MTN-020 Data Communiqué #10- October 25, 2013

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

1. HIV and AE Reporting

   HIV acquisition (seroconversion) is one of the study primary endpoints, and is thus not considered an AE for data collection or reporting purposes. "HIV infection" should not be reported as an AE or written anywhere on an AE/GAE Log CRF.

   However, primary HIV infection is often symptomatic, and a constellation of symptoms may best be summarized as primary HIV infection illness. In this case, as in other cases when symptoms are best expressed as a unifying diagnosis, it is important to use that summary diagnosis. Thus, if a participant seroconverts and develops one or more signs or symptoms of acute HIV-infection, it is appropriate to report these sign(s)/symptom(s) as a single AE using ONLY the term "seroconversion illness" for item 1 on the AE/GAE Log CRF. Use the comments section of the AE/GAE Log CRF to describe each HIV-related sign/symptom (e.g., fatigue, pharyngitis). On the Rationale line for item 4, record "acute HIV". To avoid generating a QC for item 4, please ensure that the term "acute" is included.

   Complete the other items on the AE Log CRF per the general form instructions. The onset date in item 2 should be completed using the date on which the participant first reported experiencing the first sign/symptom of acute HIV-infection. If there is more than one HIV-related sign/symptom, record the highest severity grade in item 3. A seroconversion illness AE is considered 'resolved' (item 6) when all of the associated signs/symptoms have resolved or returned to baseline per participant report, and medications for the symptoms are no longer indicated. In item 7, mark any medications indicated and taken for the associated symptoms, if applicable.

   If one or more signs/symptoms, reported on separate AE/GAE Log pages, are later attributed to acute HIV-infection, change the earliest reported sign/symptom page to the "seroconversion illness" diagnosis and list any other signs or symptoms in the comments section of this AE Log page. In addition, mark the AE/GAE Log pages for the other signs/symptoms, if any, for deletion and write at the top of the page, "Delete due to diagnosis on AE Log page (insert page #)".

   Please note that this represents new reporting guidance that is considered in effect for all new AEs reported after the date of this communiqué. It is not necessary to review or modify previously reported AEs to comply with this new guidance.

2. Specimen Storage (SS-1) CRF Required at Monthly Visits for Used Vaginal Ring Collection

   The Specimen Storage CRF is required at monthly visits for collection of the used vaginal rings, beginning at each specified site implementation date. This form should be completed for all study participants.

Mark item 4 (used vaginal ring collection) “not required” for participants on temporary product holds and those participants who have been permanently discontinued from study product. If ring collection was required per protocol, but was not stored for whatever reason, mark “not stored” and indicate the reason that the ring was not stored on the adjacent line. Possible reasons include, but are not limited to, the following examples :

- participant forgot to return the ring to the clinic or
- ring was lost
- participant declined ring at previous visit
- ring had recently been inserted at an interim visit (and she was not getting a new ring at this visit)
- any other reason that a ring was not available to collect at the participant’s regularly scheduled visit.

CLARIFICATIONS

1. Concomitant Medications (CM-1) Log CRF – coding queries

   Household products should not be reported as concomitant medications on the CM-1 log CRF. Examples of household products that are not considered concomitant medications include cleaners, solvents, or Coca Cola used for at-home douching, saline sitz baths, and saline gargles.

   Traditional herbal medicines should be reported as concomitant medications. If a medication includes more than one herb, list each herb separately on the CM-1 Log CRF.

   If a medication’s trade or generic name is unknown, record “unknown” and a description or drug class.

   Examples: “unknown white tablet”, “pink and white tablet name unknown”, “unknown analgesic”, “antibiotic unknown”

REMINDERS – None

iDATAFAX CORNER – No updates