

MEMORANDUM

Date: June 13, 2011
To: HPTN066 Protocol Team, HPTN066 Sites
From: HPTN066 SCHARP Team
RE: **HPTN066 Disposition of Enrolled Participants Report**

The **Disposition of Enrolled Participants Report** for HPTN066 is updated nightly and is based on cumulative data received at SCHARP through the previous week. The report is meant for use by the protocol team to monitor study progress.

Note: The study weeks in this report correspond to the study weeks listed in Appendices IB and IC in protocol version 2.0.

Please contact the HPTN066 Project Manager at SCHARP, Laura McKinstry (lamckins@scharp.org), with any questions you may have regarding this report.

This report includes the following information:

Disposition of Enrolled Participants

This table summarizes participants' follow-up status as to whether they are still on study, have terminated early or have completed the study. Among participants who have completed the study, the number and percentage of evaluable participants are reported. In addition, the reasons why participants terminated early or the reasons that make a participant no longer evaluable are listed.

Assessment of Evaluable Participants

The evaluability of a participant is determined by his/her compliance to the dosing schedule as well as completion of PK blood and tissue sampling. Whether a participant is evaluable is assessed after the participant either completes the study or terminates early from the study.

In order to be considered evaluable, a participant must meet the following criteria:

Dosing Completion

1. Optimally, all product dosing will occur on the date scheduled (the target date).
2. Some tolerance is allowed as long as the total dosing within each week is consistent with the prescribed total (within the first 3 weeks only).
3. For Arms 1, 2, and 3, dosing can be delayed by 2 days, during the first 3 weeks only. All doses in Weeks 4 and 5 must be taken as scheduled.
4. In Arm 4, all doses must be taken as scheduled throughout the entire study.

PK Blood/Tissue Sampling Completion

1. Participants may miss one of the following pre-steady state study visits (and thus PK blood sample collection) and remain evaluable: Day 7, Day 14, or Day 21.
2. PK blood draws for Day 7, Day 14, Day 21, and Day 49 should be done within a +/- 2 day visit window.
3. Day 0, Pre-Dose #2, Day 28, and Day 35 PK blood draws are required to be done on the target day.
4. Day 35 tissue sampling cannot be missed and should be done within the +/- 1 day window around the visit.
5. Day 49 tissue sampling cannot be missed and should be done within the +/- 2 day window around the visit.
6. Rectal, vaginal and blood samples should be collected, and then processed, in the order in which the samples appear in the protocol (pages 70-71) and will be dependent upon the availability of cells in the sample. A participant must have all samples, with the exception of CD4 cells from blood or tissue, in order to be considered evaluable.

Memorandum

continued

Table 1. Scheduled date/window for dosing and PK sampling

	Visit Type	Dosing Day/Window	PK Sampling Day/Window
Week 1	Enrollment	Day 0	Day 0
	Pre-dose #2 Visit	Day 1 (Arm 4) Day 3 (Arm 3) Day 3 (Arm 2)	Day 1 (Arm 4) Day 3 (Arm 3) Day 3 (Arm 2)
Week 2	Day 7 Visit*†	Day 5-9	Day 5-9
	Day 10 Dose	Days 8-12 (Arms 2 & 3)	
Week 3	Day 14 Visit*	Day 12-16	Day 12-16
	Day 17 Dose	Day 15-19 (Arms 2 & 3)	
Week 4	Day 21 Visit*	Day 21	Day 21
	Day 24 Dose	Day 24 (Arms 2 & 3)	
Week 5	Day 28 Visit	Day 28	Day 28
	Day 31 Dose	Day 31 (Arms 2 & 3)	
Week 6	Day 35 Visit		Day 35: Blood sample Day 34-36: Tissue samples
Week 7	Day 49 Visit		Day 47-51: Blood sample Day 47-51: Tissue samples

*A participant can miss just one among Day 7, Day 14, and Day 21 visits.

†The Pre-dose #2 Visit for participants in Arm 1 is the same as the Day 7 Visit.