



Study Exit Considerations

VOICE Protocol Team Meeting
19 February 2012





Scheduling PUEV and Termination Visits

- Refer to Section 6 of the SSP Manual
- Review lists of M15 Target Dates sent by SCHARP
- When scheduling these visits, explain to the participant that oral Truvada/placebo roll-off visits are occurring due to the natural end of the study



Split PUEV Visits

- The PUEV can be conducted as a split visit
- HIV testing must occur during the first part of the visit
- Interviewer-administered CRFs and ACASI questionnaires must be completed on the same day
- Assign the same visit code to all procedures/CRFs completed as part of the PUEV.



Split PUEV Visits

- Ideally all PUEV visit procedures will take place within the PUEV visit window
- If absolutely necessary, PUEV procedures may be completed outside of the visit window – until the SEV window opens.
 - Exception made exclusively for PUEV only
 - Alert SCHARP if this occurs



Split Study Exit/Termination Visits

- The Study Exit/Termination Visit can be conducted as a split visit, through the study end date (13 August 2012).
- If a participant does not return to complete procedures, efforts to complete the remaining procedures may be discontinued after three active months of follow-up attempts or on the study end date, whichever comes first.
 - Document all efforts to complete all required study exit procedures.



Final Study Contacts

- A final contact is required after SEV visit to provide the participant with final study test results, post-test counseling, and treatment, if needed
- Additional contacts also are required for:
 - Participants who are pregnant at study exit
 - Participants with positive, indeterminate, or discordant HIV rapid or WB test results
 - Participants with certain types of AEs that are ongoing at study exit



Participants who are pregnant at SEV

- If not done already, refer participant to antenatal care
 - Participants who become both pregnant and infected with HIV will also be referred to prevention of mother-to-child transmission (PMTCT) services
- All pregnant participants also will be referred to MTN-016



Participants who are pregnant at SEV

- Inform participant that a post-study contact will be made to assess pregnancy outcome
- Complete a post-study contact to ascertain their pregnancy outcome.
- Complete a Pregnancy Outcome CRF



HIV Counseling and Testing

- For participants with positive or discordant HIV rapid tests, follow the protocol algorithm:
 - Perform WB on Sample 1 collected at the exit visit
 - If the WB is positive or indeterminate, additional specimen collection and testing will be required to confirm the participant's HIV status



HIV Counseling and Testing

- When counseling participants, inform her that:
 - Additional counseling and testing may be needed
 - Discuss visit schedule and location
 - Document this communication on chart notes
- Until HIV status is confirmed, participant is not considered exited from the study



AE Management and Documentation

- Reportable AEs ongoing at the SEV:
 - Update AE Log to “continuing at end of study participation” and re-faxed to SCHARP.
- AE Log forms should not be updated after the SEV.
 - Any additional information should be recorded in the participant’s chart notes only.



AE Management and Documentation

- The following AEs require a reassessment within 30 days of the termination visit:
 - Ongoing SAE/EAE
 - AE found to be worsening at the SEV
 - New or ongoing Grade 3 or Grade 4 AEs present at the SEV
 - regardless of relationship to study product



AE Management and Documentation

- Additional evaluations also may take place at the discretion of the IoR or designee
- The PSRT also may advise on additional follow-up on a case by case basis



AE Management and Documentation

- Send an informational query to the PSRT at the time of re-assessment
 - or if re-assessment is unable to be performed in a timely manner
- If the AE has not resolved or stabilized, continue to reassess at least once per month while the study is ongoing



AE Management and Documentation

- After the study has ended, all AEs requiring reassessment will be reassessed at least once within 30-60 days after the study end date
- All other AEs that are continuing at the SEV will be followed per the discretion of the IoR or designee
 - The PSRT is available for consultation



Other Considerations

- Obtain participant permission for post-study contacts:
 - Provide test results, counseling, and treatment
 - Provide study results and their random assignments (if not done already)
 - Contact for future studies



Other Considerations

- Final contacts could be conducted at:
 - The study site
 - Community-based locations
 - Participant home
- Review/update contact information. Ask participant to contact site if there are changes to contact information




Other Considerations

- Participants should be referred for services previously provided by study (e.g. reproductive health care, HIV counseling and testing)



Other Considerations

- All sites are strongly encouraged to provide participants with a certificate of study completion
 - Sample certificates are available in the Study Implementation Materials section of the MTN-003 web page



What are your questions about
Study Exit Considerations?

