MTN-020 Data Communiqué #12- August 8, 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

1. New Study Exit Behavior Assessment (SEV-1~5) and Social Influences Assessment (SOC-1)

New Study Exit Behavior Assessment (SEV-1) and Social Influences Assessment (SOC-1) case report forms have been created for use in ASPIRE.

The Social Influences CRF will be administered at the scheduled Product Use End Visit (PUEV) and includes questions regarding the participant's social influences on study participation and ring use.

The SEV-1~5 CRF will be administered at the participant's scheduled Study Exit/Termination Visit and includes questions on participant sexual activity, condom use, intravaginal practices and behavior change after participants have completed study product use.

The site-ready English language versions of the Study Exit Behavior Assessment CRF and the Social Influences Assessment CRF are provided with this communiqué. SCHARP will work with sites to create site-specific language versions of each CRF, which will be posted in the "Interviewer-administered Visit-based Packets" pdf files on the Atlas MTN-020 web page, once finalized.

CLARIFICATIONS

1. Genital Bleeding AE Reporting in the Context of Contraceptive Switches

This guidance applies to cases where a previously reported genital bleeding event, such as metrorrhagia, is ongoing and persists even after a participant has switched her method of contraception. This applies to contraceptive switches within the same class (e.g., from one type of injectable to another type of injectable) or between different classes of contraceptives (e.g., from an injectable to an IUCD). If the bleeding event persists at the same severity and frequency despite the change in contraceptive use, the AE should be left open and considered ongoing. If the event is deemed "not related" to study product use, sites can simply state on the item 4 "Record rationale" line, "consistent with contraceptive use". A new AE Log CRF should not be completed, as the switch in contraceptive use has not caused a new bleeding event at a different severity or frequency to occur. One AE Log CRF suffices to cover the same bleeding event if it persists even with a switch in contraceptive method.

Please apply this guidance going forward. It is not necessary to conduct a retrospective data review to ensure compliance with this guidance.

REMINDERS

1. Completion schedule of the Seroconverter Laboratory Results CRF (SCR-1)

The Seroconverter Laboratory Results CRF documents CD4+ and HIV RNA test results, MTN-015 enrollment status, and seroconverter plasma storage for participants who have been confirmed as HIV-1 infected (i.e., with a final HIV status of "HIV-infected" per the HIV Confirmatory Results CRF).

This form should be completed at scheduled ASPIRE study visits occurring 1 month, 3 months, 6 months, and every 6 months thereafter post HIV infection and should be completed for all participants, regardless of enrollment status in MTN-015. Please refer to the MTN-020 Seroconverter Specimen Collection Tool on the study webpage to determine participant-specific seroconverter specimen scheduling.

Example: A participant's HIV rapid tests are both positive at visit month 7.0. Her Western Blot is also positive.

- Documentation at Visit Month 7.0
  i. Monthly Laboratory Results (MLR-1) CRF is completed to document the HIV rapid test results and storage of confirmatory plasma.
     a. Confirmatory plasma storage corresponds to the LDMS primary specimen "Plasma for HIV Seroconversion Confirmation" with the other specimen ID field labeled with "CON"
  ii. HIV Confirmatory Results CRF is completed with a final HIV status of "HIV-infected" when confirmatory testing results are available

  Note: The SCR-1 CRF should not be completed at visit month 7.0.

- Documentation at Visit Month 8.0
  i. Complete SCR-1 to document MTN-015 enrollment status, testing results, and seroconverter plasma storage.
     a. Seroconverter plasma storage corresponds to the LDMS primary specimen "Seroconverter Plasma Storage" with the other specimen ID field labeled with "SER"
  ii. Mark Item 4 "*Was plasma stored for HIV confirmatory testing?*" on the MLR-1 form as "Not required"

The SCR-1 CRF should be completed for this participant at study visits 8.0, 10.0, 13.0, 19.0 and every six months thereafter.

iDATAFAX CORNER – No updates