

MTN 001 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	17 October 2008	<ul style="list-style-type: none"> • Update to contact information in Section 1.1 and include Figure 1-1 to outline MTN 001 Study Communication Contact Information
2	Protocol	2.0	17 October 2008	<ul style="list-style-type: none"> • Update to include Version 2.0 of the protocol, 03 September 2008
3	Documentation Requirements	2.1	5 November 2008	<ul style="list-style-type: none"> • Updated made to forms listed on Section Appendix 3-4, Section Appendix 3-5, and Section Appendix 3-6
4	Participant Accrual	2.3	10 August 2009	<ul style="list-style-type: none"> • Update to Section 4.1 to reflect change in accrual plan for study sites in Durban • Update Section 4.2.2 to clarify enrollment visit procedures must be conducted on the same day with the exception of obtaining informed consent • Update Section 4.2.6 to clarify the documentation of HIV testing • Updated Section 4.2.7.1 to clarify procedures for completing study prescription (s) at enrollment
5	Informed Consent	2.0	17 October 2008	<ul style="list-style-type: none"> • Update to Section 5.5 to include documentation procedures for the 21 week in –depth interview
6	Participant Follow-Up	2.2	10 August 2009	<ul style="list-style-type: none"> • Update Section 6.4 to clarify procedures for collecting rectal fluid samples • Update Section 6.6. to clarify procedures for completing prescriptions and/or Study Re-Supply during Follow-up • Updated Section 6.7 to clarify the documentation of HIV testing • Update to Section 6.12.6 to clarify the appropriate case report forms related to product hold/discontinuation to be completed at the study exit visit

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7	Visit Checklists	2.2	18 September 2009	<ul style="list-style-type: none"> Updated to include procedures for collecting rectal fluid samples (applicable to the Bronx site only) and to clarify hematology testing procedures
8	Participant Retention	2.2	3 September 2009	<ul style="list-style-type: none"> Update to section 8.5 to add procedures for participants who discontinue participation in the study
9	Study Product Considerations For Non-Pharmacy Staff	2.1	18 May 2009	<ul style="list-style-type: none"> Update to Section 9.4 to remove reference to the MTN 001 Pharmacist Study Product Management Procedures manual
10	Clinical Considerations	2.4	24 August 2009	<ul style="list-style-type: none"> Update to Section 10.5.4 to clarify procedures for the documentation and reporting of expected non-menstrual bleeding associated with specimen collection
11	Adverse Event Reporting and Safety Monitoring	2.0	17 October 2008	<ul style="list-style-type: none"> Protocol version and date has been updated PSRT composition and contact information was updated on Section Appendix 11-3
12	Laboratory Considerations	2.4	23 November 2009	<ul style="list-style-type: none"> Update to Section 12.8 to clarify preparation and collection of rectal procedures for the Bronx site Update to Appendix 12-3 to clarify text for Algorithm for HIV testing at screening
13	Data Collection	2.0	5 November 2008	<ul style="list-style-type: none"> Updated to include updated SPA form, the Flow Cytometry form and the updated LDMS Specimen Tracking Sheets
14	Data Communiqués	2.0	17 October 2008	<ul style="list-style-type: none"> No changes
15	Study Reporting Plan	2.0	17 October 2008	<ul style="list-style-type: none"> MTN 001 SDMC Staff has been updated The CQC queries frequency in Table 15-1 was revised
16	Week 21 In-Depth Interviews	2.1	28 August 2009	<ul style="list-style-type: none"> Updated to reflect change in accrual plan for study sites in Durban

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