

## MTN-020 Data Communiqué #13- November 18, 2014

This is official study documentation for MTN- 020. Please circulate it among relevant staff for their review, print it, and place it in your MTN-020 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-020 SSP manual.

**UPDATES** – None

### CLARIFICATIONS

#### 1. AE Outcome Date when treatment is indicated

For adverse experiences requiring treatment, record as the outcome date the date when all associated symptoms have resolved (or returned to baseline severity), or the date when treatment is completed, *whichever is later*. An AE is not considered resolved until both symptoms have resolved and treatment has been completed.

**Example:** A participant presents with Grade 2 vaginal discharge on 23May14 and is prescribed doxycycline on the same date. The participant's symptoms resolved on 27May14 and she completes her antibiotic regimen on 06Jun14. The outcome date recorded in item 6 on the corresponding AE log page CRF should be 06Jun14.

#### 2. Assignment of AE severity grade for genitourinary infections and symptoms

If an AE is graded using the 'general infection' row of the DAIDS Toxicity Table and requires systemic antimicrobial therapy, the infection must be graded automatically at Grade 2 or higher. Please refer to SSP Section 11.4 for this guidance. However, if a genitourinary AE is treated with systemic antimicrobials, the severity grade will depend on whether the Female Genital Grading Table (FGGT) or the main DAIDS Toxicity Table is used to grade the AE. For AEs graded according to the general "infections" row of the main DAIDS Toxicity Table, treatment with systemic antimicrobials warrants a severity grade of 2 or higher. For AEs graded according to the FGGT, treatment with systemic antimicrobials may still be covered under severity grade 1; grading will depend on the criteria defined in the given row.

**Example #1:** A participant presents with mild vaginal discharge and itching. Wet mount test results are positive for candida and she is given a dose of Fluconazole for treatment. This genitourinary infection should be graded as Grade 1 per the criteria of the Candida row of the FGGT regardless of whether an antimicrobial was prescribed.

**Example #2:** A participant presents with nasal congestion, fever, and headache consistent with infective frontal sinusitis and is prescribed Augmentin to treat the infection. Per the general infection row of the DAIDS Toxicity Table, this AE should be reported as at least Grade 2, since systemic antimicrobial treatment was indicated.

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### 3. Documentation of Missed Menses Events during Follow-Up

Adverse Events for missed menses that extend beyond three months or more in duration should be documented by updating the completed AE log CRF for “missed menses” with a new AE term of either “oligomenorrhea” (for missed menses events of 4-5 months in duration) or “amenorrhea” (for missed menses events of 6 months or longer) and with a new severity grade. The updated AE term and severity grade should be assessed per the FGGT row for “unexplained infrequent bleeding”, which excludes cases of missed menses due to hormonal contraception use, pregnancy, or post-partum. A new AE log CRF should not be completed to document an increased duration of the same infrequent bleeding event.

**Example:** A participant experiences unexplained infrequent bleeding for two months and an AE log CRF for grade 1 “missed menses” is completed. She continues to miss her menses for two subsequent months (for a total of 4 months duration). At this point, Item 1 on the AE for ‘missed menses’ should be updated to reflect the updated AE term “oligomenorrhea” with an updated severity grade of 2 (Item 4). If this participant continues to experience missed menses for an additional two months or more, the AE log CRF should be updated once again to reflect the new AE term, “amenorrhea”.

### 4. Cervical Ectopy Assessment

Cervical ectopy is considered to be neither a normal nor an abnormal finding, but rather, is a required separate assessment. The percentage of cervical ectopy (item 3) on the PE-1 CRF should always be completed when a pelvic exam is conducted. However, the ‘no normal variants or abnormal findings’ box on the pelvic exam diagrams non-DataFax form may be marked if only ectopy is observed. The presence of cervical ectopy is quite common, and should not be factored into the question on the diagrams form.

## REMINDERS

### 1. CRF Tracking Reports

The CRF Tracking System (CTS) provides feedback, via emailed reports, to help sites track the number of CRFs that have been received and validated at SCHARP. There are two types of reports – a Reception Report and a Validation Report. A Reception Report is a listing of transmissions received from a site’s registered devices/email addresses and includes the date and time each transmission is received, the number of pages received and a unique “Fax “Raster” ID. A Validation Report lists the Study, PTID, Fax ID page number, CRF plate number, visit code, and validation date for each CRF received at SCHARP.

Sites can manage the frequency of and staff distribution lists for these reports by emailing the CTS administrator at [support@scharp.org](mailto:support@scharp.org) and completing or updating a CRF Tracking System Registration Form. Note that the registration form must be faxed from all devices or email addresses used to transmit CRFs to SCHARP.

**iDATAFAX CORNER** – No updates