

# Notice of Funding Opportunity PS-23-004: Long-Acting Injectables for the Treatment of HIV in Non-Clinic Community-Based Settings

HIV Research Branch  
Division of HIV Prevention  
National Center for HIV, Viral Hepatitis, STD, and TB Prevention





# Overview

# Background

- **Long-acting injectable (LAI) antiretroviral therapy (ART) offers many potential advantages over daily oral treatment such as improved convenience, adherence, and treatment satisfaction.**
- **Barriers and challenges exist with implementation of LAI-ART into current healthcare practice, both in logistics and in equity.**
  - Some of these barriers may be overcome by using non-clinic sites, such as community pharmacies, to administer LAI-ART.

# Purpose

- **To support research on long-acting injectable (LAI) antiretroviral therapy (ART) by implementing LAI-ART administration in non-clinic settings.**
  - Focus on expanding treatment opportunities and decentralizing delivery of LAI-ART.
  - Provides information for improving the acceptability, availability, uptake of LAI-ART, and the HIV care continuum.
- **To describe real-world LAI-ART use in an era of multiple HIV treatment modalities.**
- **Data will be used to strengthen adherence to ART.**

# Award Information

| Type of Award                | Cooperative Agreement              |
|------------------------------|------------------------------------|
| Fiscal Year Funds            | 2023                               |
| Approximate Annual Funding   | \$1,000,000                        |
| Approximate Number of Awards | 1                                  |
| Budget Period/Length         | 12 months                          |
| Project Period               | 09/30/2023 to 09/29/2027 (4 years) |
| Estimated Total Funding      | \$4,000,000                        |

Subject to the availability of funds



# Strategies and Activities

# Strategy 1

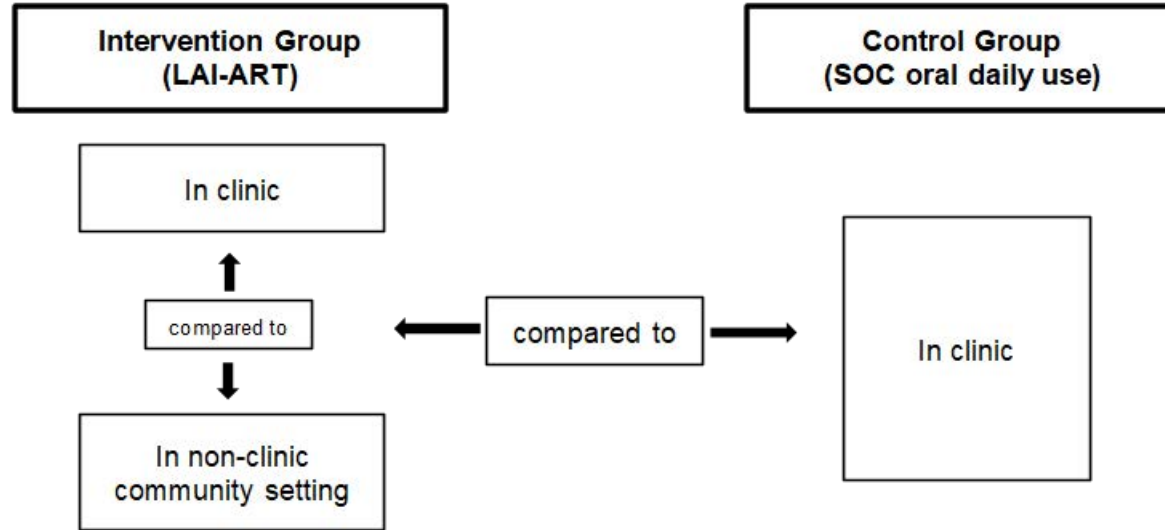
- **Increase access to LAI-ART by implementing use in non-clinic-based settings**
  - Design and develop a multisite effectiveness-implementation study with the goal of improving acceptability and uptake of LAI-ART in community settings
  - Establish collaboration between clinics and community/non-clinic settings to facilitate and coordinate timely administration and receipt of LAI-ART

# Strategy 2

- **Enhance understanding of LAI-ART and its use in non-clinic-based settings**
  - Develop and implement a sustainable program of LAI-ART in non-clinic-based settings to further understand setting-specific implementation/health outcomes and conduct comparative analyses
  - Examine acceptability and barriers to implementation of LAI-ART non-clinic-based settings, from both patient and staff perspectives
  - Establish collaboration to enhance post-implementation monitoring



# Example Design



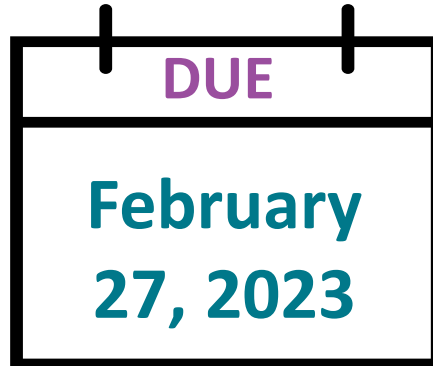
- A multi-site effectiveness-implementation research study designed to compare receiving LAI-ART in non-clinic community settings with the oral standard of care HIV clinical treatment will offer a unique source of information for implementation and health outcomes.



# Applicant Eligibility, Evaluation, and Other Info

# Important Dates

- Letter of Intent (LOI): 01/27/2023 (optional; not required)
- Applications are due **02/27/2023**
  - Submit via [www.grants.gov](http://www.grants.gov)



# Eligibility

- State, county, city or township, or special district governments
- Public and State controlled institutions of higher education
- Independent school districts
- Native American tribal governments and Native American tribal organizations
- Public housing authorities/Indian housing authorities
- Nonprofits having a 501(c)(3) status
- Private institutions of higher education
- For profit organizations other than small businesses
- Small businesses
- The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Institutions of Higher Education:
  - Hispanic-serving Institutions
  - Historically Black Colleges and Universities (HBCUs)
  - Tribally Controlled Colleges and Universities (TCCUs)
  - Alaska Native and Native Hawaiian Serving Institutions
  - Nonprofits (Other than Institutions of Higher Education)
- Governments/Other:
  - Eligible Agencies of the Federal Government
  - U.S. Territory or Possession
  - Faith-based or Community-based Organizations
  - Regional Organizations

# Evaluation Criteria



## ■ Significance

- Does the work have the potential to result in a LAI-ART delivery model that increases LAI-ART use among people with HIV (PWH)?
- Will the work help to understand determinants of successful implementation of LAI-ART?
- Will the work provide information for further integration of LAI-ART in ART treatment services in the United States?
- Does the application utilize local epidemiologic and other relevant program or clinical data to demonstrate the need for improved implementation strategies to facilitate better outcomes for populations that may benefit from this research?
- Are the proposed set of project activities methodologically strong, and yet realistic to accomplish, such that they will contribute significantly to HIV treatment implementation research in the United States?
- If successful, do the research results have the potential to be scalable and reach a large portion of populations at risk of ART non-adherence or PWH interested in LAI-ART?

# Evaluation Criteria



## ■ Investigators

- Do the investigators have the skills necessary to conduct research resulting in a LAI-ART delivery model that increases LAI-ART use among PWH?
- Do the investigators have the potential to conduct work to help understand determinants of a successful implementation of LAI-ART?
- Do the investigators have the capacity to perform work that could provide information for further integration of LAI-ART in ART treatment services in the United States?
- Do the investigators utilize local epidemiologic and other relevant program or clinical data to demonstrate the need for improved implementation strategies to facilitate better outcomes for populations that may benefit from this research?
- Are the investigators capable of carrying out a set of project activities methodologically strong, and yet realistic to accomplish, such that the activities will contribute significantly to HIV treatment implementation research in the United States?
- Do the investigators have the experience necessary to conduct research that has the potential to be scalable and reach a large portion of populations at risk of ART non-adherence or PWH interested in LAI-ART?

# Evaluation Criteria



## ■ Innovation

- Does the application clearly describe the proposed research questions and any innovation that the results may lead to?
- Do the proposed partnerships provide opportunities for innovation (particularly as it relates to innovative and feasible settings for non-clinic-based LAI-ART administration)?
- Does the project have the potential to increase efficiency or lead to innovative cost savings?
- Is the institutional support, and other resources available, adequate for the project activities proposed?

# Evaluation Criteria



## ■ Approach

- Does the application demonstrate partnerships with one or more clinics with non-clinic-based settings for administration of LAI-ART such as pharmacies, infusion centers, community health clinics, or community-based organizations?
- Does the application have a sample size that is adequate and justified in terms of statistical power?
- Is the proposed choice of LAI-ART sites justified?
- Does the clinical population volume and retention demonstrate the need for and ability to implement the LAI-ART implementation study?
- Is the approach presented in the research plan consistent with the implementation research logic model?
- Does the application describe strategies and capacities for insurance and patient navigation for initiation of LAI-ART?
- Does the application describe strategies to conduct formative work and use evaluative and iterative strategies to assess for study readiness?
- Does the application describe an approach to recruit, train, educate, and provide interactive assistance to staff, providers, and collaborators?
- Does the application describe strategies to support clinicians?
- Does the application describe change infrastructure strategies, to integrate LAI-ART interventions into workflow processes?
- Does the application describe a plan to collect and manage the relevant study data elements?
- Are outputs identified and are measures/metrics to assess implementation outcomes included?
- Does the application describe published, evidence-based LAI-ART initiation and follow up and/or adherence tools that will be used to accomplish the study goals?
- Does the application describe an approach for longitudinal monitoring of patients' ART use and adherence?



# Evaluation Criteria



## ■ Environment

- Does the project use critical partnerships or collaborations to maximize the potential for success in study implementation and translation into practice?
- Does the project support key collaborator involvement throughout the research process?
- Does the application describe plans to conduct the study at community sites experiencing issues with adherence to ART and sustained viral suppression?
- Does the application describe appropriate affiliations with clinical and non-clinic sites that have infrastructure/staff for insurance navigation to prescribe and provide LAI-ART?
- Does the application include letters of collaboration from proposed partners that reflect their role and capacity to participate in the research project?

# Website & Contact Information

## ■ Website

- <https://www.cdc.gov/hiv/funding/announcements/ps23-004/index.html>

## ■ Agency Contacts

- Program Official/Scientific Research Contact
  - Jocelyn Patterson Mosely, MPH, MA - Email: [jpatterson@cdc.gov](mailto:jpatterson@cdc.gov)
- Peer Review Contact
  - Gregory Anderson, MPH, MS - Email: [GAnderson@cdc.gov](mailto:GAnderson@cdc.gov)
- Financial/Grants Management Contact
  - Sharon Cassell – Email: [SCassell@cdc.gov](mailto:SCassell@cdc.gov)

# Thank you!

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention  
Division of HIV/AIDS Prevention

