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SSP Updates

28 June 2018

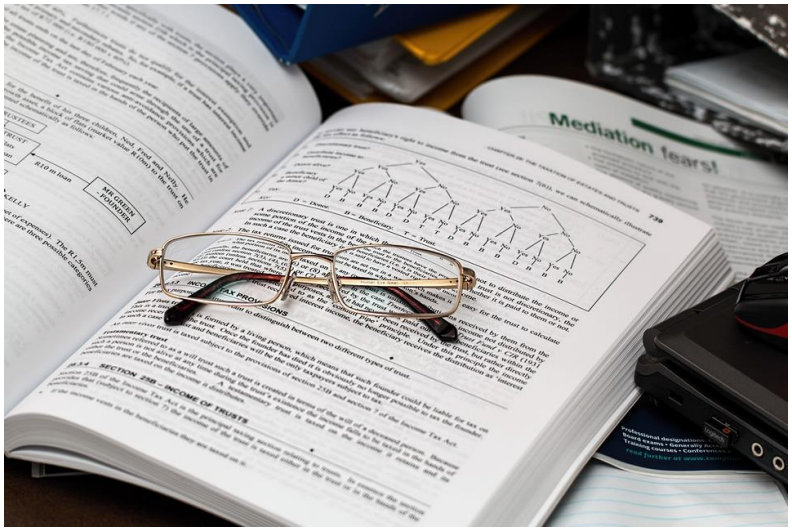
MTN
microbicide trials network

General Formatting Updates

- New: Table of Contents - Current Sections
  - Lists all current SSP sections, version numbers and dates
  - Please file at the front of your SSP manuals
- Updated: Overview and Control Document
  - Includes version history, summary of changes for current revision
  - New: Management Team sign-off
- Page numbers updated in all sections to include total number of pages; Table of Contents within each section updated to reference page numbers
  - All SSP sections will need to be printed/filed in your study essential documents
  - Sections that only had formatting updates are not covered in this training

Section 1 – Introduction

- Added all HOPE Letters of Amendment to list of protocol documentation and documents to be submitted to IRBs/ECs
- Clarified that guidance for IoR changes applies to temporary and permanent IoR transitions



Section 3 – Documentation Requirements

- Added guidance to clarify financial disclosure requirements. All investigators listed on the 1572 must adhere to this guidance.

Section 6 – Participant Follow-up

- Clarified that product holds should not be completed at PUEV.
- Added reference to HOPE study closeout checklist and Operational Guidance #3, which includes additional information on PUEV and SEV.

Section 7 – ACASI & Behavioral Assessments

- Added a reference to the Social Influences Supplement and administration tool
- Clarified that SD cards from different ACASI tablets have unique data so they should not be mixed prior to merging.

Section 10 – Clinical Considerations

- Moved guidance about Pap smear and cervical biopsy result grading and AE reporting to SSP section 11.4.
- Clarifications were made to section 10.1.2:
  - *Discrepancies between FP CRF and Con Med Log may occur and do not require reconciliation unless queried by SCHARP*
  - *Preferable to record the trade or generic n the medication based on exactly what the participant is taking within the CRF*

Section 10 – Clinical Considerations

- Updated section 10.2.3 regarding recommendations for frequency of calibrating scales.
  - *Calibrate at a frequency per the manufacture's recommendations or any local regulations, whichever is more stringent. It is recommended that scales be calibrated at least annually.*
- Added guidance to section 10.5.3 regarding follow-up for syphilis identified at PUEV.
  - *If treatment, further counseling, and reliable syphilis testing are available outside the study site, participants can be appropriately counseled and referred at PUEV/SEV.*
  - *Sites should provide these services if they are not available for participants via other service providers. For further questions, please consult the PSRT.*

Section 10 – Clinical Considerations

- Added information about MTN-029 results to Section 10.8
  - *MTN-029 showed low level of detectable dapivirine in breastmilk and a low estimated daily level of infant dapivirine exposure.*
  - *Additional studies are needed and are being planned to evaluate the safety of dapivirine ring use while breastfeeding.*
- Updates made to 10.9 to reflect updated format of resistance reports
  - *Removed participant-specific resistance counseling messages. For clinical queries regarding interpretation of resistance results, please contact the PSRT.*

Section 11: Adverse Event Reporting & Safety Monitoring

- Add clarifications regarding Pap smear and cervical biopsy results/interpretation and AE reporting to section 11.4.
  - *CIN III is a grade 3 finding*
  - *The section of the report which indicates the final "interpretation" of results should be used in AE determination and grading (rather than information in the body of the report)*
  - *Histologic cervicitis is not an AE*
- Moved text from SSP section 10 regarding AE reporting for abnormal Pap smear results in follow-up to section 11.4.

Section 11: Adverse Event Reporting & Safety Monitoring

- Clarified protocol required follow-up for AEs newly identified at study exit in section 11.7.
  - *AEs that have increased in severity at the termination visit must be re-assessed by study staff 30 days after the termination visit; additional evaluations also may take place at the discretion of the IoR or designee.* ***NOTE: this includes AEs that are newly occurring/identified at the termination visit.***
- Clarified CRF completion expectations in the event an AE is continuing at the SEV in Section 11.7.
  - *All AEs that are ongoing at the time of SEV should have a status/outcome marked as "continuing at the end of study participation."*
  - *Regardless of whether a participant has an ongoing AE requiring reassessment per protocol or clinical discretion, the termination date should be documented as the date of her SEV.*
  - *However, if a test result is still pending after the final clinic visit (SEV), it is up to the site's discretion as to when a participant is considered no longer part of the study.*
    - *For example, if lab results are pending after the SEV, it is up to the site's discretion to determine if the participant's termination date is the date of her SEV or the date that her test results were received.*

Section 12: Counseling Considerations

- 12.2.2.3 updated with additional information about residual drug feedback tools
  - Up to the discretion of each counselor whether to use the Residual Drug Feedback Over Time took, but it is required that the tool be kept up to date and filed in the participant binder.
  - Residual Drug Feedback Over Time Supplement is available on HOPE website.

Section 13: Laboratory Considerations

- 13.9 edited to allow for more flexibility in terms of where hair samples are collected
  - May be collected from more than one location, if desired or necessary
- 13.9.1 added to explain hair PK validation subset, to be collected at the three Zimbabwe sites.
  - 75 samples of 200 strands instead of 50
- 13.10 edited with information on Parexel's use of LDMS.
  - Not currently an LDMS lab. Current shipping guidance may be issued if Parexel implements LDMS in the future.

Section 14: Data Collection

- Updated SDMC contact information
- Section 14.1: Data Entry/Quality Control
  - Added guidance that all queries must be answered and closed prior to any inactivation of forms and/or log lines
- Section 14.3.3: Visit Numbers
  - Updated Visit 8.00 to Scheduled PUEV (Month 12)
  - Added information that visit numbers for the PUEV and SEV for participants who enrolled after the formal accrual period (Sep 15th) and have a shortened visit schedule will be assigned 8.00 and 9.00, respectively
    - Participants who have a modified visit schedule will still have a scheduled PUEV, but this will not equate to Month 12 (Note: Month 12 will still appear in Medidata)… more to come!

Section 16: Study Reporting Plan

- Updated SDMC contact information
- Table 16-3
  - Updated DMQR frequency to monthly
  - Updated Residual Drug Data frequency to Twice a week
- 14: Retention
  - Added a note that Retention is reported through Month 12 only
- 21: Termination
  - Clarified Termination Report is a summary of all terminations, including early terminations

Section 17: Qualitative Component

- Storage requirements for audio files clarified and references to destroying audio files removed, per LoA #2.
- 17.6.1 and 17.8 updated with instruction about accompanying documents to submit with debriefing reports to RTI.

Thank you!

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