MTN-003 (VOICE) Operational Guidance Follow-up Adverse Events and Pregnancy Continuing at Termination

- FOLLOW-UP OF ADVERSE EVENTS (AES) THAT ARE CONTINUING AT THE TERMINATION VISIT

  - Per Section 8.2 of the Protocol and 11.5 of the SSP, any ongoing SAE/EAE at the termination visit and an AE found to be worsening at the termination visit require a reassessment within 30 days of the termination visit.

  - In addition, the PSRT is requesting that any new or ongoing Grade 3 or Grade 4 AEs (regardless of relationship to study product) present at the termination visit should be included in this group.

  - For reportable AEs that fit into the above categories, the status/outcome of the AE should be updated to "continuing at end of study participation" and the AE Log form should be re-faxed to DataFax. The IoR or designee must establish a clinically appropriate follow-up plan for the AE. At a minimum, the adverse event must be re-assessed by study staff within 30 days after the termination visit; additional evaluations also may take place at the discretion of the IoR or designee. In addition, as per Section 6.14.9 of the SSP, sites are instructed to follow protocol requirements for clinical management if guidance indicates more frequent follow-up than the 30 day timeline noted here. The MTN-003 Protocol Safety Review Team (PSRT) also may advise on whether any additional follow-up is indicated on a case by case basis.

  - For those AEs requiring re-assessment, the site is to send an informational query regarding the case to the PSRT at the time of re-assessment (or if re-assessment if unable to be performed in a timely fashion). If the AE has not resolved or stabilized at the time of reassessment, study staff will continue to reassess the participant at least once per month while the study is ongoing. After the study has ended, all AEs requiring reassessment (those that have not resolved or stabilized) will be re-assessed at least once within 30-60 days after the study end date. The MTN-003 PSRT also may advise on whether any additional follow-up is indicated on a case by case basis.

  - For AEs that are re-assessed after the termination visit, information on the status of the AE at the time of re-assessment will be recorded in source documents and may be communicated to the PSRT, if applicable; however, no updates should be made to any case report forms based on the re-assessments. Please note, with the exception of the Pregnancy Outcome form, no CRFs should be submitted to SCHARP after the termination visit.

- For AEs that are continuing at the termination visit but do not meet the criteria above, it is left to the discretion of the IoR or designee as to whether the AE needs to be followed. The PSRT is always available for consultation.

FOLLOW-UP OF PREGNANCY OUTCOMES AT THE TERMINATION VISIT

- After a participant's termination visit, all pregnancies must continue to be followed until an outcome is ascertained. Once the site receives the outcome information, this should be submitted on a Pregnancy Outcome CRF to DataFax