

Subject Case Report Forms

HPTN083_version 25.0_PROD_EC_22JUL2022 - All

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

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Participant Identifier

Generated On: 25 Jul 2022 19:11:06

Participant ID: _____

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

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Date of Visit

Generated On: 25 Jul 2022 19:11:06

Local Laboratory Results	<input type="checkbox"/>
Participant Receipt	<input type="checkbox"/>
Participant Transfer	<input type="checkbox"/>
Sexually Transmitted Infections	<input type="checkbox"/>
HIV Test Results	<input type="checkbox"/>
Interviewer Administered: Follow Up 1	<input type="checkbox"/>
Study Medication Satisfaction Questionnaire (SMSQs)	<input type="checkbox"/>
Supplemental HIV Results	<input type="checkbox"/>
Vital Signs	<input type="checkbox"/>
Post-Injection Exercise Assessment	<input type="checkbox"/>

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)
Seroconverter Schedule
Standard Dose (8-week interval)
CAB-LA (Step 6)
Back to Standard Dose (8-week interval) CAB-LA (Step 4c)

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

CD4/Viral Load Results	<input type="checkbox"/>
Hepatitis Test Results	<input type="checkbox"/>
Local Laboratory Results	<input type="checkbox"/>
Participant Receipt	<input type="checkbox"/>
Participant Transfer	<input type="checkbox"/>
Sexually Transmitted Infections	<input type="checkbox"/>
Supplemental HIV Results	<input type="checkbox"/>

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Date of Visit - HIV

Generated On: 25 Jul 2022 19:11:06

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

HPTN083_version 25.0_PROD_EC_22JUL2022: All
Form: Interim Visit Summary
Generated On: 25 Jul 2022 19:11:06

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

HPTN083_version 25.0_PROD_EC_22JUL2022: All
Form: Interim Visit Summary
Generated On: 25 Jul 2022 19:11:06

Participant Transfer	Yes <input type="checkbox"/>
Sexually Transmitted Infections	Yes <input type="checkbox"/>
Specimen Storage	Yes <input type="checkbox"/>
Log Form	Yes <input type="checkbox"/>
Supplemental HIV Results	Yes <input type="checkbox"/>
Interviewer Administered: Follow Up 1	Yes <input type="checkbox"/>
Interviewer Administered: Follow Up 2	Yes <input type="checkbox"/>
Study Medication Satisfaction Questionnaire (SMSQs)	Yes <input type="checkbox"/>
Post-injection Exercise Assessment	Yes <input type="checkbox"/>

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)

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 25.0_PROD_EC_22JUL2022: All
Form: Yearly Visit Summary
Generated On: 25 Jul 2022 19:11:06

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 25.0_PROD_EC_22JUL2022: All

Form: Enrollment

Generated On: 25 Jul 2022 19:11:06

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
-

HPTN083_version 25.0_PROD_EC_22JUL2022: All
Form: Randomization
Generated On: 25 Jul 2022 19:11:06

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: _____

HPTN083_version 25.0_PROD_EC_22JUL2022: All
Form: Concomitant Medications Y/N
Generated On: 25 Jul 2022 19:11:06

Were any concomitant medications taken?

Yes

No

HPTN083_version 25.0_PROD_EC_22JUL2022: All
Form: Concomitant Medications
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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 _____

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Adverse Event Y/N

Generated On: 25 Jul 2022 19:11:06

Has the participant experienced an Adverse Event during the study?

Yes

No

If Yes, complete the Adverse Event form.

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Adverse Event

Generated On: 25 Jul 2022 19:11:06

Date reported to site _____

Adverse Event (AE) _____

Onset Date _____

At which visit was this AE first reported? V2.0 - Day 0/Enrollment

V3.0 - Week 2

V4.0 - Week 4

V5.0 - Week 5

V6.0 - Week 6

V7.0 - Week 9

V8.0 - Week 10

V9.0 - Week 17

V10.0 - Week 19

V11.0 - Week 25

V12.0 - Week 27

V13.0 - Week 33

V14.0 - Week 35

V15.0 - Week 41

V16.0 - Week 43

V17.0 - Week 49

V18.0 - Week 51

V19.0 - Week 57

V20.0 - Week 59

V21.0 - Week 65

V22.0 - Week 67

V23.0 - Week 73

V24.0 - Week 75

V25.0 - Week 81

V26.0 - Week 83

V27.0 - Week 89

V28.0 - Week 91

V29.0 - Week 97

V30.0 - Week 99

V31.0 - Week 105

V32.0 - Week 107

V33.0 - Week 113

V34.0 - Week 115

V35.0 - Week 121

V36.0 - Week 123

- V37.0 - Week 129
- V38.0 - Week 131
- V39.0 - Week 137
- V40.0 - Week 139
- V41.0 - Week 145
- V42.0 - Week 147
- V43.0 - Week 153
- V44.0 - Week 155
- V45.0 - Week 161
- V46.0 - Week 163
- V47.0 - Week 169
- V48.0 - Week 171
- V49.0 - Week 177
- V50.0 - Week 179
- V51.0 - Week 185
- V52.0 - Week 187
- V53.0 - Step 3/Day 0
- V54.0 - Step 3 or INF PTID -
Week 12
- V55.0 - Step 3 or INF PTID -
Week 24
- V56.0 - Step 3 or INF PTID -
Week 36
- V57.0 - Step 3 or INF PTID -
Week 48
- V60.0 - Exit Visit
- 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
- V80.0 - Yearly 1
- V81.0 - Yearly 2
- V82.0 - Yearly 3
- V83.0 - Yearly 4
- V91.0 - Week 12 - Seroconverter Schedule
- V92.0 - Week 24 - Seroconverter Schedule
- V93.0 - Week 36- Seroconverter Schedule
- V94.0 - Week 48- Seroconverter Schedule
- 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
- Interim Visit

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)	<input type="checkbox"/>
Relationship to study product	Related	<input type="checkbox"/>
	Not Related	<input type="checkbox"/>
Alternate etiology		
Action Taken with Study Product	dose not changed	<input type="checkbox"/>
	dose reduced	<input type="checkbox"/>
	dose increased	<input type="checkbox"/>
	drug withdrawn	<input type="checkbox"/>
	drug interrupted	<input type="checkbox"/>
	not applicable	<input type="checkbox"/>
Other action(s) taken		<input type="checkbox"/>
None		
Medication		<input type="checkbox"/>
		<input type="checkbox"/>
Therapeutic procedure/surgery		<input type="checkbox"/>
Diagnostic procedure		<input type="checkbox"/>
Other		<input type="checkbox"/>
Other, specify		
Status/Outcome	recovered/resolved	<input type="checkbox"/>
	recovering/resolving	<input type="checkbox"/>
	resolved with sequelae	<input type="checkbox"/>
	not recovered/resolved	<input type="checkbox"/>
	fatal	<input type="checkbox"/>
Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If "No", go to following question.

If "Yes", check all that apply.

Results in death	<input type="checkbox"/>
Is life-threatening	<input type="checkbox"/>
Requires inpatient hospitalization or prolongation of existing hospitalization	<input type="checkbox"/>
Results in persistent or significant disability/incapacity	<input type="checkbox"/>
Is a congenital anomaly/birth defect	<input type="checkbox"/>
Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	<input type="checkbox"/>

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Adverse Event

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Has or will this AE be reported as an EAE?

Yes

No

If yes, EAE number _____

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Missed Visit

Generated On: 25 Jul 2022 19:11:06

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

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Participant Unblinding

Generated On: 25 Jul 2022 19:11:06

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 _____

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Pre-existing Conditions Y/N

Generated On: 25 Jul 2022 19:11:06

Does the participant have any pre-existing conditions to report?

Yes

No

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Form: Pre-existing Conditions

Generated On: 25 Jul 2022 19:11:06

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 _____

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: ART Medication Y/N

Generated On: 25 Jul 2022 19:11:06

Has the participant started taking any ART medication?

Yes

No

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

Lopinavir/ritonavir (LPV/RTV; Kaletra; Aluvia)	<input type="checkbox"/>
Lamivudine/Stavudine/Nevirapin e (Triomune)	<input type="checkbox"/>
Zidovudine/Lamivudine/Nevirapi ne (Duovir-N)	<input type="checkbox"/>
Emtricitabine/Rilpivirine/Tenofov ir DF (FTC/RPV/TDF; Complera)	<input type="checkbox"/>
Elvitegravir/Cobicistat/Emtricitab ine/Tenofovir DF (EVG/COBI/FTC/TDF; Stribild)	<input type="checkbox"/>
Lamivudine (3TC; Epivir)/Tenofovir (TDF; Viread)	<input type="checkbox"/>
Dolutegravir/Abacavir/Lamivudin e (Triumeq)	<input type="checkbox"/>
Tenofovir/Lamivudine/Efavirenz (TDF/3TC/EFV)	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Cobicistat (COB)	<input type="checkbox"/>
Elvitegravir/Cobicistat/Emtricitab ine/Tenofovir AF (EVG/COBI/FTC/TAF)	<input type="checkbox"/>
Biktarvy (TAF/FTC/BIC)	<input type="checkbox"/>
Other, not listed	<input type="checkbox"/>

Date Started	_____
Date Stopped	_____
Or mark if continuing at end of study	<input type="checkbox"/>

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Protocol Deviation Y/N

Generated On: 25 Jul 2022 19:11:06

Have any protocol deviations occurred?

Yes

No

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): _____

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Product Hold - OLE Y/N

Generated On: 25 Jul 2022 19:11:06

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	<input type="checkbox"/>
	V91.0 - Week 12 - Seroconverter Schedule	<input type="checkbox"/>
	V92.0 - Week 24 - Seroconverter Schedule	<input type="checkbox"/>
	V93.0 - Week 36- Seroconverter Schedule	<input type="checkbox"/>
	V94.0 - Week 48- Seroconverter Schedule	<input type="checkbox"/>
	Interim Visit	<input type="checkbox"/>

Interim visit code	
Why is the study product being held or discontinued?	<input type="checkbox"/> one or more reactive HIV test results or acute HIV infection suspected <input type="checkbox"/> reported use of prohibited concomitant medication <input type="checkbox"/> participant is currently using or planning to use PrEP or PEP <input type="checkbox"/> Low oral adherence according to protocol <input type="checkbox"/> Clinical AE (protocol mandated) <input type="checkbox"/> Laboratory AE (protocol mandated) <input type="checkbox"/> Injection site reaction <input type="checkbox"/> CMC recommendation based on a clinical event <input type="checkbox"/> CMC recommendation based on a laboratory value <input type="checkbox"/> CMC recommendation based on a psychosocial concern <input type="checkbox"/> Other clinical reason <input type="checkbox"/> Participant request for injection intolerance (AE or ISR not protocol mandated) <input type="checkbox"/> Participant request - participant is unwilling or unable to comply with required study procedures <input type="checkbox"/> 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. Yes

no (permanently discontinued)

Has the participant resumed study product? no (hold continuing/permanently discontinued for another reason)

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Product Hold/Discontinuation – OLE

Generated On: 25 Jul 2022 19:11:06

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 _____

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

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Hematology

Generated On: 25 Jul 2022 19:11:06

Lab Name:

	Grade 2 - Moderate	<input type="radio"/>
	Grade 3 - Severe	<input type="radio"/>
	Grade 4 - Potentially life-threatening	<input type="radio"/>
	Not gradable	<input type="radio"/>
Lymphocytes Adverse event		
Monocytes		
Eosinophils		
Basophils		
Atypical lymphocytes		

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: DXA Scan

Generated On: 25 Jul 2022 19:11:06

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? Yes

Note: plasma storage is required at each visit where HIV testing is done. 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 _____

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Social Impact Y/N

Generated On: 25 Jul 2022 19:11:06

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

HPTN083_version 25.0_PROD_EC_22JUL2022: All
Form: Supplemental HIV Results
Generated On: 25 Jul 2022 19:11:06

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 _____

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Un-termination

Generated On: 25 Jul 2022 19:11:06

Un-termination date

Reason for Un-termination

Participant has requested to
participate in the open label
extension (OLE).
Other

If Other marked, specify:

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Pill Count - Enrollment

Generated On: 25 Jul 2022 19:11:06

Record the number of pills dispensed at the Enrollment visit:

Cabotegravir (real or placebo)

TDF/FTC (real or placebo)

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Pill Count - Follow Up

Generated On: 25 Jul 2022 19:11:06

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

HPTN083_version 25.0_PROD_EC_22JUL2022: All
Form: Post-injection Exercise Assessment
Generated On: 25 Jul 2022 19:11:06

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

HPTN083_version 25.0_PROD_EC_22JUL2022: All
Form: Vitamin D and Calcium Assessment
Generated On: 25 Jul 2022 19:11:06

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 25.0_PROD_EC_22JUL2022: All
Form: Product Hold/Discontinuation
Generated On: 25 Jul 2022 19:11:06

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?

V2.0 - Day 0/Enrollment

V3.0 - Week 2

V4.0 - Week 4

V5.0 - Week 5

V6.0 - Week 6

V7.0 - Week 9

V8.0 - Week 10

V9.0 - Week 17

V10.0 - Week 19

V11.0 - Week 25

V12.0 - Week 27

V13.0 - Week 33

V14.0 - Week 35

V15.0 - Week 41

V16.0 - Week 43

V17.0 - Week 49

V18.0 - Week 51

V19.0 - Week 57

V20.0 - Week 59

V21.0 - Week 65

V22.0 - Week 67

V23.0 - Week 73

V24.0 - Week 75

V25.0 - Week 81

V26.0 - Week 83

V27.0 - Week 89

V28.0 - Week 91

V29.0 - Week 97

V30.0 - Week 99

V31.0 - Week 105

V32.0 - Week 107

V33.0 - Week 113

V34.0 - Week 115

V35.0 - Week 121

V36.0 - Week 123

- V37.0 - Week 129
- V38.0 - Week 131
- V39.0 - Week 137
- V40.0 - Week 139
- V41.0 - Week 145
- V42.0 - Week 147
- V43.0 - Week 153
- V44.0 - Week 155
- V45.0 - Week 161
- V46.0 - Week 163
- V47.0 - Week 169
- V48.0 - Week 171
- V49.0 - Week 177
- V50.0 - Week 179
- V51.0 - Week 185
- V52.0 - Week 187
- V53.0 - Step 3/Day 0
- V54.0 - Step 3 or INF PTID -
Week 12
- V55.0 - Step 3 or INF PTID -
Week 24
- V56.0 - Step 3 or INF PTID -
Week 36
- V57.0 - Step 3 or INF PTID -
Week 48
- V60.0 - Exit Visit
- 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
- V80.0 - Yearly 1
- V81.0 - Yearly 2
- V82.0 - Yearly 3
- V83.0 - Yearly 4
- V91.0 - Week 12 - Seroconverter Schedule
- V92.0 - Week 24 - Seroconverter Schedule
- V93.0 - Week 36- Seroconverter Schedule
- V94.0 - Week 48- Seroconverter Schedule
- 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
- Interim Visit

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	<input type="checkbox"/>
CMC recommendation based on a clinical event	<input type="checkbox"/>
CMC recommendation based on a laboratory value	<input type="checkbox"/>
CMC recommendation based on a psychosocial concern	<input type="checkbox"/>
Other clinical reason	<input type="checkbox"/>
Participant request for injection intolerance (AE or ISR not protocol mandated)	<input type="checkbox"/>
Participant request - participant is unwilling or unable to comply with required study procedures	<input type="checkbox"/>
Other participant request	<input type="checkbox"/>
DO NOT USE-study product related toxicity	<input type="checkbox"/>
DO NOT USE-abnormal lab value	<input type="checkbox"/>
DO NOT USE-clinical reasons determined by the investigator	<input type="checkbox"/>
DO NOT USE-Hepatitis B infection	<input type="checkbox"/>
DO NOT USE-QTc > 550 ms or change of > 60 ms from the baseline EKG	<input type="checkbox"/>
DO NOT USE-request by participant to terminate study product	<input type="checkbox"/>
DO NOT USE-Other	<input type="checkbox"/>

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: _____

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Product Hold Y/N

Generated On: 25 Jul 2022 19:11:06

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

HPTN083_version 25.0_PROD_EC_22JUL2022: All
Form: Sexually Transmitted Infections
Generated On: 25 Jul 2022 19:11:06

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. gonorrhoea – URINE Negative
Positive

C. trachomatis – URINE Negative
Positive

N. gonorrhoea – RECTAL Negative
Positive

C. trachomatis – RECTAL Negative
Positive

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Log Revisions

Generated On: 25 Jul 2022 19:11:06

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 Yes

No

Is the AE / reaction still ongoing?

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

Lab Name: _____

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

Lab Name: _____

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

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Local Laboratory Results

Generated On: 25 Jul 2022 19:11:06

Lab Name:

	Grade 3 - Severe	<input type="radio"/>
	Grade 4 - Potentially life-threatening	<input type="radio"/>
	Not gradable	<input type="radio"/>

Protein (Urine) Adverse event

Glucose (Urine)	neg	<input type="radio"/>
	trace	<input type="radio"/>
	1+	<input type="radio"/>
	2+	<input type="radio"/>
	3+	<input type="radio"/>
	4+	<input type="radio"/>

Glucose (Urine) Severity Grade

	Grade 1 - Mild	<input type="radio"/>
	Grade 2 - Moderate	<input type="radio"/>
	Grade 3 - Severe	<input type="radio"/>
	Grade 4 - Potentially life-threatening	<input type="radio"/>
	Not gradable	<input type="radio"/>

Glucose (Urine) Adverse event

HPTN083_version 25.0_PROD_EC_22JUL2022: All
Form: Long Term Consent Update
Generated On: 25 Jul 2022 19:11:06

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

HPTN083_version 25.0_PROD_EC_22JUL2022: All**Form: Electrocardiogram****Generated On: 25 Jul 2022 19:11:06**

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

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Form: Electrocardiogram

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

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.

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-
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) <input type="radio"/>
	Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	Most or all of the time (5-7 days) <input type="radio"/>

14. - During the past week, I felt lonely.	Rarely or none of the time (Less than 1 day) <input type="radio"/>
	Some or a little of the time (1-2 days) <input type="radio"/>
	Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	Most or all of the time (5-7 days) <input type="radio"/>

15. - During the past week, I could not get going.	Rarely or none of the time (Less than 1 day) <input type="radio"/>
	Some or a little of the time (1-2 days) <input type="radio"/>
	Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	Most or all of the time (5-7 days) <input type="radio"/>

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. <input type="radio"/>
	No. <input type="radio"/>
	Prefer not to answer <input type="radio"/>

17. - ...tried hard not to think about it or went out of your way to avoid situations that reminded you of it?	Yes. <input type="radio"/>
	No. <input type="radio"/>
	Prefer not to answer <input type="radio"/>

18. - ...were constantly on guard, watchful, or easily startled?	Yes. <input type="radio"/>
	No. <input type="radio"/>
	Prefer not to answer <input type="radio"/>

19. - ...felt numb or detached from others, activities, or your surroundings?	Yes. <input type="radio"/>
	No. <input type="radio"/>
	Prefer not to answer <input type="radio"/>

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-boyfriend. 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 <input type="radio"/>
	2 - Rarely <input type="radio"/>
	3 - Sometimes <input type="radio"/>
	4 - Frequently <input type="radio"/>

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

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) <input type="radio"/> |
| | Some or a little of the time (1-2 days) <input type="radio"/> |
| | Occasionally or a moderate amount of time (3-4 days) <input type="radio"/> |
| | Most or all of the time (5-7 days) <input type="radio"/> |
| <hr/> | |
| 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) <input type="radio"/> |
| | Some or a little of the time (1-2 days) <input type="radio"/> |
| | Occasionally or a moderate amount of time (3-4 days) <input type="radio"/> |
| | Most or all of the time (5-7 days) <input type="radio"/> |
| <hr/> | |
| 3. - During the past week, I felt depressed. | Rarely or none of the time (Less than 1 day) <input type="radio"/> |
| | Some or a little of the time (1-2 days) <input type="radio"/> |
| | Occasionally or a moderate amount of time (3-4 days) <input type="radio"/> |
| | Most or all of the time (5-7 days) <input type="radio"/> |
| <hr/> | |
| 4. - During the past week, I felt that everything I did was an effort. | Rarely or none of the time (Less than 1 day) <input type="radio"/> |
| | Some or a little of the time (1-2 days) <input type="radio"/> |
| | Occasionally or a moderate amount of time (3-4 days) <input type="radio"/> |
| | Most or all of the time (5-7 days) <input type="radio"/> |
| <hr/> | |
| 5. - During the past week, I felt hopeful about the future. | Rarely or none of the time (Less than 1 day) <input type="radio"/> |
| | Some or a little of the time (1-2 days) <input type="radio"/> |
| | Occasionally or a moderate amount of time (3-4 days) <input type="radio"/> |
| | Most or all of the time (5-7 days) <input type="radio"/> |
| <hr/> | |
| 6. - During the past week, I felt fearful. | Rarely or none of the time (Less than 1 day) <input type="radio"/> |

	Some or a little of the time (1-2 days) <input type="radio"/>
	Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	Most or all of the time (5-7 days) <input type="radio"/>

7. - During the past week, my sleep was restless.	Rarely or none of the time (Less than 1 day) <input type="radio"/>
	Some or a little of the time (1-2 days) <input type="radio"/>
	Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	Most or all of the time (5-7 days) <input type="radio"/>

8. - During the past week, I was happy.	Rarely or none of the time (Less than 1 day) <input type="radio"/>
	Some or a little of the time (1-2 days) <input type="radio"/>
	Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	Most or all of the time (5-7 days) <input type="radio"/>

9. - During the past week, I felt lonely.	Rarely or none of the time (Less than 1 day) <input type="radio"/>
	Some or a little of the time (1-2 days) <input type="radio"/>
	Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	Most or all of the time (5-7 days) <input type="radio"/>

10. - During the past week, I could not get going.	Rarely or none of the time (Less than 1 day) <input type="radio"/>
	Some or a little of the time (1-2 days) <input type="radio"/>
	Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	Most or all of the time (5-7 days) <input type="radio"/>

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 <input type="radio"/>
	A little of the time <input type="radio"/>
	Some of the time <input type="radio"/>
	Most of the time <input type="radio"/>
	All of the time <input type="radio"/>

12. - How often is there someone available to help you attend visits for this study?	None of the time <input type="radio"/>
	A little of the time <input type="radio"/>
	Some of the time <input type="radio"/>
	Most of the time <input type="radio"/>
	All of the time <input type="radio"/>

13. - How often is there someone available to help you keep up with other study requirements?	None of the time <input type="radio"/>
---	--

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

HPTN083_version 25.0_PROD_EC_22JUL2022: All
Form: Study Medication Satisfaction Questionnaire (SMSQs)
Generated On: 25 Jul 2022 19:11:06

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 25.0_PROD_EC_22JUL2022: All
Form: Study Medication Satisfaction Questionnaire Change (SMSQc)
Generated On: 25 Jul 2022 19:11:06

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 more convenient 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 more convenient 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	<input type="radio"/>
		-2	<input type="radio"/>
		-3- Much less likely to recommend the medication now	<input type="radio"/>
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		<input type="radio"/>
		2	<input type="radio"/>
		1	<input type="radio"/>
		0	<input type="radio"/>
		-1	<input type="radio"/>
		-2	<input type="radio"/>
		-3- Much less likely to speak well of the medication now	<input type="radio"/>
9. - How satisfied would you be continue with your present form of study medication?	3- Much more satisfied now		<input type="radio"/>
		2	<input type="radio"/>
		1	<input type="radio"/>
		0	<input type="radio"/>
		-1	<input type="radio"/>
		-2	<input type="radio"/>
		-3- Much less satisfied now	<input type="radio"/>
10. - How easy or difficult have you been finding your medication to be recently?	3- Much easier now		<input type="radio"/>
		2	<input type="radio"/>
		1	<input type="radio"/>
		0	<input type="radio"/>
		-1	<input type="radio"/>
		-2	<input type="radio"/>
		-3- Much less easy now	<input type="radio"/>
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		<input type="radio"/>
		2	<input type="radio"/>
		1	<input type="radio"/>
		0	<input type="radio"/>
		-1	<input type="radio"/>
		-2	<input type="radio"/>
		-3- Much less satisfied now	<input type="radio"/>

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.	<input type="checkbox"/>
	UIC Project WISH - Chicago	<input type="checkbox"/>
	University of Miami AIDS	<input type="checkbox"/>
	University of Sao Paulo	<input type="checkbox"/>
	Via Libre - Lima	<input type="checkbox"/>
	Washington University Therapeutics	<input type="checkbox"/>
	Weill Cornell Chelsea - New York	<input type="checkbox"/>
	Yen Hoa Health Clinic	<input type="checkbox"/>

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

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

Visit Code of last completed contact with participant	V2.0 - Day 0/Enrollment	<input type="checkbox"/>
	V3.0 - Week 2	<input type="checkbox"/>
	V4.0 - Week 4	<input type="checkbox"/>
	V5.0 - Week 5	<input type="checkbox"/>
	V6.0 - Week 6	<input type="checkbox"/>
	V7.0 - Week 9	<input type="checkbox"/>
	V8.0 - Week 10	<input type="checkbox"/>
	V9.0 - Week 17	<input type="checkbox"/>
	V10.0 - Week 19	<input type="checkbox"/>
	V11.0 - Week 25	<input type="checkbox"/>
	V12.0 - Week 27	<input type="checkbox"/>
	V13.0 - Week 33	<input type="checkbox"/>
	V14.0 - Week 35	<input type="checkbox"/>
	V15.0 - Week 41	<input type="checkbox"/>
	V16.0 - Week 43	<input type="checkbox"/>
	V17.0 - Week 49	<input type="checkbox"/>
	V18.0 - Week 51	<input type="checkbox"/>
	V19.0 - Week 57	<input type="checkbox"/>
	V20.0 - Week 59	<input type="checkbox"/>
	V21.0 - Week 65	<input type="checkbox"/>
	V22.0 - Week 67	<input type="checkbox"/>

- V23.0 - Week 73
- V24.0 - Week 75
- V25.0 - Week 81
- V26.0 - Week 83
- V27.0 - Week 89
- V28.0 - Week 91
- V29.0 - Week 97
- V30.0 - Week 99
- V31.0 - Week 105
- V32.0 - Week 107
- V33.0 - Week 113
- V34.0 - Week 115
- V35.0 - Week 121
- V36.0 - Week 123
- V37.0 - Week 129
- V38.0 - Week 131
- V39.0 - Week 137
- V40.0 - Week 139
- V41.0 - Week 145
- V42.0 - Week 147
- V43.0 - Week 153
- V44.0 - Week 155
- V45.0 - Week 161
- V46.0 - Week 163
- V47.0 - Week 169
- V48.0 - Week 171
- V49.0 - Week 177
- V50.0 - Week 179
- V51.0 - Week 185
- V52.0 - Week 187
- V53.0 - Step 3/Day 0
- V54.0 - Step 3 or INF PTID -
Week 12
- V55.0 - Step 3 or INF PTID -
Week 24
- V56.0 - Step 3 or INF PTID -
Week 36
- V57.0 - Step 3 or INF PTID -
Week 48
- 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
- V91.0 - Week 12 - Seroconverter Schedule
- V92.0 - Week 24 - Seroconverter Schedule
- V93.0 - Week 36- Seroconverter Schedule
- V94.0 - Week 48- Seroconverter Schedule
- 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
- Interim Visit

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Participant Transfer

Generated On: 25 Jul 2022 19:11:06

Interim Visit Code	
Date participant records were sent to receiving study site	

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

	UCLA Vine Street - L.A.	<input type="checkbox"/>
	UIC Project WISH - Chicago	<input type="checkbox"/>
	University of Miami AIDS	<input type="checkbox"/>
	University of Sao Paulo	<input type="checkbox"/>
	Via Libre - Lima	<input type="checkbox"/>
	Washington University Therapeutics	<input type="checkbox"/>
	Weill Cornell Chelsea - New York	<input type="checkbox"/>
	Yen Hoa Health Clinic	<input type="checkbox"/>
<hr/>		
Name of transferring study site	AYAR at CORE - Chicago	<input type="checkbox"/>
	Alabama - Birmingham	<input type="checkbox"/>
	ACSA - Iquitos	<input type="checkbox"/>
	Barranco - Lima	<input type="checkbox"/>
	Bridge HIV - San Francisco	<input type="checkbox"/>
	Bronx Prevention - New York	<input type="checkbox"/>
	CITBM - Lima	<input type="checkbox"/>
	Centro Referencia - Sao Paulo	<input type="checkbox"/>
	Chapel Hill	<input type="checkbox"/>
	Chennai	<input type="checkbox"/>
	Chidren's Hospital Colorado	<input type="checkbox"/>
	Cincinnati	<input type="checkbox"/>
	CMU HIV Prevention - Chiang Mai	<input type="checkbox"/>
	East Bay AIDS Center - Oakland	<input type="checkbox"/>
	Fenway Health	<input type="checkbox"/>
	Fundación Huésped - Buenos Aires	<input type="checkbox"/>
	GW University - Washington, DC	<input type="checkbox"/>
	Greensboro - North Carolina	<input type="checkbox"/>
	Groote Schuur - Cape Town	<input type="checkbox"/>
	Harlem Prevention Center	<input type="checkbox"/>
	Hope Clinic of Emory - Georgia	<input type="checkbox"/>
	Hospital JM Ramos Mejia - Buenos Aires	<input type="checkbox"/>
	HNSC - Porto Alegre	<input type="checkbox"/>
	Houston AIDS Research	<input type="checkbox"/>
	IPEC - Rio de Janeiro	<input type="checkbox"/>
	Johns Hopkins University	<input type="checkbox"/>
	New Jersey Medical School	<input type="checkbox"/>
	New Orleans Adolescent Trials	<input type="checkbox"/>
	New York Blood Center	<input type="checkbox"/>

- 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 _____

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Injection Site Reaction Y/N

Generated On: 25 Jul 2022 19:11:06

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?

- V2.0 - Day 0/Enrollment
- V3.0 - Week 2
- V4.0 - Week 4
- V5.0 - Week 5
- V6.0 - Week 6
- V7.0 - Week 9
- V8.0 - Week 10
- V9.0 - Week 17
- V10.0 - Week 19
- V11.0 - Week 25
- V12.0 - Week 27
- V13.0 - Week 33
- V14.0 - Week 35
- V15.0 - Week 41
- V16.0 - Week 43
- V17.0 - Week 49
- V18.0 - Week 51
- V19.0 - Week 57
- V20.0 - Week 59

- V21.0 - Week 65
- V22.0 - Week 67
- V23.0 - Week 73
- V24.0 - Week 75
- V25.0 - Week 81
- V26.0 - Week 83
- V27.0 - Week 89
- V28.0 - Week 91
- V29.0 - Week 97
- V30.0 - Week 99
- V31.0 - Week 105
- V32.0 - Week 107
- V33.0 - Week 113
- V34.0 - Week 115
- V35.0 - Week 121
- V36.0 - Week 123
- V37.0 - Week 129
- V38.0 - Week 131
- V39.0 - Week 137
- V40.0 - Week 139
- V41.0 - Week 145
- V42.0 - Week 147
- V43.0 - Week 153
- V44.0 - Week 155
- V45.0 - Week 161
- V46.0 - Week 163
- V47.0 - Week 169
- V48.0 - Week 171
- V49.0 - Week 177
- V50.0 - Week 179
- V51.0 - Week 185
- V52.0 - Week 187
- V53.0 - Step 3/Day 0
- V54.0 - Step 3 or INF PTID -
Week 12
- V55.0 - Step 3 or INF PTID -
Week 24
- V56.0 - Step 3 or INF PTID -
Week 36
- V57.0 - Step 3 or INF PTID -
Week 48

- V60.0 - Exit Visit
- 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
- V80.0 - Yearly 1
- V81.0 - Yearly 2
- V82.0 - Yearly 3
- V83.0 - Yearly 4
- V91.0 - Week 12 - Seroconverter Schedule
- V92.0 - Week 24 - Seroconverter Schedule
- V93.0 - Week 36- Seroconverter Schedule
- V94.0 - Week 48- Seroconverter Schedule
- 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	<input type="checkbox"/>
	V125.0 - Step 5b - Week 48	<input type="checkbox"/>
	V126.0 - Step 5b - Week 60	<input type="checkbox"/>
	V127.0 - Step 5b - Week 72	<input type="checkbox"/>
	V128.0 - Step 5b - Week 84	<input type="checkbox"/>
	V129.0 - Step 5b - Week 96	<input type="checkbox"/>
	Interim Visit	<input type="checkbox"/>

Interim visit code, if applicable: _____

Is the reaction still ongoing? Yes

No

Outcome Date _____

Severity Grade

Grade 1 (Mild)	<input type="checkbox"/>
Grade 2 (Moderate)	<input type="checkbox"/>
Grade 3 (Severe)	<input type="checkbox"/>
Grade 4 (Potentially life-threatening)	<input type="checkbox"/>
Grade 5 (Death)	<input type="checkbox"/>

Action Taken with Study Product

dose not changed	<input type="checkbox"/>
dose reduced	<input type="checkbox"/>
dose increased	<input type="checkbox"/>
drug withdrawn	<input type="checkbox"/>
drug interrupted	<input type="checkbox"/>
not applicable	<input type="checkbox"/>

Other action(s) taken

None

Medication

Therapeutic procedure/surgery

Diagnostic procedure

Other

Other, specify _____

Status/Outcome

recovered/resolved	<input type="checkbox"/>
recovering/resolving	<input type="checkbox"/>
resolved with sequelae	<input type="checkbox"/>
not recovered/resolved	<input type="checkbox"/>
fatal	<input type="checkbox"/>

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 _____

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Inclusion / Exclusion

Generated On: 25 Jul 2022 19:11:06

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. Yes No

Mark all that apply.

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 $\geq 100,000$ /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 <input type="radio"/>
Hepatitis B virus (HBV) surface antigen (HBsAg) negative	Yes <input type="radio"/> No <input type="radio"/>
HCV Ab negative	Yes <input type="radio"/> No <input type="radio"/>
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 <input type="radio"/> No <input type="radio"/>
No medical condition that, in the opinion of the study investigator, would interfere with the conduct of the study	Yes <input type="radio"/> No <input type="radio"/>
Willing to undergo all required study procedures	Yes <input type="radio"/> No <input type="radio"/>
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 <input type="radio"/> No <input type="radio"/>
A reactive/positive rapid HIV test at Enrollment	Yes <input type="radio"/> No <input type="radio"/>
Active or recent use of any illicit intravenous drugs	Yes <input type="radio"/> No <input type="radio"/>
Co-enrollment in any other interventional research study or other concurrent studies that may interfere with this study	Yes <input type="radio"/> No <input type="radio"/>
Past or current participation in HIV vaccine trial	Yes <input type="radio"/> No <input type="radio"/>
Clinically significant cardiovascular disease	Yes <input type="radio"/> No <input type="radio"/>
QTc interval (B or F) > 500 msec	Yes <input type="radio"/> No <input type="radio"/>
Inflammatory skin conditions that compromise the safety of IM injections	Yes <input type="radio"/> No <input type="radio"/>
Has a tattoo or other dermatological condition overlying the buttock region which may interfere with interpretation of injection site reactions	Yes <input type="radio"/> No <input type="radio"/>
Current or chronic history of liver disease or known hepatic or biliary abnormalities	Yes <input type="radio"/> No <input type="radio"/>
Coagulopathy which would contraindicate IM injection	Yes <input type="radio"/> No <input type="radio"/>
Active or planned use of prohibited medications	Yes <input type="radio"/>

HPTN083_version 25.0_PROD_EC_22JUL2022: All

Form: Inclusion / Exclusion

Generated On: 25 Jul 2022 19:11:06

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

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 25.0_PROD_EC_22JUL2022: All

Form: Vital Signs

Generated On: 25 Jul 2022 19:11:06

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

HPTN083_version 25.0_PROD_EC_22JUL2022: All
Form: Informed Consent - Version 5.0
Generated On: 25 Jul 2022 19:11:06

Did the participant consent for Protocol Version 5.0?

Yes

No

If Yes, Date of Informed Consent _____
