



Sexual Health and Harm Reduction
Program (SHHRP)

976 Lenzen Ave Ste 1800

San Jose CA, 95126

Injectable PrEP (Apretude) Provider Engagement Grant 2023 Application

**Funding Opportunity for Non-Profit Community Organizations that
Perform the Following Services:**

Human Immunodeficiency Virus (HIV) Pre-Exposure Prophylaxis (PrEP)
Navigation and Clinical Services in Santa Clara County

Applicants that meet all requirements and apply on time will be eligible for
funding consideration*

Application Deadline: Wednesday, March 29 by 5:00 PM

READ ALL INSTRUCTIONS AND CRITERIA CAREFULLY

All grant materials can be accessed here: www.gettingtozeroscc.org

**Contingent on Board of Supervisors' Approval*

Key Dates Schedule

Application Released	3/14/2023
Proposal Pre-Conference (Optional)	3/16/2023 from 12-1pm Link: https://sccgov-org.zoom.us/j/93725564043
Technical Assistance Office Hours (Optional)	Fridays, 12:00AM -1:00 PM, 5/1 through 6/30/23 Link for Office Hours: https://sccgov-org.zoom.us/j/93725564043
Deadline for Electronic Submission of Application Applications submitted prior to the deadline will be processed as they are received.	3/29/23, 5:00 PM
Funding Award Notices	3/30/23
Project Period	Upon execution– June 30, 2023

Submissions

APPLICATIONS WILL ONLY BE ACCEPTED BY ELECTRONIC SUBMISSION. Applications mailed or delivered will not be accepted. If you experience any difficulties in submitting your application, please contact us for assistance at gettingtozeroscc@phd.sccgov.org.

Submit your completed application to gettingtozeroscc@phd.sccgov.org. In the subject line, please reference – **Injectable PrEP Application 2023**.

Important Submission Guidelines

To help us process your application, please follow these submission guidelines:

- Submit the application by email, including all supporting documentation.
- Submit all materials listed under “Application Materials Checklist”.
- Send all attachments in one e-mail. If your submission e-mail bounces back to you, contact us at gettingtozeroscc@phd.sccgov.org
- Submit application materials only once - be sure your materials are complete and accurate before submitting. Incomplete applications will not be accepted.
- Do not put the application content in the body of your e-mail message.

- Do not include materials not requested, such as letters of support, Memorandums of Understandings (MOUs), photos, etc.
- Printed applications will not be accepted.
- Electronic signatures (Ex. DocuSign) and wet signatures are both acceptable for the application.

Application Materials Checklist

Use Word Templates Attached to Grant Announcement

- Application Cover Sheet
- Scope of Work (no more than one page)
- Proposed Budget and Budget Explanation (no more than one page)
- Submit proof of existing PrEP navigation and/or clinical services that you provide in Santa Clara County
- Submit proof of your nonprofit status (i.e., certification from the State of California, Office of Secretary of State, **or** a letter from the Department of the Treasury, Internal Revenue Service classifying the applicant administrative agency as a private non-profit)
- Submit signed Standard Terms and Conditions

Documents May Be Required Upon Funding Award (not required to submit with application)

- Completed and signed W-9: <https://www.irs.gov/pub/irs-prior/fw9--2018.pdf>
- Copy of General Liability Insurance
- Signed Grant Agreement by organization's authorized individual

Introduction and Background

The Public Health Department's Sexual Health and Harm Reduction Program (SHHRP) is focused on promoting a comprehensive system of care, education, and prevention for all people in County of Santa Clara infected by or at risk for HIV and Sexually Transmitted Diseases. The Getting to Zero (GTZ) Program is housed within the SHHRP. The Getting to Zero Program implements a Collective Impact Model to lead, coordinate, and mobilize community HIV prevention and care activities to reach zero new HIV infections, zero HIV-related deaths and zero HIV stigma.

HIV PrEP is one of many tools that a person can use to reduce their risk for HIV infection. Prophylaxis means taking a drug or drugs before you are exposure to an organism that could cause infection. An HIV-negative person can take PrEP daily to prevent HIV infection from an exposure before, during and after sex or sharing needles. PrEP first received authorization from the Food and Drug Administration (FDA) in 2012. This authorization was received for emtricitabine and tenofovir disoproxil fumarate, also known as Truvada®, to be administered by mouth daily among patients who met the indications for the medication. In 2019, the FDA authorized a second PrEP regimen emtricitabine and tenofovir alafenamide, also known as Descovy, to be administered by mouth daily among patients who met the indications for the

medication.

Since the availability of these PrEP options, there has been a rise in PrEP uptake generally across the United States and in Santa Clara County. However, research shows that there continues to be lower uptake in people of color (African/African Ancestry and Latinx) populations, youth, and transgender people. From the medication adherence perspective, these populations similarly have lower medication adherence rates in addition to people who inject drugs and people experiencing homelessness. PrEP requires high levels of adherence to be effective and certain high-risk individuals and groups, such as young men who have sex with men, are less likely to adhere to daily medication. Other interpersonal factors, such as substance use disorders, depression, poverty and efforts to conceal medication also can impact adherence. It is hoped that the availability of a long-acting injectable PrEP option will increase PrEP uptake and adherence in these groups.

Long-acting cabotegravir, also known as CAB-LA or by its brand name Apretude, is an injectable PrEP option that is administered via an intramuscular injection once every two months. CAB-LA received FDA approval in December 2021. The safety and efficacy of Apretude to reduce the risk of acquiring HIV were evaluated in two randomized, double-blind trials that compared Apretude to Truvada. Trial 1 included HIV-uninfected men and transgender women who have sex with men and have high-risk behavior for HIV infection. Trial 2 included uninfected cisgender women at risk of acquiring HIV. Summary of key results related to these trials can be found below:

- In Trial 1, 4,566 cisgender men and transgender women who have sex with men received either Apretude or Truvada. The trial measured the rate of HIV infections among trial participants taking daily cabotegravir followed by Apretude injections every two months compared to daily oral Truvada. The trial showed participants who took Apretude had 69% less risk of getting infected with HIV when compared to participants who took Truvada.
- In Trial 2, 3,224 cisgender women received either Apretude or Truvada. The trial measured the rate of HIV infections in participants who took oral cabotegravir and injections of Apretude compared to those who took Truvada orally. The trial showed participants who took Apretude had 90% less risk of getting infected with HIV when compared to participants who took Truvada.

While the time to protection remains to be confirmed, existing research suggests that 95% of people are protected after 7 days of injection administration, and 50% of people are protected after 1 day. Given this, Apretude has the potential to increase medication adherence rates among populations who may struggle with adherence. It also provides another option for PrEP patients to receive PrEP, depending on their preference for oral vs. injectable. The purpose of this project is to expand patient access for Apretude in Santa Clara County through implementation of clinical protocols and provider trainings. These activities will build the clinical infrastructure needed to prescribe and administer Apretude within their community based organization clinical practices.

Eligibility Criteria

This funding opportunity is open to nonprofit organizations or projects with a tax-exempt nonprofit organization status under Section 501(c)(3) of the Internal Revenue Code and are designated a 509(a)(1) or 509(a)(2) organization.

Populations of Focus

Applicant organizations must be currently based in at least one city within Santa Clara County and primarily serve one or more populations disproportionately impacted by HIV and sexually transmitted diseases.

The ideal agency should already provide direct service with a long history of working with and on behalf of disproportionately impacted populations including:

- Men who have sex with men (MSM)
- People with current or history of substance use
- Those reporting multiple partners
- Transgender, non-binary, and other gender diverse people
- Heterosexual men and women with partners with or at risk for HIV
- Anyone who self-identifies a need for PrEP/PEP

An eligible organization is defined as one that:

- Has an explicit mission to serve and advocate for at least one of the populations of focus for this application.
- Is a nonprofit organization with a tax-exempt non-profit organization status under Section 501(c)(3) of the Internal Revenue Code and are designated a 509(a)(1) or 509(a)(2) organization

Santa Clara County includes the following jurisdictions: Campbell, Cupertino, Gilroy, Los Altos, Los Altos Hills, Los Gatos, Milpitas, Monte Sereno, Morgan Hill, Mountain View, Palo Alto, San José, Santa Clara, Saratoga, and Sunnyvale.

Funding Information

The funding available for this project comes from the California Department of Public Health, Sexually Transmitted Disease (STD) Program Management and Collaboration Project funds.

- The maximum award amount per organization: up to \$50,000
- The project must end by June 30, 2023
- Only one proposal per organization will be considered although multiple organizations can be awarded a contract up to the total maximum award amount.
- Those receiving awards will be required to submit a project brief progress report and supporting documents, due July 15, 2023.

Eligible applicants must meet all requirements and apply on time (pending approval of grant agreements by the Board of Supervisors) to be considered for funding award. Funds may be disbursed in two increments: upon execution of agreement and upon successful completion and approval of final brief progress report submission. Funds will not be disbursed until all documents are on file and agreement is executed.

(Note: GTZ will provide awardees with a template to submit the progress report. If the progress report is not submitted, submitted late, or submitted without completion of activities, it is the discretion of GTZ to hold disbursement of funds until receipt of the required documents.)

Budget Guidelines

Project funds may be used for (not limited to):

- Staffing and consultants
- Clinical education materials

- Signage
- Operating Expenses (examples: supplies, printing costs)
- Injectable PrEP medication costs for those tested for STIs
- Food and other incentives (no more than \$50 per person) and must follow County Nutrition Standards
- Incentives may be used to encourage or motivate participants to participate in provider training activities, but must adhere to the following requirements:
 - An individual may only receive a maximum of \$50 worth of non-consumable incentives and \$50 worth of consumable incentives for the project (e.g., if a participant receives a T-shirt worth \$10, any additional non-consumable incentives cannot exceed \$40. If they received food worth \$20, any additional consumable incentives cannot exceed \$30).
 - Recipients must do something to receive an incentive—participate in an training/course, etc. If providing incentives, a log must be kept that includes each recipient’s name, incentive item, date, and value.
 - Allowable incentive examples (not limited to): Continuing Medical Education (CME) units, T-shirts, merchandise cards for purchase of books, music, movies, food, arts and crafts, etc.
 - Prohibited incentives: cash or gift cards that could be used to purchase tobacco, nicotine products, alcohol, and/or cannabis.

Project funds may not be used for:

- Debt retirement
- Operational deficits
- Computer equipment
- Furniture
- Free Giveaways/Gift Items, such as key chains, water bottles, pens, etc. that are given to anyone without requiring an action by the recipient (Incentives that require an action by the recipient are allowable, with above noted restrictions)
- Partisan activities
- 509(a)(3) supporting organizations
- 501(c)(4) organizations or lobbying activities

Project Goal

The goal of this project is to expand patient access for Apretude in Santa Clara County through implementation of clinical protocols and provider trainings. These activities will build the clinical infrastructure needed to prescribe and administer Apretude within their community based organization clinical practices.

Project Requirements

Applicant organizations should submit proposals to accomplish all of the following:

- Agency should describe their plans to train providers and how training material will be integrated into practice
- Implement clinical workflows to prescribe and administer injectable PrEP (Apretude) in at least one community clinic.
- Agency should describe their plans to create and/or update PrEP clinical and navigation policies and procedures, PrEP case management policies and procedures, and how these updated policies and procedures will be incorporated into routine clinical operations.
 - Agency must ensure process steps related to enrollment into the ViiV payment assistance program are part of the PrEP navigation procedures
- Agency should include plans to raise awareness of this new PrEP option among eligible populations.
- Agency will collaborate with the Public Health Department for project evaluation.