GATHER AND LISTEN RFP

Viral hepatitis and human immunodeficiency virus (HIV) remain major global health challenges, with overlapping risk factors, co-infection patterns, and barriers to care. Despite advancements, significant gaps persist in access to screening, linkage to treatment, integration of care models, and addressing gender-based disparities in healthcare. The World Health Organization (WHO) has set a goal to eliminate viral hepatitis and HIV as public health threats by 2030, but achieving this requires innovative, evidence-based interventions to ensure equitable healthcare delivery. Studies have shown that gender disparity exists in viral hepatitis care.[1] Effective, gender-inclusive models must be developed and best practices for interventions replicated as part of a global commitment to achieve health equity.[2]

Beyond infectious disease, autoimmune liver conditions may pose significant issues for long-term liver health. Primary biliary cholangitis (PBC) is a chronic, autoimmune cholestatic liver disease characterized by progressive destruction of bile ducts that can lead to cirrhosis, liver failure, and in severe cases, patient mortality.[3,4] PBC is a disease with significant unmet needs that mostly affects women.

To better understand key challenges at the intersection of viral hepatitis (HBV, HCV, HDV), PBC, and HIV prevention and treatment, Gilead is launching the GATHER AND LISTEN RFP, with a focus on health equity, gender disparities, and optimizing provider and system-level practices across virology and PBC.

The GATHER AND LISTEN Request for Proposal (RFP) represents the merging of two previous initiatives – GATHER, which focused on integrating viral hepatitis and HIV care, and LISTEN, which aimed to advance gender-equitable healthcare strategies for viral hepatitis. This year, the RFP also expands to include PBC, a chronic autoimmune liver disease that disproportionately affects women, with ongoing research into new treatment options like seladelpar.

RFP Research Topics

Gilead will evaluate and support select proposals that target the following research questions:

Long-Term Health Outcomes for Women with Viral Hepatitis or Primary Biliary Cholangitis (PBC)

- What are the long-term health implications for women with PBC or women who have been previously treated for viral hepatitis?
- How do treatment-related factors (e.g., antiviral therapy, PBC therapy, disease progression) affect metabolic, cardiovascular, and reproductive health outcomes in women?
- How can women's symptoms related to liver disease be better assessed and addressed?
- What strategies can improve long-term retention in care and post-treatment follow-up for women?

Implementation of Integrated HIV & Hepatitis Care Models

- What are the real-world outcomes of integrated HIV/hepatitis care models, and how can they be scaled up and sustained? What gender barriers exist in these care models?
- What are the barriers and facilitators to integrating PrEP with blood-borne virus screening and treatment? Are there any gender-specific barriers or facilitators?
- How can technology and telemedicine be leveraged to improve linkage to care for co-infected individuals in underserved areas? Is there anything gender specific that can be leveraged as well?

Addressing Social & Structural Barriers to Care

- What interventions can improve healthcare access and narrow the disparities caused by social determinants of health or gender in individuals living with both HIV and viral hepatitis or PBC?
- What are the clinical (e.g., virologic markers, resistance, safety), humanistic (e.g. QoL, PROs, engagement in care), and economic (e.g., HCRU, costs) outcomes associated with restricted or incomplete access to viral hepatitis care or treatment?
- What are the barriers to care for women, people who inject drugs, sex workers, and other underserved populations, and how can these be overcome?
- How can gender-specific and culturally appropriate models of care improve screening, diagnosis, engagement, linkage to care, and treatment?

RFP Application Criteria

- Both investigator-sponsored research (ISR) study proposals and Collaborative research study proposals (developed in conjunction with Gilead) will be considered (link to additional information on ISR vs Collaborative studies)
- Letters of Interest (LOIs) will only be reviewed in countries where the study drug(s) have regulatory approval and are commercially available.
- Proposed research endpoints should be based on sound scientific hypotheses and generalizable across countries/regions
- Research proposals should include a comprehensive publication plan to present study results at scientific forums and to publish results in peer reviewed journals
- The proposed budget should be appropriately proportional with the study's scope
    - The proposed budget should include overhead costs and applicable taxes; overhead costs should not exceed 30% of the total budget
- The proposed study design should be feasibly executed within a reasonable timeframe proportional to the study's follow-up duration
- There must be no more than one sponsor for contract negotiations and/or Institutional Review Board (IRB) review
- 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 and ethical approvals before beginning the study

RFP Application Process

To apply for consideration for funding under the GATHER AND LISTEN RFP Program, you will need to submit an LOI* that is no longer than two pages, contains a concise overview of the proposed project and includes the total estimated budget. Applicants should submit the LOI application in the Gilead OPTICS portal.

How to Submit an LOI in Gilead OPTICS for the GATHER AND LISTEN RFP:

- Create an account, or login to your existing account in G. OPTICS
- Select "New Letter of Interest (LOI)"
- Select "Women and Viral Hepatitis: GATHER AND LISTEN RFP" from the list of active RFPs
- Complete the required fields
- Submit the LOI

Gilead will evaluate and rank all Letters of Interest (LOIs) received on a rolling basis until funds are exhausted.

- Submission window opens April 30, 2025, at 00:00 AM (in your time zone)
- Submission window closes June 20, 2025, at 23:59 PM (in your time zone)

Questions about the RFP or the application process can be submitted to your local Gilead Medical Science Liaison.

LOIs will be rigorously reviewed by a Gilead internal committee. 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 and study team's ability to recruit the proposed study population and execute on study objectives. Investigators with the top submissions will be offered the opportunity to submit a full proposal including a detailed budget, adequate and proportional to the study's scope, which will be similarly reviewed.

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.

No Guarantee of Funding

Gilead reserves the right to approve or decline any proposal at its sole discretion. Submission of an LOI or a full proposal does not guarantee funding.

Awards shall be for research purposes only; routine medical care or other costs associated with routine medical care will not be considered for 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 award/research, the awardee is not required to purchase, order,

recommend or 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.

References

1. Lindor KD, et al. Hepatology. 2019;69(1):394-419 (Primary Biliary Cholangitis: 2018 Practice Guidance from the American Association for the Study of Liver Diseases [AASLD]

2. American Liver Foundation. Primary biliary Cholangitis (PBC). Updated March 22, 2024. Accessed January 6, 2023. https://liverfoundation.org/liver-diseases/autoimmune-liver- diseases/primary- biliary-cholangitis-pbc/

3. Pearce, M, et al. "Women in the 2019 hepatitis C cascade of care: findings from the British Columbia Hepatitis Testers cohort study." *BMC Women's Health* 21 (2021): 1-15.

4. Larney, S., Madden, A., Marshall, A. D., Martin, N. K., & Treloar, C. (2022). A gender lens is needed in hepatitis C elimination research. *International Journal of Drug Policy*, *103*, 103654.

Footnotes

**LOIs are not binding documents for either party. The purpose of the LOI is 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.*