

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

Subject Case Report Forms

HPTN083-01_Version 4.0_PROD_BK_29OCT2020 - ALL

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Additional Procedures

Generated On: 30 Oct 2020 23:02:41

Select any additional forms completed at this visit.

CD4 Test Results/Viral Load	<input type="checkbox"/>
Chemistry Panel	<input type="checkbox"/>
Hematology	<input type="checkbox"/>
STI Tests	<input type="checkbox"/>
Injection Administration	<input type="checkbox"/>
Fast Lipid Test Results	<input type="checkbox"/>
Hepatitis Test Results	<input type="checkbox"/>
Participant Receipt	<input type="checkbox"/>
Participant Transfer	<input type="checkbox"/>
Urinalysis	<input type="checkbox"/>
CASI	<input type="checkbox"/>
HIV Test Results	<input type="checkbox"/>
Physical Exam	<input type="checkbox"/>
Counseling	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Adverse Event

Generated On: 30 Oct 2020 23:02:41

Date AE reported to site _____

Adverse event (AE) _____

Onset date _____

Visit AE was reported V101.0 - Screening

V102.0 - Day 0/Enrollment

V103.0 - Step 1 Week 2

V104.0 - Step 1 Week 4

V201.0 - Step 2 Week 5

V202.0 - Step 2 Week 6

V203.0 - Step 2 Week 9

V204.0 - Step 2 Week 10

V205.0 - Step 2 Week 17

V206.0 - Step 2 Week 18

V207.0 - Step 2 Week 25

V208.0 - Step 2 Week 26

V209.0 - Step 2 Week 33

V210.0 - Step 2 Week 34

V301.0 - Step 3 Week +8

V302.0 - Step 3 Week +12

V303.0 - Step 3 Week +24

V304.0 - Step 3 Week +36

V305.0 - Step 3 Week +48

V401.0 - HIV Confirmation Visit

V402.0 - HIV Week 12

V403.0 - HIV Week 24

V404.0 - HIV Week 36

V405.0 - HIV Week 48

Interim Visit

Interim Visit Code _____

Is the AE still ongoing? Yes

No

If "No", outcome date _____

Severity grade Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially life-threatening)

Grade 5 (Death)

Relationship to study product Related

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Adverse Event

Generated On: 30 Oct 2020 23:02:41

Not related

Action taken with study product Dose not changed

Dose reduced

Dose increased

Drug withdrawn

Drug interrupted

Not applicable

Other actions

Mark "None" or all that apply.

None

Medication(s)

Therapeutic procedure/surgery

Diagnostic procedure

Referral

Other

If "Other", specify (max. 200 characters): _____

Status/outcome Recovered/resolved

Recovering/resolving

Recovered/resolved with sequelae

Not recovered/not resolved

Fatal

Severity/frequency increased

Is this a serious adverse event according to ICH/GCP or protocol guidelines? Yes

No

If "No", go to "Has or will this AE be reported as an EAE?". 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

SAE/EAE onset date _____

Has or will this AE be reported as an EAE? Yes

No

If "Yes", provide EAE number below.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Adverse Event

Generated On: 30 Oct 2020 23:02:41

EAE number

Begin number with 4-digit year, followed by 6-digit EAE number
(no dashes or spaces).

Was this AE a worsening of a baseline medical condition?

Yes

No

Comments (max. 450 characters):

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Adverse Event Y/N

Generated On: 30 Oct 2020 23:02:41

Has the participant experienced an adverse event during the study? Yes

No

If "Yes", update the Adverse Event log.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Behavioral Assessment

Generated On: 30 Oct 2020 23:02:41

Was a CASI questionnaire completed at this visit?

Yes

No

If no, please explain: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: CASI Tracking

Generated On: 30 Oct 2020 23:02:41

CASI collection date _____

CASI ID _____

Which questionnaire was completed?

Visit 2 Baseline CASI

Week 5 Follow-Up CASI

Week 9 Follow-Up CASI

Week 17 Follow-Up CASI

Week 25 Follow-Up CASI

Week 33 Follow-Up CASI

Week +12

Week +24

Week +36

Week +48

Week 4 Follow-Up CASI

Were there any problems or issues related to the administration or completion of the questionnaire? Yes

No

If yes, please describe _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: CD4 Test Results/Viral Load

Generated On: 30 Oct 2020 23:02:41

ABSOLUTE CD4+

Were Absolute CD4+ collected for testing? Yes
No

Specimen collection date _____
Absolute CD4+ _____ Fixed Unit: cells/mm³

Unable to analyze

HIV RNA

Was HIV RNA PCR testing completed? Yes
No

Specimen collection date _____

Operator _____ >
_____ <
_____ =

HIV RNA PCR _____ Fixed Unit: viral copies/mL

HIV RNA PCR target not detected

Detected, less than LLQ or LLD

Detected, greater than the upper limit of quantification

Additional CD4 Test Results or Viral Load data collected

Check this box if another CD4 form is needed to capture additional testing data

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Chemistry Panel

Generated On: 30 Oct 2020 23:02:41

Lab Name: _____

Was a sample collected for serum chemistries? Yes
No

Specimen collection date _____

LIVER FUNCTION TESTS

Alkaline Phosphatase Result _____

Alkaline Phosphatase severity grade Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

Alkaline Phosphatase Adverse Event _____

Not reportable as an adverse event

AST (SGOT) result _____

AST (SGOT) severity grade Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

AST (SGOT) adverse event _____

Not reportable as an adverse event

ALT (SGPT) result _____

ALT (SGPT) severity grade Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

ALT (SGPT) adverse event _____

Not reportable as an adverse event

Total Bilirubin Result _____

Total Bilirubin severity grade Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

Total Bilirubin adverse event _____

Not reportable as an adverse event

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Chemistry Panel

Generated On: 30 Oct 2020 23:02:41

Lab Name: _____

RENAL FUNCTION TESTS

Creatinine result _____

Creatinine severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Creatinine adverse event _____

Not reportable as an adverse event

Creatinine Clearance result _____

Creatinine Clearance severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Creatinine Clearance adverse event _____

Not reportable as an adverse event

BUN result _____

Urea result _____

ELECTROLYTES

Phosphate result (Phosphorous) _____

Phosphate severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Phosphate adverse event _____

Not reportable as an adverse event

Calcium result _____

Calcium severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Calcium adverse event _____

Not reportable as an adverse event

OTHER CHEMISTRIES

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Chemistry Panel

Generated On: 30 Oct 2020 23:02:41

Lab Name: _____

CPK (CK) result _____

CPK (CK) severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

CPK (CK) adverse event _____

Not reportable as an adverse event

Was a fasting sample collected for the glucose testing?

- Yes
- No

Did the participant fast for at least 8 hours prior to blood collection?

- Yes
- No

Glucose result _____

Glucose severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Glucose adverse event _____

Not reportable as an adverse event

Amylase, Pancreatic result _____

Amylase severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Amylase adverse event _____

Not reportable as an adverse event

Lipase result _____

Lipase severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Lipase adverse event _____

Not reportable as an adverse event

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Chemistry Panel

Generated On: 30 Oct 2020 23:02:41

Lab Name: _____

Comments (max. 200 characters): _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Concomitant Medications

Generated On: 30 Oct 2020 23:02:41

Reminder: Anticoagulant and antiplatelet medications as outlined in the SSP manual are prohibited within 7 days before and 7 days after injections.

Medication name _____

Indication _____

Date started _____

Date stopped _____

Or _____

Ongoing

Dose _____

Dose units _____

Grams

Micrograms

Milligrams

Milliliters

Capsules

Drops

Puffs

Sachets

Suppository

Tablets

Units

Unknown

Other

If "Other", specify: _____

Frequency _____

PRN

QD

BID

TID

QID

QM

QH

ONCE

Other

If "Other", specify: _____

Route _____

Oral

Intramuscular

Intravenous

Topical

Inhalation

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Concomitant Medications

Generated On: 30 Oct 2020 23:02:41

	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If "Other", specify: _____

Taken for a reported AE? Yes

No

If "Yes", select adverse event. _____

Select additional adverse event, if applicable _____

Taken for a reported Injection site reaction? Yes

No

If "Yes", select injection site reaction event. _____

Select additional injection site reaction, if applicable _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Concomitant Medications Y/N

Generated On: 30 Oct 2020 23:02:41

Were any concomitant medications taken?

Yes

No

If "Yes", update the Concomitant Medications log.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Counseling

Generated On: 30 Oct 2020 23:02:41

Did a counseling session occur at this visit?

Yes

No

Indicate which topic areas were covered during this session. Mark all that apply.

- | | |
|----------------------------------|--------------------------|
| Adherence goal setting | <input type="checkbox"/> |
| Adherence reminder strategies | <input type="checkbox"/> |
| Barriers to adherence | <input type="checkbox"/> |
| Communication skills | <input type="checkbox"/> |
| Product Storage | <input type="checkbox"/> |
| Disclosing product use to others | <input type="checkbox"/> |
| Planning for future PrEP use | <input type="checkbox"/> |
| Pill or injection education | <input type="checkbox"/> |
| Problem solving | <input type="checkbox"/> |
| Social Support | <input type="checkbox"/> |
| Parental Support | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

If other, please specify: _____

Indicate which adherence barriers/challenges were explored during this session. Mark all that apply or only "None could be identified".

- | | |
|---|--------------------------|
| None could be identified | <input type="checkbox"/> |
| Barriers to return for study visits (e.g., money, transportation, time) | <input type="checkbox"/> |
| Disruption in routine (for example, travel away from home) | <input type="checkbox"/> |
| Forgetting/no pills available | <input type="checkbox"/> |
| Job/School commitments | <input type="checkbox"/> |
| Lack of privacy | <input type="checkbox"/> |
| Medication side effects | <input type="checkbox"/> |
| Negative reactions (family, friends, partner) | <input type="checkbox"/> |
| Partying/drugs/alcohol | <input type="checkbox"/> |
| Side effects | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

If other, please specify: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL
Form: Date of Visit - Seroconverter Schedule
Generated On: 30 Oct 2020 23:02:41

Did the participant complete this visit? Yes
No

Visit Date _____
Did the participant exit/terminate the study at this visit? Yes
No

Were any new adverse events (AEs) reported at this visit? Yes
No

Is the participant taking any concomitant medications that have not been previously reported? Yes
No

Have any protocol deviations been reported at this visit? Yes
No

Did the participant have any additional procedures at this visit? Yes
No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Date of Visit - Step 1

Generated On: 30 Oct 2020 23:02:41

Did the participant complete this visit? Yes
No

Visit Date _____

Did the participant exit/terminate the study at this visit? Yes
If "Yes", please complete the Study Termination CRF. No

Were any new adverse events (AEs) reported at this visit? Yes
If "Yes", please complete the Adverse Event Log. No

Is the participant taking any concomitant medications that have not been previously reported? Yes
If "Yes", please complete the Concomitant Medications Log. No

Have any protocol deviations been reported at this visit? Yes
If "Yes", please complete the Protocol Deviations Log. No

Was the participant observed taking the study product? Yes
No

If the participant was NOT observed taking the study product, was it already taken before this visit? Yes
No

Did the participant have any additional procedures at this visit? Yes
If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit. No

WEEK 4 Visit ONLY

Is the participant moving to a Step 2? Yes
No

If the participant is not moving to Step 2, please specify. _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Date of Visit - Step 2

Generated On: 30 Oct 2020 23:02:41

Did the participant complete this visit? Yes
No

Visit Date _____

Did the participant exit/terminate the study at this visit? Yes
If "Yes", please complete the Study Termination CRF. No

Were any new adverse events (AEs) reported at this visit? Yes
If "Yes", please complete the Adverse Event Log. No

Is the participant taking any concomitant medications that have not been previously reported? Yes
If "Yes", please complete the Concomitant Medications Log. No

Have any protocol deviations been reported at this visit? Yes
If "Yes", please complete the Protocol Deviations Log. No

Did the participant have any additional procedures at this visit? Yes
No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

Is the participant moving to a different step or visit schedule? Yes
No

If yes, please indicate which step or visit schedule. Step 3
Seroconverter Schedule

Week 5 Visit ONLY

Date of participant's last dose of oral study product _____

Time of participant's last dose of oral study product _____

WEEK 33 Visit ONLY or early discontinuation

Date of participant's last injection _____

WEEK 34 Visit ONLY

Was Truvada dispensed at week 34? Yes
No

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Date of Visit - Step 3

Generated On: 30 Oct 2020 23:02:41

Did the participant complete this visit? Yes
No

Visit Date _____

Did the participant exit/terminate the study at this visit? Yes
If "Yes", please complete the Study Termination CRF. No

Were any new adverse events (AEs) reported at this visit? Yes
If "Yes", please complete the Adverse Event Log. No

Is the participant taking any concomitant medications that have not been previously reported? Yes
If "Yes", please complete the Concomitant Medications Log. No

Have any protocol deviations been reported at this visit? Yes
If "Yes", please complete the Protocol Deviations Log. No

Did the participant have any additional procedures at this visit? Yes
No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

Is the participant moving to a Seroconverter Schedule? Yes
No

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Demographics

Generated On: 30 Oct 2020 23:02:41

Date of birth _____

Age _____ Fixed Unit: yrs

Sex assigned at birth _____ Male

Female

Ethnicity _____ Hispanic or Latino

Not Hispanic or Latino

Race

Mark all that apply.

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or other Pacific Islander

White

Other

If "Other", specify: _____

Gender

Mark all that apply.

Female

Gender Nonconforming/Gender Variant

Male

Self-identify

If "Self-identify", specify: _____

Transgender Female

Transgender Male

Prefer not to answer

How do you identify your sexual orientation? _____ Gay/Lesbian/Homosexual

Bisexual

Queer

Two Spirit

Straight/Heterosexual

Additional category

Not sure

Prefer not to Answer

If "Additional category", specify: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL
Form: Discontinuation of Study Product
Generated On: 30 Oct 2020 23:02:41

Date that study product use ended _____

Visit that study product use ended _____

- V101.0 - Screening
- V102.0 - Day 0/Enrollment
- V103.0 - Step 1 Week 2
- V104.0 - Step 1 Week 4
- V201.0 - Step 2 Week 5
- V202.0 - Step 2 Week 6
- V203.0 - Step 2 Week 9
- V204.0 - Step 2 Week 10
- V205.0 - Step 2 Week 17
- V206.0 - Step 2 Week 18
- V207.0 - Step 2 Week 25
- V208.0 - Step 2 Week 26
- V209.0 - Step 2 Week 33
- V210.0 - Step 2 Week 34
- V301.0 - Step 3 Week +8
- V302.0 - Step 3 Week +12
- V303.0 - Step 3 Week +24
- V304.0 - Step 3 Week +36
- V305.0 - Step 3 Week +48
- V401.0 - HIV Confirmation Visit
- V402.0 - HIV Week 12
- V403.0 - HIV Week 24
- V404.0 - HIV Week 36
- V405.0 - HIV Week 48
- Interim Visit

If 'Interim Visit' is chosen, provide interim visit code. _____

Primary reason for ending study product use:

- Scheduled study product use period completed
- Death
- Participant refused further participation
- Participant is unwilling or unable to comply with required study procedures
- Lost to follow-up
- Investigator decision
- Participant refused further study product use
- HIV infection
- Early study closure

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL
Form: Discontinuation of Study Product
Generated On: 30 Oct 2020 23:02:41

Protocol deviation

Adverse event

Withdrawal of consent by
participant

Study terminated by sponsor

One or more reactive HIV test
results or acute HIV infection
suspected

Participant unable to adhere to
visit schedule

Use of prohibited concomitant
medications

Acquired HBV infection

Injection site reaction

Other, specify

If "Other", specify: _____

If "Adverse event", select applicable adverse event. _____

If "Use of prohibited concomitant medications", select applicable
concomitant medication. _____

If "Injection site reaction", select applicable Injection site reaction
event. _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Enrollment

Generated On: 30 Oct 2020 23:02:41

Was the participant enrolled in the study? Yes
No

Date of Enrollment _____
Was the participant observed taking the first dose? Yes
No

Date of participant's first dose of oral study product _____
Time of participant's first dose of oral study product _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Fasting Lipid Test Results

Generated On: 30 Oct 2020 23:02:41

Lab Name: _____

SERUM LIPID

Was a fasting sample collected for the lipid profile? Yes
No

Did the participant fast for at least 8 hours prior to blood collection? Yes
No

Date of collection: _____

Total Cholesterol result _____

Total Cholesterol severity grade
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

Total Cholesterol adverse event _____

Not reportable as an adverse event

HDL Cholesterol result _____

Triglycerides result _____

Triglycerides severity grade
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

Triglycerides adverse event _____

Not reportable as an adverse event

LDL Cholesterol result _____

LDL Cholesterol severity grade

Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

LDL Cholesterol adverse event _____

Not reportable as an adverse event

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Hematology

Generated On: 30 Oct 2020 23:02:41

Lab Name: _____

HEMOGRAM

Was a hematology sample collected? Yes
No

Hematology collection date _____

Hemoglobin _____

Hemoglobin severity grade
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

Hemoglobin adverse event, if applicable _____

Not reportable as an 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, if applicable _____

Not reportable as an 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, if applicable _____

Not reportable as an adverse event

DIFFERENTIAL

Was a differential done? Yes
No

Differential collection date _____

Neutrophils _____

Neutrophils severity grade
Grade 1 (Mild)
Grade 2 (Moderate)

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Hematology

Generated On: 30 Oct 2020 23:02:41

Lab Name: _____

Grade 3 (Severe)

Grade 4 (Potentially
life-threatening)

Not gradable

Neutrophils adverse event, if applicable _____

Not reportable as an adverse event

Lymphocytes _____

Lymphocytes severity grade _____

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially
life-threatening)

Not gradable

Lymphocytes adverse event, if applicable _____

Not reportable as an adverse event

Monocytes _____

Eosinophils _____

Basophils _____

Atypical lymphocytes _____

Comments (max. 200 characters): _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Hepatitis Test Results

Generated On: 30 Oct 2020 23:02:41

Was a sample collected for Hepatitis B Surface Antigen (HBsAG) testing? Yes
No

Date of collection _____
Hepatitis B Surface Antigen (HBsAG) Positive
Negative

Was a sample collected for Hepatitis B Surface Antibody (HBsAb) testing? Yes
No

Date of collection _____
Hepatitis B Surface Antibody (HBsAb) Positive
Negative

Was a sample collected for Hepatitis B Core Antibody (HBcAb) testing? Yes
No

Date of collection _____
Hepatitis B Core Antibody (HBcAb) Positive
Negative

Was a sample collected for Hepatitis C Antibody (HCAb) testing? Yes
No

Date of collection _____
Hepatitis C Antibody (HCAb) Positive
Negative

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: HIV Test Results

Generated On: 30 Oct 2020 23:02:41

Specimen Collection Date _____

Was this sample collected for additional testing? Yes
No

HIV Rapid test result Reactive/Positive
Non-Reactive/Negative
Invalid
Not Done

HIV Laboratory based immunoassay test result Reactive/Positive
Non-Reactive/Negative
Invalid
Not Done

HIV-1 RNA Qualitative test result Reactive/Positive
Non-Reactive/Negative
Invalid
Not Done

Was a viral load done? Yes
No

Final HIV status Reactive/Positive
Non-Reactive/Negative
Additional testing required

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Inclusion Exclusion Criteria

Generated On: 30 Oct 2020 23:02:41

Has the participant screened for the study before? Yes
No

If yes, record the first Rave PTID assigned: _____

Date the participant or guardian marked or signed the study screening and enrollment consent form _____

The following are Inclusion criteria. Any box checked "No" disqualifies the person from enrollment.

Assigned male at birth (includes MSM, TGW, and gender non-conforming people) Yes
No

At enrollment, aged below 18 years Yes
No

At enrollment, body weight \geq 35 kg (77 lbs.) Yes
No

Willing to provide written informed assent/consent for the study and/or able to obtain written parental/guardian informed consent. Yes
No

Self-reported sexual activity with a male (oral or anal) in the past 12 months. Yes
No

In general, good health, as evidenced by the following laboratory values. Mark all that apply Yes
No

Non-reactive / negative HIV test results

Absolute neutrophil count $>$ 799 cells/mm³

Platelet count \geq 100,000/mm³

Hemoglobin \geq 11g/dL

Calculated creatinine clearance \geq 60 mL/minute using modified Schwartz equation (\leq grade 2)

Alanine aminotransferase (ALT) \leq 2.0 times the upper limit of normal (ULN) and total bilirubin (Tbili) \leq 2.5 x ULN

Hepatitis B virus (HBV) surface antigen (HBsAg) negative and accepts vaccination

HCV Antibody negative

Willing to undergo all required study procedures. Yes
No

If currently on PrEP from a non-study source, willing to stop said PrEP prior to enrollment and agree to switch to oral CAB for the lead-in period and CAB LA injections. Yes
No

The following are Exclusion criteria. Any box checked "Yes" disqualifies the person from enrollment.

Co-enrollment in any other HIV interventional research study or other concurrent studies which may interfere with this study (as provided by self-report or other available documentation). Yes
No

Currently receiving PrEP from a non-study source. Yes
No

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Inclusion Exclusion Criteria

Generated On: 30 Oct 2020 23:02:41

Past or current participation in HIV vaccine trial with exception for participants who can provide documentation of receipt of placebo. Yes
No

Exclusively had sex with biological females in lifetime. Yes
No

In the last 6 months (at the time of screening): self-reported unprotected anal intercourse with someone known to be HIV-infected, Yes
No

In the last 6 months (at the time of screening): self-reported illicit injection drug use of any kind or stimulant use (including inhaled nitrate, cocaine in any form, methamphetamine, or non-physician prescribed pharmaceutical-grade stimulants) Yes
No

In the last 6 months (at the time of screening): active or planned use of any substance use which would, in the opinion of the site investigator, would hinder study participation (including herbal remedies), as described in the IB or listed in the SSP, and/or Protocol Section 4.4 Yes
No

In the last 6 months (at the time of screening): self-report of greater than 5 different sexual partners (anal or vaginal), regardless of use of protection or knowledge of HIV status Yes
No

Known history of clinically significant cardiovascular disease, as defined by history/evidence of symptomatic arrhythmia, angina/ischemia, coronary artery bypass grafting (CABG) surgery or percutaneous transluminal coronary angioplasty (PTCA) or any clinically significant cardiac disease. Yes
No

Inflammatory skin conditions that compromise the safety of intramuscular (IM) injections. Yes
No

Tattoo or other dermatological condition overlying the buttock region that may interfere with interpretation of injection site reactions. Yes
No

Current or chronic history of liver disease (e.g., non-alcoholic or alcoholic steatohepatitis) or known hepatic or biliary abnormalities (with the exception of Gilbert's syndrome, asymptomatic gallstones, or cholecystectomy). Yes
No

Known history of clinically significant bleeding. Yes
No

Surgically-placed or injected buttock implants or fillers, per self-report. Contact the CMC for guidance regarding questions about individual cases. Yes
No

A history of seizure disorder, per self-report. Yes
No

Medical, social, or other condition that, in the opinion of the site investigator, would interfere with the conduct of the study or the safety of the participant (e.g., provided by self-report, or found upon medical history and examination or in available medical records). Yes
No

If "Investigator decision", specify (max. 200 characters): _____

Plans to move out of the geographic area within the next 18 months or otherwise unable to participate in study visits, according to the site investigator. Yes
No

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Inclusion Exclusion Criteria

Generated On: 30 Oct 2020 23:02:41

Did the participant meet all eligibility criteria? Yes

No

Eligibility status Eligible and enrolled

Eligible/Not enrolled

Ineligible

Incomplete screening

Date participant was found "Eligible/Not Enrolled" or "Ineligible" _____

If eligible, but participant declined enrollment, specify reason: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Informed Consent Form

Generated On: 30 Oct 2020 23:02:41

Date the participant or guardian marked or signed the study screening and enrollment consent form _____

Did the participant or guardian consent to long-term specimen storage? Yes
No

Did the participant or guardian consent to future testing? Yes
No

Did the participant or guardian consent to genetic testing? Yes
No

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Injection Administration

Generated On: 30 Oct 2020 23:02:41

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/dispensing of study product.

Was an injection given at this visit? Yes
No

If injection was given:

Injection date _____

Needle gauge 21 G
23 G
25 G
Other

If other needle gauge, specify: _____

Needle length 1 in
1.5 in
2 in
Other

If other needle length, specify: _____

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, temporarily held, permanently discontinued or other reason why injection was not provided. Injection missed
Injection refused
Injection schedule on hold or permanently discontinued
Other, specify

If Other, specify _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Injection Site Reaction

Generated On: 30 Oct 2020 23:02:41

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

- Right buttock
- Left buttock

Onset date

At which visit was this ISR first reported?

- V101.0 - Screening
- V102.0 - Day 0/Enrollment
- V103.0 - Step 1 Week 2
- V104.0 - Step 1 Week 4
- V201.0 - Step 2 Week 5
- V202.0 - Step 2 Week 6
- V203.0 - Step 2 Week 9
- V204.0 - Step 2 Week 10
- V205.0 - Step 2 Week 17
- V206.0 - Step 2 Week 18
- V207.0 - Step 2 Week 25
- V208.0 - Step 2 Week 26
- V209.0 - Step 2 Week 33
- V210.0 - Step 2 Week 34
- V301.0 - Step 3 Week +8
- V302.0 - Step 3 Week +12
- V303.0 - Step 3 Week +24
- V304.0 - Step 3 Week +36
- V305.0 - Step 3 Week +48

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Injection Site Reaction

Generated On: 30 Oct 2020 23:02:41

	V401.0 - HIV Confirmation Visit	<input type="radio"/>
	V402.0 - HIV Week 12	<input type="radio"/>
	V403.0 - HIV Week 24	<input type="radio"/>
	V404.0 - HIV Week 36	<input type="radio"/>
	V405.0 - HIV Week 48	<input type="radio"/>
	Interim Visit	<input type="radio"/>

If 'Interim Visit' is chosen, provide interim visit code. _____

Is the reaction still ongoing? Yes

No

If no, provide an outcome date _____

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"/>
Grade 5 (Death)	<input type="radio"/>

Action taken with study product

Dose not changed	<input type="radio"/>
Dose reduced	<input type="radio"/>
Dose increased	<input type="radio"/>
Drug withdrawn	<input type="radio"/>
Drug interrupted	<input type="radio"/>
Not applicable	<input type="radio"/>

Other action(s) taken (Select "none" or all that apply)

None

Medication(s)

Therapeutic procedure/surgery

Diagnostic procedure

Other

Other, specify: _____

Status/Outcome

Recovered/resolved	<input type="radio"/>
Recovering/resolving	<input type="radio"/>
Recovered/resolved with sequelae	<input type="radio"/>
Not recovered/not resolved	<input type="radio"/>
Fatal	<input type="radio"/>
Severity/frequency increased	<input type="radio"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Injection Site Reaction

Generated On: 30 Oct 2020 23:02:41

Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines?

Yes

No

If "No", go to "Has or will this AE be reported as an EAE?". 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 another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above

SAE/EAE onset date _____

Has or will this AE be reported as an EAE?

Yes

No

If "Yes", provide EAE number below.

EAE number _____

Begin number with 4-digit year, followed by 6-digit EAE number (no dashes or spaces). _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Injection Site Reaction Y/N

Generated On: 30 Oct 2020 23:02:41

Has the participant experienced any Injection Site Reactions?

Yes

No

If yes, complete the Injection Site Reaction Log.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Interim Visit

Generated On: 30 Oct 2020 23:02:41

Interim visit date _____

Interim visit code _____

Was study product use permanently discontinued (scheduled or early) at this visit? Yes
If "Yes", please complete the Discontinuation of Study Product" CRF. No

Did the participant exit/terminate the study at this visit? Yes
If "Yes", please complete the Study Termination CRF. No

Were any new adverse events (AEs) reported at this visit? Yes
If "Yes", please complete the Adverse Event Log. No

Is the participant taking any concomitant medications that have not been previously reported? Yes
If "Yes", please complete the Concomitant Medications Log. No

Have any protocol deviations been reported at this visit? Yes
If "Yes", please complete the Protocol Deviations Log. No

Reason for interim visit (Mark all that apply)

AE report or follow-up

ISR report or follow-up
If checked, please complete the Injection Site Reaction Log.

Report social harm
If checked, please complete the Social Impact Log.

Additional laboratory testing

Product Hold
If checked, please complete the Product Hold Log.

Other

If other, specify: _____

Were vital signs (such as weight) taken at this visit? Yes
No

Is the participant moving to a new visit schedule? Yes
No

If yes, please indicate which visit schedule. Step 2
Step 3
Seroconverter schedule

Mark all forms completed at this visit.

CD4 Test Results

Chemistry Panel

Counseling

Fasting Lipid Test Results

Hematology

Hepatitis Test Results

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Interim Visit

Generated On: 30 Oct 2020 23:02:41

HIV Test Results	<input type="checkbox"/>
Injection Administration	<input type="checkbox"/>
CASI	<input type="checkbox"/>
Participant Receipt	<input type="checkbox"/>
Participant Transfer	<input type="checkbox"/>
Specimen Collection and Storage	<input type="checkbox"/>
STI Test Results	<input type="checkbox"/>
Urinalysis	<input type="checkbox"/>
Physical Exam	<input type="checkbox"/>
Vital Signs	<input type="checkbox"/>
Pill Count Step 1	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Medical History

Generated On: 30 Oct 2020 23:02:41

Date medical history collected _____

Description of medical history condition/event _____

Is condition/event gradable? Yes
No

Severity grade Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

Start date of medical history condition/event _____

Is the condition ongoing? Yes
No

Date medical history/condition ended/resolved _____

Comments (max. 200 characters): _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Medical History Y/N

Generated On: 30 Oct 2020 23:02:41

Does the participant have any medical history to report?

Yes

No

If "Yes", update the Medical History log.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Missed Visit

Generated On: 30 Oct 2020 23:02:41

Target visit date _____

- Reason visit was missed
- Unable to contact participant
 - Participant unable to schedule visit within window
 - Participant refused visit
 - Participant incarcerated
 - Participant admitted to healthcare facility
 - Participant withdrew from study
 - Participant deceased
 - Other

If "Other", specify: _____

Steps taken to address the missed visit (corrective action plan) _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Participant Identifier

Generated On: 30 Oct 2020 23:02:41

Participant ID: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Participant Receipt

Generated On: 30 Oct 2020 23:02:41

Name of receiving study site	AYAR at CORE (31958) <input type="checkbox"/>
	St. Jude CRS (6501) <input type="checkbox"/>
	Fenway Health CRS (31785) <input type="checkbox"/>
<hr/>	
Name of transferring study site	AYAR at CORE (31958) <input type="checkbox"/>
	St. Jude CRS (6501) <input type="checkbox"/>
	Fenway Health CRS (31785) <input type="checkbox"/>
<hr/>	
Date informed consent signed at receiving site	_____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Participant Transfer

Generated On: 30 Oct 2020 23:02:41

Name of transferring study site AYAR at CORE (31958)
St. Jude CRS (6501)
Fenway Health CRS (31785)

Name of receiving study site AYAR at CORE (31958)
St. Jude CRS (6501)
Fenway Health CRS (31785)

Visit of last completed contact with participant V101.0 - Screening
V102.0 - Day 0/Enrollment
V103.0 - Step 1 Week 2
V104.0 - Step 1 Week 4
V201.0 - Step 2 Week 5
V202.0 - Step 2 Week 6
V203.0 - Step 2 Week 9
V204.0 - Step 2 Week 10
V205.0 - Step 2 Week 17
V206.0 - Step 2 Week 18
V207.0 - Step 2 Week 25
V208.0 - Step 2 Week 26
V209.0 - Step 2 Week 33
V210.0 - Step 2 Week 34
V301.0 - Step 3 Week +8
V302.0 - Step 3 Week +12
V303.0 - Step 3 Week +24
V304.0 - Step 3 Week +36
V305.0 - Step 3 Week +48
V401.0 - HIV Confirmation Visit
V402.0 - HIV Week 12
V403.0 - HIV Week 24
V404.0 - HIV Week 36
V405.0 - HIV Week 48
Interim Visit

If "Interim visit", specify Interim visit code.

Date participant's records were sent to receiving study site _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Patient Health Questionnaire

Generated On: 30 Oct 2020 23:02:41

Over the last 2 weeks, how often have you been bothered by any of the following problems?

Little interest or pleasure in doing things

Not at all

Several days

More than half the days

Nearly every day

Feeling down, depressed, or hopeless

Not at all

Several days

More than half the days

Nearly every day

Trouble falling or staying asleep, or sleeping too much

Not at all

Several days

More than half the days

Nearly every day

Feeling tired or having little energy

Not at all

Several days

More than half the days

Nearly every day

Poor appetite or overeating

Not at all

Several days

More than half the days

Nearly every day

Feeling bad about yourself - or that you are a failure or have let yourself or your family down

Not at all

Several days

More than half the days

Nearly every day

Trouble concentrating on things, such as reading the newspaper or watching television

Not at all

Several days

More than half the days

Nearly every day

Moving or speaking so slowly that other people could have noticed. Or the opposite - being so figety or restless that you have been moving around a lot more than usual

Not at all

Several days

More than half the days

Nearly every day

Thoughts that you would be better off dead, or of hurting yourself

Not at all

Several days

More than half the days

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Patient Health Questionnaire

Generated On: 30 Oct 2020 23:02:41

Nearly every day

PHQ Calculated Total

If you mentioned any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all

Somewhat difficult

Very difficult

Extremely difficult

In the past year, have you felt depressed or sad most days, even if you felt OK sometimes?

Yes

No

Has there been a time in the past month when you have had serious thoughts about ending your life?

Yes

No

Have you ever, in your whole life, tried to kill yourself or made a suicide attempt?

Yes

No

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Physical Exam

Generated On: 30 Oct 2020 23:02:41

Was a physical exam performed? Yes
No

Date of exam _____

BODY SYSTEM

HEENT Not done
Normal
Abnormal

If "Abnormal", specify: _____

Neck Not done
Normal
Abnormal

If "Abnormal", specify: _____

Lymph Nodes Not done
Normal
Abnormal

If "Abnormal", specify: _____

Heart/Cardiovascular Not done
Normal
Abnormal

If "Abnormal", specify: _____

Lung/Respiratory Not done
Normal
Abnormal

If "Abnormal", specify: _____

Abdomen Not done
Normal
Abnormal

If "Abnormal", specify: _____

Genitourinary Not done
Normal
Abnormal

If "Abnormal", specify: _____

Extremities Not done
Normal
Abnormal

If "Abnormal", specify: _____

Neurological Not done

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Physical Exam

Generated On: 30 Oct 2020 23:02:41

Normal

Abnormal

If "Abnormal", specify: _____

Skin

Not done

Normal

Abnormal

If "Abnormal", specify: _____

General appearance

Not done

Normal

Abnormal

If "Abnormal", specify: _____

Other system finding

Not done

Normal

Abnormal

If "Other system finding", specify: _____

If "Abnormal", specify: _____

Comments (max. 200 characters): _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Pill Count Enrollment

Generated On: 30 Oct 2020 23:02:41

Record the number of pills dispensed at the Enrollment Visit.

Number of pills dispensed _____

Comments (max. 450 characters) _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Pill Count Step 1

Generated On: 30 Oct 2020 23:02:41

Date of pill count _____

Number of pills at this visit _____

Did the participant return any pills at this visit? Yes

If yes, record the number of pills returned at this visit. No

Number of pills returned _____

Was the participant dispensed any additional pills at this visit? Yes

If yes, record the number of pills dispensed at this visit. No

Number of additional pills dispensed _____

Comments (max. 450 characters) _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Protocol Deviations Log

Generated On: 30 Oct 2020 23:02:41

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
- 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
- Other

Description of deviation _____

Plans and/or action taken to address the deviation _____

Plans and/or action taken to prevent future occurrences of the deviation _____

Deviation reported by _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Protocol Deviations Y/N

Generated On: 30 Oct 2020 23:02:41

Have any protocol deviations been reported?

Yes

No

If "Yes", update the Protocol Deviations log.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Product Hold Y/N

Generated On: 30 Oct 2020 23:02:41

Does the participant have any clinical product holds to be applied?

Yes

No

If Yes, complete the Product Hold Log form

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Product Hold Log

Generated On: 30 Oct 2020 23:02:41

Date of last oral study product use: _____

Date of last injection: _____

Date when this study product hold was initiated: _____

At what visit was this product hold initiated? _____

- V101.0 - Screening
- V102.0 - Day 0/Enrollment
- V103.0 - Step 1 Week 2
- V104.0 - Step 1 Week 4
- V201.0 - Step 2 Week 5
- V202.0 - Step 2 Week 6
- V203.0 - Step 2 Week 9
- V204.0 - Step 2 Week 10
- V205.0 - Step 2 Week 17
- V206.0 - Step 2 Week 18
- V207.0 - Step 2 Week 25
- V208.0 - Step 2 Week 26
- V209.0 - Step 2 Week 33
- V210.0 - Step 2 Week 34
- V301.0 - Step 3 Week +8
- V302.0 - Step 3 Week +12
- V303.0 - Step 3 Week +24
- V304.0 - Step 3 Week +36
- V305.0 - Step 3 Week +48
- V401.0 - HIV Confirmation Visit
- V402.0 - HIV Week 12
- V403.0 - HIV Week 24
- V404.0 - HIV Week 36
- V405.0 - HIV Week 48
- Interim Visit

Interim visit code _____

- Why is the study product being held?
- Reported of use of prohibited concomitant medications
 - One or more reactive HIV test results or expresses concern about having acute HIV infection
 - Receiving PEP for potential HIV exposure
 - Adverse Event
 - Injection Site Reaction

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Product Hold Log

Generated On: 30 Oct 2020 23:02:41

Participant unable/unwilling to comply with the required study procedures, or otherwise might be put at undue risk to their safety and well-being by continuing product use according to the judgment of IoR/designee

Other

If "Other" is selected, please specify: _____

If product hold was associated with an adverse event, select the applicable AEs: _____

If product hold was associated with an injection site reaction, select the applicable ISR: _____

If product hold was associated with a new or updated concomitant medication, select applicable medication(s): _____

Will the participant resume study product? Yes

No - Hold continuing for another reason

No - Early termination

No - Permanently discontinued

Date participant resumed study product: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Social Impact

Generated On: 30 Oct 2020 23:02:41

Date reported to site _____

Concisely describe social impact (max. 200 characters). _____

Onset date _____

Reported at visit code _____

- V101.0 - Screening
- V102.0 - Day 0/Enrollment
- V103.0 - Step 1 Week 2
- V104.0 - Step 1 Week 4
- V201.0 - Step 2 Week 5
- V202.0 - Step 2 Week 6
- V203.0 - Step 2 Week 9
- V204.0 - Step 2 Week 10
- V205.0 - Step 2 Week 17
- V206.0 - Step 2 Week 18
- V207.0 - Step 2 Week 25
- V208.0 - Step 2 Week 26
- V209.0 - Step 2 Week 33
- V210.0 - Step 2 Week 34
- V301.0 - Step 3 Week +8
- V302.0 - Step 3 Week +12
- V303.0 - Step 3 Week +24
- V304.0 - Step 3 Week +36
- V305.0 - Step 3 Week +48
- V401.0 - HIV Confirmation Visit
- V402.0 - HIV Week 12
- V403.0 - HIV Week 24
- V404.0 - HIV Week 36
- V405.0 - HIV Week 48
- Interim Visit

If "Interim visit", specify Interim visit code _____

Social impact _____

Personal Relationships - Had any negative experiences with family, friends, significant others, or sex partners.

Travel/Immigration - Had problems obtaining formal permission to travel to or enter another country, such as being denied a visa, or had a problem with immigration/naturalization.

Employment - Been turned down for a job, lost a job, study visits interfering with work/work performance or experienced other problems at work.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Social Impact

Generated On: 30 Oct 2020 23:02:41

-
- Education - Been turned down by an educational program, told to leave an educational program, study visits interfering with school attendance/performance, or experienced other problems at school.
 - Medical/Dental - Been told you have an HIV test by a health care provider, been refused medical or dental treatment or treated negatively by a health care provider.
 - Health Insurance - Lost health insurance, had a problem getting new health insurance, or experienced other problems related to health insurance.
 - Life Insurance/Funeral coverage - Lost your life insurance policy or funeral cover policy, had a problem getting new life insurance policy or funeral cover policy, or experienced other problems related to life insurance policy or funeral cover policy.
 - Housing - Had trouble getting or keeping housing, had negative experience with landlord, or had other problems related to housing.
 - Military/Other Government Agency - Had a problem with the military or any other government agencies.
 - Other - Had other problems not covered in the list above.

If "Other", specify (max. 200 characters): _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Social Impact Y/N

Generated On: 30 Oct 2020 23:02:41

Has the participant experienced any social impacts related to study participation?

Yes

No

If "Yes", update the Social Impact log.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL
Form: Specimen Collection and Storage
Generated On: 30 Oct 2020 23:02:41

Specimen type Plasma
Dried Blood Spot

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters): _____

Specimen type Plasma
Dried Blood Spot

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters): _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: STI Tests

Generated On: 30 Oct 2020 23:02:41

Was a pharyngeal sample collected for N. gonorrhoea and C. trachomatis testing? Yes
No

Collection date _____

N. gonorrhoea - Pharyngeal test result
Detected
Non-detected
Equivocal
Invalid

C. trachomatis - Pharyngeal test result
Detected
Non-detected
Equivocal
Invalid

Was a urine sample collected for N. gonorrhoea and C. trachomatis testing? Yes
No

Collection date _____

N. gonorrhoea - URINE test result
Detected
Non-detected
Equivocal
Invalid

C. trachomatis - URINE test result
Detected
Non-detected
Equivocal
Invalid

Was a rectal swab sample collected for N. gonorrhoea and C. trachomatis testing? Yes
No

Collection date _____

N. gonorrhoea - RECTAL SWAB test result
Detected
Non-detected
Equivocal
Invalid

C. trachomatis - RECTAL SWAB test result
Detected
Non-detected
Equivocal
Invalid

Was a sample collected for Syphilis testing? Yes
No

Collection date _____

Syphilis screening test (Non-Treponemal) Non-reactive

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: STI Tests

Generated On: 30 Oct 2020 23:02:41

	Reactive	<input type="radio"/>
	Not reported	<input type="radio"/>
	Not done	<input type="radio"/>

Syphilis titer	
Syphilis confirmatory test (Treponemal)	Postive <input type="radio"/>
	Negative <input type="radio"/>
	Indeterminate <input type="radio"/>
	Not done <input type="radio"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Study Termination

Generated On: 30 Oct 2020 23:02:41

Date of study exit _____

Primary reason for completion/termination

Scheduled exit visit/end of study

Death

Participant refused further participation

Participant is unwilling or unable to comply with required study procedures

Lost to follow-up

Investigator decision

Participant refused further study product use

Early study closure

Protocol deviation

Adverse event

One or more reactive HIV test results or acute HIV infection suspected - Step 1

Other, specify

If "Other", specify (max. 200 characters): _____

If "Death", enter date of death. _____

If "Adverse event", select applicable adverse event. _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Supplemental HIV Results

Generated On: 30 Oct 2020 23:02:41

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Supplemental HIV Results

Generated On: 30 Oct 2020 23:02:41

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)

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Urinalysis

Generated On: 30 Oct 2020 23:02:41

Was a sample collected for urine tests? Yes
No

Date of collection: _____

Protein (Urine) Negative
Trace
1+
2+
3+
4+

Protein (Urine) Severity Grade Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

Protein (Urine) Adverse Event
Not reportable as an adverse event

Glucose (Urine) Negative
Trace
1+
2+
3+
4+

Glucose (Urine) Severity Grade Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

Glucose (Urine) Adverse Event
Not reportable as an adverse event

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

HPTN083-01_Version 4.0_PROD_BK_29OCT2020: ALL

Form: Vital Signs

Generated On: 30 Oct 2020 23:02:41

Were vital signs done? Yes
No

Date of assessment _____ Fixed Unit: cm

Height _____ Fixed Unit: cm

Weight _____ Fixed Unit: kg

BMI calculated _____ Fixed Unit: kg/m2

Body temperature _____ Fixed Unit: C

Systolic blood pressure _____ Fixed Unit: mmHg

Diastolic blood pressure _____ Fixed Unit: mmHg

Pulse _____ Fixed Unit: beats/min

Rate of respiration _____ Fixed Unit: breaths/min