Gilead Sciences Medical Affairs Request for Proposal (RFP)

LINK-DBU (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] 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;[7,8] 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)[9-12] as well as the country-level (e.g. China, Taiwan, Korea, Japan)[13-16] 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.

As a result, Gilead is interested in supporting research aimed at:

1) Understanding the reason(s) for lack of treatment among HBV patients who are diagnosed, qualify for treatment, and yet remain untreated

   and/or

2) Identifying ways to improve linkage of these patients 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.

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

Preference will be given to studies employing **existing data sources** (eg, real world databases, existing cohorts) rather than the establishment of prospective cohorts. 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 2024 RFP**, dependent upon availability of funds and receipt of meritorious 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 should not exceed 30% of the total budget. Awards shall be for research purposes only; routine medical care or other costs associated with routine medical care will not be considered for funding. As this study focuses on understanding and/or improving the linkage of DBU patients to care, study designs should not involve drug treatment. Proposals should be agnostic as to choice of treatment and should not require the use of a specific HBV drug.

Application Process & Key Dates:

To apply for consideration for funding under the **LINK-DBU RFP Program**, you will need to submit a letter of intent (LOI) that is no longer than two pages, containing a concise overview of the proposed project, including the total estimated budget. Applicants should submit the LOI in the Gilead OPTICS portal. Submitted LOIs can be investigator-sponsored research (ISRs) or collaborative studies.

Gilead will evaluate all LOI requests 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, April 15, 2024 at 00:00 AM GMT: Submission window opens**
- **Friday, July 26, 2024 at 23:59 PM GMT: Submission window closes**

The LOIs will be rigorously reviewed by an internal Gilead committee on a competitive basis. The committee will 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 execution of study objectives. The LOIs are not binding documents for either party.

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

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.

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. The awardee is not required to purchase, order, recommend or prescribe to any patients any products manufactured by or available through Gilead. Gilead's approval of awards will depend on the availability of funds and receipt of meritorious and complete proposals.

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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