HBV B-PRO Request for Proposals (RFP)

Evaluating Patient-Reported Outcomes Associated with HBV Treatment

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 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]

Understanding the patient experience, beyond clinical endpoints, is critical for optimizing patient care and improving overall health outcomes. Utilizing patient-reported outcomes (PROs) in addition to clinical data as a tool to provide insight into patients' perspectives on treatment experience, quality of life, and overall well-being can shed light on how HBV treatment affects individuals' daily lives and influence perspectives on their healthcare and well-being.

Evaluating the impact of HBV treatment on patient-reported outcomes is a gap that can complement clinical data to shape therapeutic strategies, clinical decision making, educational initiatives and policy decisions to enhance the outcomes for HBV patients.

RFP Research Topics

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

Innovation & Implementation

1. How can patient-reported outcomes, such as treatment satisfaction and perceptions of care, be integrated into the clinical decision-making process for CHB and/or used to enhance the overall quality of care for patients? Can PROs be utilized to guide decisions on initiating therapy?
2. What existing PRO tools (e.g. Hepatitis B Quality of Life instrument [HBQOL], Adelphi Disease Specific Programmes [DSPs], etc.) can be effectively implemented to engage patients in their management of CHB? How can they be revised to involve patients in their care more effectively?
3. Are there additional innovative PRO tools that can be developed to engage patients in their care, empowering patients as the key stakeholder in their management of HBV?
4. How can we utilize patient-reported outcomes to understand what challenges/barriers exist with HBV treatment?
5. How can digital tools be utilized to capture and measure patient-reported outcomes? Can the tool be used to enhance overall patient outcomes? What specific features should these tools have to ensure they capture meaningful and actionable insights?

Patient Experience and Outcomes

1. What patient-reported outcomes can provide insights into the patient experience living with HBV both on and off treatment?
2. What physical, emotional, mental, and social challenges do patients commonly face in maintaining consistent adherence to their HBV treatment plans? What strategies or interventions could effectively address these barriers and enhance adherence?
3. How do perceived medication adherence and patient satisfaction differ between patients on tenofovir alafenamide (TAF) vs. those on other nucleos(t)ide analogues for the treatment of HBV?
4. What patient-reported outcomes are predictors and risk factors for suboptimal response to antiviral therapies or other long-term treatment related outcomes?

Along with 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 and presentation 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 **B-PRO 2025 RFP**, dependent upon availability of funds and receipt of meritorious and complete applications. Any proposal greater than $200,000 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 **B-PRO RFP 2025 Program**, you will need to submit an 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 application in the Gilead OPTICS (G. OPTICS) portal. Submitted LOIs can be investigator-sponsored research (ISRs) or collaborative studies.

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, March 10th, 2025 at 00:00 AM (in your time zone): Submission window opens**
- **Monday, May 19th, 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 B-PRO RFP

1. Create an account or log into your account in G.OPTICS.
2. Select "New Letter of Interest (LOI)."
3. Select "HBV: B-PRO 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.

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

1. Jeng WJ et al. *Lancet* 2023; 401:1039-52.
2. Huang YT et al. *J Clin Oncol* 2011; 29:3643-50.
3. Wong GL et al. *Aliment Pharmacol Ther* 2018; 47:730-737
4. Gordon SC et al. *Clin Gastroenterol Hepatol* 2014; 12: 885-893.
5. Liaw YF et al. *N Engl J Med* 2004; 351:1521-1531.
6. Seto WK et al. *Aliment Pharmacol Ther* 2017; 45: 501-509.

**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.*