



HPTN058 Data Communiqué #1

27 March, 2008

This is official study documentation for the HPTN058 clinical trial. Please print it and circulate among relevant staff for their review, and file it in your HPTN058 SSP Manual behind the “Communiqués” tab. This document is considered part of the SSP manual.

CLARIFICATION

Combining Visit Procedures for Weeks 24 and 26

Protocol HPTN 058 indicates that some visits procedures are to be performed at 4 and 12 weeks intervals. Section 7 of the Study-Specific Procedures manual indicates that the Urine Test Results (UTR-1) and Social Impact Assessments (SIA-1) DataFax forms are to be completed from week 4 to week 52, at 4 weeks intervals and again at the 26 week follow-up visit.

Since weeks 24 and 26 visits are only 2 weeks apart, it is not necessary to perform these procedures twice during that period.

To simplify scheduling, the lower window for week 26 has been extended to 4 weeks (28 days) prior to the target visit date. This means that all of week 26 visit procedures can be performed at the week 24 time point, but the corresponding CRFs must be marked with **Visit Code 026.0**. This is because week 26 visit is an endpoint visit.

The table below shows the weeks, visit codes, relevant visit windows and the required CRFs for both Weeks 24 and 26 visits. The Urine Test Results (UTR-1) and Social Impact Assessments (SIA-1) CRFs will be completed only once during the 2 week interval and will be marked with **Visit Code 026.0**. There will be no CRFs expected at Visit 24.0 other than the Weekly Dosing Record CRF (DR-1) and optional forms such as missed or interim visits CRFs, if needed.

Week #	Counseling	Substitution Dosing	Detox Dosing	Follow-up	Visit Code	Target Day	Visit Window (in days)		Required CRFs
							Opens	Closes	
24	X	X			024.0*	168	--	--	DR-1, UTR-1, SIA-1
25		X			025.0*	175	--	--	DR-1
26		X	X	X	026.0	182	154	210	DR-1, AA-1, HTR-1, LLF-1, RA 1-8, SIA-1, UTR-1

* Only use visit code on optional forms as necessary.

REMINDERS

- DR-1 CRF is not affected by this change and will have Week# 24 code as expected.
- Though the visit windows are large, it is strongly recommended that each visit be performed as closely as possible to the Target Day.

Please contact Huguette Redinger (redinger@scharp.org) for questions regarding this Communiqué.