**

- LEN PrEP must be leveraged from existing, local public health systems (for example, Ministry or Department of Health supply). **Requests for LEN PrEP supply from Gilead will not be considered.**

#### **Proposals should include descriptions of:**

- Partnership(s) with or endorsement by the relevant Ministry or Department of Health or relevant health authorities confirming that LEN PrEP will be accessible for the participants involved in the research;
- 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 including the number of participants engaged in the research and the PrEP implementation approach;
- Potential for scalability and sustainability of the program after funding completion (when applicable);
- Generalizability to other settings;
- Feasibility of completion of the project within 18 months, followed by rapid dissemination and presentation of results; and
- Plans to present and publish results in scientific forums and peer-reviewed journals.
- Researchers should disclose any sources of funding that may be supporting their research proposals. Funding overlap should be avoided. Otherwise, Gilead reserves the right to request recovery of any misused funds.

**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.**

.....

### Key Dates & Program Specifics:

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

- **1 December 2025:** LOI submission window opens
- **30 January 2026 11:59pm Pacific Standard Time (PST):** LOI submission window closes

LOIs must be submitted via the [Gilead Optics online portal \(G.OPTICS\)](#) in the **HIV Prevention: INCLUSION Global 2026** section.

LOIs are not binding documents on either party. The purpose of the LOI is to provide a 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.

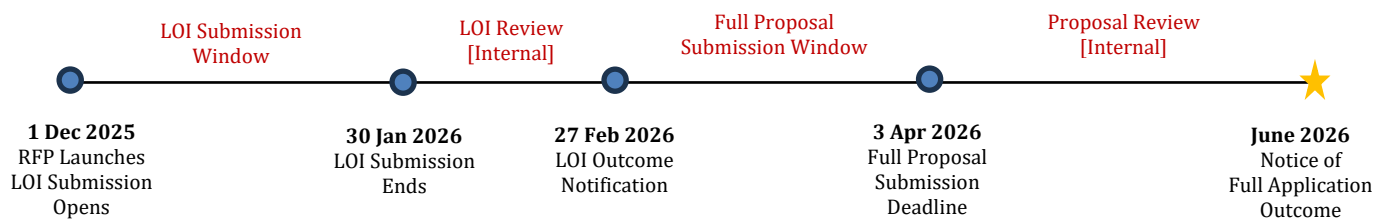
Any questions about the INCLUSION Global 2026 program or application process can be submitted to the Project Officer via [INCLUSION@gilead.com](mailto:INCLUSION@gilead.com).

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 27 February 2026. 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:

- **3 April 2026 at 11:59pm Pacific Standard Time (PST):** Deadline for receipt of full application
- **June 2026:** Notice of full application outcome

### Timeline summary:



Full applications must be completed in [Gilead Optics online portal \(G.OPTICS\)](#) following approval to submit.

Investigators who meet criteria for a standard [Gilead ISR](#) and have a proven track record of conducting research in HIV prevention are encouraged to apply.

The program provides awards for research 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 INCLUSION Global RFP 2026 Program, dependent upon availability of funds and receipt of meritorious applications. Any proposal greater than \$500,000 total costs should be discussed with the Project Officer via [INCLUSION@gilead.com](mailto:INCLUSION@gilead.com). 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.

#### Review Process

LOIs will be rigorously reviewed by a Gilead internal committee. Each complete LOI that meets program requirements will be assigned to multiple reviewers. Each reviewer will review the LOI and 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 deliver on study objectives. This is a competitive process, where proposals will be ranked according to the overall strengths of the submissions. Investigators with the top submissions will be offered the opportunity to submit a full application including a detailed budget, adequate and proportional to the study's scope, 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 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.

Parties confirm that they will not make any payment of money or other assets, including but not limited to the research funds, for lobbying activities, i.e., for discussions with or gifts to government officials or political party officials, candidates for public office or representatives of other businesses or persons acting on behalf of the foregoing aimed at improperly influencing their decisions or actions with respect to the Investigator's research or its affiliates' specific business interests. This includes any payments or any benefit to a government official, to induce such government official to make any governmental act or decision to help the Applicant to obtain or retain business and will not make, and has not made, a payment or offered any item or benefit, regardless

of value, as an improper inducement for such government official to approve, reimburse, prescribe, or purchase a product of Gilead's, or otherwise improperly to benefit Gilead's business activities. For further information, please review our [Anti-Corruption and Anti-Bribery Policy](#).

## 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.

## References:

1. UNAIDS. AIDS, crisis and the power to transform: UNAIDS Global AIDS Update 2025. Geneva: Joint United Nations Programme on HIV/AIDS; 2025. Licence: CC BY-NC-SA 3.0 IGO. Accessed August 21, 2025.
2. HIV.gov. Ending the HIV Epidemic in the US: <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>. Accessed October 30, 2024.
3. UNAIDS. Fact Sheet 2025. [https://www.unaids.org/sites/default/files/2025-07/2025\\_Global\\_HIV\\_Factsheet\\_en.pdf](https://www.unaids.org/sites/default/files/2025-07/2025_Global_HIV_Factsheet_en.pdf) Accessed October 17 2025.
4. UNAIDS. Regional profile: Eastern and Southern Africa. [https://www.unaids.org/sites/default/files/media\\_asset/2024-unaids-global-aids-update-eastern-southern-africa\\_en.pdf](https://www.unaids.org/sites/default/files/media_asset/2024-unaids-global-aids-update-eastern-southern-africa_en.pdf) Accessed October 21, 2025.
5. International AIDS Society. HIV Program in the Philippines. March 14, 2024. Luxent, QC. <https://www.iasociety.org/sites/default/files/2024-03/The%20HIV%20response%20in%20the%20Philippines%20in%202024-Mikhail%20Zion%20Taguegg.pdf> Accessed October 23, 2025.
6. UNAIDS. The path that ends AIDS: UNAIDS Global AIDS Update 2023. Geneva: Joint United Nations Programme on HIV/AIDS; 2023. Licence: CC BY-NC-SA 3.0 IGO. Accessed November 9, 2025.
7. WHO. *HIV/AIDS fact sheet*. World Health Organization 2025. <https://www.who.int/news-room/fact-sheets/detail/hiv-aids>. Accessed November 9, 2025.
8. Payi MA, Abaver D, Apalata T. (2025) A longitudinal macro analysis of social determinants of health and their impacts on HIV prevalence and nutritional deficiencies in Sub-Saharan Africa, *Acta Psychologica*, Volume 255, 2025, 104869, SSN 0001-6918, <https://doi.org/10.1016/j.actpsy.2025.104869>.
9. UNAIDS. Focus: AIDS and Conflict: A Growing Problem Worldwide <https://www.unhcr.org/sites/default/files/legacy-pdf/412ef6452.pdf> Accessed November 9 2025.
10. Peck ME, Davis S, Odoyo-June E, et al. Progress Toward UNAIDS Global HIV Pre-Exposure Prophylaxis Targets: CDC-Supported Oral Pre-Exposure Prophylaxis — 37 Countries, 2017–2023. *MMWR Morb Mortal Wkly Rep* 2024;73:1082–1086. DOI: <http://dx.doi.org/10.15585/mmwr.mm7347a3>.
11. WHO. FDA approval of injectable lenacapavir marks progress for HIV prevention. <https://www.who.int/news/item/19-06-2025-fda-approval-of-injectable-lenacapavir-marks-progress-for-hiv-prevention>. Accessed August 24, 2025.
12. <https://www.gilead.com/news/news-details/2025/european-commission-authorizes-twice-yearly-yeytuo-lenacapavir-for-hiv-prevention>. Accessed August 25, 2025.
13. Bekker L-G, et al. *N Engl J Med*. July 2024 [ePub]. doi: 10.1056/NEJMoa2407001
14. <https://clinicaltrials.gov/study/NCT04925752>
15. WHO. Guidelines on lenacapavir for HIV prevention and testing strategies for long-acting injectable pre-exposure prophylaxis (PrEP). Geneva: World Health Organization; 2025. Licence: CC BY-NC-SA 3.0 IGO.
16. Tao L, et al. IDWeek 2023, Poster 1557