NOVA 2026 Topic of Interest (TOI): Innovative, Scalable Models for Long-Acting HIV Pre-Exposure Prophylaxis (PrEP) Care Delivery in the United States

BACKGROUND

Gilead Sciences invites research proposals that advance the evidence base for innovative and scalable models of delivery for long-acting (LA) HIV pre-exposure prophylaxis (PrEP) in the United States.

This Topic of Interest (TOI) is focused on **care delivery models** implemented in non-traditional settings, defined as clinical and non-clinical environments where PrEP services are not routinely provided. Emphasis is placed on approaches that reflect real-life practice and address gaps in current PrEP delivery infrastructure.

Persistent inequities in PrEP uptake in the U.S. suggest that expanding availability within traditional clinical settings alone is unlikely to reach all populations with unmet PrEP need.[1,2] Rigorous implementation studies in non-traditional settings where PrEP services are not routinely provided are needed to evaluate whether these models can reduce access barriers and improve equitable reach among individuals who may benefit from PrEP.[2,3,4]

The goal of this TOI is to generate practical, decision-relevant evidence that informs how LA PrEP can be implemented, scaled, and sustained in real-life U.S. settings.

PURPOSE AND SCOPE

This TOI is intended to support real-life **interventional research**.

For the purposes of this TOI, “interventional” refers to studies that evaluate a care delivery strategy, workflow, policy, service model, or implementation approach. Studies that are purely descriptive or observational are not responsive to this TOI. Examples of responsive study designs include, but are not limited to, experimental and quasi-experimental studies, pragmatic trials, and hybrid type 2/3 effectiveness-implementation designs.

The overarching aim of this TOI is to support the development of sustainable, transportable, and generalizable models for delivering LA PrEP in diverse, real-life settings. Priority will be given to studies that generate actionable, real-life evidence relevant to stakeholders, including health systems, care providers, payers, and policy decision-makers.

Preference is given to settings not currently receiving PrEP research funding. This TOI is not intended to duplicate other Gilead funding programs or induce or reward prescription of any Gilead product

REQUIRED ELEMENTS FOR RESPONSIVE LETTERS OF INTENT (LOIs)

To be considered responsive, LOIs MUST meet the following three requirements:

1. Address at least one of the following areas:
    a. Evaluation of care delivery models that integrate LA PrEP, such as lenacapavir or cabotegravir into clinical settings that do not routinely provide PrEP
    b. Evaluation of care delivery models that integrate LA PrEP into community-based or non-clinical settings where PrEP delivery has not previously been established or is not routinely provided

2. The proposal must be interventional (as defined above).
3. The proposal must include outcomes that inform implementation, operational feasibility, scalability, or sustainability.

HIGH-PRIORITY SETTINGS AND POPULATIONS

This TOI prioritizes research on U.S.-based PrEP care delivery models designed to address documented PrEP implementation gaps and objective indicators of unmet need, as reflected in CDC guidelines and surveillance data, AIDSVu/PrEPVu PrEP coverage metrics, and peer-reviewed implementation science literature.[5-9]

Populations and settings of particular interest include:

- Persons receiving care in obstetrical, reproductive health or other women's health settings, including during pregnancy and the postpartum period
- Youth (i.e., persons 15-24 years old)
- University, community college, and other higher education settings, including student health services and campus-based care
- Outpatient mental health and substance use treatment settings
- Street medicine programs and other low-barrier care environments serving individuals with limited access to traditional healthcare
- Home-based care and telehealth models
- Transitional housing programs
- Community pharmacies
- Geographically underserved settings

These areas should be interpreted as high-priority examples, and applicants are not required to address all areas listed above. However, strong applications should clearly align with at least one high-priority population and/or setting.

OUTCOMES OF INTEREST

Proposals should prioritize outcomes at the **system-level or program-level**, rather than focusing exclusively on individual-level outcomes.

Studies are expected to focus on **implementation, operational, and/or care delivery endpoints** that inform the **feasibility, scalability, and sustainability** of LA PrEP delivery.

Outcomes of interest include:

- Service delivery efficiency (e.g., visit burden, visits per patient-year)
- Resource utilization and operational feasibility of care delivery models
- Workforce requirements, including use of task-shifting or non-physician staff
- Retention within PrEP delivery programs at the clinic or system level
- Proportion of PrEP-eligible individuals reached within defined populations or settings
- Alignment of care delivery models with reimbursement or payer mechanisms (e.g., reimbursement success, proportion of costs supported through routine payment systems)
- Implementation outcomes based on established implementation science frameworks (e.g., Proctor[10]), including:
    - Feasibility
    - Acceptability
    - Adoption
    - Appropriateness
    - Coverage (reach/penetration)
    - Sustainability (maintenance)
    - Implementation cost

Applicants should select a focused set of primary outcomes that best align with their proposed intervention, rather than attempting to measure all possible implementation constructs.

The most responsive proposals will demonstrate how these outcomes inform whether the care delivery model is feasible, scalable, and sustainable in real-life practice.

FUNDING AND PROJECT DURATION

Gilead plans to award funds for research proposals under the NOVA 2026 TOI Program. Any proposal with total costs greater than $500,000 should be discussed with the Project Officer via NOVA2026@gilead.com. Proposed overhead costs should not exceed 30% of the 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.

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.

Please note:

- Only proposals where study sites, participants, and investigators located in the United States will be considered.
- Requests for drug supply will not be considered.

SUBMISSION

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

- LOI submission window opens: 31 July 2026
- LOI submission window closes: 15 September 2026, 11:59 PM Pacific Time (PT)

LOIs must be submitted via the Gilead Optics online portal (G.OPTICS)

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 TOI. Any questions about the NOVA 2026 TOI program or application process can be submitted to the Project Officer via NOVA2026@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 16 October 2026. Certain applicants will be invited to submit a full application, including a detailed budget. Full applications must submitted in G.OPTICS.

The timelines for submission and review of full applications are as follows:

- Full application deadline: 15 December 2026, 11:59 PM Pacific Time (PT)
- Notice of full application outcome: 01 March 2027

REFERENCES

1. Sullivan PS, DuBose SN, Castel AD, et al. Equity of PrEP uptake by race, ethnicity, sex and region in the United States in the first decade of PrEP: a population-based analysis. *Lancet Reg Health Am.* 2024;33:100738. doi:10.1016/j.lana.2024.100738
2. Mantell JE, Bauman LJ, Bonett S, et al. Innovation in providing equitable pre-exposure prophylaxis (PrEP) services in the US: expanding access in non-traditional settings. *J Acquir Immune Defic Syndr.* 2025;98(5 Suppl):e156-e169. doi:10.1097/QAI.0000000000003610
3. Kamitani E, Mizuno Y, DeLuca JB, Collins CB. Systematic review of alternative HIV pre-exposure prophylaxis (PrEP) care delivery models to improve PrEP services. *AIDS.* 2023;37(10):1593-1602. doi:10.1097/QAD.0000000000003601
4. Merle JL, Benbow N, Li DH, et al. Improving delivery and use of HIV pre-exposure prophylaxis in the US: a systematic review of implementation strategies and adjunctive interventions. *AIDS Behav.* 2024;28(7):2321-2339. doi:10.1007/s10461-024-04331-0
5. Centers for Disease Control and Prevention. Clinical guidance for PrEP. HIV Nexus. Updated April 30, 2026. Accessed July 21, 2026. https://www.cdc.gov/hivnexus/hcp/prep/index.html
6. Siegler AJ, Mouhanna F, Giler RM, et al. The prevalence of pre-exposure prophylaxis use and the pre-exposure prophylaxis-to-need ratio in the fourth quarter of 2017, United States. *Ann Epidemiol*. 2018;28(12):841-849. doi:10.1016/j.annepidem.2018.06.005
7. AIDSVu. AIDSVu releases 2024 PrEP use data showing growing use across the U.S. Published June 26, 2025. Accessed July 21, 2026. https://aidsvu.org/news-updates/aidsvu-releases-2024-prep-use-data-showing-growing-use-across-the-u-s/
8. Tran J, Mishra A, Zimmermann M, Hansen R. Bridging PrEP access gaps: mapping geospatial accessibility across the United States and leveraging community pharmacies for expansion. *J Am Pharm Assoc (2003)*. 2025;65(2):102274. doi:10.1016/j.japh.2024.102274
9. Rutstein SE, Muessig KE. Leveling up PrEP: implementation strategies at system and structural levels to expand PrEP use in the United States. *Curr HIV/AIDS Rep*. 2024;21(2):52-61. doi:10.1007/s11904-024-00697-x
10. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health*. 2011;38(2):65-76. doi:10.1007/s10488-010-0319-7