

MTN-042 Study-Specific Procedures Manual Overview and Control Document – Version History and Notice of Changes

Section Number	Section Title	Version Number(s)*	Version Date(s)*	Notice of Changes*
1	Introduction	1.0 1.1 1.2 1.3	19DEC2019 9APR2020 30JUN2020 17MAY2021	<ul style="list-style-type: none"> Added reference to CM#01 and CM#02 to section 1.1 Added reference to COVID-19 MTN-042 Contingency Plan to section 1.1 Updated DAIDS policy references Added guidance around documentation of training and qualifications to section 1.3 Clarified that separate activation is not required for each cohort of the study in section 1.5
2	Documentation Requirements	1.0 1.1	19DEC2019 17MAY2021	<ul style="list-style-type: none"> Updated DAIDS policy references COVID preparedness checklist, Cohort 2 readiness checklist, and equipment calibration records added to list of study essential documents in section 2.1 Clarified that participant declines of study product should be reported as protocol deviations in section 2.9 Added guidance on how to report significant deviations following the obsolescence of the DAIDS critical events policy to section 2.9 Reorganized record retention section 2.13 for clarity
3	Accrual and Retention	1.0 1.1 1.2 1.3	19DEC2019 9APR2020 30JUN2020 17MAY2021	<ul style="list-style-type: none"> Added reference to cohort-specific readiness checklists and the IRP SOP to section 3.2.2 Clarified that aside from the PPO visit, missed visits are not expected to be made up in section 3.3.1
4	Informed Consent	1.0 1.1	19DEC2019 17MAY2021	<ul style="list-style-type: none"> Added reference to cohort-specific mother ICF in section 4.0 Updates to DAIDS policy references Added DAIDS guidance on timing of consent and re-consent of ICFs in 4.9
5	Study Procedures	1.0 1.1 1.2 1.3	19DEC2019 9APR2020 30JUN2020 17MAY2021	<ul style="list-style-type: none"> Updated DAIDS policy references Added guidance for providing IRP recommendations during IC process in section 5.3 Removed cohort 1 reference to rescreening in section 5.3 Added guidance for obtaining adequate ultrasound results for screening and updated GA parameters from cohort 1 to cohort 2 in section 5.3.1

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				<ul style="list-style-type: none"> • Updated guidance for PTID Name Linkage and logs and Screening and Enrollment Log for cohort 2 in section 5.3.2 • Added SSP section references for GA dating in 5.4.11 • Revised IDI selection criteria and behavioral assessment guidance at Enrollment visits in section 5.4.1.2 • Updated follow-up visit types for cohort 2 in section 5.5 • Clarified guidance for conducting the PPO Phone contact and PPO visit in section 5.5 • Updated follow-up visit procedures for cohort 2 in section 5.5.3 • Clarified missed visit guidance in section 5.5.5 • Removed references to pre-LOA #1 procedures for infant seroconversion in section 5.6.3 • Clarified that participants who experience a pregnancy loss will be followed per their original visit scheduled in section 5.7 • Added access to HIV prevention product to referrals upon study exit in section 5.13.5 • Added guidance for documenting contacts made with participants for study results dissemination in section 5.13.6
6	Study Product Considerations for Non-Pharmacy Staff	1.0 1.1	19DEC2019 9APR2020	<ul style="list-style-type: none"> • No updates
7	Clinical Considerations	1.0 1.1 1.2	19DEC2019 9APR2020 17MAY2021	<ul style="list-style-type: none"> • Updated section 7.7 per protocol requirements for cohort 2 ultrasound results to be performed no later than the 28th week gestational age (GA) • Added clarification to section 7.7 regarding specific GA that ultrasounds must be from for all cohorts • Added reference to new gestational age redating tool to SSP section 7.8 and clarified the column headings in the table for redating based on ultrasounds

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				<ul style="list-style-type: none"> Added a reminder to section 7.10.2 that outcomes reported on the PO CRF should be reconciled with any maternal AEs reported prior to the mother's study exit Specified that calibration records should be maintained as part of study essential documents in 7.11.1.1 Updated section 7.12.5 to be reflective of vaginal swab changes issued as part of operational guidance #02 and clarification memo #02 Added guidance for documentation of product holds for the reason of "suspected onset of labor or rupture of membranes" to section 7.17 Added a footnote to table 7-3 to note the conditions that are scheduled reasons for discontinuation per protocol Removed references to pre-LOA #1 procedures for infant creatinine testing in section 7.19.3 Updated guidance regarding assessment, reporting, and photographing suspected congenital anomalies in sections 7.19.8 and 7.19.9 Added the WHO guidelines for best practices in infant phlebotomy to section 7.19.11
8	Adverse Event Reporting and Safety Monitoring	1.0 1.1 1.2 1.3	19DEC2019 9APR2020 30JUN2020 17MAY2021	<ul style="list-style-type: none"> Guidance on reporting intrapartum hemorrhage was added to section 8.4, and a grading table for this condition was added to 8.5 Guidance on grading cephalon-pelvic disproportion as grade 2 was added to section 8.12.1 Updates were made to AE reporting requirements for congenital anomalies in section 8.17 Reference on archived DAIDS policy removed from section 8.19 Updated assessment of social harms frequency in section 8.24 to include 1st 4-week Visit as per protocol schedule of procedures for Cohort 2
9	Counseling Considerations	1.0 1.1	19DEC2019 9APR2020	<ul style="list-style-type: none"> No updates
10	Laboratory Considerations	1.0 1.1	19DEC2019 9APR2020	<ul style="list-style-type: none"> No updates

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		1.2	30JUN2020	
		1.3	01FEB2021	
11	Data Collection	1.0	19DEC2019	<ul style="list-style-type: none"> • Updated SCHARP study team member list • Updated guidance for documenting a second screening attempt • Updated pre-PO visits throughout to include up to visit 13 • Changed references to week 2 and week 4 bi-weekly visits to 2-week and 4-week visits • Updated tables 1 and 3 to include cohort 2 visits • Updated table 5 to list forms for cohort 2 visits
		1.1	9APR2020	
		1.2	30JUN2020	
		1.3	17MAY2021	
12	Data Communiques	1.0	19DEC2019	<ul style="list-style-type: none"> • (no updates)
13	Reporting Plan	1.0	19DEC2019	<ul style="list-style-type: none"> • Updated SCHARP study team member list • Removed Mother-Infant Listing
		1.1	17MAY2021	
14	DELIVER Qualitative Component	1.0	19DEC2019	<ul style="list-style-type: none"> • Updates related to cohort 2 will be released separately
		1.1	9APR2020	

***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.**

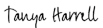
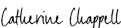
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<p>SCHARP CDM</p>	<p>Sections 5, 7-8, 11-13</p>	<p>Tanya Harrell, SCHARP</p>	<p>DocuSigned by:  Signer Name: Tanya Harrell Signing Reason: I approve this document Signing Time: 17-May-2021 16:33 EDT 7CFE3850AA7E4DCB84A1AE4FF6736AD0</p>
<p>Protocol Safety Physician</p>	<p>Sections 7, 8</p>	<p>Catherine Chappell, MTN LOC</p>	<p>DocuSigned by:  Signer Name: Catherine Chappell Signing Reason: I approve this document Signing Time: 18-May-2021 12:21 CDT 15F372D806EC4E9C9175092C8F464FB1</p>

**Applicable section version numbers and dates as listed in Overview and Control Document table, Version 1.4, dated 17MAY2021*

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