

HPTN046 Data Communiqué #9

03 November 2008

This is official study documentation for the HPTN046 trial. Please print it and circulate among relevant staff for their review, and file it in your HPTN046 SSP Manual behind the “Communiqués” tab. This document is considered part of the SSP manual.

CLARIFICATIONS

Infant’s Study Drug Dosing (IDD-1-2): There are some infants who are permanently discontinued from open-label nevirapine dosing but who are not randomized until a later visit. When completing item #4 on the IDD-1, which asks if dosing has been permanently discontinued, please interpret this item in the following way: “Has open-label NVP/study drug been permanently discontinued at this visit?” This item should be marked ‘yes’ only once prior to randomization (at the visit where open-label nevirapine is permanently discontinued and the IOD-1 is completed), and once post-randomization (at the visit where study drug is permanently discontinued and the IPD-1 is completed).

Do not complete the IDD-1-2 if an infant:

- permanently discontinued open-label NVP at a previous visit, and
- has not yet started study drug and no study drug is to be dispensed at the current visit

REMINDERS

Infant’s Breastfeeding and Open-label NVP Dosing Initiation (IDI-1): This is a required form that should be completed and submitted to DataFax at the two-week visit or the first completed visit thereafter (regular or interim).

UPDATES

- 1. Infant’s Interim Visit Form (IV-1):** We discovered an out-of-date version of the IV-1 was still on file with our printer, and that consequently the wrong version was used to fill site orders for this form. We have corrected this by sending sites an “emergency” supply via Fed Ex and refilling site orders with the correct version. The correct version has a date of 06-MAY-08 on the front of the form (and 31-OCT-07 on the back). Please remove all older versions from circulation once you have the correct form.