

MTN-015 Study Specific Procedures Manual

Overview of Section Contents and Identification of Current Section Versions

Section Number	Section Title	Version Number(s)	Version Date(s)	Updates and Comments
1	Introduction	2.0 2.1	15 August 2013 14 Jun 2017	<ul style="list-style-type: none"> Updated requirements for protocol signature page Added procedures for change in IoR
2	Protocol	2.0	15 August 2013	
3	Documentation Requirements	2.0 2.1	15 August 2013 14 Jun 2017	<ul style="list-style-type: none"> Added guidance on generation of certified copies from Medidata Added protocol signature page to essential document filing structure Added Pap Test Result CRF and clarification on version of select CRFs to appendix 3-3 and 3-4
4	Participant Accrual	2.0 2.1	15 August 2013 14 Jun 2017	<ul style="list-style-type: none"> Added guidance on recruitment strategies for MTN-015
5	Participant Follow-up	2.0	15 August 2013	
6	Visit Checklists	2.0	15 August 2013	
7	Co-Enrollment Considerations	2.0 2.1	15 August 2013 14 Jun 2017	<ul style="list-style-type: none"> Added guidance on expectations for certified copies from the parent study. Updated guidance to allow for single centralized locator forms for co-enrolled participants.
8	Clinical Considerations	2.0 2.1	15 August 2013 14 Jun 2017	<ul style="list-style-type: none"> Clarification made regarding potential availability of resistance information Added reference to Pap CRF and to local cervical cancer screening guidelines Added that asymptomatic BV does not require treatment, and that BV and candida do not require retesting following treatment unless the participant is

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				<p>symptomatic.</p> <ul style="list-style-type: none"> Updated Figure 8-1 to align with STI/RTI signs/symptoms from more recent reference Added guidance on how to implement use of newer versions of DAIDS toxicity table, should one be issued during study follow-up
9	Counseling Considerations	2.0 2.1	15 August 2013 14 Jun 2017	<ul style="list-style-type: none"> Updated reference documents
10	Laboratory Considerations	2.0 2.1	15 August 2013 14 Jun 2017	<ul style="list-style-type: none"> Updated HIV testing information Updated LDMS information Updated GC/CT testing information Clerical updates
11	Safety Monitoring and Reporting	2.0 2.1	15 August 2013 14 Jun 2017	<ul style="list-style-type: none"> Updated notification requirements to be management team, not full protocol team.
12	Data Collection	2.0 2.1	15 August 2013 14 Jun 2017	<ul style="list-style-type: none"> Removed form instructions in item 2 for ART Enrollment, V2.0 CRF, as the follow-up behavioral assessment is required at M3, 12, and 24 for all enrolled participants ATLAS CRF packets updated with new VRF version Added guidance on how to complete parent protocol visit codes for item 3a on Microbicide Trial Participation CRF Removed option to fax CRFs via phone line
13	Data Communiqués	2.0	15 August 2013	

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14	Study Reporting Plan	2.0	15 August 2013	
15	ACASI Manual	2.1	5 August 2014	