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SPEARHEAD 2024 RFP:

Screening imPlEmentation and linkage to cARe in HEpAtitis Delta

Chronic hepatitis delta virus (HDV) is the most severe form of viral hepatitis, occurring in some patients who are infected with hepatitis B virus (HBV). HDV leads to a rapid progression of liver disease, increasing the risk of cirrhosis, decompensated cirrhosis, liver transplant, HCC, and mortality compared to HBV alone. [1,2,3] The global prevalence of HDV is estimated to be between 5% to 13% in HBsAg-positive patients, accounting for 12 to 60 million infected individuals worldwide.[4,5] However, HDV is largely underdiagnosed due to due to the lack of universal testing of HBV-positive individuals for HDV.[6] Given the disease severity and general underdiagnosis of HDV, there is an unmet need for enhanced screening and linkage to care in those with HBV.

The European Association for the Study of the Liver (EASL) recommends HDV screening for all patients infected with HBV.[8] Even with this guideline recommendation in place, recent data from Europe have demonstrated a large proportion of HBV patients remain untested for HDV.[9,10] However, interventions such as the implementation of reflex testing have shown to be effective at significantly improving screening practice leading to the identification of previously undiagnosed patients.[11,12]

To understand and address barriers to HDV screening and linkage to care, Gilead launched the **SPEARHEAD** RFP program in 2022 in the US, extended the program to Europe in 2023, and will relaunch the program globally in 2024. The program will support individual projects up to 200,000 USD. Projects greater than 200,000 USD will require discussion with Gilead before submission.

Applications should include projects that can be completed within 18 months and demonstrate clear objectives, include defined timelines, offer a comprehensive operational plan, propose data that has relevance to the medical community and policymakers, and includes plans for the data to be submitted to relevant congresses and journals. The program is open to applications from all countries; however, special emphasis will be placed on geographies with high HDV burden and in countries in which treatment for HDV is available.

Gilead may provide research funds for screening & testing support only if it is an essential component of a valid study design to address the research needs outlined in the RFP. Gilead will not consider proposals that request HDV study drugs and is not seeking studies that focus on treatment outcomes. Proposals should be treatment/drug agnostic.

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Application Criteria

- Gilead will evaluate and support select programs which will:
    1. Generate data to understand the impact of HDV screening implementation in individuals living with HBV
        - Examples include but are not limited to:
            - Implementation of reflex testing to screen all positive HBV samples for HDV
            - Leveraging EMR and other digital platforms to enhance screening rates
            - Optimization of screening rates for appropriate patients in high-prevalence settings
            - Enhancing screening awareness within varied populations and settings such as primary care, HIV clinic, safety-net clinics
        - Studies should aim to perform HDV screening in individuals with known HBV status only
        - Studies should aim to evaluate HDV screening practice before and after study implementation, including the proportion of HBsAg+ patients screened, number of HDV diagnoses, and HDV prevalence rates
    2. Generate data to assess current HDV linkage to care practice, identify barriers, develop, and implement novel approaches to enhance linkage to care
        - Examples include but are not limited to:
            - Healthcare provider survey to understand current care approaches to generate insights on existing barriers
            - Chart analyses to identify patient or institutional factors associated with suboptimal linkage to care and implement quality improvement measures
            - Implementation of case managers and other patient resources to decrease rates of patient disengagement
            - Novel approaches to engage and educate patients and caregivers
- Both investigator-sponsored research study proposals and collaborative research study proposals (developed in conjunction with Gilead) will be considered
- Study sponsor is not currently receiving Gilead grants to conduct HDV screening
    - The same institution may receive multiple grants for HDV screening if they are mutually exclusive to the sponsoring department (i.e. Hepatology vs ED)
- Research proposals should include a comprehensive publication plan to present study results in scientific forums, and to publish results in peer reviewed journals
- Proposed budget is under 200,000 USD; advance discussion with Gilead is required prior to submission of proposal with a budget over 200,000 USD
    - The budget should include overhead costs and applicable taxes
    - Proposed overhead costs should not exceed 30% of the total budget
- The proposed study design will not take longer than 18 months to complete
- Proposals will be evaluated for scalability and sustainability of the program after funding completion (when applicable)
- Funding for screening & testing supplies may be provided as part of a valid study design to address the research needs outlined in the RFP
- Funding for or contribution of study drugs will not be provided
- There must be no more than one sponsor for contract negotiations and/or Institutional Review Board (IRB) review

Application Process

To apply for consideration for funding under the SPEARHEAD RFP Program, you will need to submit a Letter of Intent (LOI) that is no longer than two pages, contains a concise overview of the proposed project and includes the total estimated budget. Applicants should submit the LOI application in the Gilead OPTICS portal.

Gilead will evaluate and rank all letters of intent (LOIs) received on a rolling basis until funds are exhausted. **It is recommended to submit earlier than later to ensure that funding is available for your proposal.**

- Monday March 4th, 2024 at 00:00 AM GMT: Submission window opens
- Friday September 27th, 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 Scientist or SPEARHEAD@gilead.com. A review of the LOIs will result in invitations for selected LOI applicants to submit a full application with detailed budget.

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.

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.

The program provides awards for proposals completed in up to 18 months. 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 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.

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