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| | | 1.3 | 17MAY2021 | • Table 11-6 updated to include Participant Transfer and Receipt CRFs }

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### MTN-042 Study-Specific Procedures Manual

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- SDMC staffing updates made within the Introduction section.
- Table 14-1 updated to reflect updated targets for Cohort 3 qualitative accrual.
- Eligibility Criteria section moved earlier, now section 14.3.1; associated section number updates made throughout.
- New section 14.3.3 added to outline the Cohort 3 qualitative accrual plan and the site-specific accrual targets.
- Table 14-4 updated to include the Cohort 3 Sample Qualitative Participant Log.
- New section 14.5 added to provide guidance on qualitative considerations for participants transfers.
- New section 14.10.3 added to provide guidance on use of the Timeline Tool for Cohort 3; reference to the timeline tool also added to Appendix 14-1 (SFTP Instructions) and new section 14-3 (Example of a Timeline Tool)
- Section 14.10.6 updated to reflect file naming conventions for Cohort 3.

*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.*
## MTN-042 Study-Specific Procedures Manual

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#### SSP Approval Sheet

**Review Period:** 17MAR2022-09MAY2022

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|                      |                   |                                      | Signing Time: 13-May-2022 | 07:03 PDT
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| FHI 360 CRM          | All Sections      | Ashley Mayo, FHI 360                 | DocuSigned by: Ashley Mayo
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*Applicable section version numbers and dates as listed in Overview and Control Document table, Version 2.2, dated 10MAY2022*
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Ashley Mayo
amayo@fhi360.org
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