

ART Medication Log

ART Medication Log

1. Has any ART medication been initially prescribed or refilled in the last year?

- Yes
- No

ART Medication Log

2. Medication name.

- Fuzeon (enfuvirtide)
- Rukubio (fostemsavir)
- Selzentry (maraviroc)
- Trogarzo (ibalizumab)
- Isentress (raltegravir)
- Isentress HD (raltegravir)
- Tivicay (dolutegravir)
- Vocabria (cabotegravir)
- Emtriva (emtricitabine)
- Epivir (lamivudine)
- Retrovir (zidovudine)
- Viread (tenofovir)
- Ziagen (abacavir)
- Edurant (rilpivirine)
- Intelence (etravirine)
- Pifeltro (doravirine)
- Sustiva (efavirenz)
- Viramune IR - immediate-release (nevirapine)
- Viramune XR - extended- release (nevirapine)
- Aptivus (tipranavir)
- Lexiva (fosamprenavir)
- Prezista (darunavir)
- Reyataz (atazanavir)
- Norvir (ritonavir)
- Tybost (cobicistat)
- Sunlenca (lenacapavir)

- Atripla (efavirenz, emtricitabine, and tenofovir disoproxil fumarate)
- Biktarvy (bictegravir, emtricitabine, and tenofovir alafenamide)
- Cabenuva (cabotegravir and rilpivirine)
- Cimduo (lamivudine and tenofovir disoproxil fumarate)
- Combivir (lamivudine and zidovudine)
- Complera (emtricitabine, rilpivirine, and tenofovir disoproxil fumarate)
- Descovy (emtricitabine and tenofovir alafenamide)
- Delstrigo (doravirine, lamivudine, and tenofovir disoproxil fumarate)
- Dovato (dolutegravir and lamivudine)
- Epzicom (abacavir and lamivudine)
- Evotaz (atazanavir and cobicistat)
- Genvoya (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide)
- Juluca (dolutegravir and rilpivirine)
- Kaletra (lopinavir and ritonavir)
- Odefsey (emtricitabine, rilpivirine, and tenofovir alafenamide)
- Prezcoibix (darunavir and cobicistat)
- Symtuza (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide)
- Symfi (efavirenz, lamivudine, and tenofovir disoproxil fumarate)
- Symfi Lo (efavirenz, lamivudine, and tenofovir disoproxil fumarate)
- Stribild (elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate)
- Triumeq (abacavir, dolutegravir, and lamivudine)
- Truvada (emtricitabine and tenofovir disoproxil fumarate)
- Other

2a. If 'Other', specify:

3. Date of initial prescription or refill

(YYYY-MM-DD)

4. Is this medication part of the participant's current ART regimen?

Yes

No

Enrollment

Participant Identifier

Screening ID

Date of Enrollment

(YYYY-MM-DD hh:mm)

Timepoint:

- Baseline (1-4 months)
- Midpoint (12-15 months)
- Post-Intervention (24-27 months)

1. Is Participant at least 18 years of age?

- Yes
- No

2. Does the participant self-identify as a man (inclusive of cisgender and transgender men)?

- Yes
- No

3. Does Participant self-report a lifetime history of anal sex with another man? (i.e., at anytime of their life)

- Yes
- No

4. Is the participant HHI, per CDC surveillance data? In the southern US, HHI MSM are Black men who have sex with men.

- Yes
- No

5. Is Participant willing and able to provide a verbal consent to participate in the study?

- Yes
- No

6. Does Participant have a medical visit during the designated sampling period at a PHASE treatment or prevention healthcare facility?

- Yes
- No

7. Did Participant sign HIPAA form?

- Yes
- No

Confirm that the participant meets all eligibility criteria (check the box)

 Confirm

8. What is Participant's current HIV status?

- Living with HIV.
- Not Living with HIV.

9. What is Participant's care history at this facility?

- In Care: Has a medical visit within the past 6 months (Excluding this healthcare visit).
- Gap in Service/New Client: Has not had a medical visit within the past 6 months (Excluding this healthcare visit).

10. What is Participant's current PrEP usage?

- Received or has an existing PrEP prescription at this healthcare visit.
- Did not receive or does not have an existing PrEP prescription at this healthcare visit.



Healthcare Facility Visit

Healthcare Facility Visit

Healthcare Facility Visit

1. Date of first medical visit.

(YYYY-MM-DD)

Unknown

Unknown

HIV Diagnosis

HIV Diagnosis

HIV Diagnosis

1. Date of HIV Diagnosis

(YYYY-MM-DD)

HIV RNA Results Log

HIV RNA Results Log

Please provide Viral load results within the past 12 months

1. Are HIV RNA viral load results available in the participant's chart from within the past 12 months?

- Yes
 No

HIV RNA Results Log

2. HIV RNA specimen collection date.

(YYYY-MM-DD)

3. HIV RNA result.

- Reportable Viral Load
 Not Detected
 Detected, under LLOQ
 Detected, great than ULOQ

4. Operator

- >
 <
 =

5. Viral Copies/mL.

HIV Test

HIV Test

HIV Test

1. Are HIV test results available in participant's chart?

Yes

No

2. Date of most recent HIV Test.

(YYYY-MM-DD)

3. What is the confirmed result of this HIV test?

HIV-negative

HIV-positive

Informed Consent

Informed Consent

Completed by Study Participant

Thank you for agreeing to take this survey. Your responses will provide information for the HIV Prevention Trials Network (HPTN) research study called "HPTN 096: BETA." We will ask some basic questions about you, your social support, and your experiences with the healthcare system. We will also ask about your experience navigating sexual health and HIV services. Your responses will help us to understand what challenges and supports other men like you experience. This information could also assist in enhancing the quality of services at this facility.

A few more details about the survey:

This survey is VOLUNTARY – You do not have to take the survey.

This survey is part of a research study. You ARE NOT REQUIRED to take part in the research study.

There is no direct benefit to you, but your responses will help us understand more about the health care environment at this facility.

There is no cost to you for taking the survey.

This survey is CONFIDENTIAL – we will collect some basic information about you to help us understand the experiences that different people may have in this healthcare facility.

Responses to this survey will be collected by the researchers conducting the HPTN 096 study. The researchers do not work for this healthcare facility. This healthcare facility will not receive your individual responses to this survey. The researchers conducting the study will not receive any identifying information linking you to your survey responses.

Only the HPTN 096 research team, the study sponsor (the National Institutes of Health), the US Office for Human Research Protections (ORHP), and the Advarra Institutional Review Board (IRB) may have access to the survey responses.

A summary of anonymous responses may be used in publications about this study.

Your decision to take (or not take) this survey will not affect the care you receive at this facility. There will be no negative consequences and no loss of benefits if you decide not to take this survey or do not complete this survey.

This survey will take approximately 15 to 20 minutes to complete.

If you finish the survey, we will offer you \$50 for your time. Please see the healthcare facility staff at the end of your survey to collect your payment.

For issues or questions about the survey, please contact 096CSA@fhi360.org . For questions about your rights as a research subject completing the survey, contact the Advarra IRB study subject adviser at 877-992-4724 or adviser@advarra.com.

Before we begin, please confirm that you understand the purpose of the survey and are willing to complete this survey by checking the "I agree" box below.

I agree to complete this survey.

Yes, I agree

No, I don't agree

Medical Visits Log

Medical Visits Log

Please provide the dates and primary reason of all medical visits more than enrollment visit and within the past 12 months (if applicable)

Today's date:

_____ (YYYY-MM-DD)

1. Are prior medical visits available in participant's chart?

- Yes
- No

Medical Visits Log

2. Date of prior medical visit.

_____ (YYYY-MM-DD)

3. Primary reason for visit.

- PrEP initiation/Follow-up Visit
- HIV Test Visit
- STI Visit
- Non-HIV prevention/STI-related Visit
- Other

3a. If 'Other', specify:

=====

Protocol Deviation Log

Protocol Deviation Log

Protocol Deviation Log

1. Which study component is reporting the protocol deviation?

- Participant in the cross-sectional assessment
- PHASE
- Health Access
- Peer Support
- Social Media

2. Participant ID (If no PTID, please leave blank)

3. Date of site awareness

(YYYY-MM-DD)

4. Deviation start date

(YYYY-MM-DD)

5. Deviation stop date

(YYYY-MM-DD)

6. Provide a description of the deviation

7. Has or will this deviation be reported to single IRB (Advarra)?

- Yes
- No

8. Deviation category:

- Survey not completed
- Did not meet eligibility criteria
- Conduct of non-protocol procedure
- AE/SAE/EAE reporting deviation
- Breach of confidentiality
- Staff performing duties that they are not qualified or delegated to perform
- Use of non-IRB/EC-approved materials
- IRB, ethics, or regulatory review deviation
- Other

8a. If deviation category is "Eligibility criteria" indicate the category not met:

- Inclusion criteria
- Exclusion criteria

8b. Protocol version to which the participant enrolled:

8c. Which criteria did the participant not meet:

- 17 years of age or younger
- Does not self-identify as a man
- Does not self-report a lifetime history of anal sex with another man
- Not determined to be HHI within the community
- Not willing or able to provide consent to participate in the study
- Does not have a medical visit scheduled at a PHASE facility during the sampling period
- No enrollment slot available
- Withdrew consent to participate in the study
- Has a condition that would make participation unsafe, complicate interpretation of outcome data, or interfere with achieving study objectives
- IoR determination
- Other

8d. If 'Other', specify:

8e. Which criteria did the participant not meet:

- 15 years of age or younger
- Does not self-identify as a man
- Does not self-report a lifetime history of anal sex with another man
- Not determined to be HHI within the community
- Not willing or able to provide consent to participate in the study
- Does not live in one of the selected study communities
- No enrollment slot available
- Withdrew consent to participate in the study
- Has a condition that would make participation unsafe, complicate interpretation of outcome data, or interfere with achieving study objectives
- IoR determination
- Other

8f. If 'Other', specify:

PrEP Log

PrEP Log

Please enter all PrEP Prescriptions in the last 12 months

1. Are PrEP prescriptions available in participant's chart?

Yes

No

Pre-exposure Prophylaxis Log

2. Medication name.

Descovy

Truvada

Apretude

Long-acting lenacapivir

Other

2.1 If 'Other', please specify:

3. Date started.

(YYYY-MM-DD)

4. Date stopped.

Or

(YYYY-MM-DD)

5. Currently taking this prescription (as noted in the chart).

Yes

6. Number of refills.

Retention In Care Log

Retention In Care Log

1. Date of medical visit at enrollment.

_____ (YYYY-MM-DD)

Please provide the dates and primary reason of all medical visits within the past 12 months. (if applicable)

2. Are prior medical visits available in participant's chart?

Yes

No

Retention In Care Log

3. Date of prior medical visit.

_____ (YYYY-MM-DD)

4. Primary reason for visit.

Initial HIV test (brand new)

HIV Follow-up Visit

STI Visit

Non-HIV prevention/STI-related Visit

Other

4a. If 'Other', specify:

Social Harm Log

Social Harm Log

Social Harm Log

1. Which study component is reporting the social harm?

- Participant in the cross-sectional assessment
- PHASE
- Health Access
- Peer Support
- Social Media

2. Participant ID (If no PTID, please leave blank)

3. Form completion date:

(YYYY-MM-DD)

4. Study community:

5. Staff member initials:

6. Date social harm reported to study staff:

(YYYY-MM-DD)

7. Concisely describe social impact:

8. Onset date:

(YYYY-MM-DD)

9. Please select the social impact:

- Personal Relationships - Had any negative experiences with family, friends, significant others, or sex partners
- Travel/Immigration - Had problems obtaining formal permission to travel to or enter another country, such as being denied a visa, or had a problem with immigration/naturalization.
- Employment - Been turned down for a job, lost a job, study visits interfering with work/work performance or experienced other problems at work.
- Education - Been turned down by an educational program, told to leave an educational program, study visits interfering with school attendance /performance, or experienced other problems at school
- Medical/Dental - Been told you have an HIV test by a health care provider, been refused medical or dental treatment or treated negatively by a health care provider.
- Health Insurance - Lost health insurance, had a problem getting new health insurance, or experienced other problems related to health insurance.
- Life Insurance/Funeral coverage - Lost your life insurance policy or funeral cover policy, had a problem getting new life insurance policy or funeral cover policy, or experienced other problems related to life insurance policy or funeral cover policy.
- Housing - Had trouble getting or keeping housing, had negative experience with landlord, or had other problems related to housing.
- Military/Other Government Agency - Had a problem with the military or any other government agencies
- Other - Had other problems not covered in the list above

9.1 If 'Other', please specify:

STI Diagnosis Log

STI Diagnosis Log

Please provide STI diagnosis and dates over the past year

1. Are STI test results available in participant's chart within the past 12 months?

- Yes
- No

STI Diagnosis Log

2. STI test date.

(YYYY-MM-DD)

3. STI test performed.

- Herpes Simplex Virus 1 (HSV-1)
- Herpes Simplex Virus 2 (HSV-2)
- Chlamydia
- Gonorrhea
- Hepatitis A
- Hepatitis B
- Hepatitis C
- Syphilis
- Trichomoniasis
- HPV
- Mpox
- Other

3a. If 'Other', specify:

4. STI Test Result.

- Not detected/Negative
- Positive/Reactive
- Invalid
- Indeterminate