HIV Prevention Trials Network

Letter of Amendment # 3 to:

HPTN 084-01

HPTN 084-01: Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Females – A Sub-study of HPTN 084

DAIDS Study ID: 38655

Version 1.0, dated 14 October 2019

Date of Letter of Amendment: 25 February 2022

LETTER OF AMENDMENT SIGNATURE PAGE

I will conduct the study in accordance with the provisions of this protocol and all applicable protocol-related documents. I agree to conduct this study in compliance with United States (US) Health and Human Service regulations (45 CFR 46); applicable U.S. Food and Drug Administration regulations; standards of the International Conference on Harmonization Guideline for Good Clinical Practice (E6); Institutional Review Board/Ethics Committee determinations; all applicable in-country, state, and local laws and regulations; and other applicable requirements (e.g., US National Institutes of Health, Division of AIDS) and institutional policies.

I have read and understand the information in this protocol and will ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about the obligations incurred by their contribution to the study.

Signature of Investigator of Record

Date

Name of Investigator of Record
(printed)

HIV Prevention Trials Network

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DAIDS Study ID: 38655

Version 1.0, dated 14 October 2019

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The following information impacts the HPTN 084-01 study and must be forwarded to all responsible Institutional Review Boards/Ethics Committees (IRBs/ECs) as soon as possible for their information and review. This Letter of Amendment (LoA) must be approved by all responsible IRBs/ECs before implementation.

The information contained in this LoA does impact the informed consent forms (ICFs).

Upon receiving final IRB/EC approval for this LoA, sites should implement the LoA immediately. Sites are required to submit an LoA registration packet to the DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center (RSC). As part of the registration package, sites must submit the Letter of Amendment Investigatory Signature Page, signed and dated by the Investigator of Record. Sites will receive a registration notification for the LoA once the DAIDS PRO verifies that all the required LoA registration documents have been received and are complete. A LoA registration notification from the DAIDS PRO is not required prior to implementing the LoA. A copy of the LoA registration notification along with the LoA and any IRB correspondence should be retained in the site's regulatory files.

If the full HPTN 084-01 protocol is amended in the future, the changes in this LoA will be incorporated into the next version.

Preamble

Necessary, albeit minor, changes were made to the protocol objectives and references to Truvada®, if chosen by participants in Step 3. Per Letter of Amendment #2, the HPTN 084-01 study allows sites to procure either generic TDF/FTC or brand name TDF/FTC (Truvada®). The DAIDS policy referenced herein directs site leadership and staff on the process to acquire generic. The choice for participants to join the HPTN 084 OLE (Open Label Extension), in order to remain on CAB LA injections, is further clarified. Also included is a new secondary objective to allow for exploratory analyses of the clinical and laboratory data, including ART resistance testing (if applicable). See below for a more comprehensive Summary of Revisions and Rationale.

Summary of Revisions and Rationale

1. SCHEMA: One secondary objective is edited, to create a new secondary objective and delete the former one. An additional secondary objective is added.
2. Section 1.12: Reference to potential FDA approval has been removed, since CAB LA was approved by the FDA in December 2021 for adults and adolescents weighing at least 35 kg.
3. Section 2.2: One secondary objective is edited, to create a new secondary objective and delete the former one. An additional secondary objective is added.
4. Section 2.3: Study Design and Overview:
    a. Clarification to an errant mention of participants choosing Truvada® (or generic) or CAB LA in Step 3.
    b. Clarification is made to indicate that an adverse event (AE) due to study product would result in discontinuation of study product during Step 2 “due to AE occurrence” (to be in-line with HPTN 083-01).
5. Section 4.1.2: Clarification is made to approval of CAB LA by the FDA.
6. Section 4.2.1: With regards to Letter of Amendment (LoA) #2 to Protocol Version 1.0 of HPTN 084-01 and according to DAIDS Policy DWD-POL-RA-014.02, the Clinical Research Site (CRS) Leader at a given site should follow the instructions outlined in said DAIDS policy, *Use of Drug Products Not Marketed in the United States* (Approval Date: 21 JAN 2015; Effective Date: 23 FEB 2015), if the site wishes to procure generic TDF/FTC (which is not already FDA approved) for use in Step 3.
7. Section 5.8 (Loading Dose Visit…): This is a new sub-section including re-loading instructions, to be in-line with a similar recent change in HPTN 083-01.
8. Section 7: Statistical Considerations
    a. Section 7.2.2 (Secondary Endpoints): Secondary endpoints are edited to be in-line with those in the Schema and Section 2 (see above).
    b. Section 7.3 (Sample Size): Sample size is adjected to account for loss-to-follow-up.
        i. Table 3: Clarification is provided and confidence intervals for the true proportion of participants anticipated to begin Step 2 are adjusted.
    c. Section 7.6.1 (Study Monitoring Committee): Two sentences, duplicates of earlier wording, are deleted.
    d. Section 7.7.1 (Primary Analyses, Safety Endpoints): Clarification is made to follow newly edited secondary objective on safety and follow-up.
    e. Section 7.8.2 (Secondary Analyses, Safety Endpoints): Clarification on the safety endpoint secondary analysis is given, including the addition of an ITT (intent-to-treat) analysis.
9. Appendix III:
    a. Clarification in title is made to specify use only in participants who choose to remain on Truvada® (or generic) instead of moving to the HPTN 084 Open-Label Extension (OLE), once the OLE is formally approved at sites.
    b. Adherence counseling is added to all visits, except Week +8, at which time no TDF/FTC is distributed. An associated footnote is included.
    c. HIV testing and (relatedly) medical history, concomitant medications, and targeted medical history are added to the Week +8 visit, with associated footnote.
    d. Chemistry and liver function testing are removed from the Week +12 and +36 visits.
10. Appendix IV: Chemistry and liver functioning are removed from the Week +12 and +36 visits.

11. Appendix VII: Clarification is provided with reference to FDA approval and to include the opportunity to roll onto the HPTN 084 OLE in four instances (artifacts of previous LoA).

12. Additional changes (not listed in the Implementation Section following this section):

a. Formatting and minor typographical errors have been fixed.
b. Clarification is made in multiple parts of the protocol to include the option for use of generic TDF/FTC in Step 3.
c. CAB LA IB version and date have been updated (Section 1.2).
d. The opportunity for participants to enter the HPTN 084 OLE is clarified in Section 4.1. The opportunity to enter a locally-available open-label extension CAB LA study was previously approved in earlier protocol change documents.
e. In Section 4.4, a change has been made to refer to the HPTN 084-01 CMC, vs. the HPTN 084 CMC.
f. In Section 5.9, clarification is made to indicate the target visit window for most (not all) injection visits is +/- 3 days.
g. Numbers for footnotes in the Appendices have been updated.

IMPLEMENTATION SECTION

Deletions to the protocol text are indicated by ~~strikethrough~~; additions are indicated in **bold**. In certain cases, changes are highlighted for clarity.

Revision 1: SCHEMA

Secondary Objectives:

- To examine adherence to and timeliness of injections over time among adolescent participants provided CAB LA and information regarding its safety and efficacy.
- To examine patterns of sexual risk behavior over time among adolescent participants provided CAB LA and information regarding its safety and efficacy.
- **To evaluate the safety of oral CAB during step 1 (oral phase) as well as all study products during the aggregate oral+injectable period for all enrolled participants. Additionally, we will include an intention to treat analysis for the primary safety endpoint.**
- ~~To evaluate the safety of CAB LA for up to 48 weeks of follow-up after final injection.~~
- To characterize the pharmacokinetics of CAB LA.
- **Additional exploratory analyses may be performed using laboratory and clinical data from the study, including analysis of HIV drug resistance among participants with confirmed HIV infection.**

Revision 2: 1.12 Rationale for use of Oral Run-in Prior to Injectable Dosing

The current plans for product labeling~~, should FDA approval be granted,~~ include an oral lead-in strategy when adequate safety is established after four weeks of oral drug exposure. The 5-week exposure in this study is designed to provide un-interrupted study product coverage while awaiting return of the Week 4 safety laboratory assessments.

Revision 3: 2.2 Secondary Objectives

2.2 Secondary Objectives

- To examine adherence to and timeliness of injections over time among adolescent participants provided CAB LA and information regarding its safety and unknown efficacy.
- To examine patterns of sexual risk behavior over time among adolescent participants provided CAB LA and information regarding its safety and unknown efficacy.
- **To evaluate the safety of oral CAB during step 1 (oral phase) as well as all study products during the aggregate oral+injectable period for all enrolled participants. Additionally, we will include an intention to treat analysis for the primary safety endpoint.**
- ~~To evaluate the safety of CAB LA for 48 weeks of follow-up after final injection.~~
- To characterize the pharmacokinetics of CAB LA.
- **Additional exploratory analyses may be performed using laboratory and clinical data from the study, including analysis of HIV drug resistance among participants with confirmed HIV infection.**

Revision 4: 2.3 Study Design and Overview

Section 2.3 Study Design and Overview

Study participation includes~~:~~ Step 1: a 5-week oral CAB 30 mg QD safety lead-in**,** followed by a series of 5 intramuscular (IM) injections of 3 mL (600 mg) administered at 8-week intervals after a 4-week loading dose (injections at weeks 5, 9, 17, 25 & 33) in Step 2. Adherence support strategies (e.g., counseling, reminders, pill cases) will be included to support pill-taking during the first five weeks and to support retention during the injectable phase. A safety visit will follow each injection to ascertain pharmacokinetic-peak safety data, including injection site reactions. Step 3: A blood draw visit, the +8 Week Visit, will follow the last injection to monitor CAB drug levels. All participants who have received at least one injection will be followed for 48 weeks after their last injection. Waning levels of cabotegravir (the PK tail) will be covered with locally sourced oral **generic TDF/FTC or brand name TDF/FTC (Truvada®)** for daily use for 48 weeks. **Participants will be offered the option to enroll in the HPTN 084 OLE (open-label extension) study if they would like to remain on CAB LA.** ~~may be offered the opportunity to join an open label CAB study instead, if such a study is being implemented in their area at the time.~~ Behavioral and acceptability data will be collected via computer-assisted self-interview (CASI).

Participants who discontinue study product during Step 2 for any reason other than HIV infection or AE occurrence **related to study product** will be transitioned to open label **generic TDF/FTC or brand name TDF/FTC (Truvada®)** for 48 weeks.

Revision 5: Section 4.1.2 Injectable Suspension

The CAB study product (oral and LA injectable) being tested in this study **was approved by the US FDA for** ~~is investigational and not yet approved by the US FDA for the treatment or~~ prevention of HIV-1 infection **in adults and adolescents weighing at least 35 kg**. Further information on the study product is available in the IB, which will be provided by the DAIDS Regulatory Support Center (RSC).

Revision 6: Section 4.2.1 Study Product Acquisition

Section 4.2.1 Study Product Acquisition

Generic TDF/FTC or brand name TDF/FTC (Truvada®) ~~TENOFOVIR/EMTRICITABINE (TRADE NAME: TDF/FTC, TRUVADA®)~~ will be obtained locally by the site. **If sites choose to procure generic TDF/FTC, they must follow the appropriate DAIDS policy to procure it, when such products have not been approved or tentatively approved by the U.S. FDA.**

Revision 7: Section 5.8 Loading Dose Visit for Injectable Cabotegravir for Participants Restarting CAB Injections

5.8 Loading Dose Visit for Injectable Cabotegravir for Participants Restarting CAB Injections

In general, if it has been >15 weeks since a participant's prior CAB LA injection, a reload of CAB LA injections (two injections, 4 weeks apart) will take place. The participant will then continue Step 2 or transition to Step 3 four weeks later. Contact the CMC for guidance regarding all reloading cases.

Revision 8: Section 7 Statistical Considerations

7.2.2 Secondary Endpoints

- Plasma CAB pharmacokinetics
- Proportion of participants experiencing Grade 2 or higher clinical AEs and laboratory abnormalities in the oral phase and the aggregate over the entire study period. **Additionally, we will include an intention to treat analysis for the primary safety endpoint.**
- ~~48 weeks following final injection~~
- Proportion of injection visits that occurred "on-time"
- Change from enrollment of self-reported sexual behavior (number of sexual partners, increased episodes of unprotected vaginal or anal intercourse) during the study period
- **Additional exploratory analyses may be performed using laboratory and clinical data from the study, including analysis of HIV drug resistance among participants with confirmed HIV infection.**

7.3 Sample Size

The study target is to enroll more than 50 participants (n=55) with the anticipation that 50 participants receiving at least one injection (allowing for early study termination, or failure to move on after Step 1, the oral phase). The sample size for this protocol (n=50) is the number of participants agreed upon by the industry sponsor and regulators in order to provide supplementary safety and behavioral data on adolescents in collaboration with the HPTN 083 and HPTN 084 adult trials. The goal of the safety evaluation for this study is to identify safety concerns associated with CAB LA.
Since each of the primary endpoints is a proportion, Table 1. Width of 95% confidence interval for estimated proportion as a function of the true proportion, assuming a sample size of 5**0 participants anticipated to begin Step 2, among 5**5 **enrolled.** shows the precision (confidence interval width) that will be obtained for each endpoint with a sample size of ~~55~~**50**.

Table 1. Width of 95% confidence interval for estimated proportion as a function of the true proportion, assuming a sample size of 5**0 participants anticipated to begin Step 2, among 5**5 **enrolled.**	
True proportion	Width of 95% CI
0.1	± 0.083~~± 0.079~~
0.2	± 0.11~~± 0.10~~
0.3	± 0.13~~± 0.12~~
0.4	± 0.14~~± 0.13~~
0.5	± 0.14~~± 0.13~~

The study will recruit participants to ensure that at least ~~55~~**50** participants progress to the injection phase.

7.4 Randomization

There is no treatment randomization due to this study being a single arm, open label trial.

7.5 Blinding

Participants and site staff will be unblinded throughout the trial.

7.6 Data and Safety Monitoring Analysis

7.6.1 Study Monitoring Committee

NIAID DSMB oversight is planned for this study. Monitoring guidance will be detailed in a separate Interim Monitoring Plan. In addition, approximately every six months the HPTN SMC will conduct interim reviews of study progress, including rates of participant accrual, visit

retention, and completion of primary and main secondary endpoint collection. The frequency and content of SMC reviews will be determined prior to the start of the study as outlined in the HPTN Manual of Procedures (MOP).

~~In addition, approximately every six months the HPTN SMC will conduct interim reviews of study progress, including rates of participant accrual, visit retention, and completion of primary and main secondary endpoint collection. The frequency and content of SMC reviews will be determined prior to the start of the study as outlined in the HPTN Manual of Procedures (MOP).~~

7.7 Primary Analyses

All participants who receive at least one injection will contribute to the primary analyses. The safety and tolerability will be analyzed in aggregate. When the use of descriptive statistics to assess group characteristics or differences is required, the following methods will be used: for categorical variables, the number and percent in each category; for continuous variables, the mean, median, standard deviation, quartiles and range (minimum, maximum).

7.7.1 Safety Endpoints

The primary safety analysis will include Grade 2 or higher clinical and laboratory events that occur from the initial injection ~~to 48 weeks after the last injection~~**to the last Step 2 safety visit (up to week 34 for participants completing all injections)** among participants who receive at least one injection. ~~Secondary safety analyses will include the same definition applied over the oral phase only (week 0 to week 4) and the aggregate oral+injectable+follow-up period.~~

7.8.2 Safety Endpoints

Secondary safety analyses will be summarized using the same method described in section 7.6.3, applied over the oral phase only (week 0 to week 4) and the aggregate oral+injectable **period for all enrolled participants** ~~+follow-up period~~. **Additionally, we will include an intention to treat analysis for the primary safety endpoint for all participants receiving at least one injection, using the time from first injection to approximately 34 weeks later (or study termination, if terminated early) regardless of whether participants received all 5 injections.**

Revision 9: Section 12.3 APPENDIX III: SCHEDULE OF EVALUATIONS –FOLLOW-UP PHASE (Step 3) – **Oral PrEP (only)***

12.3 APPENDIX III. SCHEDULE OF EVALUATIONS –FOLLOW-UP PHASE (Step 3) – Oral PrEP (only)*

This Schedule of Evaluations is only for HPTN 084-01 participants who choose to remain on generic TDF/FTC or brand name TDF/FTC (Truvada®) instead of moving to the HPTN 084 Open-Label Extension (OLE), once the OLE is formally approved at sites.

WEEKS SINCE LAST INJECTION	Wk +8	Wk +12	Wk +24	Wk +36	Wk +48	Early Discontinuation
ADMINISTRATIVE, BEHAVIORAL, REGULATORY						

Locator information	X	X	X	X	X	X
HIV prevention & risk reduction counseling	X	X	X	X	X	X
Condoms per local SOC	X	X	X	X	X	X
Behavioral/Acceptability assessment (CASI)		X	X	X	X	X
CLINICAL EVALUATIONS & PROCEDURES						
Qualitative interviews continue (approximately)		X	X			
Contraception counselling and provision or verification of use		X	X	X	X	
Medical history[1], concomitant medications, targeted physical exam	**X**	X	X	X	X	X
Hep B vaccination (if needed) [2]						X
Blood collection	X	X	X	X	X	X
Urine collection		X	X	X	X	X
Provision of **generic TDF/FTC or brand name TDF/FTC (Truvada®)**(3 months' worth)		X	X	X		X
Adherence Counseling[3]		**X**	**X**	**X**	**X[3]**	**X[3]**
LOCAL LABORATORY EVALUATIONS & PROCEDURES						
HIV testing[34]	**X**	X	X	X	X	X
Pregnancy testing[45]		X	X	X	X	X
CBC with differential		X	X	X	X	X
Chemistry testing[65]		~~X~~	X	~~X~~	X	X
Liver function testing[76]		~~X~~	X	~~X~~	X	X
Syphilis testing				X		
GC/CT testing (urine or vaginal swab)		X	X	X	X	X
Urinalysis (protein, glucose)		X	X	X	X	
Plasma storage[8]	X	X	X	X	X	X
DBS storage		X	X		X	

FOOTNOTES FOR APPENDIX III:

[1] Medical history must include pulse, blood pressure, weight and Body Mass Index (BMI) calculated at each visit.

[2] The initial dose of the HBV vaccination is ideally given at Week 2, though there is flexibility around the timing of the vaccination. Subsequent doses may be given at different visits than indicated in this SOE, as long as sites follow manufacturer guideline timing.

[3] At Week +48 and Early Discontinuation visits, Adherence Counseling consists of transition to local care/publicly available product.

[4] HIV viral load RNA testing is required for all participants at every visit, even those without documented seroconversion or other reactive/positive test results. Testing should include an HIV rapid test, laboratory-based HIV antigen/antibody assay, and HIV viral load test. HIV viral load testing should be performed using an assay with a lower limit of detection/quantification <50 copies/mL. The HIV testing algorithm is provided in the SSP Manual. If HIV rapid testing is indicated, this testing may be performed in the clinic or the laboratory. At least one HIV test must be available and reviewed the same day as sample collection and before product is administered.

[54] Pregnancy testing may be performed in the clinic or the laboratory. Results must be available the same day as sample collection and before product is administered. Testing may be performed using a urine, plasma, or serum sample. The assay used for pregnancy testing must have a limit of detection of 25 mIU/mL or lower. Confirmation of pregnancy at a subsequent visit at least 4 weeks after the initial pregnancy test is required. Participants with confirmed pregnancies in Step 3 will continue to be followed by the study every 12 weeks for 48 weeks after the last CAB LA injection or delivery, whichever comes last. Open label **generic TDF/FTC or brand name TDF/FTC (Truvada®)** will be provided for 48 weeks after the last CAB injection. Site staff will refer to their SOP for detailed management.
[65] BUN/urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, and lipase.
[76] AST, ALT, TBili, and alkaline phosphatase.
[8] Stored plasma will be used for Quality Assurance testing and other assessments at the HPTN LC (see Section 9), including potential assay for plasma CAB concentrations. Assessments will be performed retrospectively; results will not be returned to study sites or participants, except as noted in SSP

Revision 10: Section 12.4 APPENDIX IV: SCHEDULE OF ADDITIONAL PROCEDURES FOR REACTIVE/POSITIVE HIV TESTS

Participants who acquire HIV infection in Steps 2 and 3 only					
	HIV Confirmation Visit	Week 12	Week 24	Week 36	Week 48
ADMININISTRATIVE, BEHAVIORAL, REGULATORY					
Locator information	X	X	X	X	X
Offer condoms	X	X	X	X	X
HIV counseling	X				
CLINICAL EVALUATIONS AND PROCEDURES					
Targeted history, con meds, targeted physical exam	X	X	X	X	X
Blood collection	X	X	X	X	X
LOCAL LABORATORY EVALUATIONS					
HIV testing[1]	X				
CD4 cell count	X		X		X
HIV viral load testing[2]	X		X		X
HIV resistance testing[23]	X				
Chemistry testing[34]		~~X~~	X	~~X~~	X
Liver function testing[45]		~~X~~	X	~~X~~	X
Plasma storage[56]	X	X	X	X	X
DBS storage	X				

FOOTNOTES FOR APPENDIX IV:

[1] The HIV confirmatory visit must be held on a different day from the visit where the participant had their initial reactive/positive HIV test. The testing algorithm for the HIV Confirmation Visit is provided in the SSP Manual. If HIV rapid testing is included in the HIV testing algorithm, this testing may be performed in the clinic or the laboratory.

[2] HIV viral load testing should be performed using an assay with a limit of detection/quantification <50 copies/mL.

[23] Sites will collect specimens for resistance testing at a local laboratory to assist with clinical management; results from resistance testing performed at local laboratories will not be reported to the SDMC. Stored plasma may not be used real-time/local resistance testing; additional samples must be collected for this testing.

[34] Required chemistry testing: BUN/urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, and lipase.

[45] Required LFTs: AST, ALT, total bilirubin, and alkaline phosphatase.

[56] Stored plasma will be used for Quality Assurance testing and other assessments at the HPTN LC (see Section 9) including potential assay for plasma CAB concentrations. Assessments will be performed retrospectively; results will not be returned to study sites or participants, except as noted in Section 9.0.

Revision 11: Section 12.7 Appendix VII: SAMPLE INFORMED CONSENT with PARENT/GUARDIAN PERMISSION

2. What will happen to me during the study?

- HIV Prevention – We will offer you Truvada **(or generic)** tablets as PrEP after you stop~~s~~ the CAB injections. You may, instead, have the opportunity to join **the HPTN 084 OLE (open-label extension study for CAB LA)** ~~an open label CAB study, if available~~.

WHAT IS THIS STUDY ABOUT?

In this study, we want to know if it is safe and acceptable for adolescent women who do not have HIV to take an anti-HIV drug called cabotegravir (CAB). We would also like to look at the tolerability, or side effects, of CAB. CAB is a new drug that is still being studied and **was approved in December 2021 by the FDA** ~~is not yet approved by the FDA~~, or U.S. Food and Drug Administration**, for adults and adolescents weighing at least 35 kg**. Other studies showed that CAB can treat people who have HIV infection and it has recently been shown to prevent HIV infection.

WHAT WILL I HAVE TO DO IN THE STUDY?

If you want to be in this study, you will sign this consent form before you begin the study.

Study Visit Schedule

- Step 3 (5 visits **or transition to HPTN 084 OLE**) – **For Step 3, you will have the option of remaining in HPTN 084-01 and taking generic TDF/FTC or brand name TDF/FTC (Truvada®) or transitioning onto the HPTN 084 OLE.**
    - **If you choose Truvada® or generic for Step 3:** After **an initial Week +8 Visit,** ~~a blood draw 8 weeks after your last injection,~~ you will come to the clinic quarterly

(every 3 months) for almost a year to check how you are doing and to see how long CAB remains in your body after your last injection (~~+8,~~ +12, +24, +36, +48 weeks). In most people, CAB disappears from the body slowly over 6 months, but it may last for a year or so. During this Step, you will be provided with **generic TDF/FTC or brand name TDF/FTC (Truvada®)** ~~Tenofovir/emtricitabine (Trade name: TDF/FTC, Truvada® or generic)~~ to take daily.~~, or be offered the opportunity to join an open label CAB study if available, so we will be following you to see how well things are going on oral PrEP, doing bloodwork, as well as HIV and other STI testing.so we will be following you to see how well things are going on oral PrEP and doing bloodwork, as well as HIV and other STI testing.~~

Study Visit Procedures

- *HIV Prevention* – **CAB LA has been shown to prevent HIV in adult women.** ~~We do not know for sure if CAB will protect you from getting HIV.~~ **The** ~~Also, the~~ amount of CAB remaining in the body disappears slowly after you stop~~s~~ the CAB injections – it can last in the body for about one year, so you must use other ways of preventing HIV if you are at risk of infection. For this reason, we will offer you **generic TDF/FTC or brand name TDF/FTC (Truvada®)** ~~Tenofovir/emtricitabine (Trade name: TDF/FTC, Truvada® or generic)~~ tablets as PrEP after you stop the CAB injections or offer you the opportunity to join **the HPTN 084 OLE** ~~an open-label CAB study, if available~~. Before you leave the study, we will help you find a place where you can continue getting HIV prevention care *[sites to add information here or elsewhere in the consent form]*.

Tables of Study Visit Procedures

Step 3 Follow-Up Visits**, if you choose TDF/FTC or generic for Step 3** – to see how long the CAB remains in your body

	+8 Weeks	+12 Weeks	+24 Weeks	+36 Weeks	+48 Weeks
Questions/CASI		√	√	√	√
Counselling	√	√	√	√	√
Brief physical exam	√	√	√	√	√
Blood	√	√	√	√	√
Urine		√	√	√	√
Vaginal swab		√	√	√	√
PrEP pills offered		√	√	√	