MTN-003 Study-Specific Procedures Manual
Overview of Section Contents and Identification of Current Section Versions

Section Number	Section Title	Current Version Number	Current Version Date	Updates and Comments
1	Introduction	2.0	18 FEB 11	• Updated link for FAQs on MTN-003 web page • Updated email alias list for MTN-003 Safety Physicians
2	Protocol	2.0	18 FEB 11	• Substituted Version 2.0 of the protocol
3	Documentation Requirements	2.1	10 JUN 11	• Provided further guidance on chart notes as source documentation in section 3.2.2.
4	Participant Accrual	2.0	18 FEB 11	• Updated relevant sections with new accrual targets and time to complete accrual • Modified text in figure 4-1 to indicate PEP provision is for HIV exposure, rather than infection • Included guidance on cervical bleeding associated with speculum insertion and/or specimen collection • Added Section 4.2.1.1: Assessment of Acute HIV Infection Prior to Enrollment • Included option to conduct IC Enrollment prior to confirmation of eligibility • In section 4.2.10.2 deleted reference to LOA#1
5	Informed Consent	2.0	18 FEB 11	• Updated references to Version 2.0 of the protocol • Included option to conduct IC Enrollment prior to confirmation of eligibility • Provided guidance on DAIDS Protocol Registration requirements for updated IC forms • Added section 5.6 and appendices 5-4, 5-5, 5-6 to provide guidance on the on-going IC Comprehension Assessment process
6	Participant Follow-Up	2.5	20 DEC 11	• Incorporated guidance from CM #1 • Included details and instructions on the study close-out plan • Updated guidance on AE management following study exit
7	Visit Checklists	2.0	18 FEB 11	Updated per Version 2.0
8	Participant Retention	2.0	18 FEB 11	• Updated Section 8.2 to include information on how retention rate is calculated • Updated Figure 8-1 to include retention targets for study Months 35 and 36 • Administrative changes to Section 8.5 related to procedures for participants who voluntarily discontinue participation in the study

9	Study Product Considerations For Non-Pharmacy Staff	2.0	2 MAY 11	• Updated per Version 2.0
				• Added guidance on gel leakage
				• Updated per VASP guidelines
				• Included the following new sections:
				  • 9.6: Dispensing Study Products and Collecting Unused Study Products at In-Home Follow-Up Visits
				  • 9.6.1: Delivering Study Products During an In-Home Visit for a Participant Who Left the Clinic Early

10	Clinical Considerations	2.3	10 JUN 11	• Updated flow sheet guidance for 3+ proteinuria, for consistency with protocol
11	Adverse Event Reporting and Safety Monitoring	2.0	18 FEB 11	• Section 11.1.2 updated to expand exceptions to reproductive system AEs, provide guidance for reporting amenorrhea as an AE, include a table for AE terminology for bleeding/pelvic pain in a pregnant participant • Figure 11-1 updated to provide further guidance on genital bleeding and hematuria • Sections 11.1.3 and 11.1.4 updated to reflect procedures and reporting of SAEs/ EAEs, RCC updated to RSC (throughout the section) • Figure 11-3 deleted since all sites will be operating under protocol Version 2.0 • Figure 11-5 updated to specify that terminology for RTIs should be based on both clinical evaluation and confirmed laboratory results when applicable • Section 11.3 updated to remove guidance for spontaneous abortions and pregnancy losses provided under protocol version 1.0, includes additional guidance related to abnormal pap examinations. • Section 11.4 updated to remove guidance on AE relationship categories applicable to protocol version 1.0. • Section 11.5 updated to include guidance to update EAE reports submitted to DAIDS RSC if there is a change in assessment of severity of the AE • Appendix 11-1 updated to include Devika Singh as a member of the PSRT
12	Counseling Considerations	2.2	22 SEP 11	• Clarified HIV Counseling Messages for sites participating in PBMC Collection, per LoA #1 (Table 12-1b)
13	Laboratory Considerations	2.2	22 SEP 11	• Included PK Hair collection specifications per LoA #02

14	Data Collection	2.0	18 FEB 11	• Updated SCHARP team membership on page 14-1 • Section 14.2.1, last bullet, specified priority fax time frames for AE Log and PH Log CRFs • Sections 14.2.6 and 14.2.7 – minor updates to date of initialed and dated correction examples • Section 14.3.2– updated references to maximum product use period from 33 to 36 months; updated dates in examples under "Target Days and Visit Windows" and "Missed Visits"; added third paragraph under "Split Visits"; updated examples under "Interim Visits" • Table 14-1- added Month 34-36 visits; added footnotes • Table 14-2- added Month 24-36 visits • Section 14.3.3- updated example under "Visit Codes for Split Visits"; updated example under "Visit Codes for Interim Visits" • Table 14-3- updated visit codes for Monthly, Quarterly, and Semiannual Visits; added Ongoing Informed Consent Comprehension (ICC) form to "as needed" section under Monthly Visits, changed name of Product Returns, and Dispensations form to Product Re-supplies and Re-issues (PRD); added Product Returns (PRT) form to Monthly, Quarterly, Semiannual, Annual, and PUEV visits; updated notes under Product Use End Visit and Study Exit Visit • Section 14.5- added third paragraph note; added "When to Skip Product Adherence Questions" section • Section 14.6- added clarification on common data issues noted in data communiqués and in site QC reports to date • CRF Table of Contents and CRFs-updated to include ICC, PRD and PRT forms • Minor wording and typographical corrections
15	Data Communiqués	2.0	18 FEB 11	Only the footer updated; version 2.0
16	ACASI Users Manual	2.0	18 FEB 11	Updated footers for version 2.0
17	Study Reporting Plan	2.0	18 FEB 11	• Updated SCHARP team membership on page 17-1 • Table 17-1- Data QC Report, Distribution Frequency updated to 'every month, or as needed'
18	Bone Mineral Density Substudy	1.2	21 JUL 10	Updated to include MTN-003B Clarification Memo #02 and LOA #01.

19	Household and Community Factors Associated with VOICE Product Adherence Substudy (VOICE-C)	1.4	26 JAN 12	• Revised to reflect CM#04 including update to Group 1 exclusion criteria • Updated Section 19.5 allowing the signing of the Informed Consent to occur on a different day prior to data collection for FGD participants. • Updated Section 19.6.1 regarding interview scheduling and data collection activities of Group 1 EI participants; there will be a minimum of 2 interviews and may be scheduled after the participant's VOICE TEV.