

HIV Prevention Trials Network

Clarification Memo # 2 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 3.0, dated 12 August 2021

DAIDS Document ID: 38070

Date of FINAL Clarification Memo: 21Jul2022

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 ~~striketrough~~ will be deleted; text appearing below in **bold** will be added

Summary of Revisions and Rationale

1. A typographical error to the Schedule of Evaluations for “Appendix VIII: Schedule of Evaluations for Step 4c- Procedures for Participants on Maintenance Doses of CAB LA or TDF/FTC” was corrected.

<p>Revision 1-Related Changes: Clarified that the verbiage indicating a CBC does not have to be repeated if conducted during Step 4a or 4b only applies to the Week 0 visit of Step 4c.</p>
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Revision 1, Change 1) Edited the row titled “CBC with differential, if not done in Step 4a or 4b” of “Appendix VIII: Schedule of Evaluations for Step 4c- Procedures for Participants on Maintenance Doses of CAB LA or TDF/FTC.” Removed the text “~~if not done in Step 4a or 4b~~” as it does not apply to the whole row. Added a footnote, footnote ¹¹, to the Week 0 visit of Step 4c in that same row.

LOCAL LABORATORY EVALUATIONS & PROCEDURES													
HIV testing ⁴	X		X		X		X		X		X		X
HIV viral load testing ⁵	X		X		X		X		X		X		X
Pregnancy testing ¹	X		X		X		X		X		X		X
CBC with differential, if not done in Step 4a or 4b	X ¹¹						X						X

¹¹ Only for those that did not have this collected in steps 4a and b.