LISTEN RFP

viraL hepatItiS equiTy for womEN

The **LISTEN** Request for Proposal (RFP) is a call to action through Gilead's Medical Affairs Phase 4 Investigator-Sponsored Research (ISR) and Collaborative Research program. Gilead supports academic institutions, clinical investigators, research networks, community-based organizations, and others, to conduct new and innovative studies that address health disparities relevant for women and viral hepatitis.

The World Health Organization (WHO) set a goal for Elimination of Hepatitis by 2030 attainable through targeted rates for diagnosis, treatment, reducing incidence and preventing deaths[1]. However, studies have shown that gender disparity exists in viral hepatitis care[2]. Effective, gender-inclusive models must be developed and best practices for interventions replicated as part of a global commitment to achieve health equity in viral hepatitis care[3].

Research Objectives

The **LISTEN** RFP underscores our commitment to health equity for women and presents the opportunity to advance effective gender-appropriate care for viral hepatitis. It is critical that research continues to focus on the experience of women and include data stratified by gender to correct existing disparities for hepatitis B, C, and D. Gilead champions research that would add new evidence, insights, and knowledge. Proposals that simultaneously target HCV, HBV and/or HDV are encouraged. Gilead will consider research proposals that address (but are not limited to) the following research questions:

Innovation & Implementation

1. What are ways to evaluate screening, linkage to care, and treatment that may show previously unidentified gender disparities in viral hepatitis? For identified areas of disparities, what predictors (if any) were found and what actions can lead to improvements?
2. How can simplified treatment algorithms can be used to enhance the care and treatment of women with viral hepatitis? What are innovative models for the care and treatment of women?
3. What opportunities exist for enhancing the adoption and implementation of guidelines regarding the screening, linkage to care, and treatment of women with viral hepatitis?
4. Where are effective locations in which providers can meet women at risk for viral hepatitis, perhaps in non-traditional settings outside of typical health care visits)? What system innovations and processes would expedite engagement of women in the care continuum for viral hepatitis?

Women's Experience - A Holistic Framework

1. What factors have led to improved outcomes for women? What constitutes a positive experience, and what are the barriers and concerns that may prevent women from initiating and completing therapy?
2. What are ways to improve screening for viral hepatitis during pregnancy and postpartum? How can screening of children born to mothers with viral hepatitis be improved (e.g. in the foster care system)?
3. What can we learn from patient-reported experiences (qualitative research) about gender disparities as well as solutions for those disparities?

Extrahepatic Manifestations and Outcomes of Viral Hepatitis Affecting Women

1. What are the predictors and risk factors specifically associated with disease progression in women with viral hepatitis? Are there any clinical outcomes specifically associated with viral hepatitis in women?
2. What is the safety and efficacy of antiviral therapy in women at particular risk of complications from treatment, including bone/renal risk, age of patients, etc.?
3. In patients with suboptimal response to antiviral therapies, what are ways that we can support women to improve engagement and treatment outcomes?

Proposals should include:

- Clear scientific objectives, endpoints, and study design based on sound scientific hypotheses
- Appropriate, defined, and specific data collection/data analysis methods
- Incorporation of people with lived experience, community/participant involvement in study planning and study design and protocol (when applicable)
- No more than one sponsor for contract negotiations and/or Institutional Review Board (IRB) / Ethics Committee (EC) review
- Scalability and sustainability of the program after funding completion (when applicable)
- Generalizability to other settings; and
- Feasibility of project completion within 18 months, followed by rapid dissemination/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.

Application Process & Key Dates:

To apply for consideration for funding under the **LISTEN RFP Program**, you will need to submit a Letter of Intent (LOI) 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 LOI request in the Gilead OPTICS portal.

Gilead will evaluate and rank 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 ensure that funding is available for your proposal.**

- Friday, April 12th, 2024, at 00:00 AM GMT: Submission window opens
- Saturday, June 15th, 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.

Budget Considerations

- Gilead plans to award funds for research proposals under the **LISTEN 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,
    - The total budget should include overhead costs and applicable taxes;
    - Overhead costs should not exceed 30% of the total budget

No Guarantee of Funding

Gilead reserves the right to approve or decline any application at its sole discretion. Submission of a 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.

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 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. Further, 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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