

(Gateway for Access, Testing, and Hepatitis/HIV Evaluation and Referral)  
**Gilead GATHER RFP 2024**

Through the Medical Affairs Investigator-Sponsored Research (ISR) Program, Gilead supports the research efforts of academic institutions, clinical investigators, and community-based organizations. Gilead supports these studies based on the validity of the scientific question proposed to be addressed, and whether the results will fill a data gap in clinical research and not duplicate previous studies/data that are already available. Recognizing that risk factors and populations of interest overlap across Hepatitis B, C, and D, as well as HIV treatment and prevention, Gilead is issuing a specific call for studies and proposals that encompass multiple disease areas.

The global burden of viral hepatitis is estimated to affect approximately 354 million people, with hepatitis B and C being the most prevalent forms.<sup>1</sup> HDV presents a risk for people living with hepatitis B and can exacerbate the severity of HBV-related liver disease.<sup>1</sup> Meanwhile, HIV affects roughly 38 million people globally.<sup>2</sup> Co-infection with multiple viruses is not uncommon due to overlapping potential exposures, with an estimated 5% to 20% of people with HIV experiencing chronic HBV infection and approximately 25% are coinfecting with HCV.<sup>3,4</sup> Many individuals living with these viruses are unaware of their status and may face barriers to accessing care and treatment. Furthermore, stigma and discrimination continue to be significant barriers to support and care for people living with these viruses, especially relating to precluding PrEP engagement and people living with bloodborne pathogens (PWBPs).<sup>5</sup> In 2014, the HIV 95:95:95 UNAIDS 2030 goals for HIV treatment aimed to ensure that 95% of people living with HIV know their status, 95% of those diagnosed with HIV receive sustained antiretroviral therapy, and 95% of people receiving antiretroviral therapy have viral suppression.<sup>6</sup> In 2016, the WHO Global Health Sector Strategy (GHSS) provided a framework for the elimination of viral hepatitis and HIV as a public health problem by 2030.<sup>7</sup> However, continued investment, collaboration, and commitment are needed to evaluate and address remaining challenges to achieve these goals.

### **Research Objectives:**

Gilead recognizes the unmet need for comprehensive and innovative healthcare strategies and research that address the holistic health needs of patients. Through the **Gilead GATHER 2024** request for proposals (RFP) process, Gilead will evaluate and potentially support research proposals worldwide that address the following areas of interest and seek to answer the following open research questions:

### **Testing and Screening Optimization:**

1. What are the most cost-effective strategies and settings for implementing opt-out testing for blood-borne viruses?
2. How can screening programs be optimized to reach key populations, such as people who inject drugs, gay men and other men who have sex with men, and individuals who may be exposed from multiple infections concurrently?
3. What strategies are effective to integrate pan-viral (HBV/HCV/HDV/HIV) testing and linkage to treatment and/or prevention services in drug treatment centers, family planning settings, and sexual health clinics or other settings offering sexual health services?

### **Access and Integration**

1. What interventions are effective in helping to improve healthcare access and narrow the disparities caused by social determinants of health in people living with both HIV/hepatitis?
2. What are the barriers and facilitators to accessing hepatitis care among individuals living with HIV or people who could benefit from PrEP and vice versa?

3. How can we implement interventions to increase PrEP usage among individuals who could benefit from pre-exposure prophylaxis (PrEP) regardless of their viral hepatitis status?
4. What are the outcomes of integrated care models that combine HIV and hepatitis services, and how can these models be scaled up and sustained in all health care settings?
5. What is the feasibility and acceptability of integrated care models from a patient, provider, community, and healthcare administrator perspective?
  - a. What are the barriers and facilitators to integrating PrEP and blood-borne virus screening within existing healthcare systems?

### **Provider Practices and System Optimization:**

1. What factors may contribute to viral hepatitis transmission among individuals who are on PrEP for HIV prevention or those living with HIV? Are there specific behavioral, social, or biological factors besides injection drug use and certain sexual practices that increase the risk of HCV transmission despite PrEP use?
2. How can referral and navigation systems be optimized to facilitate seamless transitions between HIV PrEP and treatment as well as hepatitis care settings?
3. How can technology and telemedicine be leveraged to improve linkage to care for co-infected individuals, particularly in remote or underserved areas?
4. What is the level of knowledge and awareness among healthcare providers regarding the co-occurrence of HIV and HCV, and the need for integrated screening and prevention services? Are there gaps in provider training and education that impact the delivery of comprehensive care?

### **Proposals should include (where appropriate) descriptions of:**

- Incorporation of people with lived experience, community, and/or user/participant involvement in study planning and study design and protocols
- Clear scientific objectives and endpoints, based on sound scientific hypotheses
- Appropriate, defined, and specific data collection/evaluation methods
- 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 data dissemination and presentation of results.

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.

### **Budget Considerations**

Gilead plans to award funds for research proposals under the Gilead GATHER 2024 RFP, dependent upon availability of funds and receipt of meritorious applications. Any proposal greater than \$200,000 should be discussed with your Gilead Medical Science Liaison prior to submission.

### **Application Process & Key Dates:**

To apply for consideration for funding under the **Gilead GATHER RFP Program**, you will need to submit a concept request that is no longer than two pages, containing a concise overview of the proposed project, including the total estimated budget. Applicants should submit the concept request in the [Gilead OPTICS portal](#).

Gilead will evaluate and rank all concept requests received on a rolling basis until funds are exhausted. After an initial concept review, invitations will be issued for selected applicants to submit a full application with a detailed budget. **It is recommended to submit as soon as possible to ensure that funding is available for your proposal.**

- April 15, 2024 at 00:00 AM GMT: Submission window opens
- June 15, 2024 at 23:59 PM GMT: Submission window closes

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

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 application at its sole discretion. Submission of a concept or a full application 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's 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.

### **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. World Health Organization . *Global Progress Report on HIV, Viral Hepatitis and Sexually Transmitted Infections*. Geneva: WHO; (2021).
2. Challacombe SJ. Global inequalities in HIV infection. *Oral Dis*. 2020;26 Suppl 1:16-21. doi:10.1111/odi.13386
3. Mohd A, Sami H, Khan PA, Khan HM. A Review on the Epidemiology of HBV and HIV Co-Infection. *CHRISMED Journal of Health and Research*. 2023;10(1):1. doi:https://doi.org/10.4103/cjhr.cjhr\_34\_22
4. Bar N, Bensoussan N, Rabinowich L, et al. Barriers and Facilitators of Hepatitis C Care in Persons Coinfected with Human Immunodeficiency Virus. *Int J Environ Res Public Health*. 2022;19(22):15237. Published 2022 Nov 18. doi:10.3390/ijerph192215237
5. Smith-Palmer J, Cerri K, Sbarigia U, et al. Impact of Stigma on People Living with Chronic Hepatitis B. *Patient Relat Outcome Meas*. 2020;11:95-107. Published 2020 Mar 9. doi:10.2147/PROM.S226936
6. Musuka G, Moyo E, Cuadros D, Herrera H, Dzinamarira T. Redefining HIV care: a path toward sustainability post-UNAIDS 95-95-95 targets. *Front Public Health*. 2023;11:1273720. Published 2023 Oct 19. doi:10.3389/fpubh.2023.1273720
7. Hutin Y, Low-Beer D, Bergeri I, et al. Viral Hepatitis Strategic Information to Achieve Elimination by 2030: Key Elements for HIV Program Managers. *JMIR Public Health Surveill*. 2017;3(4):e91. Published 2017 Dec 15. doi:10.2196/publichealth.7370