

## **HIV Prevention Trials Network**

### **Summary of Changes Included in the Full Protocol Amendment of HPTN 084DAIDS**

**Document ID # 38070**

#### **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**

**The Amended Protocol is identified as:**

**Version 3.0, dated 12 August 2021**

#### *Information for Investigators*

The modifications included in this protocol amendment and the associated rationale are summarized briefly below. HPTN 084 study investigators will submit this Summary of Changes and the corresponding protocol Version 2.3 and informed consents to all relevant regulatory authorities and Institutional Review Boards/Ethics Committees (IRBs/ECs) for approval. Upon receipt of all IRB/EC approvals, sites should begin implementation of the amended protocol immediately. The site will submit all required documents to DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center.

This Amendment and all related IRB/EC correspondence must be retained in the site regulatory file in other pertinent files.

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### **RATIONALE**

The version 2.0 protocol of 6 November 2019 is being updated to provide instructions to offer all currently enrolled HPTN 084 participants the option to choose to continue or initiate CAB-LA, or choose to continue or initiate TDF/FTC. This full amendment also incorporates four Letters of Amendment (LoAs) and two Clarification Memos (CMs).

#### **Summary of Revisions and Rationale**

##### **General Updates:**

- The protocol is being updated to incorporate LoA #1, LoA #2, LoA #3, LoA#4, CM #1, and CM #2 (please note that the revisions and rationales affiliated with all LoAs and CMs)

are not included in this summary, as they are outlined in each previously approved LoAs and CMs).

- The protocol is updated throughout for minor editorial changes and typographical errors.

#### **List of Abbreviations and Acronyms:**

- Two acronyms (IQA and pSMILE) were removed as they are no longer referenced in the protocol.

#### **Protocol Team Roster:**

- Lynda Stranix-Chibanda and Friday Saidi were added to the protocol roster as pregnancy and infant sub-study advisors.

#### **Appendix VIII:**

- Appendix VIII is a new section. The purpose of Appendix VIII is to provide instructions to offer all currently enrolled HPTN 084 participants the option to choose to continue or initiate CAB-LA, or choose to continue or initiate TDF/FTC.