



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

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ALAI UP Goals

In partnership with a diverse set of Clinical Sites, ALAI UP Goals are to:

- Expand access to LAI ARV
- By partnering with clinical sites to co-develop, implement, and refine protocols for implementing long-acting injectable cabotegravir/rilpivirine
- In order to create models that will help to accelerate equitable LAI ARV implementation at diverse Clinical Sites across the US and territories.



Reduce HIV-related health inequities in achieving and maintaining viral suppression among priority populations.

Types of Project Activities

1. Community Engagement
2. Detailing and Needs Assessment
3. Program Builder
4. Technical Assistance (TA)
5. Communities of Practice (CoP)
6. Continuous Quality Improvement (CQI) of Clinical Outcomes
7. Monitoring the Implementation Process
8. Cost of Implementing New Strategies (COINS)
9. ALAI UP Monitoring and Evaluation

	ALAI UP Team	ALAI UP Clinical Site
<p>Activity 1</p> <p>Community Engagement</p>	<p>Description: Listening Sessions will ensure that long-acting cabotegravir/rilpivirine implementation planning begins with listening to the knowledge and expertise of community members and understanding potential local barriers and facilitators to equitable implementation of LAI ARVs.</p> <p>Activity: ALAI Up Team will support Clinical Sites to conduct at least two Listening Sessions in Year 1 with people with lived experience accessing/trying to access HIV treatment and local community members of color. Listening Sessions will elicit community input into clinic protocols and consumer-facing materials. Listening Sessions should continue in Years 2 and 3 of the project at to-be-determined intervals.</p>	<p>Activity: Clinical Sites will commit to planning, conducting, and summarizing key findings from at least 2 Listening Sessions in Year 1 with support from the ALAI UP Team. Listening Sessions to provide feedback to the Clinical Site on how implementation of injectable treatment is perceived in the community will continue in Years 2 and 3 of the project at to-be-determined intervals.</p> <p>Deliverable: After each Listening Session, Clinical Sites will summarize key findings from the Listening Session to submit to the ALAI UP Team, including planned strategies to address issues raised in the Listening Session.</p>

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Activity 2 Detailing and Needs Assessment	<p>Description: Detailing sessions are designed to understand Clinical Site needs, strengths, and challenges to long-acting cabotegravir/rilpivirine implementation and to develop a strong working relationship between Sites and the ALAI UP Team. Detailing sessions will inform future site-specific Technical Assistance.</p> <p>Activity: During Year 1, the ALAI UP Team will conduct 4-6, virtual Detailing sessions (15-30 minutes long) with Clinical Sites.</p>	<p>Activity: Clinical Sites will commit members of their Implementation Team to participating in virtual Detailing sessions (15-30 minutes each) in Year 1. There will be anticipated 4-6 virtual detailing sessions at each site.</p> <p>Deliverable: Clinical Sites will review materials shared by the Detailing Team to support LAI ARV implementation.</p>

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<p>Activity 3</p> <p>Program Builder</p>	<p>Description: The ALAI UP Team will develop a draft toolkit (“Program Builder”) of equity-focused, comprehensive resources to help Clinical Sites introduce and implement LAI ARV in their clinics. The Program Builder will include template protocols, guides, SOPs, job aids, checklists, training manuals, and patient-facing materials.</p> <p>Activity: Through in-person Program Builder Workshops, the ALAI UP Team will work with Clinical Sites to adapt these template resources to the unique context of each Clinical Site. The ALAI Up Team will also iteratively refine Program Builder resources based on feedback from Demonstration Sites.</p>	<p>Activity: Clinical Sites will commit to sending 2-3 members of their Implementation Team (ideally in person) to attend two Program Builder Workshops in Year 1, during which sites will be presented Program Builder resources and guided on how to adapt them to each clinic context. Program Builder Workshops will be held to coincide with Annual Meetings.</p> <p>Deliverable: Clinical sites will have developed written protocols for all aspects of long-acting cabotegravir/rilpivirine implementation by the end of the second Program Builder Workshop.</p>

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<p>Activity 4</p> <p>Technical Assistance (TA)</p>	<p><u>Description</u>: The ALAI UP Team will provide Clinical Sites with tailored technical assistance (TA) delivered by comprehensive TA teams consisting of TA providers, clinicians, implementation scientists, and trainers.</p> <p><u>Activity</u>: Beginning in the second half of Year 1, TA will be delivered in monthly calls with Clinical Sites during which the TA team will work with Sites to adapt and implement Program Builder template resources; identify and resolve workflow concerns; and assist with quality improvement efforts, with particular focus on addressing equitable implementation of LAI ARV. Concepts learned through TA will be reinforced through an interactive gamified program of daily quizzes.</p>	<p><u>Activity</u>: Beginning in the second half of Year 1, Clinical Sites will commit to participating in monthly Technical Assistance calls; in Year 2, TA calls may switch to a bi-monthly schedule. In person TA visits will also occur at regular intervals to be decided in discussion with sites.</p> <p><u>Deliverable</u>: Clinical Sites will review any materials shared by the TA Team to support LAI ARV implementation. Clinical Sites will engage with the interactive program of daily quizzes to reinforce key concepts from TA.</p>

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<p>Activity 5</p> <p>Communities of Practice (CoP)</p>	<p><u>Description:</u> Communities of Practice (CoP) are an effective strategy to strengthen knowledge networks, promote multidirectional learning, and present opportunities for real-time problem solving. ALAI UP CoPs will bring together staff from Clinical Sites to share information; discuss implementation challenges and facilitators; and improve skills building and knowledge attainment. Given likely variation in Sites’ progress, these CoPs will be an important mechanism to allow Sites that are earlier in their process to learn from Sites that are further.</p> <p><u>Activity:</u> The ALAI UP Team will support the coordination and implementation of a virtual CoP. In addition, the ALAI UP team will host a 2-day Annual Meeting per year which will include Communities of Practice sessions. Annual meetings will alternate between New York City and Nashville.</p>	<p><u>Activity:</u> Clinical Sites will commit to participating in every other month Communities of Practice virtual meetings starting in the second half of Year 1. In addition, 2-3 members of the Implementation Team from each Clinical Site will attend Annual Meetings, with strong preference for in-person attendance. The Annual Meetings will include Communities of Practice sessions for sharing experiences across sites. Sites will be asked to budget for airfare to attend the meetings.</p> <p><u>Deliverable:</u> Sustained engagement in CoP and co-creation of summary reports of key lessons learned through site-to-site sharing through CoPs.</p>

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<p>Activity 6</p> <p>Continuous Quality Improvement of Clinical Outcomes</p>	<p><u>Description:</u> Continuous Quality Improvement (CQI) is a quality management process that prompts healthcare teams to assess clinical and process data to continuously assess how their clinic is performing and how to make meaningful use of their data to create a plan of action.</p> <p><u>Activity:</u> To support CQI, the ALAI UP team will develop a data monitoring system to help Sites generate patient outcome reports disaggregated by key equity metrics (e.g., race/ethnicity, age, sex, gender, insurance status). The ALAI UP team may develop a Dashboard, which will visually display reported Site data to generate new insights about the impact of current LAI ARV implementation strategies on patients' clinical outcomes. The ALAI UP Team will review data reports with Sites and assist Sites in modifying LAI ARV protocols, as necessary. Each year, we will produce a short Preliminary Annual Site Snapshot.</p>	<p><u>Activity:</u> Clinical Sites will participate in quarterly calls with the ALAI UP Team to discuss quality metrics, site goals, and strategies for modifying LAI ARV protocols to site goals, as necessary.</p> <p><u>Deliverable:</u> Clinical Sites will generate and share patient outcome reports disaggregated by key equity metrics (e.g., race/ethnicity, age, sex, gender, insurance status) with the ALAI UP team. Clinical sites will modify LAI ARV protocols in response to ALAI UP data feedback as necessary.</p>

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<p>Activity 7</p> <p>Monitoring the Implementation Process</p>	<p><u>Description:</u> The Stages of Implementation Completion (SIC) is a standardized measure of implementation process and milestones. The SIC documents “what it takes” to implement evidence-based practices and organizes a list of 40+ implementation activities into eight key Implementation Stages.</p> <p><u>Activity:</u> The ALAI UP Team will use the SIC as a Planning Roadmap to guide how we support Clinical Sites to complete key implementation activities and move through the eight stages of implementation. We will also use the SIC to monitor implementation progress and inform the Technical Assistance delivered to Sites.</p>	<p><u>Activity:</u> Clinical Sites will agree to participate in the monitoring of their cabotegravir/rilpivirine implementation process and progress. This will be achieved through periodic phone calls with the ALAI UP Team to elucidate implementation activities.</p> <p><u>Deliverable:</u> Co-creation of a standard LAI implementation process roadmap.</p>

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<p>Activity 8</p> <p>Cost of Implementing New Strategies (COINS)</p>	<p>Description: The Cost of Implementing New Strategies (COINS) is a tool for assessing implementation costs across phases of implementation as described by the SIC. Information gathered through COINS (e.g., costs associated with training new staff, expenditures) will help Sites plan and budget for future implementation of other LAI ARV modalities as well as ensure the sustainability of the long-acting cabotegravir/rilpivirine program.</p> <p>Activity: The ALAI UP Team will use COINS to estimate the cost (human resources and fixed expenditures) of each SIC implementation activity completed to implement LAI ARV.</p>	<p>Activity: Clinical Sites will agree to regular phone calls with the ALAI UP Team to document resources spent on each implementation activity. Calls will coincide with periodic SIC activity completion calls.</p> <p>Deliverable: Co-creation of cost estimation for introduction of injectable treatment into clinic flow.</p>

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<p>Activity 9</p> <p>ALAI UP Monitoring and Evaluation</p>	<p><u>Description:</u> A goal of the ALAI UP Project is to generate generalizable implementation knowledge and strategies that can be disseminated to diverse sites across the US to promote equitable access and maximize utility of protocols. Clinical Sites' evaluation of their satisfaction with ALAI UP activities and resources will provide critical feedback to the ALAI UP team to understand the relative usefulness of different activities, allowing ALAI UP to course correct as needed.</p> <p><u>Activity:</u> The ALAI UP team will review evaluation data in close to real time to understand the degree to which program inputs are perceived as useful, to sites' satisfaction, feasible and acceptable to implement. Feedback on ALAI UP inputs will be used to adjust ALAI UP activities as needed.</p>	<p><u>Activity:</u> Clinical Sites will provide feedback in the form of a short satisfaction survey after each ALAI UP activity (e.g., detailing visit, technical assistance visit, Program Builder Workshop). Sites will additionally participate in annual focus groups led by an external evaluator to gather site opinions on the barriers and facilitators to LAI ARV implementation and the usefulness of ALAI UP activities.</p> <p><u>Deliverable:</u> Co-creation of ALAI UP evaluation report.</p>

Application Overview

Funding Source	The Trustees of Columbia University in the City of New York / 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)
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

Application Process

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
- Attachment 1. Budget spreadsheet
- Attachment 2. Budget justification spreadsheet
- Attachment 3. Patient demographic table
- Attachment 4. Existing Protocols (optional)

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.

Budgeting

Allowable Budget Categories

- Personnel
- Supplies / Equipment
- Meeting Convening
- Travel
- Other

Not allowable

- Providing general healthcare
- Medication purchase
- Shipping or storing medication through third-party
- Purchasing or construction of property
- International travel
- Payment of items or services covered through health benefits program / insurance

Budget Components of the Application

- 1) Budget Spreadsheet
- 2) Budget Justification (Narrative form of Budget)
- 3) First Year Budget only at time of application
- 4) Years 2 & 3 Budget to be developed after selection as an ALAI UP Site.

	Evaluation Criteria	Relative Weight
1	History and commitment to serving under-served and excluded populations <ul style="list-style-type: none"> 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.) 	15
2	Experienced and Motivated Project Champion and Implementation Team <ul style="list-style-type: none"> 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. 	15
3	Size of your HIV Program and Organizational Readiness to Introduce/Scale Up LAI ART <ul style="list-style-type: none"> 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 organizational readiness to implement or begin planning for implementation of long-acting cabotegravir/rilpivirine 	10
4	Data Infrastructure <ul style="list-style-type: none"> 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. 	15
5	Continuous Quality Improvement <ul style="list-style-type: none"> Demonstrated experience with continuous quality monitoring and improvement initiatives (e.g., using clinical or process metrics to inform clinic protocols) 	5
6	Motivation and Follow-Through <ul style="list-style-type: none"> Motivation to participate in The ALAI UP Project and ability to engage meaningfully in ALAI UP project activities through the whole project period. 	15
7	Generalizability and Diversity <ul style="list-style-type: none"> Generalizability of protocols co-developed through The ALAI UP Project to inform LAI ARV implementation in other settings. 	25
	Total	100

Questions & Answers

FAQs can be found at <https://www.alai-up.org/faq>.

Please note that we will be adding new questions and answers on this page as we receive them, so please check back periodically.

Contact Us!

Webinar recording will be available at www.alai-up.org on December 5, 2022.

If you have any questions throughout the application process, please send an email to Ben Lane (bvl2110@cumc.columbia.edu)

Thank you for your interest in the ALAI UP Project!