

HPTN046 Data Communiqué #12

14 January 2010

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.

UPDATES

Changes to AE Reporting: As indicated in Clarification Memorandum #3 dated on 23 November 2009 for HPTN 046 Protocol Version 3.0, some additions have been made to the list of childhood illnesses that will be recorded in participant source records and captured in the study database as interim medical history or physical examination findings, but will not be reported separately as adverse experiences. The newly added items are **infantile colic pain, oral thrush, gastrointestinal reflux and constipation.**

For purposes of completing CRFs these conditions should not be counted as AEs (e.g. on the IFU-1 items #3). These conditions constitute abnormal physical exam findings (IFU-1 item #7) but should not be reported on the AE-1 CRF even if they occurred prior to 23 November 2009.

Infant’s Study Drug Dosing (IDD-1-2): There are only spaces for six (6) study drug labels on the IDD-2 but occasionally sites may need to dispense seven (7) bottles of study drug. If 7 bottles are dispensed sites should place the 7th label in the right margin next to item #7 or next to 6a-c, taking care not to obscure the other labels or any other data.

Infant’s End of Study Inventory (IEI-1): Item 1 (What is the last visit code for which data has been submitted, not including Missed Visit or Comments forms?) may be a missed visit IF the IOD-1 or IPD-1 was the last data submitted and it was submitted for a missed visit.

CLARIFICATIONS

Infant’s Interim Visit CRF (IV-1): Item 2 and item 3 should only be marked 'yes' if the infant has been given any new medications that are first being reported at the current visit (see instructions on back of the IV-1 form). If medication previously reported is continuing and there is no new medication to report, mark the item 'no'.

Mother’s Follow-up Visit (MFU-1): Item 1, weight: If the mother weight is > 99.9 kilograms, line through the boxes and write in the weight nearby, initial and date. Previously we asked that weight be noted in comments, but this information is more accessible to our staff if written near the item itself.

REMINDERS

Mother's Screening Outcome (MSO-1): This form is required for all mothers who are assigned a Participant ID number during screening or enrollment, whether or not the mother and infant enroll in the study. For mothers who don't enroll this is the only CRF completed and faxed to SCHARP. After study enrollment is complete, we will send lists to sites of PTIDs for which this form has not yet been received.

Infant's Interim Visit (IV-1): Don't assign interim visit code or submit IV-1 if no other new CRFs are submitted

Infant's Adverse Experience Log (AE-1): Remember the following when completing the AE-1:

- complete all items
- do not mark more than one box if item does not say "mark all that apply"
- any change/update must be initialed/dated/refaxed
- never re-use AE log page numbers
- Item #1: only enter one diagnosis/condition on each AE-1
- Item #3:
 - o when a grade 4 lab value is asymptomatic and is not life-threatening, record "asymptomatic" in the comments; these AEs are not considered to be SAEs (item #8 should be "no")
 - o when a grade 4 AE is life-threatening, including symptomatic abnormal lab values, the event is considered to be an SAE so item #8 must be marked "yes"
- Item #6:
 - o when "severity/frequency increased" is marked an outcome date must be provided and a new AE-1 must be completed and submitted; the onset date of the new AE must be the same date as the outcome date of the original AE
 - o when the AE status/outcome is "resolved" an outcome date must be provided
 - o when an AE is continuing at the time of termination from the study, update the status/outcome to "continuing at the end of study participation"
- Item #7:
 - o when "new/prolonged hospitalization" is marked, regardless of severity grade, this meets SAE criteria and item #8 should be marked "yes"
 - o for any SAE (item #8 = "yes") with any relationship other than "not related" an EAE must be reported and item #9 must be marked "yes"