

Request for Applications

Accelerating Implementation of Multilevel-strategies to
Advance Long-Acting Injectables for Underserved Populations
(The ALAI UP Project)

Release Date: November 17, 2022

Due Date: January 20, 2023

Funding Opportunity Overview

Project Name	Accelerating Implementation of Multilevel-strategies to Advance Long-Acting Injectables for Underserved Populations (The ALAI UP Project)
Funding Source	The Trustees of Columbia University in the City of New York (Columbia University) / Health Resources and Services Administration HIV/AIDS Bureau
Project Duration	3 years
Maximum Available Funding per Site	\$90,000 per year; \$270,000 total
Target Number of Sites	8
Eligible Locations	Any US State or Territory
Eligible Clinic Type	Any clinic currently providing HIV treatment to at least 25 people (e.g., federally-qualified health center (FQHC), specialty clinic, Veterans Affairs (VA), community health center, transition clinic, etc)
Optional English-Language Application Assistance Webinar* to learn more about Funding Opportunity	December 2, 2022, 12-1pm ET
Application Due Date	January 20, 2023
Estimated Date for Finalists' Interview	Week of February 6, 2023
Estimated Date for Site Selection	February 17, 2023
Estimated Project Start Date	March 1, 2023
Contact Person	Ben Lane, MPH
Contact Email Address	bvl2110@cumc.columbia.edu

*If you require information about The ALAI UP Project in a language other than English, please email us and we will do our best to accommodate your request.

1. Background

FDA approved the first long-acting injectable (LAI) antiretroviral (ARV) medication (long-acting cabotegravir/rilpivirine) in January 2021, heralding a new era of HIV treatment. LAI ARV formulations have the potential to dramatically transform HIV care delivery by providing a treatment option that is discrete, long-acting, does not require adherence to daily oral medication, and may reduce stigma. However, introducing LAI ARV to new settings and delivering it to people with HIV (PWH) at scale in a way that advances health equity requires significant investment to overcome logistical, financial, clinical, and psychosocial barriers. Without targeted interventions designed specifically to help clinics implement and sustain LAI ARV programs among priority

populations, only the most resourced clinics and the most resourced patients will have access to this important discovery, thereby exacerbating rather than ameliorating health disparities.

“Accelerating Implementation of Multilevel-strategies to Advance Long-Acting Injectables for Underserved Populations” (The ALAI UP Project) is a Special Project of National Significance funded by HRSA that will support the implementation and delivery of LAI ARV at 8 Clinical Sites across the US providing HIV treatment to underserved populations and communities of color. The goal of ALAI UP is to increase access to and uptake of LAI ARV in areas most impacted by the HIV epidemic. Expanding access to LAI ARV at these sites will help reduce HIV-related health inequities in achieving and maintaining viral suppression among priority populations.

This goal will be achieved through a partnership between a multidisciplinary Coordination and Evaluation Provider (CEP) and 8 Clinical Sites. The CEP is comprised of experts from the Aaron Diamond AIDS Research Center, the Division of Infectious Diseases, and Department of Psychiatry at Columbia University Irving Medical Center; the New York City Department of Health and Mental Hygiene’s Bureau of Hepatitis, HIV, and Sexually Transmitted Infections; the Southeast Regional AIDS Education and Training Center housed at Vanderbilt University; and the Hunter Alliance for Research and Translation at Hunter College of the City University of New York. CEP members bring expertise in clinical, behavioral, and implementation science and extensive training, capacity building, and evaluation experience – and will rely on critical input from the ALAI UP Advisory Board, which includes people with diverse lived experiences and will grow to include local community members to be recruited from Clinical Site jurisdictions.

2. Project Goals and Scope

The goal of The ALAI UP Project is to partner with a diverse set of Clinical Sites to develop, implement, and modify protocols for implementing LAI ARVs (specifically long-acting injectable cabotegravir/rilpivirine), expand access to LAI ARV at selected Clinical Sites, and inform future efforts to support LAI ARV implementation at diverse Clinical Sites across the US and territories. Expanding access to LAI ARV at Clinical Sites serving communities of color will help reduce HIV-related health inequities in achieving and maintaining viral suppression among priority populations.

3. ALAI UP Commitment to Clinical Sites

The ALAI UP Project will support Clinical Sites to implement, deliver, and ultimately sustain provision of LAI ARV through:

1. Co-development of protocols and implementation training resources for clinical, psychosocial, and logistical aspects of implementation of LAI ARVs.
2. Technical assistance (TA) on how to use these resources through monthly TA calls and annual training opportunities.
3. Capacity building through didactic and experiential learning and supportive supervision with the goal of implementing long-acting cabotegravir/rilpivirine in ways that confront disparities and inequities suffered by historically-underserved and excluded groups.
4. Support in the development of strategies for community education, awareness, and demand generation that specifically address historical inequities in treatment access and uptake.

5. Opportunities for information sharing across sites through communities of practice.
6. A rigorous monitoring and evaluation plan to inform continuous quality improvement.
7. Support in the creation of an LAI ARV sustainability plan in Year 3 of the project to describe how long-acting cabotegravir/rilpivirine and/or new to the market LAI ARVs will be integrated into services in a sustainable fashion.

4. Clinical Sites' Commitment to ALAI UP

The ALAI UP Project is seeking to support up to 8 Clinical Sites from across the United States and territories prepared to introduce or scale up LAI ARV and willing to partner with The ALAI UP Project to document the process of implementation. Through these partnerships, The ALAI UP Project will contribute to the generation of knowledge and models that can be replicated nationally to accelerate equitable implementation of long-acting cabotegravir/rilpivirine and future long-acting treatment regimens.

By applying to this opportunity, your Clinical Site is committing to:

1. Partner with The ALAI UP Project in the development, implementation, and modification (as needed) of protocols to support implementation of long-acting cabotegravir/rilpivirine at your clinic.
2. Identify a champion for long-acting cabotegravir/rilpivirine implementation with decision-making authority within your clinic leadership or staff to serve as the project point person.
3. Participate in one-on-one or group monthly virtual Technical Assistance calls with The ALAI UP Project team and/or other Clinical Sites in Year 1, moving to bimonthly meetings in Year 2 and quarterly meetings in Year 3.
4. Facilitate recruitment of community members for Community Listening Sessions to ensure that community concerns and priorities are addressed in the design of services.
5. Respond to quarterly data request, including aggregate patient data on clinical outcomes, implementation process measures, and implementation outcomes. The clinic should ideally have an Electronic Health Record system (HER) with the ability to capture and report on patient data, disaggregated by key equity metrics (e.g., race, ethnicity, gender, sexual identity, insurance status). A clinic without an EHR may also apply as long as data reporting described above is feasible.
6. Respond to monthly short evaluation surveys on the usefulness, acceptability, and feasibility of The ALAI UP Project Activities.
7. Commit 2-3 individuals to participate in one 2-day Annual Meeting in each of the three years of the project. In Years 1 and 2, one additional 2-day training event will also be offered. Strong preference for in-person attendance.

A more detailed description of what The ALAI UP Project commits to provide to Clinical Sites and what Clinical Sites will be expected to commit in return will be presented at the optional application assistance webinar on December 2, 2022 at 12 PM ET and made available on the ALAI UP website afterwards (www.alai-up.org).

5. Budget & Funding Timeline

HRSA has committed ~\$2,000,000 to support Clinical Sites of The ALAI UP Project. Each clinic may apply for \$90,000 per year for three years for a total of \$270,000. To request the maximum annual amount, a portion of the funding must be allocated to support travel to participate in Annual Meetings and training opportunities in person.

Funding may be allocated for the following types of expenses:

- Personnel – including support to existing staff or new hires;
- Data-related activities;
- Community engagement activities;
- Convening of meetings and listening sessions with community members;
- Travel (Please budget at minimum \$2500 per year for travel for three individuals to attend Annual Meetings and trainings);
- Supplies (e.g., refrigerator for medication storage);
- Other categories in discussion with The ALAI UP Project Team.

As per HRSA, funds may not be used for the following: providing general health care; purchasing of medication; shipping or storing of medications through a third-party vendor; purchasing or construction of real property; international travel; or payments for any item or service to the extent that payment has been made or reasonably can be expected to be made, with respect to that item or service under any state compensation program, insurance policy, federal or state health benefits program or by an entity that provides health services on a prepaid basis (except for a program administered by or providing the services of the Indian Health Services).

Clinical Sites are encouraged to identify and budget for existing or newly hired staff who will take on specific responsibilities related to the implementation of long-acting cabotegravir/rilpivirine. Examples include but are not limited to: a Project Champion; an individual responsible for data reporting; an individual who will manage the logistics related to procurement and storage; or an individual who will navigate the complex billing and coding issues related to determination of coverage (e.g., pharmacy vs medication benefit).

A portion of Year 1 funding will be made available upon execution of the agreement between Columbia University and the selected Clinical Site. Future payment scheduling will be based on milestone attainment and will be outlined in the agreement between Columbia University and the Clinical Site.

Selected Clinical Sites will be issued a one-year agreement. Clinical Site performance will be reviewed biannually. Determination of Year 2 and 3 awards will be made upon satisfactory progress towards milestones in Year 1.

While contracts will be issued by Columbia University, this project is supported by the U.S. Department of Health and Human Services (HHS) Minority HIV/AIDS Initiative Fund. As such, all federal terms, conditions, and regulations included in 45 CFR 75 will flow down to the 8 selected

Clinical Sites. Columbia University will perform contract monitoring activities in accordance with federal guidelines.

6. Eligibility Information

Clinical sites eligible for this opportunity must meet the following criteria:

- Clinical sites must be located in a US state or territory
- Clinical sites must provide HIV treatment to at least 25 people

We welcome applications from diverse clinical sites, including but not limited to: federally-qualified health centers (FQHC), specialty clinics, Veterans Affairs (VA) clinics, community health centers, and transition clinics. Receipt of Ryan White HIV/AIDS Program funding is not required to be eligible for this funding opportunity.

7. Application Process

The application process has 5 steps:

Step 1: Register to attend the optional English-Language Application Assistance Webinar on December 2, 2022, 12-1pm ET to learn more about the funding opportunity. To register, please complete the Interest Form that you will find at www.alai-up.org/clinic-application.

Step 2: Request access to online application platform (REDCap) by emailing Ben Lane at bvl2110@cumc.columbia.edu.

Step 3: Download and compile the following application components from www.alai-up.org/clinic-application:

- **Clinical Site Questionnaire:** Please note that you must submit your answers to this questionnaire on the online application platform (REDCap). We recommend that you save your answers in the Word document before copying them into the online application platform.
- **Attachment 1. Budget spreadsheet:** Please use the Excel budget template to develop a Year 1 budget. We are only requesting a Year 1 budget at this time; Years 2 and 3 budgets will be requested upon site selection.
- **Attachment 2. Budget justification spreadsheet:** Please use the budget justification template to describe how the requested funding will be used by your clinic.
- **Attachment 3. Patient demographic table:** Please complete the patient demographic table.
- **Attachment 4 (optional):** If available, please provide examples of existing protocols and workflows for HIV treatment at your clinic.

Step 4: Complete and submit the application components through the online application platform (REDCap) by January 20, 2023.

Step 5: Clinical Site finalists will be notified the week of February 6, 2023 and contacted to schedule an interview with The ALAI UP Project team.

Selected Clinical Sites will be notified on February 17, 2023. The ALAI UP Project activities are estimated to begin March 1, 2023.

8. Evaluation Criteria

Final selection of Clinical Sites will be based on evaluation of the following criteria:

- Number of people with HIV served and on treatment and proportion anticipated to be initiated on long-acting cabotegravir/rilpivirine within the first year of its implementation.
- Demonstrated history and commitment to serving and engaging patients from historically-underserved and historically-excluded groups (e.g., people of color, justice-involved individuals transitioning back to communities, transgender individuals etc.).
- An identified Project Champion with decision-making authority and experience championing a new initiative in a clinical setting.
- An Implementation Team comprised of the Project Champion and at least 2 other individuals to ensure long-acting injectable treatment becomes integrated into existing clinic workflows.
- Ability to generate quarterly reports on aggregate data of clinic patients with HIV, disaggregated by key equity metrics (e.g., race, ethnicity, gender, sexual identity, housing security, food security, insurance/payor). In most cases this would be an Electronic Health Record (EHR) system from which the clinic can extract data. However, other mechanisms (e.g., Access database, Excel spreadsheet) may be considered.
- Demonstrated experience with continuous quality monitoring and improvement initiatives (e.g., using clinical or process metrics to inform clinic protocols).
- Motivation to participate in The ALAI UP Project and ability to engage meaningfully in ALAI UP project activities through the whole project period.
- Demonstrated organizational readiness to implement or begin planning for implementation of long-acting cabotegravir/rilpivirine.
- Generalizability of protocols co-developed through The ALAI UP Project to inform LAI ARV implementation in other settings.

Additionally, to build a diverse cohort of clinics implementing LAI ARV and to generate knowledge that can help a wide range of clinics implement LAI ARV in the future, The ALAI UP Project Team will consider the following clinic characteristics when awarding funding:

- Location (urban/rural, state/territory);
- Clinic catchment area demographics (e.g., age, gender, sexual identity, race/ethnicity, poverty, housing stability, behavioral health, insurance status);
- Demographics of patients currently receiving HIV treatment (age, gender, sexual identity, race/ethnicity, housing stability, behavioral health, insurance status);

- Clinic infrastructure (e.g., wraparound HIV services);
- Type of clinic (e.g., FQHC, specialty clinic, methadone maintenance clinic, VA, transition clinic, community health center);
- Stage of LAI ARV implementation.

9. Application Assistance Webinar

The ALAI UP team will convene an optional webinar for the purpose of providing clarification about the RFA and key application submission tips. This webinar will be held on December 2, 2022, 12:00-1:00 PM ET. Please register at www.alai-up.org/clinic-application for the webinar at least one business day in advance to receive the webinar link.

10. Additional Assistance throughout the Application Process

The ALAI UP Team is committed to assisting eligible applicants with the preparation of a complete and responsive application to this RFA. Our staff will be available to answer questions and to provide technical support in the application process. We prefer that you submit questions and requests for assistance to Ben Lane at bvl2110@cumc.columbia.edu, with your organization's name in the subject line of the message.

Thank you for your interest in The ALAI UP Project and for your ongoing work in striving for more equitable health outcomes for all people with HIV.