

MTN-037 Study-Specific Manual

Overview and Control Document – Version History and Notice of Changes

Section Number	Section Title	Version Number(s)*	Version Date(s)*	Notice of Changes*
01	Introduction (Includes Protocol)	1.0 1.1	25 May 2018 5 Oct 2018	<ul style="list-style-type: none"> Added LoA #1 to section 1.1 Updated footer and TOC
02	Documentation Requirements	1.0 1.1	25 May 2018 5 Oct 2018	<ul style="list-style-type: none"> Updated footer and TOC
03	Accrual and Retention	1.0 1.1	25 May 2018 5 Oct 2018	<ul style="list-style-type: none"> Updated footer and TOC
04	Informed Consent	1.0 1.1	25 May 2018 5 Oct 2018	<ul style="list-style-type: none"> Updated footer and TOC
05	Study Procedures (SCR, ENR, FU)	1.0 1.1	25 May 2018 5 Oct 2018	<ul style="list-style-type: none"> Added note for documenting eligibility of participants assigned female at birth who are not of child-bearing potential in section 5.3.2 Added collection window instruction on the post-dose sampling assignments in section 5.4.2 Clarified CASI should be administered after gel administration at Dosing Visits in section 5.5.2 Updated footer and TOC
06	Study Product Considerations	1.0 1.1	25 May 2018 5 Oct 2018	<ul style="list-style-type: none"> Updated footer and TOC
07	Behavioral Measures	1.0 1.1	25 May 2018 5 Oct 2018	<ul style="list-style-type: none"> Revised timing of CASI in relation to gel administration during Dosing Visits in section 7.4.1.2 Updated footer and TOC
08	Clinical Considerations	1.0 1.1	25 May 2018 5 Oct 2018	<ul style="list-style-type: none"> Clarified menses during the enrollment visit is permissible in section 8.1.1 Clarified when an anoscopy should occur during study visits in section 8.5.4 Updated footer and TOC
09	AE Reporting and Safety Monitoring	1.0 1.1	25 May 2018 5 Oct 2018	<ul style="list-style-type: none"> Updated footer and TOC

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10	Laboratory Considerations	1.0 1.1	25 May 2018 5 Oct 2018	<ul style="list-style-type: none"> • Updated 10.8.2, 10.9.3, 10.9.5, and 10.9.8 with instructions on management of negative net weights for vaginal and rectal samples • Updated footer and TOC
11	Counseling Procedures	1.0 1.1	25 May 2018 5 Oct 2018	<ul style="list-style-type: none"> • Updated footer and TOC
12	Data Collection	1.0 1.1	25 May 2018 5 Oct 2018	<ul style="list-style-type: none"> • Updated footer and TOC
13	Data Communiques	1.0 1.1	25 May 2018 5 Oct 2018	<ul style="list-style-type: none"> • Updated footer and TOC
14	Study Reporting Plan	1.0 1.1	25 May 2018 5 Oct 2018	<ul style="list-style-type: none"> • Updated footer and TOC

***Highest version number/date listed is current and supersedes all previous listed version(s). Notice of Changes summarizes any significant changes that have been made during the current review period.**

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SSP Approval Sheet

Review Period: 19SEP2018-03OCT2018

Entity	Sections Approved*	Print Name, Role	Signature	Date
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Protocol Safety Physician	Sections 8, 9	Devika Singh, MTN LOC	DocuSigned by: <i>DS</i> 17AE8D9813E6457...	12-Oct-18

*Applicable section version numbers and dates as listed in MTN-037 Overview and Control Document, Version 1.1, dated 5 Oct 2018.