To: IMPAACT Principal Investigators and Study Coordinators at Sites Participating in IMPAACT P1058A

From: IMPAACT P1058A Protocol Team

Date: May 18, 2012


Non-IND; DAIDS ES #: 10809

This is Clarification Memo #1 for IMPAACT P1058A, Version 2.0, dated February 22, 2012. This Memo can be obtained from the P1058A Protocol Specific Web Page (PSWP) tab on the IMPAACT web site https://impaactgroup.org/. Enter the Member/MIS area using your individual username and password. Search for the study number. From the protocol [P1058A] web page you will have the option to click the PSWP tab. The document is located under the section titled Current Version-2.0, Dated 02/22/2012.

The purpose of this memo is to clarify the intensive pharmacokinetic (PK) blood draw schedule in the Schema, Section 3.0 (Study Design) and Appendix I (Schedule of Evaluations).

All regimen groups in Version 2.0, Groups M – Q, will have an intensive 24-hour PK study which includes both 12 and 24 hour blood draws. Blood samples for the intensive 24-hour PK will be drawn at the following time points: 0 (pre-dose) and 1, 2, 4, 6, 8, 12 and 24 hours post dosing.

Subjects in Group N who are on etravirine (ETV) 200 mg BID should, optimally, have the 12-hour blood sample taken before the second ETV dose of the day is given. This will allow the measurement of the true concentration at 12 hours for ETV.

This clarification will be included in the next version of the protocol when it is amended. Please contact the protocol team at impaact.teamp1058a@fstrf.org if you have any questions. Thank you for your interest in IMPAACT P1058A.