Gilead Sciences Medical Affairs Request for Proposal (RFP)

LINK-DBU 2.0 (Linking Diagnosed but Untreated HBV Patients to Care)

Chronic hepatitis B (CHB) can be a life-threatening liver infection caused by the hepatitis B virus (HBV).[1] CHB continues to be a major public health issue despite the availability of an effective vaccine and potent antiviral therapies. Untreated individuals with CHB have an estimated 30%- 40% lifetime risk of cirrhosis or hepatocellular carcinoma (HCC).[2] Therapy for HBV has greatly improved, with the availability of effective and safe oral antivirals with high barriers to resistance.[3] Additionally, treatment has been shown to decrease the occurrence of complications such as liver decompensation and hepatocellular carcinoma.[4-6]

Globally, it is estimated that over 250 million individuals are Hepatitis-B surface antigen (HBsAg)-positive, of which 36 million patients are diagnosed as of 2022.[7] Among 83.3 million estimated to be treatment eligible based on 2022 criteria, only 6.8 million are actually being treated.[7] Additionally, an estimated 1.1 million deaths were due to HBV, mostly due from cirrhosis and HCC.[8] For example, in the United States, it is estimated that among 1.6 million infections, 323,000 are diagnosed and 499,000 qualify for treatment;[7,9] yet, only 144,000 are estimated to receive treatment.[7] Similar trends with diagnosed but untreated (DBU) patients have also been observed in other parts of the world, despite variations in practice guidance on the regional and country-levels.[7]

These DBU patients—particularly those who are diagnosed, qualify for treatment, and remain untreated—represent an important patient segment. By definition, clinical guidelines on both the regional society level (e.g. EASL, APASL, AASLD)[10-13] as well as the country-level (e.g. China, Taiwan, Korea, Japan)[14-17] have identified patients who fit these profiles as benefiting from treatment. Therefore, these patients represent an important missed opportunity to mitigate the risks of HBV-related morbidity and mortality.

Collectively, these data suggest that regardless of treatment guideline, there remains a gap between recommended clinical guidance and actual practice. The underlying cause(s) of the gap is not understood.

RFP Research Topics

Gilead is interested in supporting global research proposals that address, but are not limited to, the following research questions:

1) What methods can be utilized to find diagnosed but untreated patients that have been lost to follow-up?

2) What are the reason(s) for lack of treatment among HBV patients who are diagnosed, qualify for treatment, yet remain untreated? How can these be addressed?

3) What effective strategies and interventions can be incorporated for HBV treatment and improve linkage to care for the diagnosed but untreated HBV population?

4) What existing healthcare policies and infrastructures can be modified or improved to enhance linkage to care and treatment?

5) What personalized approaches and patient-centric aspects can be designed or utilized to address the unique barriers faced by individual patients with CHB to ensure effective linkage to care?

Please note that the purpose of this RFP is not to establish a mechanism for disease screening. The primary focus is on ensuring effective linkage to care.

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. There must be no more than one sponsor for contract negotiations and/or Institutional Review Board (IRB) review.

The letter of interest (LOI) should include (where appropriate) descriptions of:

- 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;
- Generalizability to other settings; and
- Feasibility of completion of the project within 18 months, followed by rapid data dissemination, presentation and publication of results.

Additional consideration will be given to study proposals that also provide insights on how to address potential disparities by gender, race, or ethnicity.

Budget Considerations
Gilead plans to award funds for research proposals under the **LINK-DBU 2.0 RFP**, dependent upon availability of funds and receipt of meritorious and complete applications. Any proposal greater than $150,000 should be discussed with your Gilead Medical Science Liaison prior to submission. The proposed budget should include overhead costs and applicable taxes. Proposed overhead costs cannot exceed 30% of the total budget.

Application Process
To apply for consideration for funding under the **LINK-DBU 2.0 RFP** program, you will need to submit an LOI that contains a concise overview of the proposed project, including the total estimated budget. Applicants should submit the LOI application in the Gilead OPTICS (G. OPTICS) portal. Submitted LOIs can be investigator-sponsored research (ISRs) or collaborative studies. More information about these types of research can be found here.

Gilead will evaluate all LOIs received on a rolling basis until funds are exhausted. After an initial LOI 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 increase the likelihood that funding is available for your proposal.**

- **Monday, June 23rd, 2025 at 00:00 AM (in your time zone): Submission window opens**
- **Monday, August 11th, 2025 at 23:59 PM (in your time zone): Submission window closes**

Questions about the RFP or the application process can be submitted to your local Gilead Medical Science Liaison. A review of the LOIs will result in invitations for selected LOI applicants to submit a full proposal with a detailed budget.

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 execute on study objectives. Investigators with the top submissions will be offered the opportunity to submit a full proposal, which should include a comprehensive publication plan to present study results at scientific forums and publish results in peer-reviewed journals as well as a detailed budget, adequate and proportional to the study's scope, which will be similarly reviewed.

How to Submit an LOI in G.OPTICS for the LINK-DBU 2.0 RFP

1. Create an account or log into your account in G.OPTICS.
2. Select "New Letter of Interest (LOI)."
3. Select "**HBV: LINK-DBU 2.0 RFP**" from the list of active RFPs.
4. Complete the required fields.
5. Submit the LOI.

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. Awards shall be for research purposes only; routine medical care or other costs associated with routine medical care will not be considered for funding. Gilead discourages proposals that solely request study drug or funds for HBV screening costs. 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.

If study drug is requested, Gilead may only provide it in countries where the study drug(s) have regulatory approval and are commercially available.

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 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

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**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.*