Subject Case Report Forms

HPTN084-01_eCRFs - ALL

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

Form: Screening Date of Visit

Screening visit date	

Form: Date of Visit - Step 1

Did the participant complete this visit?	Yes ☐ No ☐
Visit Date	_____
Did the participant exit/terminate the study at this visit? If "Yes", please complete the Study Termination CRF.	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit? If "Yes", please complete the Adverse Event Log.	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported? If "Yes", please complete the Concomitant Medications Log.	Yes ☐ No ☐
Have any protocol deviations been reported at this visit? If "Yes", please complete the Protocol Deviations Log.	Yes ☐ 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? If yes, complete the Additional Procedures form, indicating which additional forms were needed 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.	Step 2 ☐ Pregnancy Schedule ☐
If the participant is not moving to Step 2 or the Pregnancy Schedule, please specify.	_____

Form: Date of Visit - Step 2

Did the participant complete this visit?	Yes ☐ No ☐
Visit Date	_____
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
If "Yes", please complete the Study Termination CRF.	
Were any new adverse events (AEs) reported at this visit?	Yes ☐ No ☐
If "Yes", please complete the Adverse Event Log.	
Is the participant taking any concomitant medications that have not been previously reported?	Yes ☐ No ☐
If "Yes", please complete the Concomitant Medications Log.	
Have any protocol deviations been reported at this visit?	Yes ☐ No ☐
If "Yes", please complete the Protocol Deviations Log.	
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 ☐ Pregnancy Schedule ☐ Seroconverter Schedule ☐ OLE ☐ OLE Pregnancy ☐
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 in Step 2	_____
WEEK 34 Visit ONLY	
Was Open Label PrEP dispensed at week 34?	Yes ☐ No ☐
If Oral PrEP was not dispensed, did the participant choose to continue to the 084 OLE?	Yes ☐ No ☐

Form: Date of Visit - Step 3

Did the participant complete this visit?	Yes ☐ No ☐
Visit Date	_____
Did the participant exit/terminate the study at this visit? If "Yes", please complete the Study Termination CRF.	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit? If "Yes", please complete the Adverse Event Log.	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported? If "Yes", please complete the Concomitant Medications Log.	Yes ☐ No ☐
Have any protocol deviations been reported at this visit? If "Yes", please complete the Protocol Deviations Log.	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.	
Is the participant moving to a different schedule?	Yes ☐ No ☐
If yes, please indicate which visit schedule.	Pregnancy Schedule ☐ Seroconverter Schedule ☐ OLE ☐ OLE Pregnancy ☐

Form: Date of Visit - OLE

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 ☐ No ☐
If "Yes", please complete the Concomitant Medications Log.	
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 schedule?	Yes ☐ No ☐
If yes, please indicate which visit schedule.	CAB ☐ TDF/FTC (Step 4c- TDF/FTC) ☐ Seroconvertor Schedule previous version ☐ Open Label Truvada Schedule previous version ☐ Pregnancy Schedule previous version ☐ Pregnancy and Infant Sub-Study ☐

Form: Date of Visit - Seroconverter

Schedule

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

Date of Visit - Pregnancy Schedule

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

Form: Informed Consent

Log Line #: _____

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 ☐

Form: Inclusion Exclusion Criteria **Log Line #:** _____

Has the participant screened for the study before?	Yes ☐ No ☐
If yes, record the first Rave PTID assigned:	_____
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," "Ineligible," or "Incomplete screening"	_____

If "Eligible and enrolled", or "Incomplete screening", end of form.

Select reason(s) why participant is ineligible.	I1. Assigned female at birth ☐ I2. At enrollment, below 18 years of age ☐ I3. At enrollment, body weight ≥ 35 kg (77 lbs.) ☐ I4. Willing to provide written informed assent/consent for the study and/or able to obtain written parental/guardian informed consent ☐ I5. Self-reported sexual activity with a male (oral, anal or vaginal) in the past 12 months ☐ I6a. Non-reactive / negative HIV test results ☐ I6b. Absolute neutrophil count > 799 cells/mm3 ☐ I6c. Platelet count ≥ 100,000/mm3 ☐ I6d. Hemoglobin ≥ 11g/dL ☐ I6e. Calculated creatinine clearance ≥ 60 mL/minute using modified Schwartz equation ☐ I6f. Alanine aminotransferase (ALT) < 2.0 times the upper limit of normal (ULN) (≤ grade 1) and total bilirubin (Tbili) ≤ 2.5 x ULN ☐ I6g. Hepatitis B virus (HBV) surface antigen (HBsAg) negative and accepts vaccination ☐ I6h. HCV Antibody negative ☐ I7. Willing to undergo all required study procedures ☐

Form: Inclusion Exclusion Criteria

	☐ I8. Must have a negative beta human chorionic gonadotropin (βHCG) pregnancy test (sensitivity of ≤ 25 mIU/mL) performed (and results known) on the same day as Enrollment and before initiating study product
	☐ I9. Must agree to use a reliable form of long acting contraception, during the trial and for 48 weeks after stopping the long acting injectable, or 30 days after stopping oral study product, from the list: Intrauterine device (IUD) or intrauterine system (IUS) that meets <1% failure rate as stated in the product label OR Hormone-based contraceptive that meets <1% failure rate when used consistently and correctly as stated in the product label (implants or injectables only; this excludes combined oral contraception)
	☐ I10. 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.
	☐ E1. 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)
	☐ E3. Past or current participation in HIV vaccine trial with exception for participants who can provide documentation of receipt of placebo
	☐ E4. Exclusively had sex with biological females in lifetime
	☐ E5c. 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

Form: Inclusion Exclusion Criteria

	E6. 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 ☐
	E7. Inflammatory skin conditions that compromise the safety of intramuscular (IM) injections ☐
	E8. Tattoo or other dermatological condition overlying the buttock region that may interfere with interpretation of injection site reactions ☐
	E9. 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) ☐
	E10. Known history of clinically significant bleeding ☐
	E11. A history of seizure disorder, per self-report ☐
	E12. 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) ☐
	E13. 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 ☐
	E14. Pregnant or currently breastfeeding at the time of screening or intends to become pregnant and/or breastfeed while on study ☐
If "Investigator decision", specify (max. 200 characters):	_____
If eligible, but participant declined enrollment, specify reason:	_____

Form: Enrollment

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	_____

Form: Demographics

Date of birth	_____
Age	Fixed Unit: yrs
	_____
Sex at birth	Male ☐
	Female ☐
Race	_____
Gender	
Mark all that apply.	
Gender Female	☐
Gender Nonconforming/Gender Variant	☐
Gender Male	☐
Gender Self-identify	☐
Gender Self-identify Other Specify	_____
Gender Transgender Female	☐
Gender Transgender Male	☐
Gender 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:	_____

Form: Vital Signs

Were vital signs done?	Yes ☐ No ☐
Date of assessment	
Height	Fixed Unit: cm
Weight	Fixed Unit: kg
BMI calculated	Fixed Unit: derived field (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
Oxygen Saturation	Fixed Unit: %

Form: HIV Test Results **Log Line #: _____**

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 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 ☐

Form: Pregnancy Test Results

Was a pregnancy test done?	Yes ☐
	No ☐
Date of pregnancy test	_____
Specimen type (Mark only one):	Urine ☐
	Plasma ☐
	Serum ☐
Pregnancy test result	Positive ☐
	Negative ☐

Form: Adverse Event Y/N

Has the participant experienced an adverse event during the study?	Yes ☐ No ☐

If "Yes", update the Adverse Event log.

Form: Adverse Event

Log Line #: _____

Date AE reported to site	_____
Adverse event (AE)	_____
Onset date	_____
Visit AE was reported	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 ☐
	V501.0 - Pregnancy Confirmation Visit ☐
	V502.0 - Pregnancy Week 12 ☐
	V503.0 - Pregnancy Week 24 ☐
	V504.0 - Pregnancy Week 36 ☐
	V505.0 - Pregnancy Week 48 ☐
	V600.0 - OLE Week 0 ☐
	V601.0 - OLE Week 8 ☐
	V602.0 - OLE Week 16 ☐
	V603.0 - OLE Week 24 ☐
	V604.0 - OLE Week 32 ☐
	V605.0 - OLE Week 40 ☐

Form: Adverse Event

- [ ] V606.0 - OLE Week 48
- [ ] V55.0 - Step 4a - Day 0
- [ ] V56.0 - Step 4b - Day 0
- [ ] V57.0 - Step 4c-CAB LA - Week 0
- [ ] V58.0 - Step 4c-CAB LA - Week 8
- [ ] V59.0 - Step 4c-CAB LA - Week 16
- [ ] V60.0 - Step 4c-CAB LA - Week 24
- [ ] V61.0 - Step 4c-CAB LA - Week 32
- [ ] V62.0 - Step 4c-CAB LA - Week 40
- [ ] V63.0 - Step 4c-CAB LA - Week 48
- [ ] V64.0 - Step 4c-TDF/FTC - Week 0
- [ ] V65.0 - Step 4c-TDF/FTC - Week 8
- [ ] V66.0 - Step 4c-TDF/FTC - Week 16
- [ ] V67.0 - Step 4c-TDF/FTC - Week 24
- [ ] V68.0 - Step 4c-TDF/FTC - Week 32
- [ ] V69.0 - Step 4c-TDF/FTC - Week 40
- [ ] V70.0 - Step 4c-TDF/FTC - Week 48
- [ ] V71.0 - Step 5-TDF/FTC - Day 0
- [ ] V72.0 - Step 5-TDF/FTC - Week 12
- [ ] V73.0 - Step 5-TDF/FTC - Week 24
- [ ] V74.0 - Step 5-TDF/FTC - Week 36
- [ ] V75.0 - Step 5-TDF/FTC - Week 48
- [ ] V76.0 - Step 4d - Week 0
- [ ] V77.0 - Step 4d - Week 4
- [ ] V78.0 - Step 4d - Week 8
- [ ] V79.0 - Step 4d - Week 12
- [ ] V80.0 - Step 4d - Week 16
- [ ] V81.0 - Step 4d - Week 20
- [ ] V82.0 - Step 4d - Week 24
- [ ] V83.0 - Step 4d - Week 28
- [ ] V84.0 - Step 4d - Week 32
- [ ] V85.0 - Step 4d - Week 36
- [ ] V86.0 - Step 4d - Week 40

Adverse Event

	V87.0 - Step 4d - Week 2 PP ☐
	V88.0 - Step 4d - Week 4 PP ☐
	V89.0 - Step 4d - Week 8 PP ☐
	V90.0 - Step 4d - Week 16 PP ☐
	V91.0 - Step 4d - Week 24 PP ☐
	V92.0 - Step 4d - Week 32 PP ☐
	V93.0 - Step 4d - Week 40 PP ☐
	V94.0 - Step 4d - Week 48 PP ☐
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 ☐
	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 ☐

Form: Adverse Event

	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? If "No", go to "Has or will this AE be reported as an EAE?". If "Yes", check all that apply.	Yes ☐ No ☐
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? If "Yes", provide EAE number below.	Yes ☐ No ☐
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):	_____

Form: Participant Identifier

Participant ID: _____

Form: Injection Administration

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	_____

Form: Supplemental HIV Results

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	

Form: Supplemental HIV Results

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)	_____

Form: Interim Visit

Interim visit date	_____
Interim visit code	_____
Was study product use permanently discontinued (scheduled or early) at this visit? If "Yes", please complete the Discontinuation of Study Product" CRF.	Yes ☐ No ☐
Did the participant exit/terminate the study at this visit? If "Yes", please complete the Study Termination CRF.	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit? If "Yes", please complete the Adverse Event Log.	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported? If "Yes", please complete the Concomitant Medications Log.	Yes ☐ No ☐
Have any protocol deviations been reported at this visit? If "Yes", please complete the Protocol Deviations Log.	Yes ☐ 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 ☐ Pregnancy Schedule ☐ OLE ☐ OLE Pregnancy ☐
Mark all forms completed at this visit.	
CD4 Test Results/Viral Load	☐
Chemistry Panel	☐
Counseling	☐
Fasting Lipid Test Results	☐

Form: Interim Visit

Hematology	☐
Hepatitis Test Results	☐
HIV Test Results	☐
Injection Administration	☐
CASI	☐
Participant Receipt	☐
Participant Transfer	☐
Specimen Collection and Storage	☐
STI Tests	☐
Urinalysis	☐
Physical Exam	☐
Vital Signs	☐
Pill Count Step 1	☐
Pregnancy Test Results	☐
Contraception	☐
Product Choice OLE	☐

Form: Additional Study Procedures

Select any additional forms completed at this visit.	
CD4 Test Results/Viral Load	☐
Chemistry Panel	☐
Hematology	☐
STI Tests	☐
Injection Administration	☐
Fasting Lipid Test Results	☐
Hepatitis Test Results	☐
Participant Receipt	☐
Participant Transfer	☐
Urinalysis	☐
CASI	☐
HIV Test Results	☐
Physical Exam	☐
Counseling	☐
Pregnancy Test Results	☐
Contraception	☐
Supplemental HIV Results	☐
Product Choice OLE	☐

Form: Specimen Collection and Storage

Log Line #: _____

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).	_____

Form: Behavioral Assessment

Was a CASI questionnaire completed at this visit?	Yes ☐
	No ☐
If no, please explain:	

Form: CASI Tracking

CASI collection date	_____
CASI ID	_____
Which questionnaire was completed?	V102.0 - Day 0/Enrollment ☐
	V104.0 - Step 1 Week 4 ☐
	V201.0 - Step 2 Week 5 ☐
	V203.0 - Step 2 Week 9 ☐
	V205.0 - Step 2 Week 17 ☐
	V207.0 - Step 2 Week 25 ☐
	V209.0 - Step 2 Week 33 ☐
	V302.0 - Step 3 Week +12 ☐
	V303.0 - Step 3 Week +24 ☐
	V304.0 - Step 3 Week +36 ☐
	V305.0 - Step 3 Week +48 ☐
	V502.0 - Pregnancy Week 12 ☐
	V503.0 - Pregnancy Week 24 ☐
	V504.0 - Pregnancy Week 36 ☐
	V505.0 - Pregnancy Week 48 ☐
	V501.0 - Pregnancy Week 4 ☐
	V600.0 - OLE Week 0 ☐
	V601.0 - OLE Week 8 ☐
	V602.0 - OLE Week 16 ☐
	V603.0 - OLE Week 24 ☐
	V604.0 - OLE Week 32 ☐
	V605.0 - OLE Week 40 ☐
	V606.0 - OLE Week 48 ☐
	V55.0 - Step 4a - Day 0 ☐
	V56.0 - Step 4b - Day 0 ☐
	V57.0 - Step 4c-CAB LA - Week 0 ☐
	V58.0 - Step 4c-CAB LA - Week 8 ☐
	V59.0 - Step 4c-CAB LA - Week 16 ☐
	V60.0 - Step 4c-CAB LA - Week 24 ☐
	V61.0 - Step 4c-CAB LA - Week 32 ☐
	V62.0 - Step 4c-CAB LA - Week 40 ☐
	V63.0 - Step 4c-CAB LA - Week 48 ☐
	V64.0 - Step 4c-TDF/FTC - Week 0 ☐
	V65.0 - Step 4c-TDF/FTC - Week 8 ☐

Form: CASI Tracking

	V66.0 - Step 4c-TDF/FTC - Week 16 ☐
	V67.0 - Step 4c-TDF/FTC - Week 24 ☐
	V68.0 - Step 4c-TDF/FTC - Week 32 ☐
	V69.0 - Step 4c-TDF/FTC - Week 40 ☐
	V70.0 - Step 4c-TDF/FTC - Week 48 ☐
	V71.0 - Step 5-TDF/FTC - Day 0 ☐
	V72.0 - Step 5-TDF/FTC - Week 12 ☐
	V73.0 - Step 5-TDF/FTC - Week 24 ☐
	V74.0 - Step 5-TDF/FTC - Week 36 ☐
	V75.0 - Step 5-TDF/FTC - Week 48 ☐
	V76.0 - Step 4d - Week 0 ☐
	V77.0 - Step 4d - Week 4 ☐
	V78.0 - Step 4d - Week 8 ☐
	V79.0 - Step 4d - Week 12 ☐
	V80.0 - Step 4d - Week 16 ☐
	V81.0 - Step 4d - Week 20 ☐
	V82.0 - Step 4d - Week 24 ☐
	V83.0 - Step 4d - Week 28 ☐
	V84.0 - Step 4d - Week 32 ☐
	V85.0 - Step 4d - Week 36 ☐
	V86.0 - Step 4d - Week 40 ☐
	V87.0 - Step 4d - Week 2 PP ☐
	V88.0 - Step 4d - Week 4 PP ☐
	V89.0 - Step 4d - Week 8 PP ☐
	V90.0 - Step 4d - Week 16 PP ☐
	V91.0 - Step 4d - Week 24 PP ☐
	V92.0 - Step 4d - Week 32 PP ☐
	V93.0 - Step 4d - Week 40 PP ☐
	V94.0 - Step 4d - Week 48 PP ☐
Were there any problems or issues related to the administration or completion of the questionnaire?	Yes ☐ No ☐
If yes, please describe	_____

Form: CD4 Test Results/Viral Load

ABSOLUTE CD4+	
Were Absolute CD4+ collected for testing?	Yes ☐ No ☐
Specimen collection date	_____
Absolute CD4+	_____
Unable to analyze	☐
HIV RNA	
Was HIV RNA PCR testing completed?	Yes ☐ No ☐
Specimen collection date	_____
Operator	> ☐ < ☐ = ☐
HIV RNA PCR	_____
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 Test Results/Viral Load form is needed to capture additional testing data	

Form: Concomitant Medications Y/N

Were any concomitant medications taken?	Yes ☐
	No ☐

If "Yes", update the Concomitant Medications log.

Form: Concomitant Medications **Log Line #: _____**

Medication name _____

Select if this is generic TDF/FTC (Truvada) ☐

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 - As needed ☐
- QD - Once a day ☐
- BID - Twice a day ☐
- TID - Three times a day ☐
- QID - Four times a day ☐
- QM - Every morning ☐
- QH - Every Hour ☐
- ONCE - Single dose ☐
- Other ☐

If "Other", specify: _____

Route

- Inhalation ☐
- Intramuscular ☐
- Intravenous ☐
- Other ☐
- Oral ☐

Form: Concomitant Medications

	Rectal ☐
	Subcutaneous ☐
	Topical ☐
	Vaginal ☐
If "Other", specify:	_____
Taken for a reported AE?	Yes ☐
	No ☐
If "Yes", select adverse event.	_____
Taken for a reported Injection site reaction?	Yes ☐
	No ☐
If "Yes", select injection site reaction event.	_____
Select additional injection site reaction, if applicable	_____

Form: Counseling

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	☐
Adherence reminder strategies	☐
Barriers to adherence	☐
Communication skills	☐
Product Storage	☐
Disclosing product use to others	☐
Planning for future PrEP use	☐
Pill or injection education	☐
Problem solving	☐
Social Support	☐
Parental Support	☐
Other	☐
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	☐
Barriers to return for study visits (e.g., money, transportation, time)	☐
Disruption in routine (for example, travel away from home)	☐
Forgetting/no pills available	☐
Job/School commitments	☐
Lack of privacy	☐
Medication side effects	☐
Negative reactions (family, friends, partner)	☐
Partying/drugs/alcohol	☐
Side effects	☐
Other	☐
If other, please specify:	_____

Form: Discontinuation of Study Product

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 ☐
	V501.0 - Pregnancy Confirmation Visit ☐
	V502.0 - Pregnancy Week 12 ☐
	V503.0 - Pregnancy Week 24 ☐
	V504.0 - Pregnancy Week 36 ☐
	V505.0 - Pregnancy Week 48 ☐
	V600.0 - OLE Week 0 ☐
	V601.0 - OLE Week 8 ☐
	V602.0 - OLE Week 16 ☐
	V603.0 - OLE Week 24 ☐
	V604.0 - OLE Week 32 ☐
	V605.0 - OLE Week 40 ☐
	V606.0 - OLE Week 48 ☐

Form: Discontinuation of Study Product

- [ ] V701.0 - OLE Pregnancy Week 4
- [ ] V702.0 - OLE Pregnancy Week 8
- [ ] V703.0 - OLE Pregnancy Week 12
- [ ] V704.0 - OLE Pregnancy Week 16
- [ ] V705.0 - OLE Pregnancy Week 20
- [ ] V706.0 - OLE Pregnancy Week 24
- [ ] V707.0 - OLE Pregnancy Week 28
- [ ] V708.0 - OLE Pregnancy Week 32
- [ ] V709.0 - OLE Pregnancy Week 36
- [ ] V710.0 - OLE Pregnancy Week 40
- [ ] V711.0 - OLE Pregnancy Delivery
- [ ] V712.0 - OLE Pregnancy Week 1 PP
- [ ] V713.0 - OLE Pregnancy Week 4 PP
- [ ] V714.0 - OLE Pregnancy Week 8 PP
- [ ] V715.0 - OLE Pregnancy Week 16 PP
- [ ] V716.0 - OLE Pregnancy Week 24 PP
- [ ] V717.0 - OLE Pregnancy Week 32 PP
- [ ] V718.0 - OLE Pregnancy Week 40 PP
- [ ] V719.0 - OLE Pregnancy Week 48 PP
- [ ] V55.0 - Step 4a - Day 0
- [ ] V56.0 - Step 4b - Day 0
- [ ] V57.0 - Step 4c-CAB LA - Week 0
- [ ] V58.0 - Step 4c-CAB LA - Week 8
- [ ] V59.0 - Step 4c-CAB LA - Week 16
- [ ] V60.0 - Step 4c-CAB LA - Week 24
- [ ] V61.0 - Step 4c-CAB LA - Week 32
- [ ] V62.0 - Step 4c-CAB LA - Week 40
- [ ] V63.0 - Step 4c-CAB LA - Week 48
- [ ] V64.0 - Step 4c-TDF/FTC - Week 0
- [ ] V65.0 - Step 4c-TDF/FTC - Week 8
- [ ] V66.0 - Step 4c-TDF/FTC - Week 16

Form: Discontinuation of Study Product

	V67.0 - Step 4c-TDF/FTC - Week 24 ☐
	V68.0 - Step 4c-TDF/FTC - Week 32 ☐
	V69.0 - Step 4c-TDF/FTC - Week 40 ☐
	V70.0 - Step 4c-TDF/FTC - Week 48 ☐
	V71.0 - Step 5-TDF/FTC - Day 0 ☐
	V72.0 - Step 5-TDF/FTC - Week 12 ☐
	V73.0 - Step 5-TDF/FTC - Week 24 ☐
	V74.0 - Step 5-TDF/FTC - Week 36 ☐
	V75.0 - Step 5-TDF/FTC - Week 48 ☐
	V76.0 - Step 4d - Week 0 ☐
	V77.0 - Step 4d - Week 4 ☐
	V78.0 - Step 4d - Week 8 ☐
	V79.0 - Step 4d - Week 12 ☐
	V80.0 - Step 4d - Week 16 ☐
	V81.0 - Step 4d - Week 20 ☐
	V82.0 - Step 4d - Week 24 ☐
	V83.0 - Step 4d - Week 28 ☐
	V84.0 - Step 4d - Week 32 ☐
	V85.0 - Step 4d - Week 36 ☐
	V86.0 - Step 4d - Week 40 ☐
	V87.0 - Step 4d - Week 2 PP ☐
	V88.0 - Step 4d - Week 4 PP ☐
	V89.0 - Step 4d - Week 8 PP ☐
	V90.0 - Step 4d - Week 16 PP ☐
	V91.0 - Step 4d - Week 24 PP ☐
	V92.0 - Step 4d - Week 32 PP ☐
	V93.0 - Step 4d - Week 40 PP ☐
	V94.0 - Step 4d - Week 48 PP ☐
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 ☐

Form: Discontinuation of Study Product

	☐ Investigator decision
	☐ Participant refused further study product use
	☐ HIV infection
	☐ Early study closure
	☐ 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
	☐ Positive pregnancy test result
	☐ Low oral adherence - Step 1
	☐ Other, specify
If "Other" is selected, please 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.	_____

Form: Protocol Deviations Y/N

Have any protocol deviations been reported?	Yes ☐
	No ☐

If "Yes", update the Protocol Deviations log.

Form: Protocol Deviations Log

Log Line #: _____

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 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	_____

Form: Injection Site Reaction Y/N

Has the participant experienced any Injection Site Reactions?	Yes ☐ No ☐

If yes, complete the Injection Site Reaction Log.

Form: Hematology

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) ☐

Form: Hematology

	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):	

Form: Chemistry Panel

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	☐

Form: Chemistry Panel

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

Form: Chemistry Panel

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 ☐

Form: Chemistry Panel

Albumin result	
Albumin severity grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable ☐
Albumin adverse event	
Not reportable as an adverse event	☐
Comments (max. 200 characters):	

Form: Hepatitis Test Results

Was a sample collected for Hepatitis B Surface Antigen (HBsAG) testing?	Yes ☐ No ☐
Date of collection	_____
Hepatitis B Surface Antigen (HBsAG)	Positive/Reactive ☐ Negative/Non-reactive ☐ Not Done ☐
Was a sample collected for Hepatitis B Surface Antibody (HBsAb) testing?	Yes ☐ No ☐
Date of collection	_____
Hepatitis B Surface Antibody (HBsAb)	Positive/Reactive ☐ Negative/Non-reactive ☐ Not Done ☐
Was a sample collected for Hepatitis B Core Antibody (HBcAb) testing?	Yes ☐ No ☐
Date of collection	_____
Hepatitis B Core Antibody (HBcAb)	Positive/Reactive ☐ Negative/Non-reactive ☐ Not Done ☐
Was a sample collected for Hepatitis C Antibody (HCAb) testing?	Yes ☐ No ☐
Date of collection	_____
Hepatitis C Antibody (HCAb)	Positive/Reactive ☐ Negative/Non-reactive ☐ Not Done ☐

Form: Fasting Lipid Test Results

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	☐

Form: STI Tests

Was a urine sample collected for N. gonorrhea and C. trachomatis testing?	Yes ☐ No ☐
Collection date	_____
N. gonorrhea - URINE test result	Detected ☐ Non-detected ☐ Equivocal ☐ Invalid ☐
C. trachomatis - URINE test result	Detected ☐ Non-detected ☐ Equivocal ☐ Invalid ☐
Was a vaginal swab sample collected for N. gonorrhea and C. trachomatis testing?	Yes ☐ No ☐
Collection date	_____
N. gonorrhea - VAGINAL SWAB test result	Detected ☐ Non-detected ☐ Equivocal ☐ Invalid ☐
C. trachomatis - VAGINAL SWAB test result	Detected ☐ Non-detected ☐ Equivocal ☐ Invalid ☐
Was a sample collected for TV	Yes ☐ No ☐
Collection date	_____
Trichomonas vaginalis - Rapid Test	Negative ☐ Positive ☐ Invalid ☐
Or select if not done	☐
Trichomonas vaginalis - Wet prep	Negative ☐ Positive ☐ Invalid ☐
Or select if not done	☐
SCREENING, WEEK 33, STEP 3 WEEK +36 ONLY	
Was a sample collected for Syphilis testing?	Yes ☐ No ☐
Collection date	_____

Form: STI Tests

Syphilis screening test (Non-Treponemal)	Non-reactive ☐ Reactive ☐ Not reported ☐ Not done ☐
Syphilis titer	_____
Syphilis confirmatory test (Treponemal)	Positive ☐ Negative ☐ Indeterminate ☐ Not done ☐

Form: Urinalysis

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	_____
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	_____

Form: Medical History Y/N

Does the participant have any medical history to report?	Yes ☐ No ☐

If "Yes", update the Medical History log.

Form: Medical History

Log Line #: _____

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):	_____
Comments (max. 200 characters):	_____

Form: Missed Visit

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)	_____

Form: Physical Exam

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 ☐

Form: Physical Exam

	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):	_____

Form: Product Hold Y/N

Does the participant have any clinical product holds to be applied?	Yes ☐ No ☐
If Yes, complete the Product Hold Log	

Form: Product Hold Log

Log Line #: _____

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
- ☐ V501.0 - Pregnancy Confirmation Visit
- ☐ V502.0 - Pregnancy Week 12
- ☐ V503.0 - Pregnancy Week 24
- ☐ V504.0 - Pregnancy Week 36
- ☐ V505.0 - Pregnancy Week 48
- ☐ V600.0 - OLE Week 0
- ☐ V601.0 - OLE Week 8
- ☐ V602.0 - OLE Week 16
- ☐ V603.0 - OLE Week 24
- ☐ V604.0 - OLE Week 32

Form: Product Hold Log

- [ ] V605.0 - OLE Week 40
- [ ] V606.0 - OLE Week 48
- [ ] V701.0 - OLE Pregnancy Week 4
- [ ] V702.0 - OLE Pregnancy Week 8
- [ ] V703.0 - OLE Pregnancy Week 12
- [ ] V704.0 - OLE Pregnancy Week 16
- [ ] V705.0 - OLE Pregnancy Week 20
- [ ] V706.0 - OLE Pregnancy Week 24
- [ ] V707.0 - OLE Pregnancy Week 28
- [ ] V708.0 - OLE Pregnancy Week 32
- [ ] V709.0 - OLE Pregnancy Week 36
- [ ] V710.0 - OLE Pregnancy Week 40
- [ ] V711.0 - OLE Pregnancy Delivery
- [ ] V712.0 - OLE Pregnancy Week 1 PP
- [ ] V713.0 - OLE Pregnancy Week 4 PP
- [ ] V714.0 - OLE Pregnancy Week 8 PP
- [ ] V715.0 - OLE Pregnancy Week 16 PP
- [ ] V716.0 - OLE Pregnancy Week 24 PP
- [ ] V717.0 - OLE Pregnancy Week 32 PP
- [ ] V718.0 - OLE Pregnancy Week 40 PP
- [ ] V719.0 - OLE Pregnancy Week 48 PP
- [ ] V55.0 - Step 4a - Day 0
- [ ] V56.0 - Step 4b - Day 0
- [ ] V57.0 - Step 4c-CAB LA - Week 0
- [ ] V58.0 - Step 4c-CAB LA - Week 8
- [ ] V59.0 - Step 4c-CAB LA - Week 16
- [ ] V60.0 - Step 4c-CAB LA - Week 24
- [ ] V61.0 - Step 4c-CAB LA - Week 32
- [ ] V62.0 - Step 4c-CAB LA - Week 40
- [ ] V63.0 - Step 4c-CAB LA - Week 48
- [ ] V64.0 - Step 4c-TDF/FTC - Week 0

Form: Product Hold Log

	V65.0 - Step 4c-TDF/FTC - Week 8 ☐
	V66.0 - Step 4c-TDF/FTC - Week 16 ☐
	V67.0 - Step 4c-TDF/FTC - Week 24 ☐
	V68.0 - Step 4c-TDF/FTC - Week 32 ☐
	V69.0 - Step 4c-TDF/FTC - Week 40 ☐
	V70.0 - Step 4c-TDF/FTC - Week 48 ☐
	V71.0 - Step 5-TDF/FTC - Day 0 ☐
	V72.0 - Step 5-TDF/FTC - Week 12 ☐
	V73.0 - Step 5-TDF/FTC - Week 24 ☐
	V74.0 - Step 5-TDF/FTC - Week 36 ☐
	V75.0 - Step 5-TDF/FTC - Week 48 ☐
	V76.0 - Step 4d - Week 0 ☐
	V77.0 - Step 4d - Week 4 ☐
	V78.0 - Step 4d - Week 8 ☐
	V79.0 - Step 4d - Week 12 ☐
	V80.0 - Step 4d - Week 16 ☐
	V81.0 - Step 4d - Week 20 ☐
	V82.0 - Step 4d - Week 24 ☐
	V83.0 - Step 4d - Week 28 ☐
	V84.0 - Step 4d - Week 32 ☐
	V85.0 - Step 4d - Week 36 ☐
	V86.0 - Step 4d - Week 40 ☐
	V87.0 - Step 4d - Week 2 PP ☐
	V88.0 - Step 4d - Week 4 PP ☐
	V89.0 - Step 4d - Week 8 PP ☐
	V90.0 - Step 4d - Week 16 PP ☐
	V91.0 - Step 4d - Week 24 PP ☐
	V92.0 - Step 4d - Week 32 PP ☐
	V93.0 - Step 4d - Week 40 PP ☐
	V94.0 - Step 4d - Week 48 PP ☐
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 ☐

Form: Product Hold Log

	Adverse Event ☐ Injection Site Reaction ☐ Positive pregnancy test result ☐ Hepatitis B infection ☐ 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:	_____

Form: Outcome Log **Log Line #:** _____

Is the outcome of this pregnancy obtainable?	Yes ☐ No ☐
If "No", end of form.	
How many pregnancy outcomes resulted from this reported pregnancy?	_____
Outcome date	_____
Place of delivery/outcome	Home ☐ Hospital ☐ Clinic ☐ Unknown ☐ Other ☐
If "Other", specify:	_____
Specify outcome If "Stillbirth/intrauterine fetal demise", "Spontaneous abortion", "Ectopic pregnancy" or "Therapeutic/elective abortion" is chosen, go to "Provide a brief narrative of the circumstances:". If "Full term live birth" or "Premature live birth" , go to "Method".	Full term live birth (greater than or equal to 37 weeks) ☐ Premature live birth (less than 37 weeks) ☐ Stillbirth/intrauterine fetal demise (greater than or equal to 20 weeks) ☐ Spontaneous abortion (less than 20 weeks) ☐ Ectopic pregnancy ☐ Therapeutic/elective abortion ☐ Other ☐
If "Other", specify:	_____
Method	C-section ☐ Standard vaginal ☐ Operative vaginal ☐
Provide a brief narrative of the circumstances (max. 400 characters).	_____
Were there any complications related to the pregnancy outcome? If "No", skip to "Were any fetal/infant congenital anomalies identified?".	Yes ☐ No ☐
Delivery-related complications.Mark "None" or all that apply.	☐
None	
Intrapartum hemorrhage	☐
Postpartum hemorrhage	☐
Non-reassuring fetal status	☐
Chorioamnionitis	☐
Other	☐

Form: Pregnancy Outcome Log

If "Other", specify:	_____
Non-delivery related complications.Mark "None" or all that apply.	☐
None	
Hypertensive disorders of pregnancy	☐
Gestational diabetes	☐
Other	☐
If "Other", specify:	_____
Were any fetal/infant congenital anomalies identified? Mark all that apply.	Yes ☐ No ☐ Not assessed ☐ Unknown ☐
If "No" or "Unknown", go to "Complete the infant items below for live births only."	
Central nervous system, cranio-facial	☐
Central nervous system, spinal	☐
Cardiovascular	☐
Renal	☐
Gastrointestinal	☐
Pulmonary	☐
Musculoskeletal/extremities	☐
Physical defect	☐
Skin	☐
Genitourinary	☐
Chromosomal	☐
Cranio-facial (structural)	☐
Hematologic	☐
Infectious	☐
Endocrine/metabolic	☐
Other	☐
Describe congenital anomaly/defect (max. 200 characters).	_____
Specify congenital anomaly/defect AE.	
Complete AE Log and EAE Reporting form.	_____

Form: Pregnancy Outcome Log

Complete the infant items below for live births only. Otherwise, end of form.

Male ☐
Female ☐

Infant sex

Infant birth weight — Fixed Unit: kg

Or

Infant birth weight unavailable ☐

Infant birth length — Fixed Unit: cm

Or

Infant birth length unavailable ☐

Infant birth head circumference — Fixed Unit: cm

Or

Infant birth head circumference unavailable ☐

Infant birth abdominal circumference — Fixed Unit: cm

Or

Infant birth abdominal circumference unavailable ☐

Infant gestational age by examination in weeks — Fixed Unit: Weeks

Infant gestational age by examination in days — Fixed Unit: Days

Or

Infant gestational age by examination unavailable ☐

If unavailable, end of form.

Form: Pregnancy Outcome Log

Method used to determine gestational age	Ballard ☐
	Dubowitz ☐
	Other ☐
If "Other", specify (max. 200 characters):	_____

Form: Participant Receipt

Name of receiving study site	Harare - Spilhaus ☐ Johannesburg - Ward 21 ☐ Makerere, Kampala, Uganda ☐
Name of transferring study site	Harare - Spilhaus ☐ Johannesburg - Ward 21 ☐ Makerere, Kampala, Uganda ☐
Date informed consent signed at receiving site	_____

Form: Pregnancy History

Date pregnancy history collected	_____
Has the participant ever been pregnant before?	Yes ☐ No ☐
If "No", end of form.	
Number of full term live births (>=37 weeks)	_____
Number of premature live births (Less than 37 weeks)	_____
Number of spontaneous fetal deaths and/or still births (>=20 weeks)	_____
Number of spontaneous abortions (Less than 20 weeks)	_____
Number of therapeutic/elective abortions	_____
Number of ectopic pregnancies	_____
Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?	Yes ☐ No ☐
If "Yes", specify (max. 200 characters):	_____

Form: Pregnancy Report

Date pregnancy reported to site	_____
Visit at which this pregnancy 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 ☐
	V501.0 - Pregnancy Confirmation Visit ☐
	V502.0 - Pregnancy Week 12 ☐
	V503.0 - Pregnancy Week 24 ☐
	V504.0 - Pregnancy Week 36 ☐
	V505.0 - Pregnancy Week 48 ☐
	V600.0 - OLE Week 0 ☐
	V601.0 - OLE Week 8 ☐
	V602.0 - OLE Week 16 ☐
	V603.0 - OLE Week 24 ☐
	V604.0 - OLE Week 32 ☐
	V605.0 - OLE Week 40 ☐
	V606.0 - OLE Week 48 ☐

Form: Pregnancy Report

- [ ] V701.0 - OLE Pregnancy Week 4
- [ ] V702.0 - OLE Pregnancy Week 8
- [ ] V703.0 - OLE Pregnancy Week 12
- [ ] V704.0 - OLE Pregnancy Week 16
- [ ] V705.0 - OLE Pregnancy Week 20
- [ ] V706.0 - OLE Pregnancy Week 24
- [ ] V707.0 - OLE Pregnancy Week 28
- [ ] V708.0 - OLE Pregnancy Week 32
- [ ] V709.0 - OLE Pregnancy Week 36
- [ ] V710.0 - OLE Pregnancy Week 40
- [ ] V711.0 - OLE Pregnancy Delivery
- [ ] V712.0 - OLE Pregnancy Week 1 PP
- [ ] V713.0 - OLE Pregnancy Week 4 PP
- [ ] V714.0 - OLE Pregnancy Week 8 PP
- [ ] V715.0 - OLE Pregnancy Week 16 PP
- [ ] V716.0 - OLE Pregnancy Week 24 PP
- [ ] V717.0 - OLE Pregnancy Week 32 PP
- [ ] V718.0 - OLE Pregnancy Week 40 PP
- [ ] V719.0 - OLE Pregnancy Week 48 PP
- [ ] V55.0 - Step 4a - Day 0
- [ ] V56.0 - Step 4b - Day 0
- [ ] V57.0 - Step 4c-CAB LA - Week 0
- [ ] V58.0 - Step 4c-CAB LA - Week 8
- [ ] V59.0 - Step 4c-CAB LA - Week 16
- [ ] V60.0 - Step 4c-CAB LA - Week 24
- [ ] V61.0 - Step 4c-CAB LA - Week 32
- [ ] V62.0 - Step 4c-CAB LA - Week 40
- [ ] V63.0 - Step 4c-CAB LA - Week 48
- [ ] V64.0 - Step 4c-TDF/FTC - Week 0
- [ ] V65.0 - Step 4c-TDF/FTC - Week 8
- [ ] V66.0 - Step 4c-TDF/FTC - Week 16

Form: Pregnancy Report

	V67.0 - Step 4c-TDF/FTC - Week 24 ☐
	V68.0 - Step 4c-TDF/FTC - Week 32 ☐
	V69.0 - Step 4c-TDF/FTC - Week 40 ☐
	V70.0 - Step 4c-TDF/FTC - Week 48 ☐
	V71.0 - Step 5-TDF/FTC - Day 0 ☐
	V72.0 - Step 5-TDF/FTC - Week 12 ☐
	V73.0 - Step 5-TDF/FTC - Week 24 ☐
	V74.0 - Step 5-TDF/FTC - Week 36 ☐
	V75.0 - Step 5-TDF/FTC - Week 48 ☐
	V76.0 - Step 4d - Week 0 ☐
	V77.0 - Step 4d - Week 4 ☐
	V78.0 - Step 4d - Week 8 ☐
	V79.0 - Step 4d - Week 12 ☐
	V80.0 - Step 4d - Week 16 ☐
	V81.0 - Step 4d - Week 20 ☐
	V82.0 - Step 4d - Week 24 ☐
	V83.0 - Step 4d - Week 28 ☐
	V84.0 - Step 4d - Week 32 ☐
	V85.0 - Step 4d - Week 36 ☐
	V86.0 - Step 4d - Week 40 ☐
	V87.0 - Step 4d - Week 2 PP ☐
	V88.0 - Step 4d - Week 4 PP ☐
	V89.0 - Step 4d - Week 8 PP ☐
	V90.0 - Step 4d - Week 16 PP ☐
	V91.0 - Step 4d - Week 24 PP ☐
	V92.0 - Step 4d - Week 32 PP ☐
	V93.0 - Step 4d - Week 40 PP ☐
	V94.0 - Step 4d - Week 48 PP ☐
If "Interim visit", specify Interim visit code	_____
Date of onset of last menstrual period	_____
Or	
Amenorrheic for past 6 months	☐
Estimated date of delivery	_____
What primary information was used to estimate the date of delivery?	Last menstrual period ☐
	Initial ultrasound <20 weeks ☐
	Initial ultrasound >= 20 weeks ☐

Form: Pregnancy Report

	Physical examination ☐ Conception date by assisted reproduction ☐ Other ☐
If "Other", specify:	_____
Is this the participant's first pregnancy since enrollment in this study?	Yes ☐ No ☐
If "Yes", complete Pregnancy History form.	

Form: Social Impact

Log Line #: _____

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 ☐
	V501.0 - Pregnancy Confirmation Visit ☐
	V502.0 - Pregnancy Week 12 ☐
	V503.0 - Pregnancy Week 24 ☐
	V504.0 - Pregnancy Week 36 ☐
	V505.0 - Pregnancy Week 48 ☐
	V600.0 - OLE Week 0 ☐
	V601.0 - OLE Week 8 ☐
	V602.0 - OLE Week 16 ☐
	V603.0 - OLE Week 24 ☐
	V604.0 - OLE Week 32 ☐

Form: Social Impact

- [ ] V605.0 - OLE Week 40
- [ ] V606.0 - OLE Week 48
- [ ] V701.0 - OLE Pregnancy Week 4
- [ ] V702.0 - OLE Pregnancy Week 8
- [ ] V703.0 - OLE Pregnancy Week 12
- [ ] V704.0 - OLE Pregnancy Week 16
- [ ] V705.0 - OLE Pregnancy Week 20
- [ ] V706.0 - OLE Pregnancy Week 24
- [ ] V707.0 - OLE Pregnancy Week 28
- [ ] V708.0 - OLE Pregnancy Week 32
- [ ] V709.0 - OLE Pregnancy Week 36
- [ ] V710.0 - OLE Pregnancy Week 40
- [ ] V711.0 - OLE Pregnancy Delivery
- [ ] V712.0 - OLE Pregnancy Week 1 PP
- [ ] V713.0 - OLE Pregnancy Week 4 PP
- [ ] V714.0 - OLE Pregnancy Week 8 PP
- [ ] V715.0 - OLE Pregnancy Week 16 PP
- [ ] V716.0 - OLE Pregnancy Week 24 PP
- [ ] V717.0 - OLE Pregnancy Week 32 PP
- [ ] V718.0 - OLE Pregnancy Week 40 PP
- [ ] V719.0 - OLE Pregnancy Week 48 PP
- [ ] V55.0 - Step 4a - Day 0
- [ ] V56.0 - Step 4b - Day 0
- [ ] V57.0 - Step 4c-CAB LA - Week 0
- [ ] V58.0 - Step 4c-CAB LA - Week 8
- [ ] V59.0 - Step 4c-CAB LA - Week 16
- [ ] V60.0 - Step 4c-CAB LA - Week 24
- [ ] V61.0 - Step 4c-CAB LA - Week 32
- [ ] V62.0 - Step 4c-CAB LA - Week 40
- [ ] V63.0 - Step 4c-CAB LA - Week 48
- [ ] V64.0 - Step 4c-TDF/FTC - Week 0

Form: Social Impact

	V65.0 - Step 4c-TDF/FTC - Week 8 ☐
	V66.0 - Step 4c-TDF/FTC - Week 16 ☐
	V67.0 - Step 4c-TDF/FTC - Week 24 ☐
	V68.0 - Step 4c-TDF/FTC - Week 32 ☐
	V69.0 - Step 4c-TDF/FTC - Week 40 ☐
	V70.0 - Step 4c-TDF/FTC - Week 48 ☐
	V71.0 - Step 5-TDF/FTC - Day 0 ☐
	V72.0 - Step 5-TDF/FTC - Week 12 ☐
	V73.0 - Step 5-TDF/FTC - Week 24 ☐
	V74.0 - Step 5-TDF/FTC - Week 36 ☐
	V75.0 - Step 5-TDF/FTC - Week 48 ☐
	V76.0 - Step 4d - Week 0 ☐
	V77.0 - Step 4d - Week 4 ☐
	V78.0 - Step 4d - Week 8 ☐
	V79.0 - Step 4d - Week 12 ☐
	V80.0 - Step 4d - Week 16 ☐
	V81.0 - Step 4d - Week 20 ☐
	V82.0 - Step 4d - Week 24 ☐
	V83.0 - Step 4d - Week 28 ☐
	V84.0 - Step 4d - Week 32 ☐
	V85.0 - Step 4d - Week 36 ☐
	V86.0 - Step 4d - Week 40 ☐
	V87.0 - Step 4d - Week 2 PP ☐
	V88.0 - Step 4d - Week 4 PP ☐
	V89.0 - Step 4d - Week 8 PP ☐
	V90.0 - Step 4d - Week 16 PP ☐
	V91.0 - Step 4d - Week 24 PP ☐
	V92.0 - Step 4d - Week 32 PP ☐
	V93.0 - Step 4d - Week 40 PP ☐
	V94.0 - Step 4d - Week 48 PP ☐
If "Interim visit", specify Interim visit code	_____
Social impact	Personal Relationships - Had negative experiences with family, friends, significant others, or sex partners. ☐

Form: Social Impact

	☐ 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 (max. 200 characters):	_____

Form: Social Impact Y/N

Has the participant experienced any social impacts related to study participation?	Yes ☐ No ☐

If "Yes", update the Social Impact log.

Form: Study Termination

Date of study exit	
Primary reason for completion/discontinuation	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 ☐ Low oral adherence – Step 1 ☐ Other, specify ☐
If "Other", specify (max. 200 characters):	
If "Death", enter date of death.	
If "Adverse event", select applicable adverse event.	

Form: Participant Transfer

Name of transferring study site	Harare - Spilhaus ☐
	Johannesburg - Ward 21 ☐
	Makerere, Kampala, Uganda ☐
Name of receiving study site	Harare - Spilhaus ☐
	Johannesburg - Ward 21 ☐
	Makerere, Kampala, Uganda ☐
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 ☐
	V501.0 - Pregnancy Confirmation Visit ☐
	V502.0 - Pregnancy Week 12 ☐
	V503.0 - Pregnancy Week 24 ☐
	V504.0 - Pregnancy Week 36 ☐
	V505.0 - Pregnancy Week 48 ☐
	V600.0 - OLE Week 0 ☐

Form: Participant Transfer

V601.0 - OLE Week 8 ☐
V602.0 - OLE Week 16 ☐
V603.0 - OLE Week 24 ☐
V604.0 - OLE Week 32 ☐
V605.0 - OLE Week 40 ☐
V606.0 - OLE Week 48 ☐
V701.0 - OLE Pregnancy Week 4 ☐
V702.0 - OLE Pregnancy Week 8 ☐
V703.0 - OLE Pregnancy Week 12 ☐
V704.0 - OLE Pregnancy Week 16 ☐
V705.0 - OLE Pregnancy Week 20 ☐
V706.0 - OLE Pregnancy Week 24 ☐
V707.0 - OLE Pregnancy Week 28 ☐
V708.0 - OLE Pregnancy Week 32 ☐
V709.0 - OLE Pregnancy Week 36 ☐
V710.0 - OLE Pregnancy Week 40 ☐
V711.0 - OLE Pregnancy Delivery ☐
V712.0 - OLE Pregnancy Week 1 PP ☐
V713.0 - OLE Pregnancy Week 4 PP ☐
V714.0 - OLE Pregnancy Week 8 PP ☐
V715.0 - OLE Pregnancy Week 16 PP ☐
V716.0 - OLE Pregnancy Week 24 PP ☐
V717.0 - OLE Pregnancy Week 32 PP ☐
V718.0 - OLE Pregnancy Week 40 PP ☐
V719.0 - OLE Pregnancy Week 48 PP ☐
V55.0 - Step 4a - Day 0 ☐
V56.0 - Step 4b - Day 0 ☐
V57.0 - Step 4c-CAB LA - Week 0 ☐
V58.0 - Step 4c-CAB LA - Week 8 ☐
V59.0 - Step 4c-CAB LA - Week 16 ☐
V60.0 - Step 4c-CAB LA - Week 24 ☐
V61.0 - Step 4c-CAB LA - Week 32 ☐

Form: Participant Transfer

V62.0 - Step 4c-CAB LA - Week 40	☐
V63.0 - Step 4c-CAB LA - Week 48	☐
V64.0 - Step 4c-TDF/FTC - Week 0	☐
V65.0 - Step 4c-TDF/FTC - Week 8	☐
V66.0 - Step 4c-TDF/FTC - Week 16	☐
V67.0 - Step 4c-TDF/FTC - Week 24	☐
V68.0 - Step 4c-TDF/FTC - Week 32	☐
V69.0 - Step 4c-TDF/FTC - Week 40	☐
V70.0 - Step 4c-TDF/FTC - Week 48	☐
V71.0 - Step 5-TDF/FTC - Day 0	☐
V72.0 - Step 5-TDF/FTC - Week 12	☐
V73.0 - Step 5-TDF/FTC - Week 24	☐
V74.0 - Step 5-TDF/FTC - Week 36	☐
V75.0 - Step 5-TDF/FTC - Week 48	☐
V76.0 - Step 4d - Week 0	☐
V77.0 - Step 4d - Week 4	☐
V78.0 - Step 4d - Week 8	☐
V79.0 - Step 4d - Week 12	☐
V80.0 - Step 4d - Week 16	☐
V81.0 - Step 4d - Week 20	☐
V82.0 - Step 4d - Week 24	☐
V83.0 - Step 4d - Week 28	☐
V84.0 - Step 4d - Week 32	☐
V85.0 - Step 4d - Week 36	☐
V86.0 - Step 4d - Week 40	☐
V87.0 - Step 4d - Week 2 PP	☐
V88.0 - Step 4d - Week 4 PP	☐
V89.0 - Step 4d - Week 8 PP	☐
V90.0 - Step 4d - Week 16 PP	☐
V91.0 - Step 4d - Week 24 PP	☐
V92.0 - Step 4d - Week 32 PP	☐
V93.0 - Step 4d - Week 40 PP	☐
V94.0 - Step 4d - Week 48 PP	☐
If "Interim visit", specify Interim visit code	_____
Date participant's records were sent to receiving study site	_____

Form: Patient Health Questionnaire

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 ☐

Form: Patient Health Questionnaire

	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 at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
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 ☐

Form: Contraception

Visit	
	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 ☐
	V501.0 - Pregnancy Confirmation Visit ☐
	V502.0 - Pregnancy Week 12 ☐
	V503.0 - Pregnancy Week 24 ☐
	V504.0 - Pregnancy Week 36 ☐
	V505.0 - Pregnancy Week 48 ☐
	V600.0 - OLE Week 0 ☐
	V601.0 - OLE Week 8 ☐
	V602.0 - OLE Week 16 ☐
	V603.0 - OLE Week 24 ☐
	V604.0 - OLE Week 32 ☐
	V605.0 - OLE Week 40 ☐
	V606.0 - OLE Week 48 ☐

Form: Contraception

- [ ] V701.0 - OLE Pregnancy Week 4
- [ ] V702.0 - OLE Pregnancy Week 8
- [ ] V703.0 - OLE Pregnancy Week 12
- [ ] V704.0 - OLE Pregnancy Week 16
- [ ] V705.0 - OLE Pregnancy Week 20
- [ ] V706.0 - OLE Pregnancy Week 24
- [ ] V707.0 - OLE Pregnancy Week 28
- [ ] V708.0 - OLE Pregnancy Week 32
- [ ] V709.0 - OLE Pregnancy Week 36
- [ ] V710.0 - OLE Pregnancy Week 40
- [ ] V711.0 - OLE Pregnancy Delivery
- [ ] V712.0 - OLE Pregnancy Week 1 PP
- [ ] V713.0 - OLE Pregnancy Week 4 PP
- [ ] V714.0 - OLE Pregnancy Week 8 PP
- [ ] V715.0 - OLE Pregnancy Week 16 PP
- [ ] V716.0 - OLE Pregnancy Week 24 PP
- [ ] V717.0 - OLE Pregnancy Week 32 PP
- [ ] V718.0 - OLE Pregnancy Week 40 PP
- [ ] V719.0 - OLE Pregnancy Week 48 PP
- [ ] V55.0 - Step 4a - Day 0
- [ ] V56.0 - Step 4b - Day 0
- [ ] V57.0 - Step 4c-CAB LA - Week 0
- [ ] V58.0 - Step 4c-CAB LA - Week 8
- [ ] V59.0 - Step 4c-CAB LA - Week 16
- [ ] V60.0 - Step 4c-CAB LA - Week 24
- [ ] V61.0 - Step 4c-CAB LA - Week 32
- [ ] V62.0 - Step 4c-CAB LA - Week 40
- [ ] V63.0 - Step 4c-CAB LA - Week 48
- [ ] V64.0 - Step 4c-TDF/FTC - Week 0
- [ ] V65.0 - Step 4c-TDF/FTC - Week 8
- [ ] V66.0 - Step 4c-TDF/FTC - Week 16

Contraception

- V67.0 - Step 4c-TDF/FTC - Week 24
- V68.0 - Step 4c-TDF/FTC - Week 32
- V69.0 - Step 4c-TDF/FTC - Week 40
- V70.0 - Step 4c-TDF/FTC - Week 48
- V71.0 - Step 5-TDF/FTC - Day 0
- V72.0 - Step 5-TDF/FTC - Week 12
- V73.0 - Step 5-TDF/FTC - Week 24
- V74.0 - Step 5-TDF/FTC - Week 36
- V75.0 - Step 5-TDF/FTC - Week 48
- V76.0 - Step 4d - Week 0
- V77.0 - Step 4d - Week 4
- V78.0 - Step 4d - Week 8
- V79.0 - Step 4d - Week 12
- V80.0 - Step 4d - Week 16
- V81.0 - Step 4d - Week 20
- V82.0 - Step 4d - Week 24
- V83.0 - Step 4d - Week 28
- V84.0 - Step 4d - Week 32
- V85.0 - Step 4d - Week 36
- V86.0 - Step 4d - Week 40
- V87.0 - Step 4d - Week 2 PP
- V88.0 - Step 4d - Week 4 PP
- V89.0 - Step 4d - Week 8 PP
- V90.0 - Step 4d - Week 16 PP
- V91.0 - Step 4d - Week 24 PP
- V92.0 - Step 4d - Week 32 PP
- V93.0 - Step 4d - Week 40 PP
- V94.0 - Step 4d - Week 48 PP

If 'Interim visit', provide interim visit code _____

Have there been any changes to your method(s) of birth control since the last visit?

- Yes
- No

If YES, please complete all sections below that apply. If NO, end form.

Select Concomitant Medication Log line.

Select from the drop-down list 1 _____

Form: Contraception

Select from the drop-down list 2	
Have you had a tubal ligation or hysterectomy surgery since last visit?	Yes ☐ No ☐
If yes, Date of procedure	
Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit?	Yes ☐ No ☐
If yes, please update Concomitant Medications and select the medication(s) below.	
If yes, select from the drop-down list 1	
If yes, select from the drop-down list 2	
Have you stopped an oral contraceptive, removed an implant or IUD device since last visit?	Yes ☐ No ☐
If yes, please update Concomitant Medications and select the medication(s) below.	
If yes, select from the drop-down list 1	
If yes, select from the drop-down list 2	

Form: Contraception - Screening

What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

None, no birth control.	☐
Oral Contraceptive pill	☐
Intrauterine Device (IUD)	☐
Injectable	☐
Contraceptive Patch	☐
Contraceptive Vaginal Ring	☐
Implant	☐
Other Contraceptive	☐
Sterilization (Tubal ligation / hysterectomy)	☐

If Sterilization, end form. If not, select Concomitant Medication

Select Concomitant Medication Log line.

Select from the drop-down list 1	
Select from the drop-down list 2	

Form: Product Choice - OLE

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 ☐ Other ☐
Other, specify	_____
If Yes, Date of Informed Consent	_____
Select OLE Regimen	CAB ☐ TDF/FTC (Step 4c- TDF/FTC) ☐ Seroconvertor Schedule previous version ☐ Open Label Truvada Schedule previous version ☐ Pregnancy Schedule previous version ☐ Pregnancy and Infant Sub-Study ☐
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 - CAB/LA) ☐
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	_____

Form: Pill Count Enrollment

Record the number of pills dispensed at the Enrollment Visit.	
Number of pills dispensed	
Comments (max. 450 characters)	

Form: Pill Count Step 1

Date of pill count	
Number of pills the participant presented at this visit.	
Did the participant return any pills at this visit?	Yes ☐ No ☐
If yes, record the number of pills returned at this visit.	
Number of pills returned	
Was the participant dispensed any additional pills at this visit?	Yes ☐ No ☐
If yes, record the number of pills dispensed at this visit.	
Number of additional pills dispensed	
Comments (max. 450 characters)	

Form: Injection Site Reaction **Log Line #:** _____

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?	☐ 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
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) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening)

Form: Injection Site Reaction

	Grade 5 (Death) ☐
Action taken with study product	Dose not changed ☐ Dose reduced ☐ Dose increased ☐ Drug withdrawn ☐ Drug interrupted ☐ Not applicable ☐
Other action(s) taken (Select "none" or all that apply) None	☐
Medication(s)	☐
Therapeutic procedure/surgery	☐
Diagnostic procedure	☐
Other	☐
Other, specify:	_____
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 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.	

Form: Injection Site Reaction

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

Form: Date of Visit - Pregnancy OLE

Please assign a sequential number to this sub-study pregnancy. Only the pregnancies during the sub-study should be counted.	Pregnancy 1 ☐ Pregnancy 2 ☐ Pregnancy 3 ☐ Pregnancy 4 ☐ Pregnancy 5 ☐
Did the participant complete this visit?	Yes ☐ No ☐
Visit Date	_____
Weight	Fixed Unit: kg _____
OR Not Done	☐
Systolic blood pressure	Fixed Unit: mmHg _____
Diastolic blood pressure	Fixed Unit: mmHg _____
Pulse	Fixed Unit: beats/min _____
Did the participant change the OLE regimen at this visit?	Yes ☐ No ☐
If yes, select the new OLE regimen	CAB LA ☐ TDF/FTC ☐ None ☐
What is current OLE regimen at this visit	CAB LA ☐ TDF/FTC ☐ None ☐
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 complete the CASI questionnaire for this visit?	Yes ☐ No ☐
If yes, when was the CASI survey done?	Before pregnancy testing (or not pregnant) ☐ After pregnancy confirmed ☐ Both ☐

Form: Date of Visit - Pregnancy OLE

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.	
Did the product get held/discontinued at this visit?	Product Hold ☐ Product Discontinued ☐ No ☐
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Is the participant moving to a different 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 4c) ☐ TDF/FTC (Step 5) ☐ Pregnancy and Infant Sub-Study ☐ Step 6 ☐

Form: Adverse Event - Infant Y/N

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

If yes, complete the Adverse Event - Infant Log.

Form: Consent - Pregnancy Infant Sub-study

Date of consent for Pregnancy and Infant sub-study	_____
For which OLE regimen did the participant consent during pregnancy?	CAB LA ☐ TDF/FTC ☐ None ☐
Did the participant consent to having her sample collected during pregnancy?	Yes ☐ No ☐
If yes, did the participant consent to having her sample stored for future testing during pregnancy?	Yes ☐ No ☐
Did the participant consent to having her infant's sample collected after pregnancy?	Yes ☐ No ☐
If yes, did the participant consent to having her infant's sample stored for future testing during pregnancy?	Yes ☐ No ☐

Form: Contraception -OLE

Did the contraception method change since last visit?	Yes ☐ No ☐
What type of birth control method is the participant currently using? Please update the Concomitant Medications form as appropriate.	None ☐ Oral Contraceptive pill ☐ Intrauterine Device (IUD) ☐ Injectable ☐ Contraceptive Patch ☐ Contraceptive Vaginal Ring ☐ Implant ☐ Other Contraceptive ☐ Sterilization (Tubal ligation / hysterectomy) ☐ Condoms ☐ Other ☐
If "Other" Specify	_____
Onset Date / Date of Procedure	_____
Concomitant Medication Log Line	_____

Form: Infant Breastmilk Feeding Assessment

Log Line #: _____

Infant PTID	_____
Was a feeding assessment completed?	Yes ☐ No ☐
Date of assessment	_____
Has the infant ever been fed breastmilk?	Yes ☐ No ☐
Is the infant currently fed breastmilk?	Yes ☐ No ☐
Date infant last received breast milk	_____

Form: Plasma Storage- Contraceptive Sub-study

Was a plasma sample collected for storage?	Yes ☐ No ☐
If no, record reason why plasma sample was not collected.	_____
Specimen collection date:	_____
Time plasma sample collected:	_____
Was plasma stored?	Stored ☐ Not Stored ☐
If no, record reason why plasma sample was not stored.	_____

Form: Pregnancy Test Results - OLE

1. - Was a pregnancy test done?	Yes ☐ No ☐ Not applicable ☐
If no, end of form.	
2. - Date of pregnancy test	_____
3. - Specimen type (Mark only one):	Urine ☐ Plasma ☐ Serum ☐
4. - Test result If Negative, end of form.	Positive ☐ Negative ☐
5. - If Test result is positive, was the pregnancy confirmed on a second independent sample on same day? If No, go to Question 6.	Yes ☐ No ☐
5a. - If Yes, Specimen type (Mark only one):	Urine ☐ Plasma ☐ Serum ☐
5b. - If Yes, Test result	Positive ☐ Negative ☐
6. - Is the participant eligible for Pregnancy and Infant Sub-Study?	Yes ☐ No ☐
7. - Did the participant consent to participate in Pregnancy and Infant Sub-Study?	Yes ☐ No ☐
8. - Select if additional pregnancy test results form is required.	☐

Form: Infant Assessment

Log Line #: _____

1. - How many live pregnancy outcomes had resulted from this pregnancy? Complete one log line for each live outcome.	_____
2. - Infant PTID	_____
3. - Is the infant alive?	Yes ☐ No ☐
4. - Was an infant assessment done? If No, end of form.	Yes ☐ No ☐
5. - Date of assessment	_____
6. - Length	Fixed Unit: cm _____
7. - Weight	Fixed Unit: kg _____
8. - Head circumference	Fixed Unit: cm _____
9. - Abdominal circumference	_____
10. - Were any previously unreported fetal/infant congenital anomalies identified? If "Yes", mark all that apply. If "No" or "Not assessed", end of form.	Yes ☐ No ☐ Not assessed ☐
10a. - Central nervous system, cranio-facial	☐
10b. - Central nervous system, spinal	☐
10c. - Cardiovascular	☐
10d. - Renal	☐
10e. - Gastrointestinal	☐
10f. - Pulmonary	☐
10g. - Musculoskeletal/extremities	☐
10h. - Physical defect	☐
10i. - Skin	☐
10j. - Genitourinary	☐
10k. - Chromosomal	☐
10l. - Cranio-facial (structural)	☐
10m. - Hematologic	☐
10n. - Infectious	☐
10o. - Endocrine/metabolic	☐
10p. - Other	☐

Form: Infant Assessment

10q. - Describe congenital anomaly/defect (max. 200 characters):	
10r. - If fetal/infant congenital anomalies were identified, select Adverse Event log line.	
10s. - If additional fetal/infant congenital anomalies were identified, select Adverse Event log line.	

Form: Sub-study Infant PTID

Is this PTID for an Infant?	Yes ☐ No ☐
If Yes, what is the associated Mother's PTID	_____

Form: Adverse Event - Infant **Log Line #: _____**

1. - Infant PTID	_____
2. - Date reported to site	_____
3. - Adverse Event (AE)	_____
4. - Onset Date	_____
5. - At which visit was this AE first reported?	V55.0 - Step 4a - Day 0 ☐
	V56.0 - Step 4b - Day 0 ☐
	V57.0 - Step 4c-CAB LA - Week 0 ☐
	V58.0 - Step 4c-CAB LA - Week 8 ☐
	V59.0 - Step 4c-CAB LA - Week 16 ☐
	V60.0 - Step 4c-CAB LA - Week 24 ☐
	V61.0 - Step 4c-CAB LA - Week 32 ☐
	V62.0 - Step 4c-CAB LA - Week 40 ☐
	V63.0 - Step 4c-CAB LA - Week 48 ☐
	V64.0 - Step 4c-TDF/FTC - Week 0 ☐
	V65.0 - Step 4c-TDF/FTC - Week 8 ☐
	V66.0 - Step 4c-TDF/FTC - Week 16 ☐
	V67.0 - Step 4c-TDF/FTC - Week 24 ☐
	V68.0 - Step 4c-TDF/FTC - Week 32 ☐
	V69.0 - Step 4c-TDF/FTC - Week 40 ☐
	V70.0 - Step 4c-TDF/FTC - Week 48 ☐
	V71.0 - Step 5-TDF/FTC - Day 0 ☐
	V72.0 - Step 5-TDF/FTC - Week 12 ☐
	V73.0 - Step 5-TDF/FTC - Week 24 ☐
	V74.0 - Step 5-TDF/FTC - Week 36 ☐
	V75.0 - Step 5-TDF/FTC - Week 48 ☐
	V76.0 - Step 4d - Week 0 ☐
	V77.0 - Step 4d - Week 4 ☐
	V78.0 - Step 4d - Week 8 ☐
	V79.0 - Step 4d - Week 12 ☐
	V80.0 - Step 4d - Week 16 ☐
	V81.0 - Step 4d - Week 20 ☐
	V82.0 - Step 4d - Week 24 ☐
	V83.0 - Step 4d - Week 28 ☐
	V84.0 - Step 4d - Week 32 ☐

Form: Adverse Event - Infant

	V85.0 - Step 4d - Week 36 ☐
	V86.0 - Step 4d - Week 40 ☐
	V87.0 - Step 4d - Week 2 PP ☐
	V88.0 - Step 4d - Week 4 PP ☐
	V89.0 - Step 4d - Week 8 PP ☐
	V90.0 - Step 4d - Week 16 PP ☐
	V91.0 - Step 4d - Week 24 PP ☐
	V92.0 - Step 4d - Week 32 PP ☐
	V93.0 - Step 4d - Week 40 PP ☐
	V94.0 - Step 4d - Week 48 PP ☐
	Delivery - OLE - V95.0 ☐
	Delivery - OLE - V96.0 ☐
	Delivery - OLE - V97.0 ☐
	Delivery - OLE - V98.0 ☐
	Delivery - OLE - V99.0 ☐
	Interim Visit ☐
	V116.0 - Step 6-CAB LA - Week 56 ☐
	V117.0 - Step 6-CAB LA - Week 64 ☐
	V118.0 - Step 6-CAB LA - Week 72 ☐
	V119.0 - Step 4c-CAB LA - Week 80 ☐
	V120.0 - Step 4c-CAB LA - Week 88 ☐
	V121.0 - Step 4c-CAB LA - Week 96 ☐
5a. - If 'Interim Visit' is chosen, provide interim visit code.	_____
6. - Is the AE still ongoing?	Yes ☐
	No ☐
7. - Outcome Date	_____
8. - Toxicity (Severity) Grade	Grade 1 (Mild) ☐
	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
	Grade 5 (Death) ☐
9. - Relationship to Study Product	Related ☐
	Not Related ☐
9a. - Alternate etiology	_____
10. - Action Taken with Study Product:	Dose not changed ☐
	Dose reduced ☐

Form: Adverse Event - Infant

	Dose increased ☐
	Dose withdrawn ☐
	Dose interrupted ☐
	Not applicable ☐
11a. - Other action(s) taken (Select "none" or all that apply)	☐
None	
11b. - Medication(s)	☐
11c. - Therapeutic procedure/surgery	☐
11d. - Diagnostic procedure	☐
11e. - Other	☐
11e1. - Specify other:	_____
12. - Status/Outcome	Recovered/resolved ☐
	Recovering/resolving ☐
	Resolved with sequelae ☐
	Not recovered/resolved ☐
	Fatal ☐
13. - 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.	
13a. - Results in death	☐
13b. - Is life-threatening	☐
13c. - Requires inpatient hospitalization or prolongation of existing hospitalization	☐
13d. - Results in persistent or significant disability/incapacity	☐
13e. - Is a congenital anomaly/birth defect	☐
13f. - Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	☐
14. - Has or will this AE be reported as an EAE?	Yes ☐
	No ☐
14a. - If yes, EAE number	_____

Form: Specimen Storage - Contraceptive Sub-Study

Was a plasma sample collected for storage?	Yes ☐
	No ☐
Specimen collection date:	_____
Time plasma sample collected:	_____
Was plasma stored?	Stored ☐
	Not Stored ☐
Was a serum sample collected for storage?	Yes ☐
	No ☐
Specimen collection date:	_____
Time serum sample collected:	_____
Was serum sample stored?	Stored ☐
	Not Stored ☐

Form: Specimen Collection - Breast Milk

Were breast milk samples collected? If no, end of form.	Yes ☐ No ☐
Date breast milk samples collected by site	_____
Specimen collection date	_____
Specimen collection time	_____
Specimen collection method	Hand expression ☐ Pump ☐
Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	_____

Form: Infant Specimen Collection - Cord Blood

Log Line #: _____

Infant PTID	
Was specimen collected?	Yes ☐ No ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was the minimum required volume obtained?	Yes ☐ No ☐
If "No", record reason why minimum required volume was not obtained (max. 200 characters).	
Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	

Form: Infant Specimen Collection - Blood (Plasma) **Log Line #:** _____

Infant PTID	
Was specimen collected?	Yes ☐ No ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was the minimum required volume obtained?	Yes ☐ No ☐
If "No", record reason why minimum required volume was not obtained (max. 200 characters).	
Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	

Form: Interim Visit - OLE

1. - Interim Visit date	
2. - Interim visit code	
3 - Reason for interim visit (Mark all that apply)	
3a. - AE report or follow-up	☐
3b. - ISR report or follow-up	☐
3c. - Report social harm	☐
3d. - Additional laboratory testing	☐
3e. - Other	☐
3e1. - If other, specify:	
4. - Weight	Fixed Unit: kg
OR Not Done	☐
5. - Systolic blood pressure	Fixed Unit: mmHg
6. - Diastolic blood pressure	Fixed Unit: mmHg
7. - Pulse	Fixed Unit: beats/min
8. - How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?	0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐
9. - Did the product get held/discontinued at this visit?	Product Hold ☐ Product Discontinued ☐ No ☐
10. - Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
11. - Is the participant moving to a new step or visit schedule?	Yes ☐ No ☐
11a. - 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 4c) ☐ TDF/FTC (Step 5) ☐ Pregnancy and Infant Sub-Study ☐

Form: Interim Visit - OLE

	Step 6 ☐
Mark all forms completed at this visit.	
AE Log	☐
CD4/VL Results	☐
Chemistry Testing	☐
Counseling	☐
Dried Blood Spot Storage	☐
Fasting Lipid Test Results	☐
Hematology	☐
HIV Test Results	☐
HIV Supplemental Results	☐
Infant Assessment	☐
Infant Breastmilk Feeding Assessment	☐
Infant Specimen Collection - Plasma	☐
Liver Function Test Results	☐
Participant Receipt	☐
Participant Transfer	☐
Plasma Storage	☐
Pregnancy Test Results - OLE	☐
Product Hold Log - OLE	☐
Specimen Collection - Breast Milk	☐
STI Test Results	☐
Urinalysis	☐
Ultrasound - OLE	☐
Infant HIV Test Results	☐
Infant - Dried Blood Spot Storage	☐
Cell Pellet Storage	☐

Form: Pregnancy Report-OLE

Date pregnancy reported	_____
At what visit was the pregnancy reported?	V55.0 - Step 4a - Day 0 ☐
	V56.0 - Step 4b - Day 0 ☐
	V57.0 - Step 4c-CAB LA - Week 0 ☐
	V58.0 - Step 4c-CAB LA - Week 8 ☐
	V59.0 - Step 4c-CAB LA - Week 16 ☐
	V60.0 - Step 4c-CAB LA - Week 24 ☐
	V61.0 - Step 4c-CAB LA - Week 32 ☐
	V62.0 - Step 4c-CAB LA - Week 40 ☐
	V63.0 - Step 4c-CAB LA - Week 48 ☐
	V64.0 - Step 4c-TDF/FTC - Week 0 ☐
	V65.0 - Step 4c-TDF/FTC - Week 8 ☐
	V66.0 - Step 4c-TDF/FTC - Week 16 ☐
	V67.0 - Step 4c-TDF/FTC - Week 24 ☐
	V68.0 - Step 4c-TDF/FTC - Week 32 ☐
	V69.0 - Step 4c-TDF/FTC - Week 40 ☐
	V70.0 - Step 4c-TDF/FTC - Week 48 ☐
	V71.0 - Step 5-TDF/FTC - Day 0 ☐
	V72.0 - Step 5-TDF/FTC - Week 12 ☐
	V73.0 - Step 5-TDF/FTC - Week 24 ☐
	V74.0 - Step 5-TDF/FTC - Week 36 ☐
	V75.0 - Step 5-TDF/FTC - Week 48 ☐
	V76.0 - Step 4d - Week 0 ☐
	V77.0 - Step 4d - Week 4 ☐
	V78.0 - Step 4d - Week 8 ☐
	V79.0 - Step 4d - Week 12 ☐
	V80.0 - Step 4d - Week 16 ☐
	V81.0 - Step 4d - Week 20 ☐
	V82.0 - Step 4d - Week 24 ☐
	V83.0 - Step 4d - Week 28 ☐
	V84.0 - Step 4d - Week 32 ☐
	V85.0 - Step 4d - Week 36 ☐
	V86.0 - Step 4d - Week 40 ☐

Form: Pregnancy Report-OLE

	V87.0 - Step 4d - Week 2 PP ☐
	V88.0 - Step 4d - Week 4 PP ☐
	V89.0 - Step 4d - Week 8 PP ☐
	V90.0 - Step 4d - Week 16 PP ☐
	V91.0 - Step 4d - Week 24 PP ☐
	V92.0 - Step 4d - Week 32 PP ☐
	V93.0 - Step 4d - Week 40 PP ☐
	V94.0 - Step 4d - Week 48 PP ☐
	Delivery - OLE - V95.0 ☐
	Delivery - OLE - V96.0 ☐
	Delivery - OLE - V97.0 ☐
	Delivery - OLE - V98.0 ☐
	Delivery - OLE - V99.0 ☐
	Interim Visit ☐
	V116.0 - Step 6-CAB LA - Week 56 ☐
	V117.0 - Step 6-CAB LA - Week 64 ☐
	V118.0 - Step 6-CAB LA - Week 72 ☐
	V119.0 - Step 4c-CAB LA - Week 80 ☐
	V120.0 - Step 4c-CAB LA - Week 88 ☐
	V121.0 - Step 4c-CAB LA - Week 96 ☐
If 'Interim Visit' is chosen, provide interim visit code.	_____
First day of last menstrual period	_____
Estimated date of delivery	_____
What information was used to estimate the date of delivery?	Last menstrual period ☐
	Initial ultrasound <20 weeks ☐
	Initial ultrasound >=20 weeks ☐
	Physical exam ☐
	Conception date by assisted reproduction ☐
	Other ☐
If other, specify:	_____

Form: Pill Count Enrollment

Record the number of pills dispensed at the Enrollment Visit.	
Cabotegravir (active or placebo)	
TDF/FTC (active or placebo)	
Comments (max. 400 characters)	

Form: Additional Procedures - OLE

Select any additional forms completed at this visit.	
CD4/Viral Load Results	☐
Chemistry Testing	☐
Counseling	☐
Dried Blood Spot Storage	☐
Fasting Lipid Test Results	☐
Hematology	☐
HIV Supplemental Results	☐
Infant Assessment	☐
Infant Breastmilk Feeding Assessment	☐
Infant Specimen Collection - Plasma	☐
Liver Function Test Results	☐
Participant Receipt	☐
Participant Transfer	☐
Plasma Storage	☐
Pregnancy Test Results - OLE	☐
Specimen Collection - Breast Milk	☐
STI Test Results	☐
Ultrasound - OLE	☐
Urinalysis	☐
Infant HIV Test Results	☐
Infant Dried Blood Spot Storage	☐
Cell Pellet Storage	☐

Form: Pregnancy Outcome Log - OLE

Log Line #: _____

1. - Date pregnancy reported	_____
1a. - Did this pregnancy have an obtainable outcome?	Yes ☐ No ☐
1b. - If an outcome was not obtainable, please specify why: END OF FORM.	_____
2. - How many pregnancy outcomes resulted from this reported pregnancy?	_____
3. - Infant PTID	_____
4. - Pregnancy outcome date	_____
5. - Place of delivery/outcome	Home ☐ Hospital ☐ Clinic ☐ Unknown ☐ Other ☐
5a. - If other, specify:	_____
6. - Pregnancy outcome	Full term live birth (≥ 37 weeks) ☐ Premature term live birth (<37 weeks) ☐ Spontaneous abortion (< 20 weeks) ☐ Ectopic pregnancy ☐ Therapeutic/elective abortion ☐ Other ☐ Stillbirth ☐ Intrauterine fetal demise (≥ 20 weeks) ☐
6a. - If Stillbirth, Intrauterine fetal demise (≥ 20 weeks) or Other, specify:	_____
6b. - If outcome was full-term or premature live birth, select delivery methods. Delivery method	C-section ☐ Standard vaginal ☐ Operative vaginal ☐
7. - Provide a brief narrative of the circumstances.	_____
8. - Were there any delivery-related complications?	Yes ☐ No ☐ Unknown ☐
If yes, select all delivery related complications that apply:	
8a. - Intrapartum hemorrhage	☐
8b. - Postpartum hemorrhage	☐
8c. - Non-reassuring fetal status	☐
8d. - Chorioamnionitis	☐
8e. - Other	☐

Form: Pregnancy Outcome Log - OLE

8e1. - If other, specify:	_____
9. - Were there any non-delivery-related complications?	Yes ☐ No ☐ Unknown ☐
If yes, select all non-delivery related complications that apply:	
9a. - Hypertensive disorders of pregnancy	☐
9b. - Gestational diabetes	☐
9c. - Other	☐
9c1. - Other, specify	_____
10. - Were any fetal/infant congenital anomalies identified?	Yes ☐ No ☐ Unknown ☐
If yes, please select all anomalies that apply:	
10a. - Central nervous system, cranio-facial	☐
10b. - Central nervous system, spinal	☐
10c. - Cardiovascular	☐
10d. - Renal	☐
10e. - Gastrointestinal	☐
10f. - Pulmonary	☐
10g. - Musculoskeletal/extremities	☐
10h. - Physical defect	☐
10i. - Skin	☐
10j. - Genitourinary	☐
10k. - Chromosomal	☐
10l. - Craniofacial (structural)	☐
10m. - Hematologic	☐
10n. - Infectious	☐
10o. - Endocrine/metabolic	☐
10p. - Other	☐
10p1. - If Other, describe the congenital anomaly/defect:	_____
11. - Complete the infant items below for live births only. Otherwise, end of form.	Male ☐ Female ☐ Unknown ☐
Infant gender	
12. - Infant birth weight	Fixed Unit: KG _____

Form: Pregnancy Outcome Log - OLE

Or select if unavailable	☐
Infant birth weight unit	KG
13. - Infant birth length	Fixed Unit: cm
Or select if unavailable	☐
Infant birth length unit	cm
14. - Infant birth head circumference	Fixed Unit: cm
Or select if unavailable	☐
Infant birth head circumference unit	cm
15. - Infant birth abdominal circumference	Fixed Unit: cm
Or select if unavailable	☐
Infant birth abdominal circumference unit	cm
16. - Infant gestational age by obstetric assessment	Fixed Unit: days
Infant gestational age by examination in Days Unit	days
Or select if unavailable	☐
17. - Classification of the newborn by birth weight and gestational age (obstetric or by examination):	Large for gestational age (> 90%) ☐ Appropriate for gestational age ☐ Small for gestational age (< 10%) ☐ Intrauterine growth retardation (< 3%) ☐ Classification not available ☐
18. - Infant Apgar score at 1 minute:	
Or select if unavailable	☐
19. - Infant Apgar score at 5 minutes:	
Or select if unavailable	☐
20. - Infant Apgar score at 10 minutes:	
Or select if unavailable	☐

Form: Product Hold Y/N-OLE

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

Form: Product Hold/Discontinuation-OLE

Log Line #: _____

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?

- ☐ V55.0 - Step 4a - Day 0
- ☐ V56.0 - Step 4b - Day 0
- ☐ V57.0 - Step 4c-CAB LA - Week 0
- ☐ V58.0 - Step 4c-CAB LA - Week 8
- ☐ V59.0 - Step 4c-CAB LA - Week 16
- ☐ V60.0 - Step 4c-CAB LA - Week 24
- ☐ V61.0 - Step 4c-CAB LA - Week 32
- ☐ V62.0 - Step 4c-CAB LA - Week 40
- ☐ V63.0 - Step 4c-CAB LA - Week 48
- ☐ V64.0 - Step 4c-TDF/FTC - Week 0
- ☐ V65.0 - Step 4c-TDF/FTC - Week 8
- ☐ V66.0 - Step 4c-TDF/FTC - Week 16
- ☐ V67.0 - Step 4c-TDF/FTC - Week 24
- ☐ V68.0 - Step 4c-TDF/FTC - Week 32
- ☐ V69.0 - Step 4c-TDF/FTC - Week 40
- ☐ V70.0 - Step 4c-TDF/FTC - Week 48
- ☐ V71.0 - Step 5-TDF/FTC - Day 0
- ☐ V72.0 - Step 5-TDF/FTC - Week 12
- ☐ V73.0 - Step 5-TDF/FTC - Week 24
- ☐ V74.0 - Step 5-TDF/FTC - Week 36
- ☐ V75.0 - Step 5-TDF/FTC - Week 48
- ☐ V76.0 - Step 4d - Week 0
- ☐ V77.0 - Step 4d - Week 4
- ☐ V78.0 - Step 4d - Week 8
- ☐ V79.0 - Step 4d - Week 12
- ☐ V80.0 - Step 4d - Week 16
- ☐ V81.0 - Step 4d - Week 20
- ☐ V82.0 - Step 4d - Week 24

Form: Product Hold/Discontinuation-OLE

	V83.0 - Step 4d - Week 28 ☐
	V84.0 - Step 4d - Week 32 ☐
	V85.0 - Step 4d - Week 36 ☐
	V86.0 - Step 4d - Week 40 ☐
	V87.0 - Step 4d - Week 2 PP ☐
	V88.0 - Step 4d - Week 4 PP ☐
	V89.0 - Step 4d - Week 8 PP ☐
	V90.0 - Step 4d - Week 16 PP ☐
	V91.0 - Step 4d - Week 24 PP ☐
	V92.0 - Step 4d - Week 32 PP ☐
	V93.0 - Step 4d - Week 40 PP ☐
	V94.0 - Step 4d - Week 48 PP ☐
	Delivery - OLE - V95.0 ☐
	Delivery - OLE - V96.0 ☐
	Delivery - OLE - V97.0 ☐
	Delivery - OLE - V98.0 ☐
	Delivery - OLE - V99.0 ☐
	Interim Visit ☐
	V116.0 - Step 6-CAB LA - Week 56 ☐
	V117.0 - Step 6-CAB LA - Week 64 ☐
	V118.0 - Step 6-CAB LA - Week 72 ☐
	V119.0 - Step 4c-CAB LA - Week 80 ☐
	V120.0 - Step 4c-CAB LA - Week 88 ☐
	V121.0 - Step 4c-CAB LA - Week 96 ☐
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 (other than study product) ☐
	Clinical AE (protocol mandated) ☐
	Laboratory AE (protocol mandated) ☐
	Injection site reaction ☐
	CMC recommendation based on a clinical event ☐
	CMC recommendation based on a laboratory value ☐

Form: Product Hold/Discontinuation-OLE

	CMC recommendation based on a psychosocial concern ☐ Other clinical reason ☐ Hepatitis B infection ☐ Positive pregnancy test result ☐ Participant request - injection intolerance ☐ Participant request - unwilling or unable to comply with required study procedures ☐ Participant request - other reason ☐ Other ☐
If "Other clinical reason", "Participant request - other reason" or "Other" is selected, please specify:	_____
If product hold was associated with an adverse event, select the applicable AE:	_____
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):	_____
Complete this section only if participant has either resumed or permanently discontinued study drug. Has the participant resumed study product?	Yes ☐ No (permanently discontinued) ☐ No (hold continuing/permanently discontinued for another reason) ☐
Date participant resumed study product:	_____
Date participant permanently discontinued study product:	_____

Form: Ultrasound - OLE **Log Line #:** _____

1. - Was an ultrasound exam performed? If yes, go to exam date. Yes ☐ No ☐

1a. - Reason ultrasound not performed. _____

2 - Exam Date _____

3. - Number of fetuses observed on ultrasound _____

4. - Estimated gestational age (at time of ultrasound) - Weeks _____

5. - Estimated gestational age (at time of ultrasound) - Days _____

6. - If estimated gestational age is less than 14 weeks, complete crown-rump length and skip biparietal diameter and femur length (Mark "Or Not done/not collected") . If estimated gestational age is greater than or equal to 14 0/7 weeks, skip crown-rump length (Mark "Or Not done/not collected") and complete biparietal diameter and femur length. Fixed Unit: cm

Crown-rump length _____

Or Not done/not collected ☐

7. - Biparietal diameter Fixed Unit: cm _____

Or Not done/not collected ☐

8. - Femur length Fixed Unit: cm _____

Or Not done/not collected ☐

9. - Intracranial Result Not visualized ☐ Normal ☐ Abnormal ☐

If abnormal, please describe _____

10. - Face/Lip Result Not visualized ☐ Normal ☐ Abnormal ☐

If abnormal, please describe _____

11. - Spine Result Not visualized ☐ Normal ☐ Abnormal ☐

If abnormal, please describe _____

12. - Thorax Result Not visualized ☐ Normal ☐ Abnormal ☐

If abnormal, please describe _____

13. - Four-chamber heart Result Not visualized ☐

Form: Ultrasound - OLE

	Normal ☐
	Abnormal ☐
If abnormal, please describe	_____
14. - Stomach Result	Not visualized ☐
	Normal ☐
	Abnormal ☐
If abnormal, please describe	_____
15. - Kidneys Result	Not visualized ☐
	Normal ☐
	Abnormal ☐
If abnormal, please describe	_____
16. - Bladder (urinary) Result	Not visualized ☐
	Normal ☐
	Abnormal ☐
If abnormal, please describe	_____
17. - Cord insertion Result	Not visualized ☐
	Normal ☐
	Abnormal ☐
If abnormal, please describe	_____
18. - Upper limbs Result	Not visualized ☐
	Normal ☐
	Abnormal ☐
If abnormal, please describe	_____
19. - Lower limbs Result	Not visualized ☐
	Normal ☐
	Abnormal ☐
If abnormal, please describe	_____
20. - Gender Result	Not visualized ☐
	Normal ☐
	Abnormal ☐
If abnormal, please describe	_____
21. - Amniotic fluid Result	Not visualized ☐
	Normal ☐
	Abnormal ☐
If abnormal, please describe	_____

Form: Cell Pellet Storage

Was a cell pellet collected for storage?	Yes ☐ No ☐
If no, record reason why sample was not collected.	_____
Specimen collection date	_____
Time cell pellet collected	_____
Was cell pellet stored?	Stored ☐ Not Stored ☐
If no, record reason why sample was not stored.	_____

Form: Long Term Consent Update

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	_____

Form: Infant HIV Test Results

Log Line #: _____

Infant PTID	_____
HIV RNA PCR	Yes ☐ No ☐
Was HIV RNA PCR testing completed?	
If "No", skip to "Was HIV DNA PCR testing completed?"	
Date of collection	_____
Operator	> ☐ < ☐ = ☐
HIV RNA PCR (plasma)	Fixed Unit: viral copies/mL _____
Target not detected	☐
Detected, less than the lower limit of quantification	☐
Detected, above the upper limit of quantification	☐
HIV DNA PCR	Yes ☐ No ☐
Was HIV DNA PCR testing completed?	
If "No", skip to "Final HIV status"	
Date of collection	_____
HIV DNA PCR Result	Negative/non-reactive ☐ Positive/reactive ☐ Equivocal/Indeterminate ☐
Final HIV status	Negative ☐ Positive ☐
Final HIV status	Additional testing needed ☐

Form: Infant Dried Blood Spot Storage

Infant PTID	_____
Was a dried blood spot collected?	Yes ☐ No ☐
If no, record reason why sample was not collected.	_____
Specimen collection date	_____
Time dried blood spot collected	_____
Was dried blood spot stored?	Stored ☐ Not Stored ☐
If no, record reason why sample was not stored.	_____

Form: Informed Consent - Version 4.0

Did the participant consent for Protocol Version 4.0?	Yes ☐ No ☐
If Yes, Date of Informed Consent	_____