GILEAD
Creating Possible

Gilead Sciences Medical Affairs Request for Proposal (RFP)

Special Populations for TAF Safety and Efficacy (SPOT)

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]

Tenofovir alafenamide (TAF) is a phosphonamidate prodrug of tenofovir. In pivotal studies, TAF demonstrated a non-inferior efficacy and improved bone and renal profiles when compared to tenofovir disoproxil fumarate (TDF).[7,8] At 5 years, long-term follow up study participants demonstrated continued efficacy and safety in comparison to TDF, while maintaining no detectable resistance.[9-11]

TAF has been studied in diverse populations, such as those with multi-drug resistance, renal and hepatic dysfunction, renal transplantation, and stable switch from other oral antiviral agents. However, data gaps in specific populations remain and the addition of these data will facilitate clinical decision making for health care practitioners in the management of hepatitis B.

Gilead is interested in supporting research studying the efficacy and safety of TAF in special populations such as:

- Patients with decompensated cirrhosis (Child's Turcotte Pugh Score B/C)
- Older patients ≥65 years of age
- HBV reactivation in patients receiving immunosuppressants for conditions excluding cancer (eg., rheumatologic, autoimmune and dermatologic conditions, etc.)
- Patients with underlying bone and/or renal comorbidities (eg. osteopenia, osteoporosis, renal insufficiencies, chronic kidney disease)

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. TAF should have current regulatory approval for CHB at the time of study initiation in the country the study will be conducted in as well as in the population(s) that the study will be on.

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 **SPOT 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 the emphasis is on the use of existing datasets, Gilead discourages proposals that involve study drug or solely request funds for HBV screening costs.

Application Process & Key Dates:

To apply for consideration for funding under the **SPOT 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 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, April 15, 2024 at 00:00 AM GMT: Submission window opens**
- **Friday, June 14, 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. Awards shall be granted solely on the merit of the research and alignment with the criteria of this program.

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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