Request for Proposal (RFP) RFP-CDAF-2025

Center for Disease Analysis Foundation

Title: Re-linkage to HCV and HBV Care in the United States

Issue Date: September 1st, 2025

Due Date/RFP Close Date: November 1, 2025

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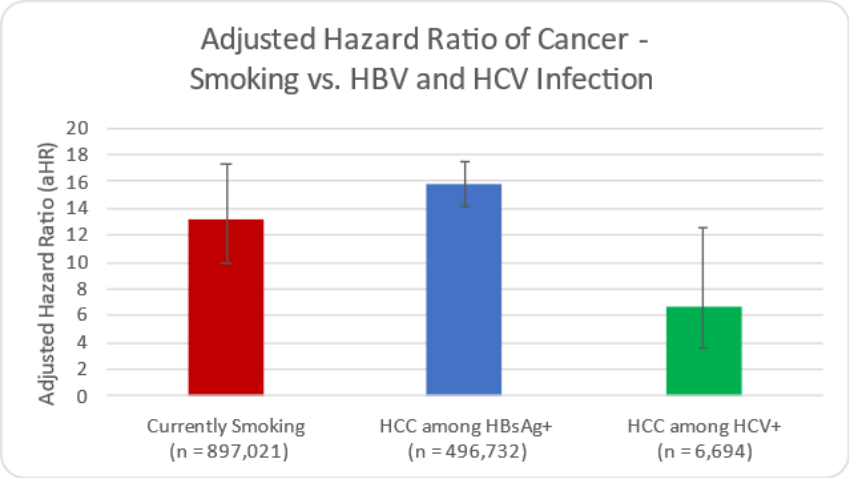
Background

According to a recent study by US CDC, more than 65% of individuals infected with hepatitis C virus (HCV), and who have continuous insurance coverage (private, Medicaid or Medicare), did not initiate treatment within one year of being diagnosed.[1] This is a disturbing statistic given that current HCV treatments are curative in more than 95% of cases, are oral treatments, and have a short duration of treatment.

US CDC analyses also showed that for people living with hepatitis B virus (HBV) infection, lack of awareness of HBV infection, poor access to testing, and linkage to care remains an issue.[2] Monitoring and treatment of HBV infection, while not curative, greatly reduce the risk of cirrhosis and hepatocellular carcinoma (HCC).

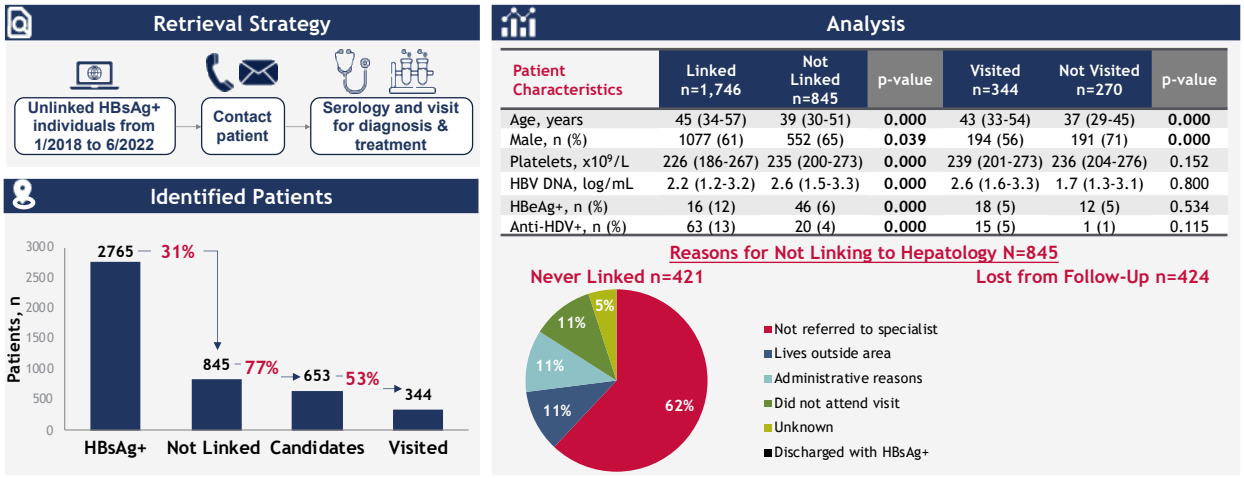
Long-term infection with Hepatitis B and C viruses (HBV & HCV) causes chronic inflammation of the liver and ultimately liver cancer. The risk of developing cancer in individuals infected with HBV and HCV is similar to the risk of cancer in someone who currently smokes.[3] In addition, treatment of those infected with HBV or HCV can reduce the risk of cancer by more than 75%.[4]



HBV and HCV infections are also associated with increased risk of non-Hodgkin's lymphoma, diabetes, insulin resistance, glomerulonephritis, renal insufficiency, fatigue, cognitive impairment, depression, impaired quality of life, polyarthritis, fibromyalgia, and cardiovascular disorders (i.e. stroke, ischemic heart disease).[5]

A study by researchers at Mount Sinai's Icahn School of Medicine showed that reaching out to HCV positive individuals who have been diagnosed but remain untreated can result in 31% linkage to care.[6] Similar studies in Spain have shown that contacting HBV positive individuals lost to care can bring back more than 50% of them into care.[7] These groundbreaking studies demonstrated that it is possible to reengage infected individual who were diagnosed but lost to follow up. Expanded treatment is required for the U.S. to eliminate viral hepatitis as a public threat before 2030.[8] Relinkage programs are thus instrumental in helping the U.S. achieve the 2030 elimination targets.

Single-center, retrospective and prospective study of HBsAg-positive cases not linked to an HBV specialist for follow-up



Patient Characteristics	Linked n=1,746	Not Linked n=845	p-value	Visited n=344	Not Visited n=270	p-value
Age, years	45 (34-57)	39 (30-51)	**0.000**	43 (33-54)	37 (29-45)	**0.000**
Male, n (%)	1077 (61)	552 (65)	**0.039**	194 (56)	191 (71)	**0.000**
Platelets, x10^9/L	226 (186-267)	235 (200-273)	**0.000**	239 (201-273)	236 (204-276)	0.152
HBV DNA, log/mL	2.2 (1.2-3.2)	2.6 (1.5-3.3)	**0.000**	2.6 (1.6-3.3)	1.7 (1.3-3.1)	0.800
HBeAg+, n (%)	16 (12)	46 (6)	**0.000**	18 (5)	12 (5)	0.534
Anti-HDV+, n (%)	63 (13)	20 (4)	**0.000**	15 (5)	1 (1)	0.115

Relink Grant Program Objectives

The Center for Disease Analysis Foundation (CDAF) has received an eight-million-dollar grant from Gilead Sciences to run the Relink program over two years. The grant will be distributed to sub-grantees in multiple rounds over two years. The objectives of the Relink program are to:

- Provide grants to demonstrate the feasibility of finding diagnosed-but-untreated (DBU) HCV infected individuals, and/or diagnosed but untreated/ not appropriately treated or lost to follow-up HBV infected individuals and help them get linked to care in different settings and geographical regions.
- Maximize the number of DBU individuals linked to care for a given amount of spending (cost-per-individual).
- Use adaptive studies to conduct tranches of funding that will identify best practices for efficiently linking the most DBU individuals to care for the least amount of spending.

Maximize the sustainability of the Relink program after funding has ended by demonstrating the simplicity and benefits of using existing records to find DBU HCV & HBV individuals.

- Promote innovation through collaboration among all grantees.
- Develop shared learning and process improvement to enhance linkage to care and retention.
- Quantify the impact of the program.
- Share key learnings through presentations of key findings at conferences.

- Publish the combined results of the studies to motivate other healthcare systems in the US and other countries to implement similar programs.
- Provide key learnings, best practices, and tools to other organizations (free of charge) to help them start their own Relink programs.

The program is treatment agnostic and Gilead Sciences will have no influence on the RFP process (including reviewing and evaluating of proposals), or on program design and implementation. Additionally, neither Gilead Sciences nor any other pharmaceutical entity will have access to any data generated by the Relink program.

Eligibility Criteria

The following type of organizations are eligible to apply for Relink grants:

- Tax-exempt organizations serving the U.S. population.
- Tax-exempt Healthcare institutions (hospitals, clinics, universities).
- Non-profits working with HBV and/or HCV individuals.
- Public Health Agencies.

For profit organizations are not eligible but can partner with a tax-exempt organization.

In addition, the grantees must agree to the following conditions:

- Have a monthly update with CDAF Project Managers to review progress and timelines (30 minutes).
- Willing to have a quarterly web-conference with the other grantees to share best practices (1 hour).
- Willing to provide depersonalized data quarterly to allow CDAF to compare metrics across grantees (individuals contacted per navigator, individuals linked to care…) and aggregate data (from all grantees) to measure progress toward goals. The data generated by each grantee will be owned by the grantee. CDAF agrees not to release or publish any data from individual grantees without their permission and will hold all provided data as confidential (this will be outlined in the agreement).
- Participate in a joint manuscript that reports aggregate data from all grantees with all participants as co-author. Each grantee is also encouraged (but not required) to publish their own data.
- Submit an abstract summarizing the grantee's key findings and present (poster or oral presentation) at a conference in the US. The cost of travel should be included as part of the proposal.

Ineligible States/Territories

Relink grants will be available to all states/territories that provide parity access to HBV and HCV medicines. The following states/territories will be excluded from the grants since they have preferential prescription agreements in place:

Louisiana	Minnesota	Montana	Texas	Puerto Rico
Michigan	Missouri	Oklahoma	Washington	Washington, DC

Key Dates

For Round 4, the following dates will apply:

RFP release date	September 1st, 2025
Proposal due date	November 1st, 2025 (23:59 MT)
Review of proposals by advisory board	November 4th – November 16th, 2025
Proposal approval notification date	December 16th , 2025
Contracts completed and distribution of the grants	January 15th, 2026

Grant Selection Process

Grants will be reviewed and ranked by an independent advisory board composed of the following individuals.

Dr. Andrea Branch – Professor in the Department of Medicine Division of Liver Diseases at Mount Sinai School of Medicine.

Dr. Robert S. Brown – Chief, Division of Gastroenterology & Hepatology, Weill Cornell Medicine.

Dr. Chari Cohen – President of the Hepatitis B Foundation.

Dr. Douglas Dieterich – Professor of Medicine in the Division of Liver Diseases and Director of Continuing Medical Education in the Department of Medicine at Mount Sinai School of Medicine.

Dr. Shyam Kottilil – Professor of Medicine, Chief, Division of Infectious Diseases, Director, Division of Clinical Care and Research, Institute of Human Virology, University of Maryland.

Dr. Paul Kwo – Professor of Medicine (Gastroenterology and Hepatology), Stanford Medicine

Michael Ninburg – Past executive director of HEP, past President of the World Hepatitis Alliance.

The rankings will be compiled by CDAF and used to develop a score for each grant. The allocated budget for each cycle of grants will be used to determine the grants to be funded. CDAF reserves the right to recommend a lower level of funding to be distributed if the quality of the proposals is not acceptable. The remaining funds will be distributed during the next funding cycle.

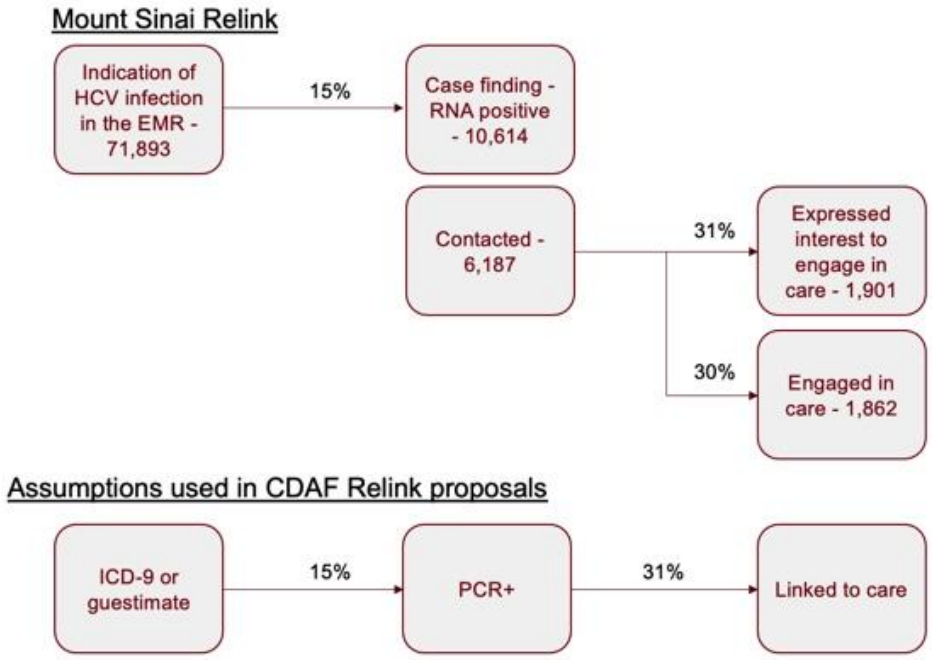
The criteria used to rank grants are shown below.

Criterion[1]	Scale	Weight
Cost per individual linked to care (i.e., Total project cost/ Total est. linked to care*)	Linear	60%
Level of previous experience with linking diagnosed but untreated individuals to care. This includes mechanisms for and success in ensuring treatment onset.	Scoring of 1-10 provided by the applicant	25%
Project timeline	Linear	15% (rejected if more than 12 months)
Geographical diversity – we don't want most grants to go one state.	Linear - number of grants from the same state	Manual distribution of grants

**Estimating the number of DBU individuals to be linked to care*

To estimate the number of DBU individuals to be linked to care, we will apply a 31% adjustment for the probability of getting linked to care to DBU populations based on PCR test results. For DBU populations based on Antibody+, ICD-9/ICD-10 or guesstimates, we will apply a 15% adjustment for the probability of individuals being confirmed PCR+, then the 31% adjustment for the probability of getting linked to care. The process is outlined in the diagram below:

[1] Eligibility criteria for subsequent rounds have been updated based on outcomes from previous rounds as well as comments from the Advisory Board. Grantee experience with relinking DBU individuals now weighs more while cost per individuals weighs less.



** Additional considerations for Round 4*

i. **To account for the important role State Health Agencies play in supporting the healthcare needs of the populations most affected by HBV and/or HCV in the United States, Round 4 of the CDAF-Relink grant will prioritize proposals from State Health Agencies with 12-month programs and a total budget at/or under $250,000.**

Guidance on the Grant Application

Patient registry – Applicants can use any data management system to find and manage DBU HBV and/or HCV individuals. For applicants who use the EPIC electronic medical record system, the Mt. Sinai SQL queries for HCV case finding are available on the CDAF-Relink Resources webpage. In collaboration with Mt. Sinai, CDAF has also developed a REDCap-based Relink Data Dictionary. **We strongly encourage applicants to allocate enough time and resources to do chart reviews and determine eligible DBU individuals and set realistic goals about how many they expect to reach.**

Proposal budget – Proposal budgets cannot exceed $250,000.

Inclusion criteria – Previous Relink studies have shown the following inclusion criteria to be effective:

HCV

- Individuals with a record of positive test results of HCV antibody (0,1), or
- Individuals with a record of positive test results of HCV-RNA (0,1), or
- Individuals who were treated for their HCV infection but have a record of not achieving SVR (0,1), and
- Individuals who were not treated for their HCV infection (0,1).

HBV

- Individuals with a record of positive test results of HBV surface antigen (0,1), or
- Individuals with a record of positive test results of HBV-DNA (0,1), or
- Individuals who were treated for their HBV infection but were lost to follow up (0,1), and
- Individuals who did not start treatment for their HBV infection but were lost to follow up (0,1).

  Note:

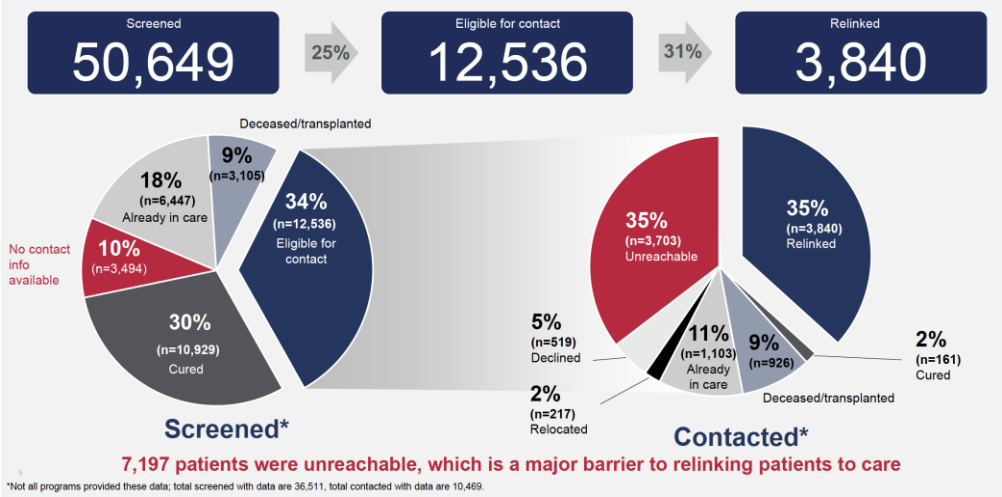
  - For immigrant populations, include if HBV surface antigen results > 12 months
  - For individuals with a record of positive test results for HBV-DNA, include if:
    - If DNA test results > 12 months
    - If DNA test results <12 months but viral load > 2000 IU/ml

Staffing needs – A typical project will have a primary investigator, a patient navigator, and an IT manager. The full implementation of a Relink project may also require a patient coordinator (to help individuals with insurance barriers) and a patient educator. However, most organizations will already have these personnel in place.

- **Primary Investigator –** Responsible for the project design, IRB approval (if needed), implementation and timelines.
- **Patient Navigator –** Responsible for contacting DBU individuals and linking them back to care. On average, a patient navigator can contact up to 40 people day. Previous studies attempted to contact each individual 3 times before giving up. One third of the individuals are expected to have bad contact information and can be eliminated after the first attempt. If the applicant has 1,000 diagnosed but untreated individuals, they should plan on 25 workdays (1,000/40 = 25) for the patient navigator to contact everyone.

- **IT Manager –** Responsible for searching the existing electronic medical record systems to find DBU individuals. These individuals will be needed at the start of the project to create a database of individuals eligible to be contacted, and then provide intermittent support to generate reports for the registry updated by the patient navigator.

  According to previous sponsored studies, one of the key reasons for individuals not getting relinked was the fact that the individual's record has outdated contact information (35% as shown below).



  Data records from all dates should be considered with priority given to patient records in years 2014-2023. Older records are likely to have a higher rate of outdated patient contact information.

- **Statistician –** CDAF will provide a statistician for statistical analysis of aggregate data.

IRB Approval - If your organization requires an IRB approval, please include this in your proposal timeline.

Timeline – For Round 4, applicant should aim to complete the project in no more than 12 months. This could be accomplished by providing multiple patient navigators who work in parallel.

Expenses not covered – the following expenses should not be included in the proposal:

- Medications or purchasing of medications.
- Direct medical expenses, including lab expenses.
- Existing deficits of grantee.
- Biomedical research, clinical research, or clinical trials.
- Projects that directly influence or advance pharmaceutical companies' business, including purchase, utilization, prescribing, formulary position, pricing, reimbursement, referral, recommendation, or payment for products.

- Individuals, individual health care providers, or physician group practices.
- Medical care – this should already be in place.
- Events or programs that have already occurred.
- Government lobbying activities.

Contract Review Before Submission

To minimize time spent on contract negotiation, a copy of the contract (that the applicant's organization is expected to sign if the application is approved) is being provided along with this RFP. We ask all applicants to review the contract with their legal team before submitting their application. If the terms of the contract are not acceptable, please do not apply. A copy of CDAF's standard Data Use and Confidentiality Agreement is also being provided. Since all reportable data is deidentified, CDAF does not require this document. It is provided for grantee convenience. If the applicant organization does require a DUA, the same terms of acceptance stated for the contract apply.

Submission Directions

1. Review contract terms with your legal team.
2. Fill out the application accompanying this RFP. The application must be returned as a Word document, or your proposal will be automatically rejected.
3. Fill out the budget and timeline form accompanying this RFP. The Budget and Timeline form must be returned as an Excel spreadsheet, or your application will be automatically rejected.
4. Send you application, budget and timeline form, a copy of your organization's W-9, and a copy of the team's CV to relink@cdafound.org.
5. The submission deadline is November 1st, 2025 (23:59 Mountain Time).
6. Any inquiries or questions (prior or post submission) should be sent to relink@cdafound.org.
7. Failure to provide all the information requested in the application and budget form may result in the grant application being declined.
8. Grant applications submitted in response to this Request for Proposal after the due date will not be reviewed.
9. All applicants will be notified of acceptance or decline by email on or before December 16th, 2025.

10. Unsuccessful grant applications will be returned with feedback for improvements. They can be resubmitted in the next round.

Inquiries

If you have questions or require assistance, please contact us at: relink@cdafound.org

Transparency

CDAF, at its sole discretion, has the right to disclose information required by federal, state, and/or local laws and regulations. This disclosure may include, but shall not be limited to, details of the activity and the grant amount.

All data will be owned by the grantees, and they are encouraged to publish their data. CDAF will publish the aggregate data with all grantees as coauthors.

Terms and Conditions

CDAF reserves the right to approve or deny any or all grant applications received as a result of this Request for Proposal (RFP) or to cancel, in part or in its entirety, this RFP. CDAF is not responsible for any costs associated with this RFP submission and application to this RFP is not a promise of funding.

About Center for Disease Analysis Foundation

CDA Foundation is a non-profit organization that seeks to help eliminate HBV and HCV globally by 2030 by providing countries across the world with verified epidemiological data, disease burden and economic impact modeling, smart intervention strategies, access to affordable diagnostics and treatments, innovative financing, and knowledge-sharing partnerships to eliminate these deadly infections. It works with more than 110 countries globally and 26 US states on their viral hepatitis elimination programs. It is headquartered in Lafayette, Colorado.

References

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