



MTN-013/IPM 026 Data Communiqué #6

May 23, 2012

This is official study documentation for MTN- 013/IPM 026. Please circulate it among relevant staff for their review, print it, and place it in your MTN-013/IPM 026 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-013/IPM 026 SSP manual.

UPDATES

None

CLARIFICATIONS

1. Last Menstrual Period dates on Pharmacokinetics Specimens (PKS-1) form

When completing item 12 (last menstrual period dates) of the PKS-1 form, only record dates of menstrual period bleeding. Do not record dates of episodes of expected breakthrough bleeding experienced while a participant is on Depo, Mirena, or other continuous contraceptive method where a woman does not experience a monthly menstrual period.

2. Laboratory AEs and AE Log item 10 (visit code)

When reporting a laboratory-based AE, record the visit code in item 10 that matches the AE's Onset Date (item 2, which is also the specimen collection date). For non-laboratory AEs, the visit code in item 10 should match the "Date Reported to Site" item

3. Reporting Abdominal Pain as an AE

When reporting abdominal pain as an AE, pain that is gastrointestinal in nature must be differentiated from pain that is genitourinary or reproductive in nature.

- If abdominal pain is assessed as gastrointestinal in nature and no other overarching or unifying diagnosis is available, the term "abdominal pain" or "lower abdominal pain" should be used on item #1 on the AE-1 CRF.
- If the pain is assessed as genitourinary, the term reported on the AE-1 CRF should be described as such (e.g., "bladder pain").
- If the pain is assessed as reproductive in nature, the term reported on the AE-1 CRF should be described as such (e.g., "adnexal pain", "uterine pain"). Pain associated with menstruation is reproductive in nature and the term reported on the AE-1 CRF should be described using the term "dysmenorrhea".
- If the pain cannot be localized to a specific organ, it should be described on the AE-1 CRF using terms that identify a reproductive or genitourinary anatomical location (e.g., "pelvic pain", "urinary tract pain").

REMINDERS

None