MTN-020 Data Communiqué #5- December 21, 2012

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. QC Report Distribution for December
Since the QC Reports for December would be scheduled to go out on the 25th, we are delaying distribution of these reports until the first week of January. Sites will receive a QC Report the 1st week of January as well as the 4th week. The regular schedule will resume in February.

CLARIFICATIONS

1. AE Log item 1 (AE text) and Comments field clarifications for AEs due to ring removal or insertion

The purpose of the below is to clarify information provided during study site trainings. During the trainings, we asked sites to never mention the study ring in the AE descriptive text (item 1). This guidance has been revised per the below.

- If the AE is **due to the act** of study ring insertion or removal, include this information in item 1. For example, use AE text of "pelvic pain due to ring removal" or "vulvar laceration due to ring insertion" rather than just "pelvic pain" or "vulvar laceration".

  It is important to clearly identify in item 1 AEs that are **due to the act** of study ring insertion or removal, as these AEs are assigned unique coding terms within the standardized MedDRA coding system.

  If the AE is **not due to the act** of study ring insertion or removal, do not include mention of the ring in item 1.

- If text is present in the "Comments" field that the AE is due to the act of ring insertion or removal, this same text needs to be in item 1. If not, this may result in a Clinical Query asking that this information be added to item 1 so that the AE is described completely and accurately.

  It is fine to include text in the "Comments" field explaining why the AE has been judged "related", but such text is not required.

2. Protocol Deviation Log (PDL-1) completion for deviations not associated with a PTID
If a deviation needs to be reported, but is not associated with a participant (for example, study product exceeds storage temperature while at the pharmacy), use a PTID that follows the format below on the PDL CRF:

<div align="center">XXX-00000-0</div>

The first 3 digits are the site's DataFax ID number (312 for Kampala, for example). All PTIDs for your site start with the same 3 digits, and these 3 digits should be used (along with 0's for the last 6 digits) for any PDL CRFs reporting non-participant related deviations. Assign page numbers sequentially (as usual) when completing new PDLs using this PTID.

3. **Product Hold (PH-1) and Vaginal Ring Request Slip completion in cases where a participant is requested to remove the ring due to more than 35 days of use**
If a participant is requested by study staff to remove the ring to avoid more than 35 days of continual use, complete a new PH-1 form and Vaginal Ring Request Slip to document this requested hold. It is expected these requests will not be made once a site is operating under Letter of Amendment #2.

   On the PH-1 form, mark item 2 as "other" and specify that more than 35 days of use as the reason for the requested hold.
   On the Vaginal Ring Request Slip, mark "hold" and specify the text above. Note that for the next ring dispensation for the participant, you will need to mark "resume" on the slip.

4. **Participant report of shorter than usual menses during follow-up**
Note that reports of shorter menstrual periods during study follow-up (which may be a change from the participant's baseline bleeding pattern) are not adverse events and do not get reporting on AE Log CRFs.

REMINDERS - none

iDATAFAX CORNER
This is a new section added to address iDataFax questions, issues, and clarifications.

1. **Faxing vs. iDataFax data entry of Missed Visit (MV-1) and Protocol Deviation Log (PDL-1) CRFs**
Remember that each completed MV-1 or PDL-1 CRF should be either electronically data entered or faxed, but not both. Corrections on the CRF page need to be provided to SCHARP in the same way as the original CRF. If a PDL-1 page was electronically data entered, then any needed corrections should be made through iDataFax. The same applies if a CRF was originally faxed - in this case, you would make the corrections to the CRF and re-fax the corrected page to SCHARP. We suggest that you indicate on the back of the CRF page whether the page was electronically data entered or faxed.

2. **Deleting MV-1 or PDL-1 in iDataFax**
In those cases where a MV or PDL page entered via iDataFax needs to be marked for delete, please do the following:
   a. Mark the completed MV or PDL hard-copy CRF for delete by drawing a diagonal line across the form page, adding a note "deleted due to _____", initial and date.
   b. Bring up the MV or PDL page (record) you wish to delete.
   c. On the **first item after the Participant ID#, typically, a form completion date or visit date** go to Field: and click on: 'Add reason for data value'
   d. Click on the ellipsis under 'Reason'.
   e. Choose the appropriate response; typically this will be #'4': delete CRF. There may be times when there is another reason to delete a CRF and you may choose "other" and provide a more descriptive reason by manually entering the reason. .
   f. Click OK and then OK again.
   g. Sign off the record which will save these changes. This will then alert SCHARP that this record needs to be deleted out of the database and it leaves an audit trail of this procedure within iDataFax.

   For deleted PDL forms, do not re-assign the page number of the deleted PDL. For example, if a participant's PLD page 03 was marked for delete, assign "04" to the next PDL page completed for the participant.

For more information on iDataFax
Remember that more information and tutorials on iDataFax can be found on the iDataFax Atlas page, link below. Questions about iDataFax can be directed to support@scharp.org.

https://atlas.scharp.org/cpas/project/iDataFax/begin.view?