

Clarification Memo # 3 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 1.0, dated 2 March 2017**

FINAL Clarification Memo (CM) Version: 2Aug2019

Summary of Revisions and Rationale

1. Text has been added to clarify that injectable study product, long-acting cabotegravir (CAB LA) is available in both 2mL and 3mL vials.

Implementation

The procedures clarified in this memorandum have been approved by the Division of AIDS (DAIDS) Medical Officer and are to be implemented immediately upon issuance. IRB approval of HPTN 084 Protocol Clarification Memo (CM) #3 to HPTN 084, Version 1.0 is not required by the sponsor; however, sites may submit the CM to the responsible IRBs for their information.

No change in the informed consent forms is necessitated by or included in this CM, aside from the corrected typographical errors.

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.

Revision 1-Related Changes: Clarified Text

Revision 1, Change 1) Edited text in Section 4.1.2, "Injectable Suspension"

"CAB LA formulation

CAB LA is formulated as a sterile white to slightly **pink** coloured suspension containing 200 mg/mL of CAB LA for administration by IM. The product is packaged in a **2mL or** 3 mL **glass** vial. Each vial is for single use containing ~~a nominal fill of~~ 2mL (400 mg), **or 3mL (600mg)**, and does not require dilution prior to administration. CAB LA injectable suspension is to be stored **up to** 30° C (**86° F**), do not freeze."