

HIV Prevention Trials Network

Clarification Memo # 1 to:

HPTN 084: A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women

Protocol Version 4.0, dated 2 November 2022

DAIDS Document ID: 38070

Date of FINAL Clarification Memo: 24Feb2023

Implementation

The items clarified in this Clarification Memorandum (CM) have been approved by the Division of AIDS (DAIDS) Medical Officer and are to be implemented immediately upon issuance. Institutional Review Boards/Ethics Committees (IRBs/ECs) approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB/EC overseeing the study at their site for information.

No change in the informed consent forms is necessitated by or included in this CM.

The modifications included in this CM will be incorporated into the next full protocol amendment. Text noted below by ~~strike through~~ will be deleted; text appearing below in **bold** will be added.

Summary of Revisions and Rationale

1. A discrepancy was found between the v4.0 protocol, Step 6 Schedule of Evaluations (SOE) and the v4.0 protocol consent form. The discrepancy arose when the team decided to remove the urinalysis from the SOE at the first Step 6 visit and at the six month visit but inadvertently left text in the consent. With this Clarification Memo, we are removing the discrepant text in the consent form.
2. Updated Section 5.8 to clarify that the first injection of Step 6 occurs at Week 56. Also corrected a typographical error by removing an “s” after the word “Step” in the same section.
3. Added a footnote to the Step 6 SOE indicating what chemistry testing is to be done.

Revision 1-Related Changes: Removed consent form verbiage indicating a urinalysis will be done.

Revision 1, Change 1) Removed text from the consent form section titled: “What will happen during the second period of open-label study visits?” The text is found in the fifth bullet of the section.

- “Collect urine samples to test you for pregnancy, if indicated [site insert sample type, blood vs. urine]. **At your first visit, and every 6 months we will also test to see if there is sugar or protein in your urine.**”

Revision 2-Related Changes: Updated Section 5.8 to clarify that the first injection of Step 6 occurs at Week 56. Also removed an “s” after “Step 6.”

Revision 2, Change 1) Replaced text “Week 0” with “first” and added “(Week 56).”

“Section 5.8 injection Visit Windows:

Steps 6

- For the **Week-0 first** injection of Step 6 (**Week 56**), the injection must be given with a minimum of 3 weeks’ time and a maximum of 10-12 weeks’ time from a previous study injection.”

Revision 3-Related Changes: Added a footnote clarifying the chemistry testing required during Step 6.

Revision 3, Change 1) Added a footnote “9” to the Step 6 Schedule of Evaluations.

“Step 6

Appendix VIII: Schedule of Evaluations for Step 6-Procedures for Participants on Maintenance Doses of CAB LA weeks 49-96

LOCAL LABORATORY EVALUATIONS & PROCEDURES						
HIV testing ⁴	X	X	X	X	X	X
HIV viral load testing ⁵	X	X	X	X	X	X
Pregnancy testing, only if indicated ¹	X	X	X	X	X	X
Chemistry testing ⁹						X
Liver function testing ⁶						X

⁹ **Chemistry testing includes: Albumin, BUN/Urea, creatinine.**”