HIV Prevention Trials Network

Clarification Memo #2 to:

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

Protocol Version 1.0, dated 14 October 2019

Date of Clarification Memo: 28 June 2022

The items clarified in this Clarification Memorandum (CM) have been approved by the 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. This CM is official HPTN 084-01 documentation and is effective immediately.

This CM and all related IRB/EC correspondence must be retained in the site regulatory file and in other pertinent files. Protocol registration approval is not required by DAIDS for CMs.

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

Summary of Revisions and Rationale

1. This Clarification Memo seeks to streamline understanding for when HCV (Hepatitis C virus) testing will be performed on HPTN 084-01 participant samples.

   The protocol intention was to capture incident hepatitis C infection during follow-up by testing for HCV antibodies at screening or entry and then at Week 33, with other STIs. HCV was not explicitly checked in the Schedule of Evaluations (SOE) by mistake. The primary reason for HCV testing is descriptive; however, the results would be of clinical relevance and should be delivered to participants who are still in Step 3 or have recently transitioned to HPTN 084 OLE (open label extension) for local referrals and/or management, per standard of care. Sufficient plasma should be in storage from the Week 33 visit for the sites to proceed with HCV testing, then provide the results to participants.

Deletions to the protocol text are indicated by ~~strikethrough~~; additions are indicated in **bold**.

Revision 1: 5.14 HBV and HCV

5.14 HBV and HCV

For enrolled individuals, HCV antibody testing will **also** be performed at **Week 33** ~~scheduled visits while on Step 2~~ (see Appendix II). Incident HCV infection during follow-up will not mandate discontinuation of study product absent other requirements per Appendix VI - Toxicity Management.

Revision 2: 12.2 APPENDIX II. SCHEDULE OF EVALUATIONS – INJECTION PHASE (Step 2)

WEEKS in Study (shaded column = injection visit)	**Wk 5**	**Wk 6**	**Wk 9**	**Wk 10**	**Wk 17**	**Wk 18**	**Wk 25**	**Wk 26**	**Wk 33**	**Wk 34**
LOCAL LABORATORY EVALUATIONS & PROCEDURES										
HIV testing[4]	X	X	X	X	X	X	X	X	X	X
Pregnancy testing[5]	X		X		X		X		X	
HCV testing									**X**	
CBC with differential	X	X	X	X	X	X	X	X	X	X
Chemistry testing[6]	X	X	X	X	X	X	X	X	X	X
Liver function testing[7]	X	X	X	X	X	X	X	X	X	X
Fasting lipid profile[8]										X
Syphilis testing									X	
GC/CT testing (urine or vaginal swab)					X				X	
Urinalysis (protein, glucose)	X	X	X	X	X	X	X	X	X	X
Plasma storage[9]	X	X	X	X	X	X	X	X	X	X