



Gilead Sciences, Inc.

Medical Affairs

Call for Proposals for HDV DESCRIBE Program

(HDV Epidemiology, Screening and Barriers to Linkage to Care)

Hepatitis delta virus (HDV) infection is recognized as the most severe form of viral hepatitis. HDV is a defective RNA virus that requires the presence of the hepatitis B virus (HBV) to replicate and infect liver cells.¹ HDV infection is an important public health issue due to the aggressive nature of the disease. Compared to HBV monoinfection, HDV/HBV infection increases the risk of cirrhosis 2 – 3 fold, the risk of hepatocellular carcinoma 3 – 6 fold, and the risk of death 2-fold.² HDV also increases the rate of disease progression with 30% of HDV infected patients progressing to cirrhosis within 5 years.³ Given the rates of disease progression and a lack of widely available therapy, HDV remains an area of large unmet need.

Of the estimated 257 million people globally who are chronically infected with HBV,⁴ 9 – 60 million are also infected with HDV, based on meta-analysis data from recent publications.^{3,5} However, the true prevalence of HDV infection is not fully understood due to insufficient data and likely underdiagnosis. The distribution of HDV-infected persons varies around the world and not all countries and geographies have consistent screening guidelines or equal availability of diagnostic tests. These challenges present large gaps in our understanding of the epidemiology of the disease. **Therefore, there is a significant need to 1) identify the true epidemiology of HDV infection and regional screening practices and 2) understand the barriers to optimal care among both patients and health care providers.**

To further understand this patient population, Gilead Medical Affairs is launching the HDV Epidemiology, Screening and Barriers to Linkage to Care (**HDV DESCRIBE**) program. The program will support individual projects up to \$150,000 USD or equivalent sum; projects greater than \$150,000 will require approval by Gilead prior to submission.

Successful projects should be able to be completed within 12 months and demonstrate clear objectives, defined timelines, a comprehensive operational plan, and propose data that has relevance to the medical community and policy makers. Priority will be given to studies exploring regional data.

Gilead will not consider proposals that solely request HDV screening costs (including test kits) or proposals that request HDV study drug. Proposals should be drug agnostic.

Gilead will consider support for research proposals that address the following:

- Generation of systematic epidemiology data of HDV.
 - Priority will be given to country and cross-country data collection versus single center data collection
- Identification of current screening practices, including but not limited to:
 - Which HDV screening tests are used
 - Which providers are ordering the screening tests

- Which patients are being selected for screening
- Turn around time to obtain test results
- Reimbursement criteria for screening
- Characterization of barriers in the cascade of care, including but not limited to:
 - Screening
 - Linkage to care
 - Treatment

Letter of intent (LOI) should adhere to the following:

- Proposed budget is ≤\$150,000 USD or equivalent sum; Gilead approval will be required prior to submission for proposal with a budget of >\$150,000
 - 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 12 months to complete
- Funding requests for the sole purpose of screening costs is not acceptable for **HDV DESCRIBE**
- Funding for or contribution of study drug is not acceptable for **HDV DESCRIBE**
- Priority will be given for proposals exploring regional data
- No more than one sponsor for contract negotiations and/or Institutional Review Board (IRB)/Ethics Committee (EC) review
- LOI details will be submitted into Gilead's G.OPTICS portal (see link below)

The Letter of Intent submission is not binding on either party. The purpose of the LOI is to provide 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.

Key Dates & Program Specifics:

- Gilead will evaluate LOI based on the following timelines:
- Submission window:
 - **May 3, 2021:** submission window opens
 - **June 4 2021:** submission window closes
- Applicants should complete the **LOI application at: [G.OPTICS Portal](https://gileadmedaffairs.appiancloud.com/suite/portal/login.jsp)**
<https://gileadmedaffairs.appiancloud.com/suite/portal/login.jsp>
- After June 4, 2021 Gilead will evaluate and rank all LOIs. Top ranked LOIs will be invited to submit a full application and additional instructions will be provided to the submitter.

Gilead approval of awards will depend on 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 RFP.

Note: 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, and awards are not being given, directly or indirectly, as an inducement or reward with respect to the purchase, utilization, recommendation or formulary placement of any Gilead product. Further, the awardee is not required to purchase, order, recommend or prescribe to any patients any products manufactured or available through Gilead.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California.

References

1. Taylor JM, et al. *Curr Top Microbiol Immunol* 2006;307:1–23
2. Da B, et al. *Gastroenterol Rep* 2019;7:231–45
3. Miao Z, et al. *J Infect Dis* 2020;221:1677–87
4. *Global Hepatitis Report 2017*. Geneva: World Health Organization; 2017
5. Stockdale AJ, et al. *J Hepatol* 2020;73:523–3

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