

MTN-039 Study-Specific Manual (SSP)

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	1.2	17 AUG 2020	N/A
02	Documentation Requirements	1.0	15 NOV 2019	N/A
03	Accrual and Retention	1.1	17 AUG 2020	N/A
04	Informed Consent	1.0	15 NOV 2019	N/A
05	Study Procedures	1.2	17 AUG 2020	N/A
06	Counseling Considerations	1.1	22 APR 2020	N/A
07	Behavioral Measures	1.0	15 NOV 2019	N/A
08	Study Product Considerations For Non-Pharmacy Staff	1.0	15 NOV 2019	N/A
09	Clinical Considerations	1.2	12 OCT 2020	<ul style="list-style-type: none"> Updated details related to approved/validated sample testing platforms and clarified the timing of required in-clinic rectal enemas in Section 9.5.3.1
10	AE Reporting and Safety Monitoring	1.1	22 APR 2020	N/A
11	Laboratory Considerations	1.2	12 OCT 2020	<ul style="list-style-type: none"> Updated details related to approved/validated sample testing platforms in Sections 11.5.2, 11.6, 11.8.1 and 11.9.1
12	Data Collection	1.3	12 OCT 2020	<ul style="list-style-type: none"> Included details on the required timing of the follow-up visit following an interim safety visit in Section 12.3.2
13	Data Communiqués	1.0	15 NOV 2019	N/A



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14	Study Reporting Plan	1.0	15 NOV 2019	N/A

*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.

SSP Approval Sheet

Study Role	Sections Approved*	Printed Name	Signature and Date
Protocol Chair	All Sections	Sharon Riddler	<p>DocuSigned by:  Signer Name: Sharon Riddler Signing Reason: I approve this document Signing Time: 12-Oct-2020 16:23 EDT 2711CF56DE604F56BA77A15C6A043F68</p>
FHI 360 CRM	All Sections	Sherri Johnson	<p>DocuSigned by:  Signer Name: Sherri Johnson Signing Reason: I approve this document Signing Time: 12-Oct-2020 15:54 EDT 1AE65A1B4467462AA6EAE7AA188A8920</p>

MTN-039 Study-Specific Manual (SSP) Overview and Control Document – Version History and Notice of Changes

<p>MTN Protocol Safety Physician</p>	<p>Section 9</p>	<p>Katie Bunge</p>	<p>DocuSigned by: <i>Katie Bunge</i></p> <p> Signer Name: Katie Bunge Signing Reason: I approve this document Signing Time: 13-Oct-2020 06:18 PDT 7ED1C5A6877240FDBBF82FFE3C69B1FA</p>
<p>MTN LC Manager</p>	<p>Section 11</p>	<p>Pam Kunjara</p>	<p>DocuSigned by: Pam Kunjara</p> <p> Signer Name: Pam Kunjara Signing Reason: I approve this document Signing Time: 12-Oct-2020 16:58 EDT 55201A2782D24795B0E77D4ED8F31783</p>
<p>SCHARP CDM</p>	<p>Section 12</p>	<p>Julie Ngo</p>	<p>DocuSigned by: <i>Julie Ngo</i></p> <p> Signer Name: Julie Ngo Signing Reason: I approve this document Signing Time: 12-Oct-2020 22:34 PDT C0C15D4D134F49C9BE9C16906C8F568B</p>

**Applicable section version numbers and dates as listed in MTN-039 Overview and Control Document, Version 1.3 dated 12OCT2020, Protocol Version 1.0 dated 06MAR2019*

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