Subject Case Report Forms

HPTN083_version 26.0_PROD_BK_09JUN2023 - All

Signature Prompt: I certify that I have ensured the accuracy and completeness of the data reported in the Case Report Forms.

Participant ID: _____

HPTN083_version 26.0_PROD_BK_09JUN2023: All
Form: Date of Visit
Generated On: 12 Jun 2023 18:42:31

Did the participant complete this visit?	Yes ☐ No ☐
Visit Date:	_____
How many bottles of TDF/FTC (real or placebo) were dispensed at this visit?	None ☐ 1 bottle ☐ 2 bottles ☐ 3 bottles ☐ 4 bottles ☐ 5 bottles ☐ 6 bottles ☐
How many bottles were lost, stolen, or damaged since the last pill dispensation?	None ☐ 1 bottle ☐ 2 bottles ☐ 3 bottles ☐ 4 bottles ☐ 5 bottles ☐ 6 bottles ☐
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Is participant moving to infected visit schedule?	Yes ☐ No ☐
Is the participant ready to move to Step 3?	Yes ☐ No ☐
Is the participant moving to yearly visits?	Yes ☐ No ☐
Did or will the participant complete the CASI questionnaire for this visit?	Yes ☐ No ☐
Complete once at Week 5 visit (or prior, if participant is discontinuing Step 1 early):	
Record the date and time of the participant's last dose of Step 1 oral study products.	_____
Is the participant moving to Step 2?	Yes ☐ No ☐
Mark any additional forms or procedures that took place at this visit	
CD4/Viral Load	☐
Hematology	☐
Hepatitis Test Results	☐
Electrocardiogram	☐

Local Laboratory Results	☐
Participant Receipt	☐
Participant Transfer	☐
Sexually Transmitted Infections	☐
HIV Test Results	☐
Interviewer Administered: Follow Up 1	☐
Study Medication Satisfaction Questionnaire (SMSQs)	☐
Supplemental HIV Results	☐
Vital Signs	☐
Post-Injection Exercise Assessment	☐

Did the participant complete this visit?	Yes ☐ No ☐
Visit Date:	_____
How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?	0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Did or will the participant complete the CASI questionnaire for this visit?	Yes ☐ No ☐
Is the participant moving to a new step or visit schedule?	Yes ☐ No ☐
If Yes, please indicate which Step or visit schedule?	Oral CAB (Step 4a) ☐ Loading Dose (4-week interval) CAB-LA (Step 4b) ☐ TDF/FTC (Step 5) ☐ Seroconvertor Schedule ☐ Standard Dose (8-week interval) CAB-LA (Step 6) ☐ Back to Standard Dose (8-week interval) CAB-LA (Step 4c) ☐ Standard Dose (8-week interval) CAB-LA (Step 7) ☐

Mark any additional forms or procedures that took place at this visit

CD4/Viral Load Results	☐
Hepatitis Test Results	☐
Local Laboratory Results	☐
Participant Receipt	☐
Participant Transfer	☐
Sexually Transmitted Infections	☐
Supplemental HIV Results	☐

Did the participant complete this visit?	Yes ☐ No ☐
Visit Date:	_____
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Mark any additional forms or procedures that took place at this visit	
CD4/Viral Load Results	☐
Participant Receipt	☐
Participant Transfer	☐
Supplemental HIV Results	☐
Local Laboratory Results	☐

Visit date	_____
Interim visit code	_____
How many bottles of TDF/FTC (real or placebo) were dispensed at this visit?	None ☐ 1 bottle ☐ 2 bottles ☐ 3 bottles ☐ 4 bottles ☐ 5 bottles ☐ 6 bottles ☐
How many bottles were lost, stolen, or damaged since the last pill dispensation?	None ☐ 1 bottle ☐ 2 bottles ☐ 3 bottles ☐ 4 bottles ☐ 5 bottles ☐ 6 bottles ☐
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Is participant moving to infected visit schedule?	Yes ☐ No ☐
Is the participant ready to move to Step 3?	Yes ☐ No ☐
Is the participant moving to yearly visits?	Yes ☐ No ☐
Complete only if participant is discontinuing Step 1 before Week 5 visit:	
Record the date and time of the participant's last dose of Step 1 oral study products.	_____
Is the participant moving to Step 2?	Yes ☐ No ☐
Mark any forms or procedures completed at this visit.	
CD4/viral load	Yes ☐
Hematology	Yes ☐
Hepatitis Test Results	Yes ☐
HIV Test	Yes ☐
Electrocardiogram	Yes ☐
Local Laboratory Results	Yes ☐
Participant Receipt	Yes ☐

Participant Transfer	Yes ☐
Sexually Transmitted Infections	Yes ☐
Specimen Storage	Yes ☐
Log Form	Yes ☐
Supplemental HIV Results	Yes ☐
Interviewer Administered: Follow Up 1	Yes ☐
Interviewer Administered: Follow Up 2	Yes ☐
Study Medication Satisfaction Questionnaire (SMSQs)	Yes ☐
Post-injection Exercise Assessment	Yes ☐

HPTN083_version 26.0_PROD_BK_09JUN2023: All
Form: Interim Visit - OLE
Generated On: 12 Jun 2023 18:42:31

Visit date	_____
Interim visit code	_____
How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?	0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Is the participant moving to a new step or visit schedule?	Yes ☐ No ☐
If Yes, please indicate which Step or visit schedule?	Oral CAB (Step 4a) ☐ Loading Dose (4-week interval) CAB-LA (Step 4b) ☐ TDF/FTC (Step 5) ☐ Seroconvertor Schedule ☐ Standard Dose (8-week interval) CAB-LA (Step 6) ☐ Back to Standard Dose (8-week interval) CAB-LA (Step 4c) ☐ Standard Dose (8-week interval) CAB-LA (Step 7) ☐
Mark any forms or procedures completed at this visit.	
CD4/Viral Load Results	Yes ☐
Hepatitis Test Results	Yes ☐
HIV Test Results	Yes ☐
Local Laboratory Results	Yes ☐
Participant Receipt	Yes ☐
Participant Transfer	Yes ☐
Sexually Transmitted Infections	Yes ☐
Specimen Storage	Yes ☐
Log Form	Yes ☐
Supplemental HIV Results	Yes ☐

HPTN083_version 26.0_PROD_BK_09JUN2023: All
Form: Yearly Visit Summary
Generated On: 12 Jun 2023 18:42:31

Did the participant complete this visit?	Yes ☐
	No ☐
Visit Date:	_____
Yearly visit code	V80.0 - Yearly 1 ☐
	V81.0 - Yearly 2 ☐
	V82.0 - Yearly 3 ☐
	V83.0 - Yearly 4 ☐
Did the participant exit/terminate the study at this visit?	Yes ☐
	No ☐
Is the participant confirmed HIV infected?	Yes ☐
	No ☐
Mark any forms or procedures completed at this visit.	
Hematology	Yes ☐
	No ☐
Hepatitis Test Results	Yes ☐
	No ☐
Electrocardiogram	Yes ☐
	No ☐
Local Laboratory Results	Yes ☐
	No ☐
Participant Receipt	Yes ☐
	No ☐
Participant Transfer	Yes ☐
	No ☐
Sexually Transmitted Infections	Yes ☐
	No ☐
Supplemental HIV Results	Yes ☐
	No ☐

HPTN083_version 26.0_PROD_BK_09JUN2023: All
Form: Enrollment
Generated On: 12 Jun 2023 18:42:31

Is the participant enrolling in the study?
- Yes
- No

If participant did not enroll, skip to "Which version of the Sex Pro Tool was used?" and complete remaining items.

Enrollment Date _____

Did the participant consent to having blood stored and used for future testing?
- Yes
- No

Did the participant consent to genetic testing?
- Yes
- No

Did the participant consent to participating in the DXA substudy?
- Yes
- No
- N/A (slots filled or site not participating)

What is the CASI ID assigned to this participant? _____

Did or will the participant complete the enrollment CASI questionnaire?
- Yes
- No

Which version of the Sex Pro Tool was used?
- South America
- North America
- Not Applicable

Record participant's Sex Pro score _____

Complete the following item only if participant does not enroll. If more than one reason, add additional log lines.

Reason participant was not enrolled in the study:
- Did not meet behavior risk category
- Intravenous drug use in last 90 days
- Reactive or positive HIV test result
- Abnormal liver or kidney function tests
- Other lab abnormality
- Hepatitis B or C positive
- Unwilling to adhere to study procedures
- Co-enrollment in another HIV interventional research study or other concurrent studies which may interfere with this study
- Past or current participation in HIV vaccine trial without documentation of receipt of placebo
- Clinically significant cardiovascular disease
- Underlying skin disease or currently active skin disorder

- [ ] Has a tattoo or other dermatological condition may interfere with interpretation of injection site reactions (over the buttock region)
- [ ] Current or chronic history of liver disease or known hepatic or biliary abnormalities
- [ ] Coagulopathy which would contraindicate IM injection
- [ ] Active or planned use of prohibited medications
- [ ] Has a history of seizure disorder
- [ ] Has surgically-placed buttock implants
- [ ] Opinion of the study investigator
- [ ] Allergy to product components
- [ ] Screening not completed prior to window closing

Is the participant ready to be randomized?	Yes ☐ No ☐

What is the participant's date of birth?	
Age	Fixed Unit: Years
What was the participant's sex at birth?	Female ☐ Male ■
What is the participant's self-identified gender?	Male ☐ Female ☐ Transgender male (female to male) ☐ Transgender female (male to female) ☐ Gender Queer ☐ Gender variant or gender non-conforming ☐ Self-identify, other ☐ Prefer not to answer ☐
If "self-identify, other" is marked, please specify:	
What is the participant's current marital status?	married/civil union/legal partnership ☐ living with primary or main partner ☐ have primary or main partner, not living together ☐ single/divorced/widowed ☐ Other ☐
If other, specify	
What is the participant's current employment status?	full-time employment ☐ part-time employment ☐ not employed ☐
What is the participant's highest level of education?	no schooling ☐ primary school, not complete ☐ primary school, complete ☐ secondary school, not complete ☐ secondary school, complete ☐ technical training, not complete ☐ technical training, complete ☐ college/university or higher, not complete ☐ college/university or higher, complete ☐
Does the participant consider him/herself to be Latino/a or of Hispanic origin?	Yes ☐ No ☐
Race	
Specify:	

Were any concomitant medications taken?	Yes ☐ No ☐

Medication Name _____

Indication _____

Mark if medication taken for cross-sex hormone therapy. ☐

Date Started _____

Date Stopped _____

Or mark if continuing at end of study. ☐

Frequency

- PRN ☐
- QD ☐
- TID ☐
- QID ☐
- QHS ☐
- ONCE ☐
- BID ☐
- Other ☐

If Other frequency, please specify: _____

Route

- PO ☐
- IM ☐
- IV ☐
- TOP ☐
- IHL ☐
- VAG ☐
- REC ☐
- SC ☐
- Other ☐

If Other route, please specify: _____

Dose _____

Dose Units

- Grams ☐
- Micrograms ☐
- Milligrams ☐
- Milliliters ☐
- Capsules ☐
- Drops ☐
- Puffs ☐
- Sachets ☐
- Suppository ☐
- Tablets ☐
- Units ☐
- Unknown ☐

	Other ☐
If Other dose units, specify	
Taken for a reported AE?	Yes ☐ No ☐
Adverse event #1	
Adverse event #2	
Adverse event #3	
Adverse event #4	
Taken for reported Injection Site Reaction?	Yes ☐ No ☐
Injection Site Reaction #1	
Injection Site Reaction #2	
Injection Site Reaction #3	
Injection Site Reaction #4	

Has the participant experienced an Adverse Event during the study? Yes ☐ No ☐

If Yes, complete the Adverse Event form.

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Form: Adverse Event
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Date reported to site	
Adverse Event (AE)	
Onset Date	
At which visit was this AE first reported?	
Interim visit code, if applicable:	
Is the AE still ongoing?	Yes ☐ No ☐
Outcome Date	
Severity Grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Grade 5 (Death) ☐
Relationship to study product	Related ☐ Not Related ☐
Alternate etiology	
Action Taken with Study Product	dose not changed ☐ dose reduced ☐ dose increased ☐ drug withdrawn ☐ drug interrupted ☐ not applicable ☐
Other action(s) taken	☐ None
Medication	☐
	☐
Therapeutic procedure/surgery	☐
Diagnostic procedure	☐
Other	☐
Other, specify	
Status/Outcome	recovered/resolved ☐ recovering/resolving ☐ resolved with sequelae ☐ not recovered/resolved ☐ fatal ☐

Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines? If "No", go to following question.	Yes ☐ No ☐

If "Yes", check all that apply.

Results in death	☐
Is life-threatening	☐
Requires inpatient hospitalization or prolongation of existing hospitalization	☐
Results in persistent or significant disability/incapacity	☐
Is a congenital anomaly/birth defect	☐
Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	☐
Has or will this AE be reported as an EAE?	Yes ☐ No ☐
If yes, EAE number	_____

Target Visit Date	_____
Reason visit was missed	unable to contact participant ☐ unable to schedule appointment(s) within allowable window ☐ participant refused visit ☐ participant incarcerated ☐ participant admitted to a health care facility ☐ participant withdrew from study ☐ participant deceased ☐ other ☐
If other, specify	_____

Only complete this form when participant has been contacted, or deceased. Otherwise, wait until the end of study follow-up to complete this form.

Was the participant informed of their study arm assignment (that is, active CAB or active Truvada)?	Yes ☐ No ☐
If yes, enter date	_____
If no, mark reason	Lost to Follow-up ☐ Other ☐
Other, specify	_____

Does the participant have any pre-existing conditions to report?	Yes ☐ No ☐

HPTN083_version 26.0_PROD_BK_09JUN2023: All
Form: Pre-existing Conditions
Generated On: 12 Jun 2023 18:42:31

Date medical history collected	
Description of medical history condition/event	
Is condition/event gradable?	Yes ☐ No ☐
Toxicity (Severity) Grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Date medical condition/event started	
Is the condition ongoing at time of assessment?	Yes ☐ No ☐
Date medical condition/event ended/resolved	

Has the participant started taking any ART medication?	Yes ☐ No ☐

ART Medication Code	Abacavir (ABC; Ziagen) ☐
	Didanosine (ddl; Videx) ☐
	Didanosine Delayed Release Capsules (ddI-EC; Videx-EC ☐
	Emtricitabine (FTC; Emtriva) ☐
	Lamivudine (3TC; Epivir) ☐
	Stavudine (d4T; Zerit) ☐
	Stavudine Extended Release Capsules (d4T XR; Zerit XR ☐
	Tenofovir Disoproxil Fumarate (TDF; Viread) ☐
	Zidovudine (AZT, ZDV, Retrovir ☐
	Delavirdine mesylate (DLV; Rescriptor) ☐
	Efavirenz (EFV; Sustiva; Stocrin) ☐
	Etravirine (Intelence) ☐
	Nevirapine (NVP; Viramune) ☐
	Rilpivirine (RPV; Edurant) ☐
	Amprenavir (APV; Agenerase) ☐
	Atazanivir (ATV; Reyataz) ☐
	Darunavir (DRV; Prezista) ☐
	Fosamprenavir (FPV; Lexiva; Telzir) ☐
	Indinavir (IDV; Crixivan) ☐
	Nelfinavir (NFV; Viracept) ☐
	Ritonavir (RTV; Norvir) ☐
	Saquinavir Hard-Gel Capsules (SQV; Invirase) ☐
	Saquinavir Soft-Gel Capsules (SQV; Fortovase) ☐
	Tipranavir (Aptivus) ☐
	Raltegravir (Isentress) ☐
	Dolutegravir ☐
	Elvitegravir ☐
	Enfurvirtide (ENF; Fuzeon) ☐
	Maraviroc (Selzentry) ☐
	Abacavir/Lamivudine (ABC/3TC; Epzicom; Kivexa) ☐
	Abacavir/Lamivudine/Zidovudine (3TC/AZT/ABC; Trizivir) ☐
	Efavirenz/Emtricitabine/Tenofovir (Atripla; Odimune; Atroiza; Tribuss) ☐
	Emtricitabine/Tenofovir (FTC/TDF; Truvada) ☐
	Lamivudine/Zidovudine (3TC/AZT; Combivir) ☐

	Lopinavir/ritonavir (LPV/RTV; Kaletra; Aluvia) ☐
	Lamivudine/Stavudine/Nevirapine (Triomune) ☐
	Zidovudine/Lamivudine/Nevirapine (Duovir-N) ☐
	Emtricitabine/Rilpivirine/Tenofovir DF (FTC/RPV/TDF; Complera) ☐
	Elvitegravir/Cobicistat/Emtricitabine/Tenofovir DF (EVG/COBI/FTC/TDF; Stribild) ☐
	Lamivudine (3TC; Epivir)/Tenofovir (TDF; Viread) ☐
	Dolutegravir/Abacavir/Lamivudine (Triumeq) ☐
	Tenofovir/Lamivudine/Efavirenz (TDF/3TC/EFV) ☐
	Unknown ☐
	Cobicistat (COB) ☐
	Elvitegravir/Cobicistat/Emtricitabine/Tenofovir AF (EVG/COBI/FTC/TAF) ☐
	Biktarvy (TAF/FTC/BIC) ☐
	Other, not listed ☐
Date Started	_____
Date Stopped	_____
Or mark if continuing at end of study	☐

Have any protocol deviations occurred?	Yes ☐ No ☐

HPTN083_version 26.0_PROD_BK_09JUN2023: All
Form: Protocol Deviation
Generated On: 12 Jun 2023 18:42:31

Prior to completing this form contact the protocol deviations alias to confirm reporting requirements.	
Site awareness date	
Deviation date	
Has or will this deviation be reported to local IRB/EC?	Yes ☐ No ☐
Has or will this deviation be reported to DAIDS as a critical event?	Yes ☐ No ☐
Type of deviation	Inappropriate enrollment. ☐ Failure to follow trial randomization or blinding procedures. ☐ Study product management deviation. ☐ Study product dispensing error. ☐ Conduct of non-protocol procedure. ☐ Breach of confidentiality. ☐ Physical assessment deviation. ☐ Lab assessment deviation. ☐ Use of non-IRB/EC-approved materials. ☐ Informed assent/consent process deviation. ☐ Failure to complete eligibility assessment prior to randomization / incomplete assessment of eligibility prior to enrollment ☐ Other ☐
Description of deviation (max. 1,000 characters):	
Plans and/or action taken to address the deviation (max. 1,000 characters):	
Plans and/or action taken to prevent future occurrences of the deviation (max. 1,000 characters):	
Deviation reported by (staff name):	

Is there a product hold or discontinuation to report?	Yes ☐ No ☐

Which study product is being held?

- Oral CAB
- CAB-LA injection
- TDF/FTC

Date of last oral study product or CAB injection: _____

Date when this study product hold or discontinuation was initiated: _____

At what visit was this product hold/discontinuation initiated?

- V61.0 - Step 4a - Day 0
- V62.0 - Step 4a - Week 4
- V63.0 - Step 4b - Day 0
- V64.0 - Step 4c - Day 0
- V65.0 - Step 4c - Week 8
- V66.0 - Step 4c - Week 16
- V67.0 - Step 4c - Week 24
- V68.0 - Step 4c - Week 32
- V69.0 - Step 4c - Week 40
- V70.0 - Step 4c - Week 48
- V71.0 - Step 6 - Week 56
- V72.0 - Step 6 - Week 64
- V73.0 - Step 6 - Week 72
- V74.0 - Step 6 - Week 80
- V75.0 - Step 6 - Week 88
- V76.0 - Step 6 - Week 96
- V101.0 - Step 5 - Day 0
- V102.0 - Step 5 - Week 12
- V103.0 - Step 5 - Week 24
- V104.0 - Step 5 - Week 36
- V105.0 - Step 5 - Week 48
- V106.0 - Step 5 - Week 60
- V107.0 - Step 5 - Week 72
- V108.0 - Step 5 - Week 84
- V109.0 - Step 5 - Week 96
- V121.0 - Step 5b - Day 0
- V122.0 - Step 5b - Week 12
- V123.0 - Step 5b - Week 24
- V124.0 - Step 5b - Week 36
- V125.0 - Step 5b - Week 48
- V126.0 - Step 5b - Week 60
- V127.0 - Step 5b - Week 72
- V128.0 - Step 5b - Week 84

	V129.0 - Step 5b - Week 96 ☐
	V91.0 - Week 12 - Seroconvertor Schedule ☐
	V92.0 - Week 24 - Seroconvertor Schedule ☐
	V93.0 - Week 36- Seroconvertor Schedule ☐
	V94.0 - Week 48- Seroconvertor Schedule ☐
	Interim Visit ☐
	V131.0 - Step 7 - Week 104 ☐
	V132.0 - Step 7 - Week 112 ☐
	V133.0 - Step 7 - Week 120 ☐
	V134.0 - Step 7 - Week 128 ☐
	V135.0 - Step 7 - Week 136 ☐
	V136.0 - Step 7 - Week 144 ☐
	V137.0 - Step 7 - Week 152 ☐
	V138.0 - Step 7 - Week 160 ☐
	V139.0 - Step 7 - Week 168 ☐
	V140.0 - Step 7 - Week 176 ☐
	V141.0 - Step 7 - Week 184 ☐
	V142.0 - Step 7 - Week 192 ☐
Interim visit code	_____
Why is the study product being held or discontinued?	one or more reactive HIV test results or acute HIV infection suspected ☐
	reported use of prohibited concomitant medication ☐
	participant is currently using or planning to use PrEP or PEP ☐
	Low oral adherence according to protocol ☐
	Clinical AE (protocol mandated) ☐
	Laboratory AE (protocol mandated) ☐
	Injection site reaction ☐
	CMC recommendation based on a clinical event ☐
	CMC recommendation based on a laboratory value ☐
	CMC recommendation based on a psychosocial concern ☐
	Other clinical reason ☐
	Participant request for injection intolerance (AE or ISR not protocol mandated) ☐
	Participant request - participant is unwilling or unable to comply with required study procedures ☐

	Other participant request ☐
If Other marked, specify:	
If product hold was associated with an Adverse event, select the applicable AE(s): Adverse Event #1	
Adverse Event #2	
Adverse Event #3	
If product hold was associated with an Injection Site Reaction, select the applicable Injection Site Reaction:	
If product hold was associated with new or updated Concomitant Medications, select the applicable medication(s).	
Complete this section only if participant has either resumed or permanently discontinued study drug. Has the participant resumed study product?	Yes ☐ no (permanently discontinued) ☐ no (hold continuing/ permanently discontinued for another reason) ☐
Date participant resumed study product:	
Date participant permanently discontinued study product:	

Will participant move to Open Label Extension (OLE)?	Yes ☐ No ☐
Date decision was made on whether to move to Open-label extension?	_____
If No, Reason (end of form)	Study participation too burdensome ☐ Already accessed TDF/FTC through another mechanism ☐ Prefer to take TAF/FTC ☐ Relocating to area where study is not offered ☐ Prefer not to answer ☐ Prefers TDF/FTC but not eligible for study-provided TDF/FTC ☐ Other ☐
Other, specify	_____
If Yes, Date of Informed Consent	_____
Select OLE Regimen	CAB ☐ TDF/FTC ☐ Seroconverter schedule – continuing from Version 3.0 of the protocol ☐ Open Label Truvada Schedule – continuing from Version 3.0 of the protocol ☐
If CAB, specify introductory regimen (mark only one):	Oral CAB (Step 4a) ☐ Loading Dose (4-week interval) CAB-LA (Step 4b) ☐ Standard Dose (8-week interval) CAB-LA (Step 4c) ☐
If CAB regimen selected, Reason	Prefer injections and/or don't like pills ☐ CAB was shown to be superior to Truvada for HIV prevention ☐ Want to avoid potential side effects of Truvada ☐ Other ☐
Other, specify	_____
If TDF/FTC regimen selected, Reason	Don't like injections and/or prefer pills ☐ The potential side effects of Truvada are better understood than those of Cabotegravir ☐ Concerned about resistance if injectable PrEP fails ☐ Other ☐
Other, specify	_____

HPTN083_version 26.0_PROD_BK_09JUN2023: All
Form: Hematology
Generated On: 12 Jun 2023 18:42:31
Lab Name:

Was a hematology sample collected?	Yes ☐ No ☐
Date of Collection	
Hemoglobin	
Hemoglobin severity grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable ☐
Hemoglobin Adverse event	
Hematocrit	
MCV	
Platelets	
Platelets Severity grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable ☐
Platelets Adverse event	
WBC	
WBC Severity grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable ☐
WBC Adverse event	
Was differential done?	Yes ☐ No ☐
Neutrophils	
Neutrophils Severity grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable ☐
Neutrophils Adverse event	
Lymphocytes	
Lymphocytes severity grade	Grade 1 – Mild ☐

	Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable ☐
Lymphocytes Adverse event	
Monocytes	
Eosinophils	
Basophils	
Atypical lymphocytes	

Did the participant have a DXA scan for this visit?	Yes ☐ No ☐ N/A (slots filled or site not participating) ☐
Date of DXA scan	_____

Was a plasma sample collected for storage? Note: plasma storage is required at each visit where HIV testing is done.	Yes ☐ No ☐
Specimen collection date	_____
Time plasma sample collected	_____
Was plasma stored?	Stored ☐ Not Stored ☐
Was a dried blood spot collected?	Yes ☐ No ☐
Specimen collection date	_____
Time Dried Blood Spot collected	_____
Was Dried Blood Spot stored?	Stored ☐ Not Stored ☐
(Complete only for Enrollment visit) Was a whole blood sample collected for storage?	Yes ☐ No ☐
Specimen collection date	_____
Time Whole Blood collected	_____
Was Whole Blood stored?	Stored ☐ Not Stored ☐
Was a cell pellet collected?	Yes ☐ No ☐
Specimen collection date	_____
Was a cell pellet stored?	Yes ☐ No ☐
Additional blood specimen collection required	☐

Date reported	
Concisely describe social impact	
Onset date	
Social impact type	☐ Personal Relationships - Had 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 new job, lost a job, or experienced other problems at work. ☐ Education - Been turned down by an educational program, told to leave an educational program, or experienced other problems at school. ☐ Medical/Dental - 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 - Lost life insurance, had a problem getting new life insurance, or experienced other problems related to life insurance. ☐ Housing - Had trouble getting or keeping housing, 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 codes above.
If other, specify	

Has the participant reported a social impact during the study?	Yes ☐ No ☐

HIV 1/2 Discriminatory Assay

Mark 'Not Done' OR enter Specimen Collection date and mark result:

Not Done ☐

OR

Specimen Collection Date _____

Assay Result

- ☐ Assay result not provided
- ☐ HIV Negative
- ☐ HIV-1 Positive
- ☐ HIV-2 Positive
- ☐ HIV-2 Positive with HIV-1 Cross-Reactivity
- ☐ HIV-1 Positive, Untypable
- ☐ HIV-1 Indeterminate
- ☐ HIV-2 Indeterminate
- ☐ HIV Indeterminate
- ☐ Other

Other assay result: _____

Comments (max. 200 characters) _____

Laboratory Reported HIV Interpretation

Mark 'Not Reported' if not provided by testing laboratory OR mark interpretation:

Not Reported ☐

OR

Interpretation

- ☐ HIV Negative
- ☐ HIV-1 antigen and HIV-1/HIV-2 antibodies were not detected. No laboratory evidence of HIV infection.
- ☐ HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected.
- ☐ HIV-1 Positive
- ☐ HIV-2 Positive
- ☐ HIV-2 Positive - This result is distinct from HIV Positive, Untypable.
- ☐ HIV Positive
- ☐ Acute HIV-1 Positive
- ☐ HIV-1 Negative, HIV-2 inconclusive
- ☐ Inconclusive
- ☐ Other

Other interpretation: _____

Comments (max. 200 characters) _____

HIV DNA

Mark 'Not performed/Not reported by Lab' OR enter Specimen Collection date and complete appropriate result field:	
Not performed/Not reported by Lab (add comment)	☐
OR	
Specimen Collection Date	
DNA Result	Detectable DNA result (record below) ☐ Detectable DNA , but below limit of detection (<4.09 copies per million cells) ☐ Detectable DNA, above the reportable range of the assay (>100 copies per million cells) ☐ Undetectable DNA, below limit of detection (<4.09 copies per million cells) ☐
Detectable DNA result:	Fixed Unit: copies per million cells
Comments (max. 200 characters)	

Termination date	_____
Reason for termination	scheduled exit visit/end of study ☐ Death ☐ participant refused further participation ☐ participant relocated, no follow-up planned ☐ investigator decision ☐ inappropriate enrollment ☐ invalid ID due to duplicate screening/enrollment ☐ other ☐ early study closure ☐ linkage to local CAB ☐
Date of death	_____
Specify	_____
Was termination associated with an adverse event?	Yes ☐ No ☐
If yes, please specify AE	_____

Un-termination date	
Reason for Un-termination	Participant has requested to participate in the open label extension (OLE). ☐ Other ☐
If Other marked, specify:	

Record the number of pills dispensed at the Enrollment visit:	
Cabotegravir (real or placebo)	
TDF/FTC (real or placebo)	

Did the participant bring in any pills at this visit? If yes, record the number of pills brought in at this visit.	Yes ☐ No ☐
Date of Pill Count	
Cabotegravir (real or placebo)	
TDF/FTC (real or placebo)	
Was the participant dispensed any additional pills at this visit? If yes, record the number of pills dispensed at this visit.	Yes ☐ No ☐
Cabotegravir (real or placebo)	
TDF/FTC (real or placebo)	

CD4

Was a CD4 done?	Yes ☐ No ☐
Date of collection:	_____
Absolute CD4+	Fixed Unit: cells/mm3 _____
Or	
Unable to analyze	☐

Viral Load

Was a viral load done?	Yes ☐ No ☐
Date of collection:	_____
HIV RNA PCR (plasma)	Fixed Unit: viral copies/mL _____
Or select if undetectable	☐
Or select if detected but less than lower limit of detection	☐
Lower limit of detection	20 ☐ 34 ☐ 40 ☐ Other ☐
RNA PCR kit code	Abbott m2000 Real-time ☐ Roche Cobas AmpliPrep/Cobas TaqMan Ver 1.0 ☐ Roche Cobas AmpliPrep/Cobas TaqMan Ver 2.0 ☐

Specimen Collection Date	_____
Mark if specimen drawn for confirmatory testing	☐
HIV Rapid 1	◯ Non-reactive/Negative ◯ Reactive/Positive
HIV Rapid 2	◯ Non-reactive/Negative ◯ Reactive/Positive ◯ Not Done
HIV 4th or 5th Gen Ag/Ab	◯ Non-reactive/Negative ◯ Reactive/Positive ◯ Indeterminate ◯ Not Done
HIV-1 RNA Qualitative	◯ Non-reactive/Negative ◯ Reactive/Positive ◯ Not Done
HIV RNA PCR	
HIV RNA PCR Not Done	☐
HIV RNA PCR (plasma)	Fixed Unit: viral copies/mL _____
Or select if undetectable	☐
Or select if detected but less than lower limit of detection	☐
Lower limit of detection	◯ 20 ◯ 34 ◯ 40 ◯ Other

If HIV testing is incomplete, mark “Additional blood specimen collection required” and save form. Add results from subsequent sample(s) on the new HIV Test Results form added in this visit's folder.

Final HIV Status from local testing:	◯ Negative ◯ Positive ◯ Indeterminate – DO NOT SELECT ◯ Redraw requested - DO NOT SELECT ◯ Additional HIV Test Results required
Additional blood specimen collection required	☐

Since the participant's last injection, did the participant perform any vigorous activities?	Yes ☐ No ☐
What type of activities?	
For how long? Record in total combined time, in hours and minutes.	
For how long? Record total combined time in hours.	Fixed Unit: hours

Was assessment done?	Yes ☐ No ☐
Any change from previous assessment of daily intake?	Yes ☐ No ☐
Record the total daily calcium intake	Fixed Unit: mg
Record the total daily Vitamin D intake	Fixed Unit: IU
Comments	

HPTN083_version 26.0_PROD_BK_09JUN2023: All
Form: Product Hold/Discontinuation
Generated On: 12 Jun 2023 18:42:31

Date of last oral study product use	
Date of last injection:	
Date when this study product hold or discontinuation was initiated:	
At what visit was this product hold/discontinuation initiated?	
Interim visit code	
Why is the study product being held or discontinued?	one or more reactive HIV test results or acute HIV infection suspected ☐ reported use of prohibited concomitant medication ☐ participant is currently using or planning to use PrEP or PEP ☐ Low oral adherence according to protocol ☐ Clinical AE (protocol mandated) ☐ Laboratory AE (protocol mandated) ☐ Injection site reaction ☐ CMC recommendation based on a clinical event ☐ CMC recommendation based on a laboratory value ☐ CMC recommendation based on a psychosocial concern ☐ Other clinical reason ☐ Participant request for injection intolerance (AE or ISR not protocol mandated) ☐ Participant request - participant is unwilling or unable to comply with required study procedures ☐ Other participant request ☐ DO NOT USE-study product related toxicity ☐ DO NOT USE-abnormal lab value ☐ DO NOT USE-clinical reasons determined by the investigator ☐ DO NOT USE-Hepatitis B infection ☐ DO NOT USE-QTc > 550 ms or change of > 60 ms from the baseline EKG ☐ DO NOT USE-request by participant to terminate study product ☐ DO NOT USE-Other ☐
If Other marked, specify:	
Mark if this hold is for Step 3 open-label product:	☐
If product hold was associated with an Adverse event, select the applicable AE(s): Adverse Event #1	
Adverse Event #2	

Adverse Event #3	
If product hold was associated with an Injection Site Reaction, select the applicable Injection Site Reaction:	
If product hold was associated with new or updated Concomitant Medications, select the applicable medication(s).	
Will the participant resume study product?	Yes ☐ no (permanently discontinued) ☐ no (hold continuing/ permanently discontinued for another reason) ☐
Date participant resumed study product:	

Is there a product hold or discontinuation to report?	Yes ☐ No ☐

HEPATITIS C	
Anti-Hepatitis C Antibody (anti-HCV):	Negative ☐ Positive ☐ Not Done ☐
HEPATITIS B	
Hepatitis B Surface Antibody (HBsAb):	Negative ☐ Positive ☐ Not Done ☐
Hepatitis B Core Antibody (HBCoreAb):	Negative ☐ Positive ☐ Not Done ☐

Syphilis screening test	
Was a sample collected for syphilis testing?	Yes ☐ No ☐
Date of collection:	_____
Mark algorithm used	Traditional ☐ Reverse ☐
Treponemal test	Non-reactive/Negative ☐ Reactive/Positive ☐
Non-Treponemal test	Non-reactive/Negative ☐ Reactive/Positive ☐
Titer if indicated	_____
Or	
N/A	☐
Second Treponemal test	Non-reactive/Negative ☐ Reactive/Positive ☐
Did the CMC designate an incident Syphilis infection at this visit?	Yes ☐ No ☐ IoR designated incident syphilis infection (OLE visits only) ☐
GC/CT NAAT	
Was a sample collected for NAAT for GC/CT?	Yes ☐ No ☐
Date of collection:	_____
N. gonorrhea – URINE	Negative ☐ Positive ☐
C. trachomatis – URINE	Negative ☐ Positive ☐
N. gonorrhea – RECTAL	Negative ☐ Positive ☐
C. trachomatis – RECTAL	Negative ☐ Positive ☐

HPTN083_version 26.0_PROD_BK_09JUN2023: All
Form: Log Revisions
Generated On: 12 Jun 2023 18:42:31

Form Name	
Event Name	
Log Line Number	
Event Term	
Onset Date	
The below fields should be updated for Adverse Event or Injection site reaction forms only Is the AE / reaction still ongoing?	Yes ☐ No ☐
Outcome Date	
Status/Outcome	recovered/resolved ☐ recovering/resolving ☐ resolved with sequelae ☐ not recovered/resolved ☐ fatal ☐
Action Taken with Study Product	dose not changed ☐ dose reduced ☐ dose increased ☐ drug withdrawn ☐ drug interrupted ☐ not applicable ☐
The below fields should be updated for Concomitant Medications or ART Medication forms only	
Date Stopped	
Or mark if continuing at end of study	☐
The below fields should be updated for Product Hold/Discontinuation form only	Yes ☐
	no (permanently discontinued) ☐
Will the participant resume study product?	no (hold continuing/ permanently discontinued for another reason) ☐
Date participant resumed study product:	

Lab Name: _____

RENAL FUNCTION TESTS

Was a sample collected for renal function testing? ☐ Yes ☐ No

Date of collection: _____

Creatinine _____

Creatinine Severity Grade ☐ Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable

Creatinine Adverse event _____

Calculated creatinine clearance _____

Calculated creatinine clearance Severity Grade ☐ Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable

Creatinine Clearance Adverse event _____

BUN _____

Urea _____

LIVER FUNCTION TESTS

Was a sample collected for Liver function testing? ☐ Yes ☐ No

Date of collection: _____

Alkaline phosphatase _____

Alkaline phosphatase Severity Grade ☐ Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable

Alkaline phosphatase Adverse event _____

AST (SGOT) _____

AST (SGOT) Severity Grade ☐ Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable

Lab Name: _____

AST (SGOT) Adverse event _____

ALT (SGPT) _____

ALT (SGPT) Severity Grade
- ☐ Grade 1 – Mild
- ☐ Grade 2 – Moderate
- ☐ Grade 3 – Severe
- ☐ Grade 4 – Potentially life-threatening
- ☐ Not gradable

ALT (SGPT) Adverse event _____

Total bilirubin _____

Total bilirubin Severity Grade
- ☐ Grade 1 – Mild
- ☐ Grade 2 – Moderate
- ☐ Grade 3 – Severe
- ☐ Grade 4 – Potentially life-threatening
- ☐ Not gradable

Total bilirubin Adverse event _____

OTHER CHEMISTRIES

Was a sample collected for other chemistry testing?
- ☐ Yes
- ☐ No

Date of collection: _____

CPK (CK) _____

CPK Severity Grade
- ☐ Grade 1 – Mild
- ☐ Grade 2 – Moderate
- ☐ Grade 3 – Severe
- ☐ Grade 4 – Potentially life-threatening
- ☐ Not gradable

CPK (CK) Adverse event _____

Glucose _____

Glucose Severity Grade
If participant is fasting at any visit, please mark 'yes' for "Did the participant fast for at least 8 hours prior to blood collection?" in Lipid Profile section.
- ☐ Grade 1 – Mild
- ☐ Grade 2 – Moderate
- ☐ Grade 3 – Severe
- ☐ Grade 4 – Potentially life-threatening
- ☐ Not gradable

Glucose Adverse event _____

Amylase _____

Amylase Severity Grade
- ☐ Grade 1 – Mild
- ☐ Grade 2 – Moderate
- ☐ Grade 3 – Severe

	Grade 4 – Potentially life-threatening ☐ Not gradable ☐
Amylase Adverse event	
Lipase	
Lipase Severity Grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable ☐
Lipase Adverse event	
Phosphorus (Phosphate)	
Phosphorus (Phosphate) Severity Grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable ☐
Phosphorus (Phosphate) Adverse event	
Calcium	
Calcium Severity Grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable ☐
Calcium Adverse event	
25-OH-vit D (Vitamin D)	
LIPID PROFILE	
Was a sample collected for the fasting lipid profile?	Yes ☐ No ☐
Date of collection:	
Did the participant fast for at least 8 hours prior to blood collection?	Yes ☐ No ☐
If participant did not fast do not record lipid results.	
Total cholesterol	
Total cholesterol Severity Grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐

	Not gradable ☐
Total cholesterol Adverse event	
Triglycerides	
Triglycerides Severity Grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable ☐
Triglycerides Adverse event	
LDL	
LDL Direct or Calculated?	Direct ☐ calculated ☐
LDL Severity Grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable ☐
LDL Adverse event	
HDL	
HDL Severity Grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable ☐
HDL Adverse event	
URINE TESTS	
Was a sample collected for urine tests?	Yes ☐ No ☐
Date of collection:	
Protein (Urine)	neg ☐ trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+ ☐
Protein (Urine) Severity Grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐

	Grade 3 – Severe ☐
	Grade 4 – Potentially life-threatening ☐
	Not gradable ☐
Protein (Urine) Adverse event	
Glucose (Urine)	neg ☐
	trace ☐
	1+ ☐
	2+ ☐
	3+ ☐
	4+ ☐
Glucose (Urine) Severity Grade	Grade 1 – Mild ☐
	Grade 2 – Moderate ☐
	Grade 3 – Severe ☐
	Grade 4 – Potentially life-threatening ☐
	Not gradable ☐
Glucose (Urine) Adverse event	

Did the participant change their long term consent since enrollment?	Yes ☐ No ☐
If Yes, indicate the current response for each of the below questions:	
Did the participant consent to having blood stored and used for future testing?	Yes ☐ No ☐
Date consent updated	_____
Did the participant consent to genetic testing?	Yes ☐ No ☐
Date consent updated	_____

Date of ECG	
QTC INTERVAL MEASUREMENT	
Not measurable	☐
Or	
QTc interval	Fixed Unit: ms
Severity Grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ Not gradable ☐
Adverse Event	
Reporting method used:	Bazett ☐ Fridericia ☐
OVERALL ECG FINDINGS	
Overall ECG findings	Normal ☐ Specific ECG Findings ☐
SPECIFIC ECG FINDINGS	
Rhythm	
Sinus arrhythmia	☐
Sinus bradycardia	☐
Sinus tachycardia	☐
Arrhythmia	
Premature atrial contractions	☐
Junctional premature contractions	☐
Premature ventricular contractions	☐
Ventricular couplets or multifocal PVC	☐
Atrial fibrillation alternating with NSR	☐
Atrial fibrillation	☐
Atrial flutter	☐
Atrial or supraventricular tachycardia	☐
Junctional rhythm	☐
Accelerated junctional rhythm	☐
Ventricular tachycardia	☐
Ventricular flutter/fibrillation	☐
Wide complex tachycardia	☐

Multifocal atrial tachycardia	☐
Wandering atrial pacemaker	☐
Ectopic atrial rhythm	☐
Torsades de Pointes	☐
Conduction Disturbance	
first degree AV block (PR > 200)	☐
Second degree AV block (Mobitz Type I)	☐
Second degree AV block (Mobitz Type II)	☐
Complete heart block	☐
Right bundle branch block	☐
Left bundle branch block complete	☐
Nonspecific IVCD	☐
Nonspecific incomplete IVCD (QRS Greater than 100 to less than 120)	☐
Left anterior hemiblock	☐
Left posterior hemiblock	☐
Wolff-Parkinson-White Syndrome	☐
Atrial-ventricular dissociation	☐
P-Wave Morphology	
Left atrial enlargement	☐
Right atrial enlargement	☐
Axis	
Left axis deviation	☐
Right axis deviation	☐
Indeterminate axis	☐
Myocardial Infarction	
Hyperacute ST changes	☐
Q-waves consistent with MI	☐
Q-waves and ST-T changes consistent with MI	☐
Ventricular Hypertrophy	
Right ventricular hypertrophy	☐
Voltage criteria for LVH	☐
LVH and ST-T segment	☐
QRS, ST-T	
Poor R wave progression	☐

Low voltage QRS	☐
Nonspecific QRS changes	☐
Nonspecific ST segment changES	☐
Nonspecific ST-T wave changes	☐
Nonspecific T-wave changes	☐
Peak T-wave	☐
Early repolarization changes	☐
U-wave and Abnormal QT findings	
U-wave abnormality	☐
QTc > 500 msec	☐
Change from baseline: QTc > 60 msec	☐
Drug Effect/Electrolyte Disturbance	
Marked QRS/ST-T abnormalities consistent with electrolyte disturbance or drug effect	☐
Other	
Other, specify:	_____

HPTN083_version 26.0_PROD_BK_09JUN2023: All
Form: Injection Administration
Generated On: 12 Jun 2023 18:42:31

Reminder: All HIV test results from previous visits and at least one HIV test result from the current visit must be confirmed negative/nonreactive prior to injection of study product.

Was an injection given at this visit?	Yes ☐ No ☐
If injection was given:	
Open label injection (active CAB LA)	☐
Injection Date	_____
Needle Size	21 G x 1 ½ in (0.8mm x 40mm) ☐ 21 G x 2 in (0.8mm x 50mm) ☐ 23 G x 1 ½ in (0.6mm x 40mm) ☐ 23 G x 2 in (0.6mm x 50mm) ☐ 25 G x 1 ½ in (0.5mm x 40mm) ☐ 25 G x 2 in (0.5mm x 50mm) ☐ Other size ☐
If other marked, record needle size	_____
Was complete dose given?	Yes ☐ No ☐
If no, what volume was given?	Fixed Unit: ml _____
Location of injection	Right buttock ☐ Left buttock ☐
Time of preparation for injection	_____
Time of injection	_____
If injection was not given:	
Indicate if injection was missed, refused, or permanently discontinued.	Injection missed ☐ Injection refused ☐ Injection schedule permanently discontinued ☐ Unblinded active Truvada participant (no longer receiving placebo injection) ☐

Thank you for participating in this study. This survey will ask you questions about your life, your beliefs, and your behavior.

Some of the questions ask about behavior that you may consider private or confidential. We are asking these questions because your answers could help us to design a new or better way to slow the spread of HIV in your community.

Some questions will ask you about your behavior during a specific time period (for example, “in the past month”). Please pay close attention to the time period and only tell us about your behavior during that time.

The information you provide is an important contribution to this study and will be kept confidential. You can skip any question that makes you feel uncomfortable or stop taking the survey at any time. We will start by asking some basic questions about you.

1. - What is your household monthly income? Please include money received for work, government grants, other income, and gifts.
- Baht ☐
- Dollar ☐
- Dong ☐
- Peso ☐
- Rand ☐
- Real ☐
- Sol ☐

1a. - Monthly income _____

2. - What is your current level of employment?
- Not employed ☐
- Full-time employed ☐
- Part-time employed ☐
- Other. ☐

3. - How much time do you typically spend traveling (one way) for a study visit? _____

3a. - How do you get to visits?
- Taxi ☐
- By foot ☐
- Public transport ☐
- Personal vehicle ☐
- Train ☐
- Other. ☐

4. - In the past year, how many times have you moved or changed where you live? _____

5. - In the next 12 months, how many times do you expect you will move or change where you live? _____

Now we’d like you to answer some questions about perceptions of people who are HIV positive. I will read each question and then read all of the response choices.

6. - Society looks down on people who have HIV.
- None of the time ☐
- A little of the time ☐
- Some of the time ☐
- Most of the time ☐
- All of the time ☐

7. - Medical providers assume people with HIV sleep around.	None of the time ☐ A little of the time ☐ Some of the time ☐ Most of the time ☐ All of the time ☐
8. - People think you can't be a good parent if you have HIV.	None of the time ☐ A little of the time ☐ Some of the time ☐ Most of the time ☐ All of the time ☐
9. - I am concerned that if I go to an AIDS organization someone I know might see me.	None of the time ☐ A little of the time ☐ Some of the time ☐ Most of the time ☐ All of the time ☐
10. - It is important for a person to keep HIV a secret from co-workers.	None of the time ☐ A little of the time ☐ Some of the time ☐ Most of the time ☐ All of the time ☐

Now, I will ask some questions about how you have been feeling in the last week. The following is a list of ways you might have felt or behaved. How often have you felt this way during the past week?

11. - During the past week, I was bothered by things that usually don't bother me.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
12. - During the past week, I had trouble keeping my mind on what I was doing.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
13. - During the past week, I felt depressed.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐

14. - During the past week, I felt that everything I did was an effort.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
15. - During the past week, I felt hopeful about the future.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
16. - During the past week, I felt fearful.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
17. - During the past week, my sleep was restless.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
18. - During the past week, I was happy.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
19. - During the past week, I felt lonely.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
20. - During the past week, I could not get going.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐

Now we are going to ask you some questions about any stressful or difficult times that you may have experienced in your lifetime. Remember, you may skip any questions that you do not wish to answer.

21. - Have you ever experienced or witnessed or had to deal with an extremely traumatic event that included actual or threatened death or serious injury to you or someone else? This includes serious accidents, sexual or physical assault, a terrorist attack, kidnapping, fire, war, or other natural disasters
- Yes.
- No.
- Prefer not to answer

Now we are going to ask you some questions about any stressful or difficult times that you may have experienced in the last 6 months. In the last 6 months, have you ever had any experience that was so frightening, horrible, or upsetting that you...

22. - ... have had nightmares about it or thought about it when you did not want to?
- Yes.
- No.
- Prefer not to answer

23. - …tried hard not to think about it or went out of your way to avoid situations that reminded you of it?
- Yes.
- No.
- Prefer not to answer

24. - …were constantly on guard, watchful, or easily startled?
- Yes.
- No.
- Prefer not to answer

25. - …felt numb or detached from others, activities, or your surroundings?
- Yes.
- No.
- Prefer not to answer

26. - How old were you when you had your first sexual experience? By sexual experience, we mean sexual touching or sexual intercourse (for example, oral, vaginal, or anal intercourse). _____

27. - Before the age of 18, did you ever have a sexual experience, including being felt up or fondled or having oral, vaginal, or anal sex, with someone who was at least 5 years older than you?
- Yes.
- No.
- Prefer not to answer

28. - Before the age of 18, did you ever have a sexual experience where you were pressured, forced, or intimidated into doing something sexually that made you feel uncomfortable or that you did not want to do (for example, masturbation, sexual touching, oral or anal sex, etc.)?
- Yes.
- No.
- Prefer not to answer

Now we are going to talk about your experience of physical and non-physical abuse by your intimate partners. By intimate partner I mean husband or boyfriend. This can be your current husband or boyfriend or an ex-husband or ex-boyfriend. In the past 6 months have any of your intimate partners:

29. - Belittled you (made fun of you)
- 1 - Never
- 2 - Rarely
- 3 - Sometimes
- 4 - Frequently
- 5 - Very Frequently
- Prefer not to answer

30. - Become very upset if dinner, housework, or laundry is not done when he thinks it should be
- 1 - Never
- 2 - Rarely
- 3 - Sometimes

	4 - Frequently ☐
	5 - Very Frequently ☐
	Prefer not to answer ☐
31. - Been suspicious and jealous of your friends	1 - Never ☐
	2 - Rarely ☐
	3 - Sometimes ☐
	4 - Frequently ☐
	5 - Very Frequently ☐
	Prefer not to answer ☐
32. - Treated you like you are stupid	1 - Never ☐
	2 - Rarely ☐
	3 - Sometimes ☐
	4 - Frequently ☐
	5 - Very Frequently ☐
	Prefer not to answer ☐
33. - Punched you with his fists	1 - Never ☐
	2 - Rarely ☐
	3 - Sometimes ☐
	4 - Frequently ☐
	5 - Very Frequently ☐
	Prefer not to answer ☐
34. - Made you perform sex acts that you do not enjoy or like	1 - Never ☐
	2 - Rarely ☐
	3 - Sometimes ☐
	4 - Frequently ☐
	5 - Very Frequently ☐
	Prefer not to answer ☐
35. - Become abusive when he drinks	1 - Never ☐
	2 - Rarely ☐
	3 - Sometimes ☐
	4 - Frequently ☐
	5 - Very Frequently ☐
	Prefer not to answer ☐
36. - Beat you so bad you have to see a doctor	1 - Never ☐
	2 - Rarely ☐
	3 - Sometimes ☐
	4 - Frequently ☐

5 - Very Frequently
Prefer not to answer

Now I will ask you some questions about concerns that you may or may not have about participation in the study.

37. - I worry that participating in the study and/or use of the study products is unsafe.

0 - Not at all
1
2
3
4
5
6 - A great deal

38. - I try to hide my participation in the study from others as I worry that others will judge me negatively as a result of my participation.

0 - Not at all
1
2
3
4
5
6 - A great deal

Next, I will ask you some questions about how you think about HIV. First I will read each question and then I will read all of the answer choices.

39. - I am worried about getting infected with HIV.

Strongly disagree
Disagree
Neither agree nor disagree
Agree
Strongly agree
Don't Know.
I prefer not to answer

40. - My sexual experiences put me at risk for HIV.

Strongly disagree
Disagree
Neither agree nor disagree
Agree
Strongly agree
Don't Know.
I prefer not to answer

41. - I think that I really could get HIV.

Strongly disagree
Disagree
Neither agree nor disagree
Agree

	Strongly agree ☐
	Don't Know. ☐
	I prefer not to answer ☐
42. - With the new medications currently available, no one has to die from HIV/AIDS.	Strongly disagree ☐
	Disagree ☐
	Neither agree nor disagree ☐
	Agree ☐
	Strongly agree ☐
	Don't Know. ☐
	I prefer not to answer ☐
43. - I am unlikely to get infected with HIV.	Strongly disagree ☐
	Disagree ☐
	Neither agree nor disagree ☐
	Agree ☐
	Strongly agree ☐
	Don't Know. ☐
	I prefer not to answer ☐
44. - It is likely that I will be infected with HIV within the next year.	Strongly disagree ☐
	Disagree ☐
	Neither agree nor disagree ☐
	Agree ☐
	Strongly agree ☐
	Don't Know. ☐
	I prefer not to answer ☐
45. - With the new medications currently available, it is possible to live a long and healthy life with HIV.	Strongly disagree ☐
	Disagree ☐
	Neither agree nor disagree ☐
	Agree ☐
	Strongly agree ☐
	Don't Know. ☐
	I prefer not to answer ☐
46. - It is important for me to remain HIV negative.	Strongly disagree ☐
	Disagree ☐
	Neither agree nor disagree ☐
	Agree ☐
	Strongly agree ☐
	Don't Know. ☐

I prefer not to answer ☐

The following questions will ask you about what kind of support from others is available to you as it relates to your health and participation in this study.

47. - How often is there someone available to help you remember to take your medications for this study?

- None of the time ☐
- A little of the time ☐
- Some of the time ☐
- Most of the time ☐
- All of the time ☐

48. - How often is there someone available to help you attend visits for this study?

- None of the time ☐
- A little of the time ☐
- Some of the time ☐
- Most of the time ☐
- All of the time ☐

49. - How often is there someone available to help you keep up with other study requirements?

- None of the time ☐
- A little of the time ☐
- Some of the time ☐
- Most of the time ☐
- All of the time ☐

50. - How often is there someone available to help you take care of your health?

- None of the time ☐
- A little of the time ☐
- Some of the time ☐
- Most of the time ☐
- All of the time ☐

Next we will talk about your feelings about using PrEP. Please respond to each of the following items in terms of how true it is for you with respect to using oral PrEP daily between now and your next visit. Please answer the questions based on how you feel at this moment. We understand that your feelings about this may be different from what it was last month and what it might be this month. Please focus on how you feel today.

51. - I feel confident in my ability to use oral PrEP daily, as recommended.

- 1 – Not at all true ☐
- 2 ☐
- 3 – Somewhat true ☐
- 4 ☐
- 5 – Very true ☐

52. - I am capable now of handling using oral PrEP daily.

- 1 – Not at all true ☐
- 2 ☐
- 3 – Somewhat true ☐
- 4 ☐
- 5 – Very true ☐

53. - I am able to do what it takes to ensure that I use oral PrEP every day.	1 – Not at all true 2 3 – Somewhat true 4 5 – Very true
54. - I feel able to meet the challenge of using oral PrEP every day.	1 – Not at all true 2 3 – Somewhat true 4 5 – Very true
55. - I feel confident in my ability to attend my injection visits as recommended.	1 – Not at all true 2 3 – Somewhat true 4 5 – Very true
56. - I am capable now of handling my injection visits as recommended.	1 – Not at all true 2 3 – Somewhat true 4 5 – Very true
57. - I am able to do what it takes to ensure that I get my injection as recommended.	1 – Not at all true 2 3 – Somewhat true 4 5 – Very true

Thank you for participating in this study. This survey will ask you questions about your life, your beliefs, and your behavior.

Some of the questions ask about behavior that you may consider private or confidential. We are asking these questions because your answers could help us to design a new or better way to slow the spread of HIV in your community.

Some questions will ask you about your behavior during a specific time period (for example, “in the past month”). Please pay close attention to the time period and only tell us about your behavior during that time.

The information you provide is an important contribution to this study and will be kept confidential. You can skip any question that makes you feel uncomfortable or stop taking the survey at any time.

Now we’d like you to answer some questions about perceptions of people who are HIV positive. First I will read a question and then I will read all of the answer choices.

1. - Society looks down on people who have HIV.
- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time

2. - Medical providers assume people with HIV sleep around.
- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time

3. - People think you can’t be a good parent if you have HIV.
- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time

4. - I am concerned that if I go to an AIDS organization someone I know might see me.
- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time

5. - It is important for a person to keep HIV a secret from co-workers.
- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time

Now, I will ask some questions about how you have been feeling in the last week. The following is a list of ways you might have felt or behaved. How often have you felt this way during the past week? First I will read a question and then I will read all of the answer choices.

6. - During the past week, I was bothered by things that usually don't bother me.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
7. - During the past week, I had trouble keeping my mind on what I was doing.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
8. - During the past week, I felt depressed.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
9. - During the past week, I felt that everything I did was an effort.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
10. - During the past week, I felt hopeful about the future.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
11. - During the past week, I felt fearful.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
12. - During the past week, my sleep was restless.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
13. - During the past week, I was happy.	Rarely or none of the time (Less than 1 day) ☐

	Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
14. - During the past week, I felt lonely.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
15. - During the past week, I could not get going.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐

Interviewer: Ask the following four items only at Week 33, Week 49, Week 105, Week 153, and Week 185; otherwise leave blank. Now we are going to ask you some questions about any stressful or difficult times that you may have experienced in the last 4 months. Remember, you may skip any questions that you do not wish to answer. In the last 4 months, have you had an experience that was so frightening, horrible, or upsetting that you...

16. - …have had nightmares about it or thought about it when you did not want to?	Yes. ☐ No. ☐ Prefer not to answer ☐
17. - …tried hard not to think about it or went out of your way to avoid situations that reminded you of it?	Yes. ☐ No. ☐ Prefer not to answer ☐
18. - …were constantly on guard, watchful, or easily startled?	Yes. ☐ No. ☐ Prefer not to answer ☐
19. - …felt numb or detached from others, activities, or your surroundings?	Yes. ☐ No. ☐ Prefer not to answer ☐

Interviewer: Ask the following eight items only at Week 33, Week 49, Week 105, Week 153, and Week 185; otherwise leave blank. Now we are going to talk about your experience of physical and non-physical abuse by your intimate partners. By intimate partner I mean husband or boyfriend. This can be your current husband or boyfriend or an ex-husband or ex-husband. First I will read a question and then I will read all of the answer choices. In the past 4 months have any of your intimate partners...

20. - Belittled you (made fun of you)	1 - Never ☐ 2 - Rarely ☐ 3 - Sometimes ☐ 4 - Frequently ☐

	5 - Very Frequently ☐
	Prefer not to answer ☐
21. - Become very upset if dinner, housework, or laundry is not done when he thinks it should be	1 - Never ☐
	2 - Rarely ☐
	3 - Sometimes ☐
	4 - Frequently ☐
	5 - Very Frequently ☐
	Prefer not to answer ☐
22. - Been suspicious and jealous of your friends	1 - Never ☐
	2 - Rarely ☐
	3 - Sometimes ☐
	4 - Frequently ☐
	5 - Very Frequently ☐
	Prefer not to answer ☐
23. - Treated you like you are stupid	1 - Never ☐
	2 - Rarely ☐
	3 - Sometimes ☐
	4 - Frequently ☐
	5 - Very Frequently ☐
	Prefer not to answer ☐
24. - Punched you with his fists	1 - Never ☐
	2 - Rarely ☐
	3 - Sometimes ☐
	4 - Frequently ☐
	5 - Very Frequently ☐
	Prefer not to answer ☐
25. - Made you perform sex acts that you do not enjoy or like	1 - Never ☐
	2 - Rarely ☐
	3 - Sometimes ☐
	4 - Frequently ☐
	5 - Very Frequently ☐
	Prefer not to answer ☐
26. - Become abusive when he drinks	1 - Never ☐
	2 - Rarely ☐
	3 - Sometimes ☐
	4 - Frequently ☐
	5 - Very Frequently ☐

	Prefer not to answer ☐
27. - Beat you so bad you have to see a doctor	1 - Never ☐ 2 - Rarely ☐ 3 - Sometimes ☐ 4 - Frequently ☐ 5 - Very Frequently ☐

Now I will ask you some questions about concerns that you may or may not have about participation in the study.

28. - I worry that participating in the study and/or use of the study products is unsafe.	0 - Not at all ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 - A great deal ☐
29. - I try to hide my participation in the study from others as I worry that others will judge me negatively as a result of my participation.	0 - Not at all ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 - A great deal ☐

Next, I will ask you some questions about how you think about HIV. First I will read a question and then I will read all of the answer choices.

30. - I am worried about getting infected with HIV.	Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree ☐ Don't Know. ☐ I prefer not to answer ☐
31. - My sexual experiences put me at risk for HIV.	Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree ☐ Don't Know. ☐ I prefer not to answer ☐

32. - I think that I really could get HIV.	Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree ☐ Don't Know. ☐ I prefer not to answer ☐
33. - With the new medications currently available, no one has to die from HIV/AIDS.	Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree ☐ Don't Know. ☐ I prefer not to answer ☐
34. - I am unlikely to get infected with HIV.	Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree ☐ Don't Know. ☐ I prefer not to answer ☐
35. - It is likely that I will be infected with HIV within the next year.	Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree ☐ Don't Know. ☐ I prefer not to answer ☐
36. - With the new medications currently available, it is possible to live a long and healthy life with HIV.	Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐ Agree ☐ Strongly agree ☐ Don't Know. ☐ I prefer not to answer ☐
37. - It is important for me to remain HIV negative.	Strongly disagree ☐ Disagree ☐

	Neither agree nor disagree ☐
	Agree ☐
	Strongly agree ☐
	Don't Know. ☐
	I prefer not to answer ☐

The following questions will ask you about what kind of support from others is available to you as it relates to your health and participation in this study.

38. - How often is there someone available to help you remember to take your medications for this study?	None of the time ☐
	A little of the time ☐
	Some of the time ☐
	Most of the time ☐
	All of the time ☐
39. - How often is there someone available to help you attend visits for this study?	None of the time ☐
	A little of the time ☐
	Some of the time ☐
	Most of the time ☐
	All of the time ☐
40. - How often is there someone available to help you keep up with other study requirements?	None of the time ☐
	A little of the time ☐
	Some of the time ☐
	Most of the time ☐
	All of the time ☐
41. - How often is there someone available to help you take care of your health?	None of the time ☐
	A little of the time ☐
	Some of the time ☐
	Most of the time ☐
	All of the time ☐

Next we will talk about your feelings about using PrEP. Please respond to each of the following items in terms of how true it is for you with respect to using oral PrEP daily between now and your next visit. Please answer the questions based on how you feel at this moment. We understand that your feelings about this may be different from what it was last month and what it might be this month. Please focus on how you feel today.

42. - I feel confident in my ability to use oral PrEP daily, as recommended.	1 – Not at all true ☐
	2 ☐
	3 – Somewhat true ☐
	4 ☐
	5 – Very true ☐
43. - I am capable now of handling using oral PrEP daily.	1 – Not at all true ☐
	2 ☐

	3 – Somewhat true ☐ 4 ☐ 5 – Very true ☐
44. - I am able to do what it takes to ensure that I use oral PrEP every day.	1 – Not at all true ☐ 2 ☐ 3 – Somewhat true ☐ 4 ☐ 5 – Very true ☐
45. - I feel able to meet the challenge of using oral PrEP every day.	1 – Not at all true ☐ 2 ☐ 3 – Somewhat true ☐ 4 ☐ 5 – Very true ☐
46. - I feel confident in my ability to attend my injection visits as recommended.	1 – Not at all true ☐ 2 ☐ 3 – Somewhat true ☐ 4 ☐ 5 – Very true ☐
47. - I am capable now of handling my injection visits as recommended.	1 – Not at all true ☐ 2 ☐ 3 – Somewhat true ☐ 4 ☐ 5 – Very true ☐
48. - I am able to do what it takes to ensure that I get my injection as recommended.	1 – Not at all true ☐ 2 ☐ 3 – Somewhat true ☐ 4 ☐ 5 – Very true ☐
I feel confident in my ability to attend my injection visits as recommended.	1 – Not at all true ☐ 2 ☐ 3 – Somewhat true ☐ 4 ☐ 5 – Very true ☐
I am able to do what it takes to ensure that I get my injection as recommended.	1 – Not at all true ☐ 2 ☐ 3 – Somewhat true ☐

	4 ☐
	5 – Very true ☐

COMPLETE THE REMAINING ITEMS ONLY AT STEP 3, DAY 0; OTHERWISE, END OF FORM.

I would like to ask you about your preferences for using an HIV prevention medication.

49. - Assuming injectable PrEP and oral PrEP are equally effective, which product would you prefer to use?	Injectable ☐
	Oral ☐

50. - Why? _____

Thinking about your choice to use either oral PrEP or injectable PrEP, how much do you agree with the following statements?

51. - My medication has more advantages than disadvantages?	Strongly Disagree ☐
	Disagree ☐
	Neither Agree Nor Disagree ☐
	Agree ☐
	Strongly Agree ☐
52. - Given the advantages and disadvantages of your medication, how much do you agree this is an acceptable solution?	Strongly Disagree ☐
	Disagree ☐
	Neither Agree Nor Disagree ☐
	Agree ☐
	Strongly Agree ☐
53. - To what degree do you feel these medications will be useful in the long term?	Strongly Disagree ☐
	Disagree ☐
	Neither Agree Nor Disagree ☐
	Agree ☐
	Strongly Agree ☐
54. - Ideally, who would give your injection?	Partner ☐
	Family member or friend ☐
	Health care provider ☐
	Self ☐
	Other. ☐

54a. - If Other, specify _____

Thank you for participating in this study. This survey will ask you questions about your life, your beliefs, and your behavior.

Some of the questions ask about behavior that you may consider private or confidential. We are asking these questions because your answers could help us to design a new or better way to slow the spread of HIV in your community.

Some questions will ask you about your behavior during a specific time period (for example, “in the past month”). Please pay close attention to the time period and only tell us about your behavior during that time.

The information you provide is an important contribution to this study and will be kept confidential. You can skip any question that makes you feel uncomfortable or stop taking the survey at any time.

Now, I will ask some questions about how you have been feeling in the last week. The following is a list of ways you might have felt or behaved. How often have you felt this way during the past week? First I will read a question and then I will read all of the answer choices.

1. - During the past week, I was bothered by things that usually don't bother me.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
2. - During the past week, I had trouble keeping my mind on what I was doing.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
3. - During the past week, I felt depressed.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
4. - During the past week, I felt that everything I did was an effort.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
5. - During the past week, I felt hopeful about the future.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
6. - During the past week, I felt fearful.	Rarely or none of the time (Less than 1 day) ☐

	Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
7. - During the past week, my sleep was restless.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
8. - During the past week, I was happy.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
9. - During the past week, I felt lonely.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐
10. - During the past week, I could not get going.	Rarely or none of the time (Less than 1 day) ☐ Some or a little of the time (1-2 days) ☐ Occasionally or a moderate amount of time (3-4 days) ☐ Most or all of the time (5-7 days) ☐

The following questions will ask you about what kind of support from others is available to you as it relates to your health and participation in this study.

11. - How often is there someone available to help you remember to take your medications for this study?	None of the time ☐ A little of the time ☐ Some of the time ☐ Most of the time ☐ All of the time ☐
12. - How often is there someone available to help you attend visits for this study?	None of the time ☐ A little of the time ☐ Some of the time ☐ Most of the time ☐ All of the time ☐
13. - How often is there someone available to help you keep up with other study requirements?	None of the time ☐

	A little of the time ☐
	Some of the time ☐
	Most of the time ☐
	All of the time ☐
14. - How often is there someone available to help you take care of your health?	None of the time ☐
	A little of the time ☐
	Some of the time ☐
	Most of the time ☐
	All of the time ☐

Next we will talk about your feelings about using PrEP. Please respond to each of the following items in terms of how true it is for you with respect to using oral PrEP daily between now and your next visit. Please answer the questions based on how you feel at this moment. We understand that your feelings about this may be different from what it was last month and what it might be this month. Please focus on how you feel today.

15. - I feel confident in my ability to use oral PrEP daily, as recommended.	1 – Not at all true ☐
	2 ☐
	3 – Somewhat true ☐
	4 ☐
	5 – Very true ☐
16. - I am capable now of handling using oral PrEP daily.	1 – Not at all true ☐
	2 ☐
	3 – Somewhat true ☐
	4 ☐
	5 – Very true ☐
17. - I am able to do what it takes to ensure that I use oral PrEP every day.	1 – Not at all true ☐
	2 ☐
	3 – Somewhat true ☐
	4 ☐
	5 – Very true ☐
18. - I feel able to meet the challenge of using oral PrEP every day.	1 – Not at all true ☐
	2 ☐
	3 – Somewhat true ☐
	4 ☐
	5 – Very true ☐
19. - I feel confident in my ability to attend my injection visits as recommended.	1 – Not at all true ☐
	2 ☐
	3 – Somewhat true ☐
	4 ☐

	5 – Very true ☐
20. - I am capable now of handling my injection visits as recommended.	1 – Not at all true ☐ 2 ☐ 3 – Somewhat true ☐ 4 ☐ 5 – Very true ☐
21. - I am able to do what it takes to ensure that I get my injection as recommended.	1 – Not at all true ☐ 2 ☐ 3 – Somewhat true ☐ 4 ☐ 5 – Very true ☐
I feel confident in my ability to attend my injection visits as recommended.	1 – Not at all true ☐ 2 ☐ 3 – Somewhat true ☐ 4 ☐ 5 – Very true ☐
I am able to do what it takes to ensure that I get my injection as recommended.	1 – Not at all true ☐ 2 ☐ 3 – Somewhat true ☐ 4 ☐ 5 – Very true ☐

HPTN083_version 26.0_PROD_BK_09JUN2023: All
Form: Study Medication Satisfaction Questionnaire (SMSQs)
Generated On: 12 Jun 2023 18:42:31

This questionnaire is about your satisfaction with the study medication and particularly your experience over the past few weeks. I will read all the instructions and the questions out to you. If you do not understand the instructions, please ask me to explain. For the answers, what we want is your opinion. Is that ok? Are you ready to begin? When answering these items please consider or think about only the oral study medications you have been taking.

Interviewer instructions: The entire question and all the response options should be read out as follows:

Please say one number. You can choose 6 (very satisfied), 5, 4, 3 (the midpoint, indicating that you are neither satisfied not dissatisfied), 2, 1 or 0 (very dissatisfied). (Modify words according to the response options provided for that question).

Survey not done ☐

1. - How satisfied are you with your current study medication?	6- Very satisfied ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0- Very dissatisfied ☐
2. - How satisfied are you with any side effects of your present study medication?	6- Very satisfied ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0- Very dissatisfied ☐
3. - How satisfied are you with the demands made by your current study medication?	6- Very satisfied ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0- Very dissatisfied ☐
4. - How convenient have you been finding your study medication to be recently?	6- Very convenient ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0- Very inconvenient ☐
5. - How flexible have you been finding your study medication to be recently?	6- Very flexible ☐

	5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0- Very inflexible ☐
6. - How satisfied are you with your understanding of your current study medication?	6- Very satisfied ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0- Very dissatisfied ☐
7. - How satisfied are you with the extent to which the study medication fits in with your lifestyle?	6- Very satisfied ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0- Very dissatisfied ☐
8a. - Would you recommend your present study medication to someone who is being offered this medication?	6- Yes, I would definitely recommend the medication ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0- No, I would definitely not recommend the medication ☐
8b. - Would you speak well of your present study medication to someone who is being offered this medication?	6- Yes, I would definitely speak well of the medication ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0- No, I would definitely not speak well of the medication ☐
9. - How satisfied would you be to continue with your present form of study medication?	6- Very satisfied ☐ 5 ☐

	4 ☐
	3 ☐
	2 ☐
	1 ☐
	0- Very dissatisfied ☐
10. - How easy or difficult have you been finding your medication to be recently?	6- Very easy ☐
	5 ☐
	4 ☐
	3 ☐
	2 ☐
	1 ☐
	0- Very difficult ☐
11. - How satisfied are you with the amount of discomfort or pain involved with your present form of study medication?	6- Very satisfied ☐
	5 ☐
	4 ☐
	3 ☐
	2 ☐
	1 ☐
	0- Very dissatisfied ☐
12. - Are there any other aspects of the study medication, causing either satisfaction or dissatisfaction that have not been covered by the questionnaire?	Yes. ☐
	No. ☐
If yes, please describe	_____

When answering these items please consider or think about only the injections you have been receiving.

1. - How satisfied are you with your current study medication?	6- Very satisfied ☐
	5 ☐
	4 ☐
	3 ☐
	2 ☐
	1 ☐
	0- Very dissatisfied ☐
2. - How satisfied are you with any side effects of your present study medication?	6- Very satisfied ☐
	5 ☐
	4 ☐
	3 ☐
	2 ☐
	1 ☐
	0- Very dissatisfied ☐

3. - How satisfied are you with the demands made by your current study medication?	6- Very satisfied 5 4 3 2 1 0- Very dissatisfied
4. - How convenient have you been finding your study medication to be recently?	6- Very convenient 5 4 3 2 1 0- Very inconvenient
5. - How flexible have you been finding your study medication to be recently?	6- Very flexible 5 4 3 2 1 0- Very inflexible
6. - How satisfied are you with your understanding of your current study medication?	6- Very satisfied 5 4 3 2 1 0- Very dissatisfied
7. - . How satisfied are you with the extent to which the study medication fits in with your lifestyle?	6- Very satisfied 5 4 3 2 1 0- Very dissatisfied
8a. - Would you recommend your present study medication to someone who is being offered this medication?	6- Yes, I would definitely recommend the medication 5

	4 ☐ 3 ☐ 2 ☐ 1 ☐ 0- No, I would definitely not recommend the medication ☐
8b. - Would you speak well of your present study medication to someone who is being offered this medication?	6- Yes, I would definitely speak well of the medication ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0- No, I would definitely not speak well of the medication ☐
9. - How satisfied would you be to continue with your present form of study medication?	6- Very satisfied ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0- Very dissatisfied ☐
10. - How easy or difficult have you been finding your medication to be recently?	6- Very easy ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0- Very difficult ☐
11. - How satisfied are you with the amount of discomfort or pain involved with your present form of study medication?	6- Very satisfied ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0- Very dissatisfied ☐
12. - Are there any other aspects of the study medication, causing either satisfaction or dissatisfaction that have not been covered by the questionnaire?	Yes. ☐ No. ☐
If yes, please describe	_____

HPTN083_version 26.0_PROD_BK_09JUN2023: All
Form: Study Medication Satisfaction Questionnaire Change (SMSQc)
Generated On: 12 Jun 2023 18:42:31

Instructions: This questionnaire is about your satisfaction with the study medication and particularly your experience over the past few months. I will read all the instructions and the questions out to you. If you do not understand the instructions, please ask me to explain. For the answers, what we want is your opinion. Is that OK? Are you ready to begin? When answering these items please consider or think about only the oral study medications you have been taking.

Interviewer instructions: The entire question and all the response options should be read out as follows:

Please say one number. You can choose 6 (very satisfied), 5, 4, 3 (the midpoint, indicating that you are neither satisfied not dissatisfied), 2, 1 or 0 (very dissatisfied). (Modify words according to the response options provided for that question).

Survey not done ☐

1. - How satisfied are you with your current study medication?	3- Much more satisfied now ☐ 2 ☐ 1 ☐ 0 ☐ -1 ☐ -2 ☐ -3- Much less satisfied now ☐
2. - How satisfied are you with any side effects of your present study medication?	3- Much more satisfied now ☐ 2 ☐ 1 ☐ 0 ☐ -1 ☐ -2 ☐ -3- Much less satisfied now ☐
3. - How satisfied are you with the demands made by your current study medication?	3- Much more satisfied now ☐ 2 ☐ 1 ☐ 0 ☐ -1 ☐ -2 ☐ -3- Much less satisfied now ☐
4. - How convenient have you been finding your study medication to be recently?	3- Much moreconvenient now ☐ 2 ☐ 1 ☐ 0 ☐ -1 ☐ -2 ☐ -3- Much less convenient now ☐
5. - How flexible have you been finding your study medication to be recently?	3- Much more flexible now ☐

	2 ☐ 1 ☐ 0 ☐ -1 ☐ -2 ☐ -3- Much less flexible now ☐
6. - How satisfied are you with your understanding of your current study medication?	3- Much more satisfied now ☐ 2 ☐ 1 ☐ 0 ☐ -1 ☐ -2 ☐ -3- Much less satisfied now ☐
7. - How satisfied are you with the extent to which the study medication fits in with your lifestyle?	3- Much more satisfied now ☐ 2 ☐ 1 ☐ 0 ☐ -1 ☐ -2 ☐ -3- Much less satisfied now ☐
8a. - How likely would you recommend your present study medication to someone who is being offered this medication?	3- Much more likely to recommend the medication now ☐ 2 ☐ 1 ☐ 0 ☐ -1 ☐ -2 ☐ -3- Much less likely to recommend the medication now ☐
8b. - How likely would you be to speak well of your present study medication to someone who is being offered this medication?	3- Much more likely to speak well of the medication now ☐ 2 ☐ 1 ☐ 0 ☐ -1 ☐ -2 ☐ -3- Much less likely to speak well of the medication now ☐
9. - How satisfied would you be to continue with your present form of study medication?	3- Much more satisfied now ☐ 2 ☐

	1 ☐
	0 ☐
	-1 ☐
	-2 ☐
	-3- Much less satisfied now ☐
10. - How easy or difficult have you been finding your medication to be recently?	3- Much easier now ☐
	2 ☐
	1 ☐
	0 ☐
	-1 ☐
	-2 ☐
	-3- Much less easy now ☐
11. - How satisfied are you with the amount of discomfort or pain involved with your present form of study medication?	3- Much more satisfied now ☐
	2 ☐
	1 ☐
	0 ☐
	-1 ☐
	-2 ☐
	-3- Much less satisfied now ☐

Instructions: When answering these items please consider or think about only the injections you have been receiving

1. - How satisfied are you with your current study medication?	3- Much more satisfied now ☐
	2 ☐
	1 ☐
	0 ☐
	-1 ☐
	-2 ☐
	-3- Much less satisfied now ☐
2. - How satisfied are you with any side effects of your present study medication?	3- Much more satisfied now ☐
	2 ☐
	1 ☐
	0 ☐
	-1 ☐
	-2 ☐
	-3- Much less satisfied now ☐
3. - How satisfied are you with the demands made by your current study medication?	3- Much more satisfied now ☐
	2 ☐

	1 ☐
	0 ☐
	-1 ☐
	-2 ☐
	-3- Much less satisfied now ☐
4. - How convenient have you been finding your study medication to be recently?	3- Much moreconvenient now ☐
	2 ☐
	1 ☐
	0 ☐
	-1 ☐
	-2 ☐
	-3- Much less convenient now ☐
5. - How flexible have you been finding your study medication to be recently?	3- Much more flexible now ☐
	2 ☐
	1 ☐
	0 ☐
	-1 ☐
	-2 ☐
	-3- Much less flexible now ☐
6. - How satisfied are you with your understanding of your current study medication?	3- Much more satisfied now ☐
	2 ☐
	1 ☐
	0 ☐
	-1 ☐
	-2 ☐
	-3- Much less satisfied now ☐
7. - How satisfied are you with the extent to which the study medication fits in with your lifestyle?	3- Much more satisfied now ☐
	2 ☐
	1 ☐
	0 ☐
	-1 ☐
	-2 ☐
	-3- Much less satisfied now ☐
8a. - How likely would you recommend your present study medication to someone who is being offered this medication?	3- Much more likely to recommend the medication now ☐
	2 ☐
	1 ☐
	0 ☐

	-1 ☐
	-2 ☐
	-3- Much less likely to recommend the medication now ☐
8b. - How likely would you speak well of your present study medication to someone who is being offered this medication?	3- Much more likely to speak well of the medication now ☐
	2 ☐
	1 ☐
	0 ☐
	-1 ☐
	-2 ☐
	-3- Much less likely to speak well of the medication now ☐
9. - How satisfied would you be continue with your present form of study medication?	3- Much more satisfied now ☐
	2 ☐
	1 ☐
	0 ☐
	-1 ☐
	-2 ☐
	-3- Much less satisfied now ☐
10. - How easy or difficult have you been finding your medication to be recently?	3- Much easier now ☐
	2 ☐
	1 ☐
	0 ☐
	-1 ☐
	-2 ☐
	-3- Much less easy now ☐
11. - How satisfied are you with the amount of discomfort or pain involved with your present form of study medication?	3- Much more satisfied now ☐
	2 ☐
	1 ☐
	0 ☐
	-1 ☐
	-2 ☐
	-3- Much less satisfied now ☐

Name of transferring study site:

- ☐ AYAR at CORE - Chicago
- ☐ Alabama - Birmingham
- ☐ ACSA - Iquitos
- ☐ Barranco - Lima
- ☐ Bridge HIV - San Francisco
- ☐ Bronx Prevention - New York
- ☐ CITBM - Lima
- ☐ Centro Referencia - Sao Paulo
- ☐ Chapel Hill
- ☐ Chennai
- ☐ Chidren's Hospital Colorado
- ☐ Cincinnati
- ☐ CMU HIV Prevention - Chiang Mai
- ☐ East Bay AIDS Center - Oakland
- ☐ Fenway Health
- ☐ Fundación Huésped - Buenos Aires
- ☐ GW University - Washington, DC
- ☐ Greensboro - North Carolina
- ☐ Groote Schuur - Cape Town
- ☐ Harlem Prevention Center
- ☐ Hope Clinic of Emory - Georgia
- ☐ Hospital JM Ramos Mejia - Buenos Aires
- ☐ HNSC - Porto Alegre
- ☐ Houston AIDS Research
- ☐ IPEC - Rio de Janeiro
- ☐ Johns Hopkins University
- ☐ New Jersey Medical School
- ☐ New Orleans Adolescent Trials
- ☐ New York Blood Center
- ☐ Ohio State University
- ☐ Penn Prevention - Philadelphia
- ☐ Ponce de Leon Center - Atlanta
- ☐ San Miguel - Lima
- ☐ Silom Community Clinic - Bangkok
- ☐ St. Jude Children's - Memphis
- ☐ Thai Red Cross - Bangkok
- ☐ UCLA Care - L.A.

UCLA Vine Street - L.A.
UIC Project WISH - Chicago
University of Miami AIDS
University of Sao Paulo
Via Libre - Lima
Washington University Therapeutics
Weill Cornell Chelsea - New York
Yen Hoa Health Clinic

Name of receiving study site:

AYAR at CORE - Chicago
Alabama - Birmingham
ACSA - Iquitos
Barranco - Lima
Bridge HIV - San Francisco
Bronx Prevention - New York
CITBM - Lima
Centro Referencia - Sao Paulo
Chapel Hill
Chennai
Chidren's Hospital Colorado
Cincinnati
CMU HIV Prevention - Chiang Mai
East Bay AIDS Center - Oakland
Fenway Health
Fundación Huésped - Buenos Aires
GW University - Washington, DC
Greensboro - North Carolina
Groote Schuur - Cape Town
Harlem Prevention Center
Hope Clinic of Emory - Georgia
Hospital JM Ramos Mejia - Buenos Aires
HNSC - Porto Alegre
Houston AIDS Research
IPEC - Rio de Janeiro
Johns Hopkins University
New Jersey Medical School
New Orleans Adolescent Trials
New York Blood Center

	Ohio State University ☐
	Penn Prevention - Philadelphia ☐
	Ponce de Leon Center - Atlanta ☐
	San Miguel - Lima ☐
	Silom Community Clinic - Bangkok ☐
	St. Jude Children's - Memphis ☐
	Thai Red Cross - Bangkok ☐
	UCLA Care - L.A. ☐
	UCLA Vine Street - L.A. ☐
	UIC Project WISH - Chicago ☐
	University of Miami AIDS ☐
	University of Sao Paulo ☐
	Via Libre - Lima ☐
	Washington University Therapeutics ☐
	Weill Cornell Chelsea - New York ☐
	Yen Hoa Health Clinic ☐
Visit Code of last completed contact with participant	_____
Interim Visit Code	_____
Date participant records were sent to receiving study site	_____

Name of receiving study site

- ☐ AYAR at CORE - Chicago
- ☐ Alabama - Birmingham
- ☐ ACSA - Iquitos
- ☐ Barranco - Lima
- ☐ Bridge HIV - San Francisco
- ☐ Bronx Prevention - New York
- ☐ CITBM - Lima
- ☐ Centro Referencia - Sao Paulo
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UCLA Vine Street - L.A.
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Washington University Therapeutics
Weill Cornell Chelsea - New York
Yen Hoa Health Clinic

Name of transferring study site

AYAR at CORE - Chicago
Alabama - Birmingham
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Johns Hopkins University
New Jersey Medical School
New Orleans Adolescent Trials
New York Blood Center

Ohio State University ☐
Penn Prevention - Philadelphia ☐
Ponce de Leon Center - Atlanta ☐
San Miguel - Lima ☐
Silom Community Clinic - Bangkok ☐
St. Jude Children's - Memphis ☐
Thai Red Cross - Bangkok ☐
UCLA Care - L.A. ☐
UCLA Vine Street - L.A. ☐
UIC Project WISH - Chicago ☐
University of Miami AIDS ☐
University of Sao Paulo ☐
Via Libre - Lima ☐
Washington University Therapeutics ☐
Weill Cornell Chelsea - New York ☐
Yen Hoa Health Clinic ☐

Date informed consent signed at receiving site _____

Has the participant experienced any injection site reactions?	Yes ☐ No ☐

Date reported to site _____

Event diagnosis
- ☐ Injection site abscess
- ☐ Injection site anesthesia
- ☐ Injection site bruising
- ☐ Injection site discoloration
- ☐ Injection site erosion
- ☐ Injection site hemorrhage
- ☐ Injection site itching
- ☐ Injection site induration
- ☐ Injection site swelling
- ☐ Injection site nodule
- ☐ Injection site pain
- ☐ Injection site tenderness
- ☐ Injection site erythema
- ☐ Injection site warmth
- ☐ Injection site hematoma

Injection site side
- ☐ Left
- ☐ Right

Onset Date _____

At which visit was this reaction first reported? _____

Interim visit code, if applicable: _____

Is the reaction still ongoing?
- ☐ Yes
- ☐ No

Outcome Date _____

Severity Grade
- ☐ Grade 1 (Mild)
- ☐ Grade 2 (Moderate)
- ☐ Grade 3 (Severe)
- ☐ Grade 4 (Potentially life-threatening)
- ☐ Grade 5 (Death)

Action Taken with Study Product
- ☐ dose not changed
- ☐ dose reduced
- ☐ dose increased
- ☐ drug withdrawn
- ☐ drug interrupted
- ☐ not applicable

Other action(s) taken ☐

None

Medication	☐
	☐
Therapeutic procedure/surgery	☐
Diagnostic procedure	☐
Other	☐
Other, specify	
Status/Outcome	recovered/resolved ☐ recovering/resolving ☐ resolved with sequelae ☐ not recovered/resolved ☐ fatal ☐
Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines?	Yes ☐ No ☐

If "No", go to following question.

If "Yes", check all that apply.

Results in death	☐
Is life-threatening	☐
Requires inpatient hospitalization or prolongation of existing hospitalization	☐
Results in persistent or significant disability/incapacity	☐
Is a congenital anomaly/birth defect	☐
Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	☐
Has or will this reaction be reported as an EAE?	Yes ☐ No ☐
If yes, EAE number	

Date the participant marked or signed the study Screening and Enrollment consent form.	_____
Did participant complete all screening for inclusion and exclusion criteria?	Yes ☐ No ☐
The following are inclusion criteria. Any box checked "No" disqualifies the person from enrollment.	
MSM or TGW	Yes ☐ No ☐
Male at birth	Yes ☐ No ☐
18 years or older at time of screening	Yes ☐ No ☐
Willing to provide informed consent for the study	Yes ☐ No ☐
At high risk for sexually acquiring HIV infection based on self-report of at least one of the following. Mark all that apply.	Yes ☐ No ☐
Any condomless receptive anal intercourse in 6 months prior to enrollment (condomless anal intercourse within a monogamous HIV seronegative concordant relationship does not meet this criterion)	☐
More than five partners in 6 months prior to Enrollment	☐
Any stimulant drug use in 6 months prior to Enrollment	☐
Rectal or urethral gonorrhea or chlamydia or incident syphilis in 6 months prior to Enrollment	☐
SexPro score of ≤ 16 (US sites only)	☐
Non-reactive / negative HIV test results.	Yes ☐ No ☐
Hemoglobin > 11 g/dL	Yes ☐ No ☐
Absolute neutrophil count > 750 cells/mm3	Yes ☐ No ☐
Platelet count ≥ 100,000/mm3	Yes ☐ No ☐
Calculated creatinine clearance ≥ 60 mL/minute using the Cockcroft-Gault equation	Yes ☐ No ☐
Alanine aminotransferase (ALT) < 2 times the upper limit of normal (ULN)	Yes ☐ No ☐
Total bilirubin < 2.5 times ULN	Yes ☐

	No ☐
Hepatitis B virus (HBV) surface antigen (HBsAg) negative	Yes ☐ No ☐
HCV Ab negative	Yes ☐ No ☐
No Grade 3 or higher laboratory abnormalities obtained at screening, including tests obtained as part of a panel of tests ordered to obtain the protocol-required laboratory test results.	Yes ☐ No ☐
No medical condition that, in the opinion of the study investigator, would interfere with the conduct of the study	Yes ☐ No ☐
Willing to undergo all required study procedures	Yes ☐ No ☐
The following are exclusion criteria. Any box checked “Yes” disqualifies the person from enrollment.	
One or more reactive or positive HIV test result at Screening	Yes ☐ No ☐
A reactive/positive rapid HIV test at Enrollment	Yes ☐ No ☐
Active or recent use of any illicit intravenous drugs	Yes ☐ No ☐
Co-enrollment in any other interventional research study or other concurrent studies that may interfere with this study	Yes ☐ No ☐
Past or current participation in HIV vaccine trial	Yes ☐ No ☐
Clinically significant cardiovascular disease	Yes ☐ No ☐
QTc interval (B or F) > 500 msec	Yes ☐ No ☐
Inflammatory skin conditions that compromise the safety of IM injections	Yes ☐ No ☐
Has a tattoo or other dermatological condition overlying the buttock region which may interfere with interpretation of injection site reactions	Yes ☐ No ☐
Current or chronic history of liver disease or known hepatic or biliary abnormalities	Yes ☐ No ☐
Coagulopathy which would contraindicate IM injection	Yes ☐ No ☐
Active or planned use of prohibited medications	Yes ☐

	No ☐
Known or suspected allergy to study product components (active or placebo), including egg or soy products	Yes ☐ No ☐
Surgically-placed or injected buttock implants or fillers, per self-report	Yes ☐ No ☐
Alcohol or substance use that would jeopardize the safety of the participant on study	Yes ☐ No ☐
History of seizure disorder	Yes ☐ No ☐

HPTN083_version 26.0_PROD_BK_09JUN2023: All
Form: Interviewer Administered: OLE
Generated On: 12 Jun 2023 18:42:31

Thank you for participating in this study. This survey will ask you questions about your life, your beliefs, and your behavior.

Some of the questions ask about behavior that you may consider private or confidential. We are asking these questions because your answers could help us to design a new or better way to slow the spread of HIV in your community.

Some questions will ask you about your behavior during a specific time period (for example, “in the past month”). Please pay close attention to the time period and only tell us about your behavior during that time.

The information you provide is an important contribution to this study and will be kept confidential. You can skip any question that makes you feel uncomfortable or stop taking the survey at any time. We will start by asking some basic questions about you.

Not Done ☐

Product Choice

Administer question 1 at the following visits:

Step 4a-Day 0, 4c-Day 0 or Step 5-Day 0

Step 4b-Day 0 only if participant did not do this survey at Step 4a-Day 0

Otherwise, mark NA.
If this question was completed at a previous visit, mark NA.

1. - Please tell me how you made the decision to use the medicine you are taking	Easier to use than other methods ☐ Can be used discreetly ☐ Does not interrupt sex ☐ Easily reversible ☐ Painless ☐ Other. ☐ Prefer not to answer ☐ NA ☐

Administer question 2 at the following visits:

Step 4a-Day 0

Step 4b-Day 0 only if participant did not do this survey at Step 4a-Day 0

Otherwise, mark NA

For persons starting cabotegravir for the first time: To participate in the study, participants had to take oral cabotegravir (the medication in injectable PrEP) for a few weeks to make sure they didn’t have any side effects that made them not want to use the medication. Now that we know that injectable PrEP works, people get to choose whether or not they take the pills before starting injections.

2a. - Did you choose to take the pills before starting the injections?	Yes. ☐ No. ☐ NA ☐

2b-i. - If Yes: What factors influenced your decision?	Worried about side effects ☐ I wanted to see what it would be like to take pills but not have injections ☐ I like to be very careful about my health and safety ☐ That is how the study was set up, so that is how I made my choice ☐ Other. ☐ Prefer not to answer ☐ NA ☐
2b-ii. - If No: What factors influenced your decision?	Wanted to start injections right away ☐ I don't like taking pills ☐ I am tired of taking pills ☐ I don't want people to see my pills ☐ The whole point of injections is not to take pills ☐ It seemed like it would be less visits / less work ☐ My schedule makes it hard to take pills ☐ I am not good at taking my pills every day ☐ Other. ☐ Prefer not to answer ☐ NA ☐
2c. - Who helped you make that decision?	No one ☐ Healthcare provider ☐ Sexual partner ☐ Family member or friend ☐ Other. ☐ Prefer not to answer ☐ NA ☐

Administer questions 3-5 at the following visits:

Step 4a-Day 0, 4c-Day 0 or Step 5-Day 0

Step 4b-Day 0 only if participant did not do this survey at Step 4a-Day 0

Otherwise, mark NA

Thinking about your choice to use either oral PrEP or injectable PrEP, how much do you agree with the following statements?

3. - My medication has more advantages than disadvantages?	Strongly disagree ☐ Disagree ☐ Neither agree nor disagree ☐

	Agree ☐
	Strongly agree ☐
	NA ☐

4. - Given the advantages and disadvantages of your medication, how much do you agree this is an acceptable solution?	Strongly disagree ☐
	Disagree ☐
	Neither agree nor disagree ☐
	Agree ☐
	Strongly agree ☐
	NA ☐

5. - To what degree do you feel these medications will be useful in the long term?	Strongly disagree ☐
	Disagree ☐
	Neither agree nor disagree ☐
	Agree ☐
	Strongly agree ☐
	NA ☐

Questions Related to Oral PrEP

Next we will talk about your feelings about using PrEP. Please respond to each of the following items in terms of how true it is for you with respect to using oral PrEP daily between now and your next visit. Please answer the questions based on how you feel at this moment. We understand that your feelings about this may be different from what it was last month and what it might be this month. Please focus on how you feel today.

Administer questions 6-9 at the following visits:

Step 5-Day 0

Step 5: Week 24, 48, 72, 96

Otherwise, mark NA

6. - I feel confident in my ability to use oral PrEP daily, as recommended.	1-Not at all ☐
	2 ☐
	3-Somewhat true ☐
	4 ☐
	5-Very true ☐
	NA ☐

7. - I am capable now of handling using oral PrEP daily.	1-Not at all ☐
	2 ☐
	3-Somewhat true ☐
	4 ☐
	5-Very true ☐
	NA ☐

8. - I am able to do what it takes to ensure that I use oral PrEP every day.	1-Not at all ☐

	2 ☐
	3-Somewhat true ☐
	4 ☐
	5-Very true ☐
	NA ☐

9. - I feel able to meet the challenge of using oral PrEP every day.	1-Not at all ☐
	2 ☐
	3-Somewhat true ☐
	4 ☐
	5-Very true ☐
	NA ☐

Administer questions 10-12 at the following visits:

Step 4a-Day 0, 4b-Day 0, Step 4c-Day 0

Step 4c: Week 16, 48

Otherwise, mark NA

10. - I feel confident in my ability to attend my injection visits as recommended.	1-Not at all ☐
	2 ☐
	3-Somewhat true ☐
	4 ☐
	5-Very true ☐
	NA ☐

11. - I am capable now of handling my injection visits as recommended.	1-Not at all ☐
	2 ☐
	3-Somewhat true ☐
	4 ☐
	5-Very true ☐
	NA ☐

12. - I am able to do what it takes to ensure that I get my injection as recommended.	1-Not at all ☐
	2 ☐
	3-Somewhat true ☐
	4 ☐
	5-Very true ☐
	NA ☐

HPTN083_version 26.0_PROD_BK_09JUN2023: All
Form: Vital Signs
Generated On: 12 Jun 2023 18:42:31

Were vital signs done?	Yes ☐ No ☐
Date of assessment	
Systolic blood pressure	Fixed Unit: mmHg
Diastolic blood pressure	Fixed Unit: mmHg
Weight	Fixed Unit: kg
Height (Complete at Enrollment only)	Fixed Unit: cm
Pulse	Fixed Unit: beats/min

This questionnaire is about your satisfaction with the study medication and particularly your experience over the past few weeks. I will read all the instructions and the questions out to you. If you do not understand the instructions, please ask me to explain. For the answers, what we want is your opinion. Is that ok? Are you ready to begin? When answering these items please consider or think about only the study medication you have chosen to take.

Interviewer instructions: The entire question and all the response options should be read out as follows:

Please say one number. You can choose 6 (very satisfied), 5, 4, 3 (the midpoint, indicating that you are neither satisfied not dissatisfied), 2, 1 or 0 (very dissatisfied). (Modify words according to the response options provided for that question).

Survey not done ☐

Administer questions 1-15 at the following visits:

Step 4b-Day 0, 4c-Day 0 or Step 5-Day 0 only if participant chose to remain on original randomized study drug

Step 4c: Week 16, 48

Step 5: Week 24, 48, 72, 96

Otherwise, mark NA

1. - How satisfied are you with your current study medication?	6-Very satisfied ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0-Very dissatisfied ☐ NA ☐
2. - How satisfied are you with any side effects of your present study medication?	6-Very satisfied ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0-Very dissatisfied ☐ NA ☐
3. - How satisfied are you with the demands made by your current study medication?	6-Very satisfied ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0-Very dissatisfied ☐

	NA ☐
4. - How convenient have you been finding your study medication to be recently?	6-Very satisfied ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0-Very dissatisfied ☐ NA ☐
5. - How flexible have you been finding your study medication to be recently?	6-Very satisfied ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0-Very dissatisfied ☐ NA ☐
6. - How satisfied are you with your understanding of your current study medication?	6-Very satisfied ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0-Very dissatisfied ☐ NA ☐
7. - How satisfied are you with the extent to which the study medication fits in with your lifestyle?	6-Very satisfied ☐ 5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0-Very dissatisfied ☐ NA ☐
8. - Would you recommend your present study medication to someone who is being offered this medication?	6-Yes, I would definitely recommend the medication ☐ 5 ☐ 4 ☐ 3 ☐

	2 ☐
	1 ☐
	0-No, I would definitely not recommend the medication ☐
	NA ☐
9. - Would you speak well of your present study medication to someone who is being offered this medication?	6-Yes, I would definitely recommend the medication ☐
	5 ☐
	4 ☐
	3 ☐
	2 ☐
	1 ☐
	0-No, I would definitely not recommend the medication ☐
	NA ☐
10. - How much does taking this medication reduce your anxiety about getting HIV?	0-Not at all ☐
	1 ☐
	2 ☐
	3 ☐
	4 ☐
	5 ☐
	6-A great deal ☐
	Prefer not to answer ☐
	NA ☐
11. - How much does taking this medication make you feel good about helping yourself prevent getting HIV?	0-Not at all ☐
	1 ☐
	2 ☐
	3 ☐
	4 ☐
	5 ☐
	6-A great deal ☐
	Prefer not to answer ☐
	NA ☐
12. - How much does taking this medication fit into your values, or things you find important?	0-Not at all ☐
	1 ☐
	2 ☐
	3 ☐
	4 ☐
	5 ☐

	6-A great deal ☐
	Prefer not to answer ☐
	NA ☐
13. - How much do you think your medication will be effective at preventing HIV?	0-Not at all ☐
	1 ☐
	2 ☐
	3 ☐
	4 ☐
	5 ☐
	6-A great deal ☐
	Prefer not to answer ☐
	NA ☐
14. - How much do you understand how your medication works?	0-Not at all ☐
	1 ☐
	2 ☐
	3 ☐
	4 ☐
	5 ☐
	6-A great deal ☐
	Prefer not to answer ☐
	NA ☐
15. - How much do you feel the benefits of taking this medication outweigh the things that make it difficult to take it?	0-Not at all ☐
	1 ☐
	2 ☐
	3 ☐
	4 ☐
	5 ☐
	6-A great deal ☐
	Prefer not to answer ☐
	NA ☐

Overall satisfaction with the study product

Administer questions 16-17 at the following visits:

Step 4a-Day 0 (oral CAB)

Step 5: Day 0, Week 24, 48, 72, 96

Otherwise, mark NA

16. - How often do you find it inconvenient or difficult to receive your oral study medication (i.e. the tablets) as recommended?	0-None of the time ☐
	1 ☐

	2 ☐
	3 ☐
	4 ☐
	5 ☐
	6-All of the time ☐
	Prefer not to answer ☐
	NA ☐
17. - How much pain or discomfort have you experienced with your oral study medication (i.e. the tablets)?	0-None of the time ☐
	1 ☐
	2 ☐
	3 ☐
	4 ☐
	5 ☐
	6-All of the time ☐
	Prefer not to answer ☐
	NA ☐

Administer questions 18-19 at the following visits:

Step 4c-Day 0 (only if participant attended Step 4b – loading injection)

Step 4c: Week 16, 48

Otherwise, mark NA

18. - How often do you find it inconvenient or difficult to receive your injection as recommended?	0-None at all ☐
	1 ☐
	2 ☐
	3 ☐
	4 ☐
	5 ☐
	6-All of the time ☐
	Prefer not to answer ☐
	NA ☐
19. - How much pain or discomfort have you experienced with your injection?	0-None at all ☐
	1 ☐
	2 ☐
	3 ☐
	4 ☐
	5 ☐
	6-A great deal ☐
	Prefer not to answer ☐

NA

Did the participant consent for Protocol Version 5.0?	Yes ☐ No ☐
If Yes, Date of Informed Consent	_____

Did the participant consent to Protocol Version 6.0?	Yes ☐ No ☐
If Yes, Date of Informed Consent	_____