

Supplemental Digital Content 1

Standardized script for verbal consent for pre-screening

“We want to tell you a little about PrEP, and to see if you are eligible to get PrEP through a demonstration project here. PrEP involves taking one pill daily to help prevent HIV infection. This pill contains two medications that are routinely used to treat people with HIV. Studies with men who have sex with men (MSM) and transgender women showed that people who took PrEP were less likely to become infected with HIV than those who did not take it, and had minimal side effects. Do you have any questions about PrEP at this point? I would like to ask you a few questions to see if this might be a good option for you. It will only take a few minutes of your time and your name is not linked to these questions. If you are eligible we’ll discuss PrEP and the study in more detail, and you can decide if you think PrEP is right for you. Do you have any questions about this? May I now ask you the questions?”



PrEP

**Pre-Exposure Prophylaxis
Demonstration Project**



We need new HIV prevention strategies.

- HIV infections are increasing worldwide. **34,000,000 living with HIV/AIDS. (2.5 million/year)**
- In SF, an estimated 10-15 new infections will occur **every week**. In 2011, 1 in 5 men **who have sex with men (MSM)** were HIV positive in San Francisco.
- In the U.S., more than 50,000 people are estimated to have become infected each year since the mid- to late-1990s. That's about 800,000 new infections since then.

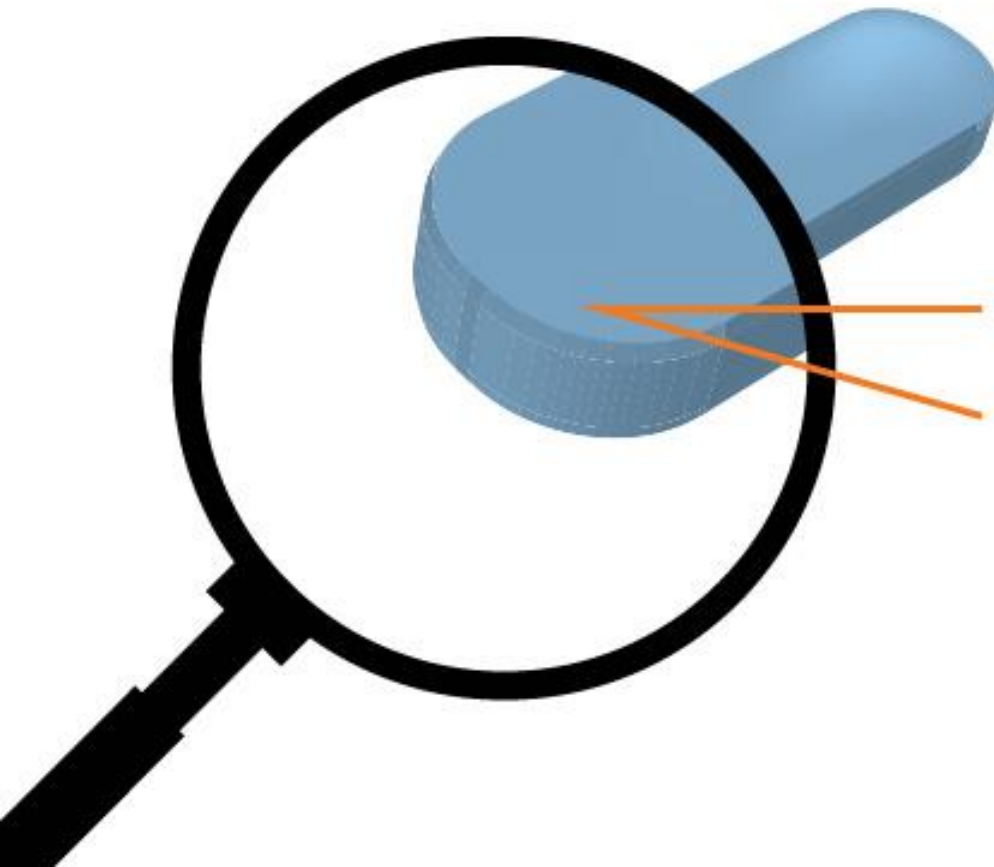
What is PrEP?



- **Pre-Exposure Prophylaxis (PrEP)** is an HIV prevention method. People who do not have HIV take anti-HIV medication, like **Truvada**, daily to try to help prevent HIV infection.

What is Truvada?

- Made by Gilead Sciences, Inc.
- FDA approved for the treatment of HIV infected individuals and, recently, for HIV prevention in combination with safer sex practices.



Truvada contains two anti-HIV medications: **tenofovir** and **emtricitabine**

Why Truvada?

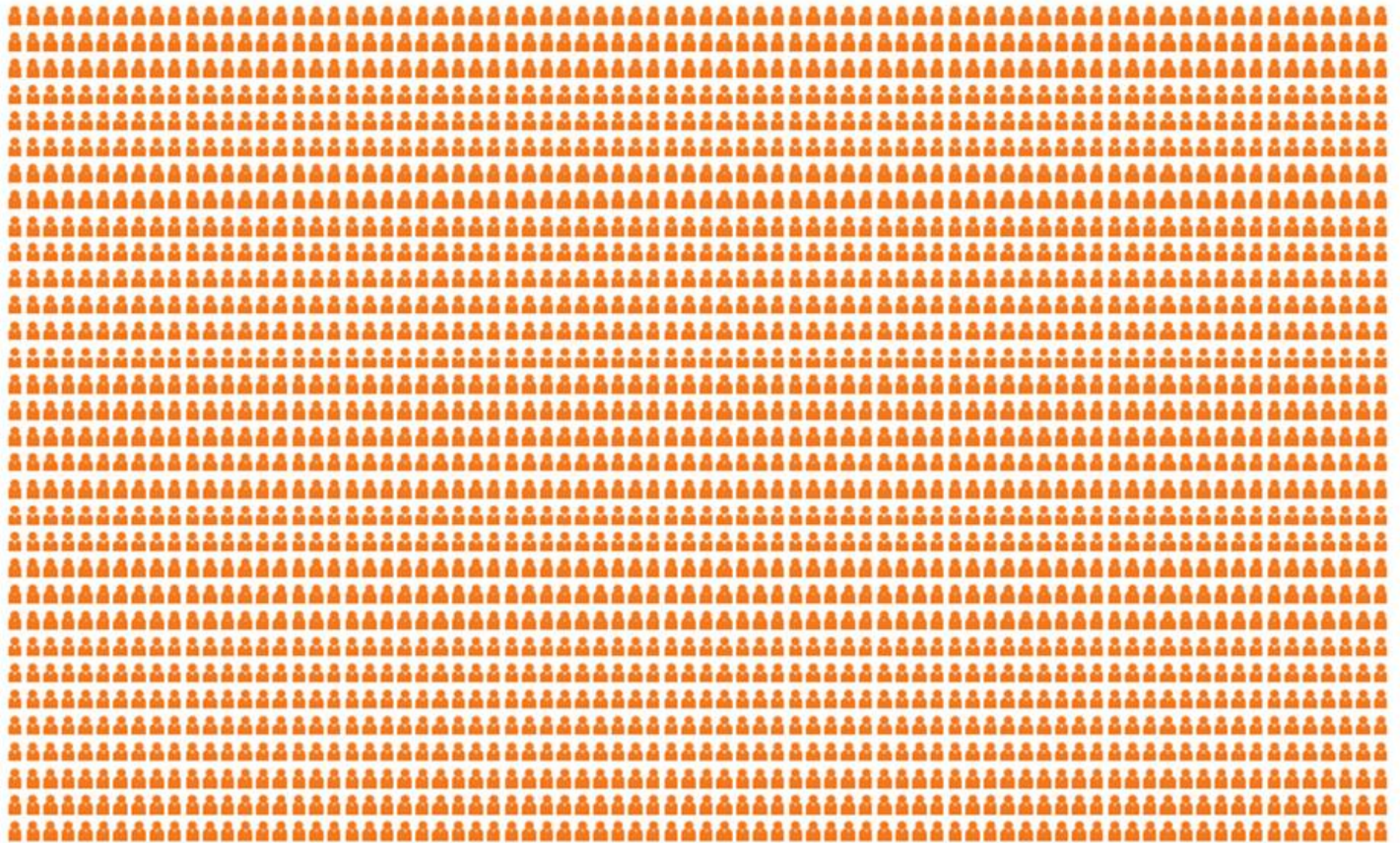


- **Truvada has been safely used in combination with other drugs to treat HIV infected people.**
- **Truvada has also been taken safely in HIV-negative people for prevention.**
- **Truvada is well tolerated and serious side effects are rare.**

Why Truvada?

- The iPrEx study showed that HIV-negative men who have sex with men (MSM) and transwomen given daily Truvada were less likely to become infected with HIV, compared with those given a placebo (dummy pill).



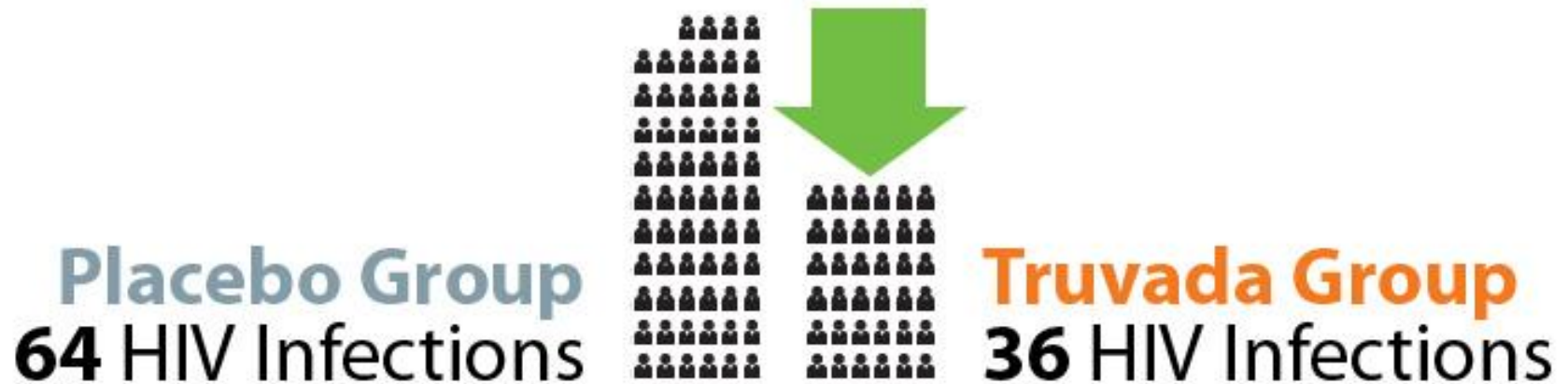


2499 participants



risk-reduction counseling

**A reduction of
44%**



Some people in **iPrEx** had difficulty taking Truvada every day.

We know



only people
who have Truvada in their body
at the time of HIV exposure
can benefit from it

Taking Truvada daily is important.



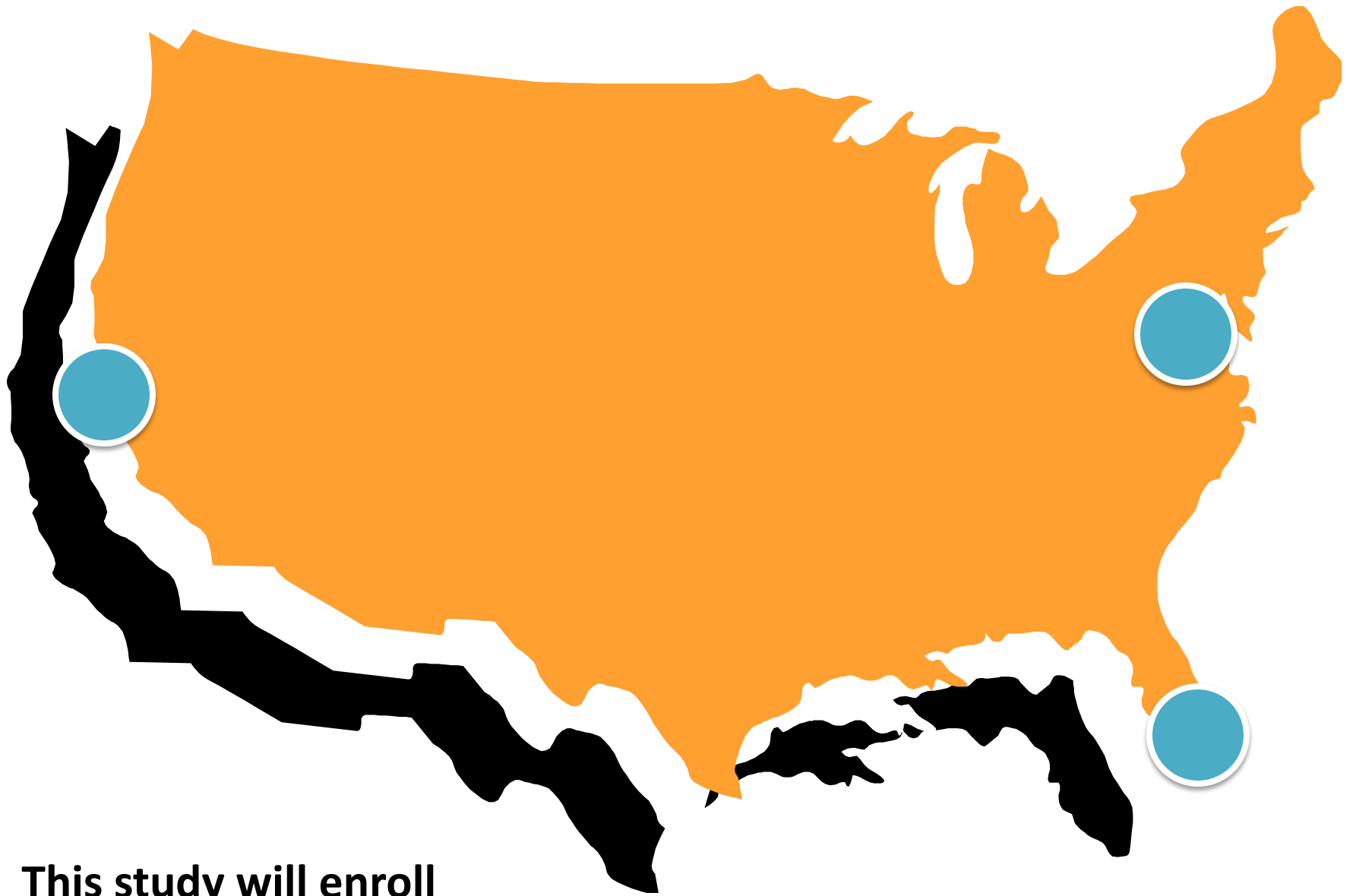
**For people
who take PrEP regularly,
protection from HIV could be
as high as 90%.**

PrEP Demonstration Project

This study will explore how PrEP can be provided to MSM and transwomen as an HIV prevention method in real world settings such as STD clinics.

What do we want to know?

- **Who** is interested in taking PrEP, for how long, and how frequently they take the medication.
- Whether there will be any **change** in the **risk behaviors** of PrEP participants.



This study will enroll

600 participants: 100 participants in Washington, DC,
200 participants in Miami, and 300 in San Francisco.

- All participants will receive once **daily** Truvada for up to **12 months**.



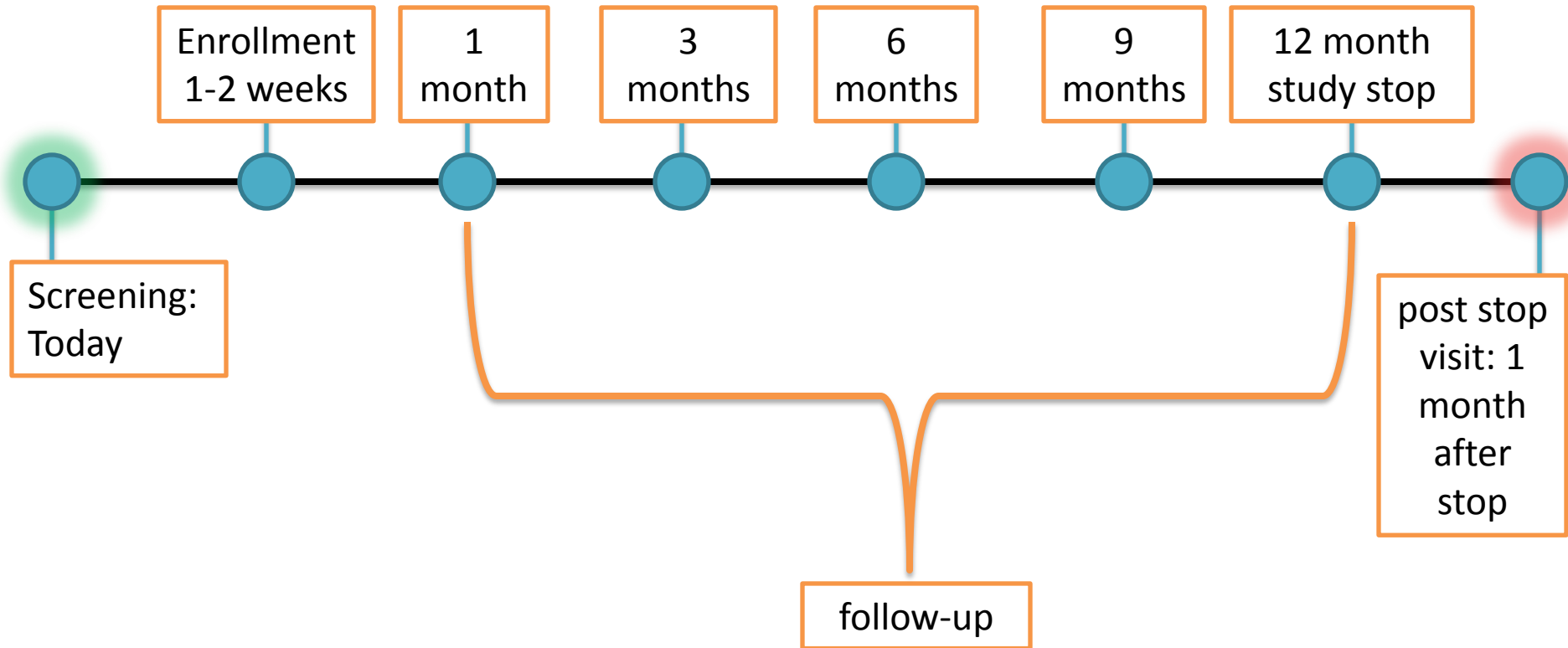
If you choose to participate...

- All visits will be conducted at **City Clinic**.
- You'll have up to 8 scheduled visits.

Study Visits

- Screening visit: **Today**
- Enrollment visit: **1-2 weeks** after today
- Post enrollment follow up:
 - **1 month** after enrollment
 - **every 3 months** after enrollment

Demonstration Project Timeline



Indicates study visit

Screening

- 1. Complete forms and review informed consent**
- 2. Provide brief medical history and physical exam, if needed**
- 3. Provide samples for lab tests, HIV testing, and STD screening**
- 4. Answer questions about demographics and sexual/drug use behavior**

Enrollment Visit

1. Brief medical history and physical exam, if necessary
2. HIV testing
3. Risk reduction and adherence counseling and condoms
4. Receive PrEP medication





A few things to consider...

There will be blood draws and urine collected at study visits.

You will be asked personal questions about your sexual behaviors and drug use.

Potential side effects of Truvada include: stomach problems, headache, dizziness, rash, and gas.

You will receive regular HIV and STD testing, and risk reduction counseling.

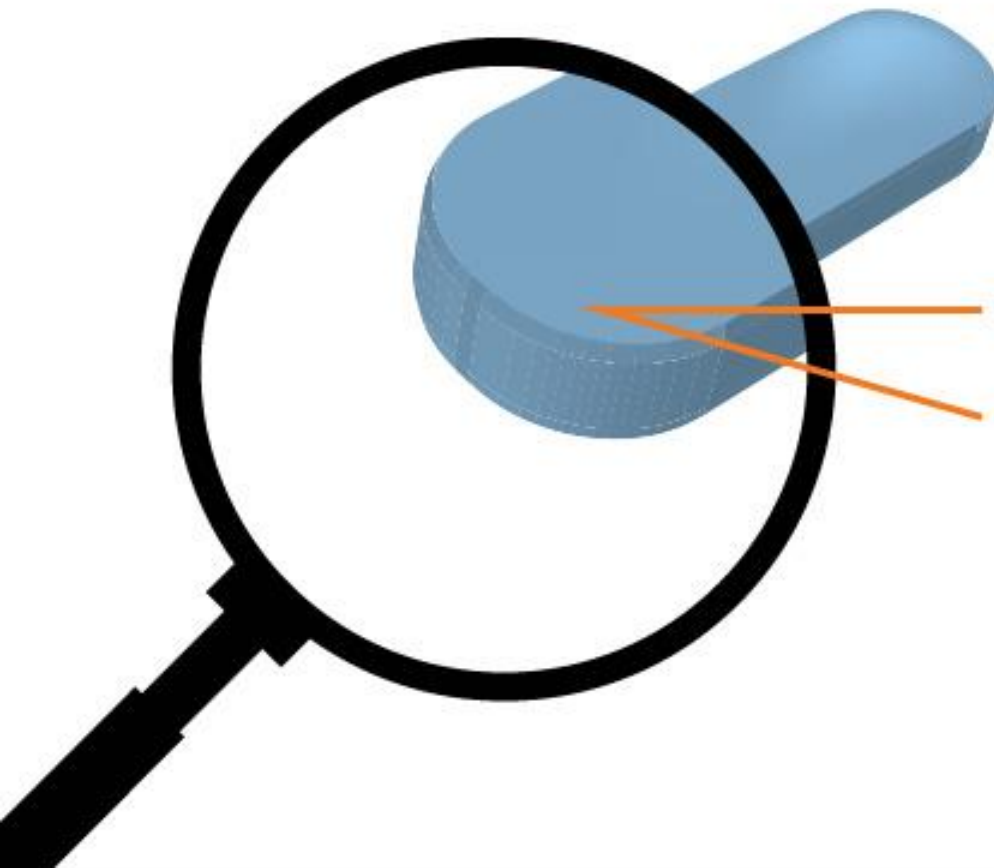
PrEP isn't 100% effective and should be combined with other prevention strategies.

Follow-up Study Visits

- 1. Brief medical history and physical exam, as necessary**
- 2. Provide samples for lab tests, HIV testing, STD screening, and monitoring medication levels**
- 3. Answer questions about sexual/drug use behavior**
- 4. Discuss PrEP use and HIV prevention efforts**
- 5. Receive PrEP medication**

HIV infection and drug resistance

If you become infected with HIV during this study and continue to take **Truvada**, there is a risk that the virus may become resistant to one or both of the medications in **Truvada**.



Truvada contains two anti-HIV medications:
tenofovir and
emtricitabine



Study Benefits

- **Receive daily PrEP for up to 48 weeks at no cost**
- **Testing for HIV and other STIs**
- **Risk reduction counseling and condoms to help protect your sexual health**
- **Testing and free vaccination for hepatitis B**
- **You will contribute to an important public health study to help find new ways to administer HIV prevention**

Your participation is **voluntary.**

You may quit the study **at any time without affecting your relationship with or ability to access services through the San Francisco Department of Public Health.**



Taking **PrEP is a personal choice**





Thank you for your time!

When you are finished with
this slideshow, please let
study staff know.



Supplemental Digital Content 3

eTable 1. Reasons for enrolling in The Demo Project

Reason	Listed as main reason N (%)	Included as one reason ^a N (%)
To protect myself against HIV	371 (66.6)	549 (98.6)
To help the community/to help fight the HIV epidemic	83 (14.9)	499 (89.6)
Because my partner has HIV	58 (10.4)	164 (29.4)
To make it safer for me to have sex without condoms	26 (4.7)	328 (58.9)
Wants to contribute to research	10 (1.8)	20 (3.6)
Other	3 (0.5)	15 (2.7)
Because joining the study is the only way to get PrEP where I live	2 (0.4)	116 (20.8)
Feel safer and decrease anxiety related to HIV risk	2 (0.4)	8 (1.5)
Because I was strongly encouraged or pressured by a friend or sexual partner to join the project	1 (0.2)	51 (9.2)
Because the reimbursement money is helpful	1 (0.2)	37 (6.6)
Because this is the only way for me to get healthcare	0	37 (6.6)
To get HIV medication to help treat someone close to me who is HIV positive	0	4 (0.7)
To get HIV medication to help prevent someone close to me who is HIV negative from getting HIV	0	10 (1.8)
Recommended by my doctor	0	2 (0.4)

^aSums to greater than 100% because participants could list more than one reason for enrolling