Section 3. Documentation Requirements

Study staff are responsible for proper collection, management, storage, quality control, and quality assurance of all study-related documentation. This section contains information on the essential documents that each study site must maintain throughout the study. It also contains information related to establishing adequate and accurate participant research records — commonly referred to as participant "case history records" — for MTN-003.

3.1 Essential Documents

The Division of AIDS (DAIDS) policy on *Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials* specifies the essential documents that study sites must maintain for DAIDS-sponsored studies, including MTN-003. When required documents are modified or updated, the original and all updated versions must be maintained. Although all required documentation must be available for inspection at any time, all documents need not be stored together in one location. In its policy on *Requirements for Manual of Operational Procedures*, DAIDS requires study sites to establish a standard operating procedure (SOP) for maintaining essential documents. This SOP should be established prior to activation of MTN-003 and should be followed for MTN-003.

Section Appendix 3-1 presents a suggested essential documents filing structure for MTN-003. The suggested structure incorporates guidance received from the DAIDS Prevention Science Program and the DAIDS Clinical Site Monitoring Group. Study sites are not required to adopt the suggested structure, but are encouraged to consider it when developing their filing approach for MTN-003. Further clarifications of the suggested filing structure are as follows:

- Essential documents may be stored in files and/or in binders. The files/binders listed in Section Appendix 3-1 may be further subdivided, consolidated, and/or re-organized if desired.

- It is recommended that a contents sheet be maintained and inserted as the first page(s) of each file/binder. Within each file/binder, it is recommended that documents be filed in ascending date order (most recent documents in front).

- To preserve blinding, certain documents related to the investigational study products will be stored in site pharmacies. A listing of essential documents to be maintained in the pharmacies is provided in Section 3.3, rather than Section Appendix 3-1.

- To facilitate routine inspection by study monitors, certain laboratory-related essential documents should be stored in the main study essential documents files/binders (see items 27-29 in Section Appendix 3-1). Other lab-related essential documents (e.g., lab SOPs) may be filed in site laboratories.

- The suggested filing structure assumes that MTN-003 participant case history records will be stored separately from the other essential documents listed in Section Appendix 3-1. Section 3.2 below provides information on the required contents of these records. The suggested filing structure also assumes that the MTN-003 Screening and Enrollment Log, Participant Name-ID Number Link Log, and Clinic Randomization Envelope Tracking Record (which are described in Section 4 of this manual) will be stored in the study clinic or data management area, and not necessarily with the other essential documents listed in Section Appendix 3-1.

3.2 Participant Case History Documentation

Study sites must maintain adequate and accurate participant case history records containing all information pertinent to MTN-003 for each study participant.

3.2.1 Case History Contents

Participant case histories should contain all of the following elements:

- Basic participant identifiers.
- Documentation that the participant provided written informed consent to screen for and participate in the study prior to the conduct of any screening or study procedures, respectively.
- Documentation that the participant met the study's selection (eligibility) criteria.
- A record of the participant's random assignment.
- A record of the participant's exposure to the investigational study products.
- A record of all contacts, and attempted contacts, with the participant.
- A record of all procedures performed by study staff during the study.
- Study-related information on the participant's condition before, during, and after the study, including:
  - Data obtained directly from the participant (e.g., interview responses and other self-reported information)
  - Data obtained by study staff (e.g., exam and lab findings)
  - Data obtained from non-study sources (e.g., non-study medical records)

In addition to the above, DAIDS requires that all protocol deviations be documented in participant records, along with reasons for the deviations, efforts made to correct the deviations, and efforts made to prevent similar deviations in the future. MTN-003 study sites also must report reportable protocol deviations per Section 15.4 of the MTN Manual of Operations.

3.2.2 Concept of Source Data and Source Documentation

The International Conference on Harmonization Consolidated Guidance for Good Clinical Practice (ICH-E6) defines the terms source data and source documentation as follows:

Source data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

Source documents: Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies of transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the trial).

Source documents are commonly referred to as the documents — paper-based or electronic — upon which source data are first recorded. All study sites must comply with the standards of source documentation specified in the DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials*. The DAIDS policy specifies both requirements and recommendations. Study sites must comply with all requirements and are encouraged, but not required, to comply with all recommendations.

For MTN-003, it is expected that participant case history records will consist of the following source documents:

- Narrative chart notes
- Clinic randomization envelopes and prescriptions documenting participants' random assignments
- Pharmacy randomization envelopes and investigational product dispensing and chain of custody records (maintained in the study site pharmacy)
- Visit checklists and/or other site-specific flowsheets
- Local laboratory testing logs and result reports
- DataFax and Non-DataFax forms provided by the MTN Statistical and Data Management Center (SDMC)
- Other source documents (e.g., site-specific worksheets, non-study medical records)

As a condition for study activation, each study site must establish an SOP for source documentation that specifies the use of the above-listed documents as source documents. Although it is the responsibility of each site to determine the most appropriate source document for each required case history element, Section Appendix 3-2 provides a guide that sites may follow.

Supplemental information on the use of chart notes, visit checklists, and forms provided by the MTN SDMC is provided below. Detailed information on proper completion, maintenance, and storage of participant randomization and product dispensing documentation is provided in Sections 4, 6, and 9 of this manual. Detailed information on proper completion of DataFax and non-DataFax forms provided by the MTN SDMC is provided in Section 14 of this manual.

Chart Notes: Study staff must document every contact with a study participant in a signed and dated chart note specifying the date, type, purpose, and location of the contact, and the general status of the participant. For field and outreach workers, participant contacts may alternatively be documented on worksheets or other forms designated for this purpose. The time at which a contact takes place, or at which particular procedures take place, also should be specified when necessary to document adherence to protocol requirements. Chart notes also should be used to document the following:

- The screening and enrollment informed consent processes (see also Section 5)
- Procedures performed that are not recorded on other source documents
- Study-specific counseling sessions, and any associated referrals, that are not documented on other source documents
- Other pertinent data about the participant that are not recorded on other source documents
- Protocol deviations that are not otherwise captured on other source documents

Study sites are strongly encouraged to adopt a common format — such as the Subjective-Objective-Assessment-Plan (SOAP) format — for all chart notes, to help ensure adequacy and consistency of note content and maximize adherence to Good Clinical Practice standards. Sample notes in SOAP format are available from the MTN Coordinating and Operations Center (CORE; FHI) upon request.

Visit Checklists: The checklists in Section 7 of this manual represent convenient tools to fulfill the requirement of documenting all study procedures performed with each study participant. Note, however, that checklists alone may not be sufficient for documenting all procedures. For example, chart notes may be required to document procedures performed at unscheduled study visits, and/or to explain why procedures in addition to those listed on a checklist may have been performed or why procedures listed on a checklist were not performed. Chart notes also may be required to document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements).

DataFax and Non-DataFax Forms Provided by the MTN SDMC: The case report forms for this study are designed for use with the DataFax data management system described in Section 14 of this manual. The SDMC will provide these forms to each site. The SDMC also will provide several study-specific non-DataFax forms to each site. See Section Appendix 3-3 for a listing of all DataFax and non-DataFax forms for this study.

The SDMC will provide all forms in pre-assembled packets for each protocol-specified study visit. Packets of other "as needed" forms also will be provided. The packets will be produced at a US-based printing company, and will be shipped from the printing company to each study site. Forms will be printed on A4 paper and four-hole punched. Forms that are administered directly to participants will be available in local languages relevant to each site.

As shown in Section Appendices 3-4 and 3-5, many of the DataFax and non-DataFax forms provided by the SDMC have been designed to serve as source documents. Each study site must document the forms that routinely will be used as source documents in its SOP for source documentation, and must follow the specifications of this SOP consistently for all study participants. In the event that study staff are not able to record data directly onto forms designated as source documents, the following procedures should be undertaken:

- Record the data onto an alternative source document
- Enter the alternative source document into the participant's study chart
- Transcribe the data from the alternative source document onto the appropriate form and enter a note on the form stating the alternate source document used
- Enter a chart note stating the relevant study visit date and the reason why an alternative source document was used

3.2.3 Document Organization

Study staff must make every effort to store all study records securely and confidentially. Case history records must be stored in the same manner for all participants, in areas with access limited to authorized study staff only. Study staff are responsible for purchasing file folders, binders, storage cabinets, and any other equipment or supplies needed to properly store all records.

Study-related documentation collected during the screening process should be stored in file folders or thin notebooks for each potential participant. All screening documentation — for potential participants who eventually enroll in the study as well as for those who do not enroll — must be maintained and available for monitoring throughout the study. This documentation also must be available for reference should participants present to the site for re-screening. For participants who enroll in the study, screening documentation should be transferred into large ring binders that will serve as participants' study notebooks for the duration of their participation in the study.

All documents contained in participant case history records must bear a participant identifier, which generally will consist of either the participant identification number (PTID) or the participant name. To maximize participant confidentiality, the PTID should be used whenever possible, and it is recommended that records that bear names or other personal identifiers, such as locator forms and informed consent forms, be stored separately from records identified by PTID. Any documents transferred or transmitted to a non-study site location — including DataFax forms — must be identified by PTID only.

Regardless of whether the identifier on a particular document consists of the participant name or PTID, the original identifier may not be obliterated or altered in any way, even if another identifier is added. When necessary to maintain confidentiality, identifiers may be obliterated on <u>copies</u> of original source documents. For example, if medical records obtained from a non-study health care provider bear the participant's name, the original documents bearing the name should be stored unaltered with other study documents bearing the name. However, a copy of the original documents could be made, the PTID could be entered onto the copies, and then the participant name could be obliterated from the copies. Copies handled in this way could then be stored in participants' study notebooks and/or transferred or transmitted to non-study site locations.

All on-site databases, and ACASI questionnaire data, must be secured with password-protected access systems. Any lists, logbooks, appointment books, or other documents that link PTIDs to other participant identifiers should be stored securely in a location separate from records identified by participant name only and separate from records identified by PTID only. When in use, documents that link PTIDs to other participant identifiers should not be left unattended or otherwise accessible to study participants, other study clinic patients, or any other unauthorized persons.

As a condition for study activation, each study site must establish an SOP for data management. This SOP minimally should contain the following elements:

- Procedures for assigning PTIDs, linking PTIDs to participant names, and storing the name-PTID link log
- Procedures for establishing participant files/charts/notebooks
- During-visit participant chart and case report form review procedures
- Post-visit participant chart and case report form review procedures and timeframes
- DataFax transmission procedures, including timeframes, case report form storage locations before and after faxing, and mechanisms for identifying when forms have been transmitted
- ACASI data collection, back-up, and transmission procedures, including timeframes, ACASI equipment storage locations, and mechanisms for identifying when questionnaires have been transmitted
- Procedures for resolving data quality control notes from the SDMC
- Procedures for handling and filing field workers' logs, worksheets, etc.
- Storage locations for blank case report forms
- Storage locations for documents identified by participant names or other personal identifiers
- Storage locations for documents identified by PTID
- Handling of participant study records for off-site contacts and visits
- Confidentiality protections
- Other ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- QC/QA procedures related to the above (if not specified elsewhere)

3.3 Study Product Accountability, Chain of Custody, and Dispensing Documentation

The essential documents listed in Figure 3-1 below should be maintained in study site pharmacies.

Pharmacy staff will document the receipt, dispensing, return, re-issuing, and final disposition of each investigational product used in the study. Separate accountability records must be maintained for product, per instructions provided in the *MTN-003 Pharmacist Study Product Management Procedures Manual* available from the DAIDS Pharmaceutical Affairs Branch (PAB).

Pharmacy staff also will maintain in the study pharmacies randomization materials for all enrolled study participants and product dispensing records for all participants, per instructions in the *MTN-003 Pharmacist Study Product Management Procedures Manual.* Study clinic staff will contribute to the documentation of product dispensation and chain of custody as described in Sections 4, 6, and 9 of this manual.

The specifications related to document security and participant confidentiality described in Section 3.2 also apply to records maintained in the study pharmacies. All records must be stored securely in the pharmacies with access limited to authorized study pharmacy staff only.

To preserve the double blinding of participants' random assignments, neither study clinic staff nor study participants will be provided access to product-related documentation maintained in the study pharmacies. Pharmacy staff will provide copies of some participant-specific documentation maintained in the study pharmacies (e.g., returned product counts) to clinic staff as described in Sections 6 and 9 of this manual, but under no circumstances will documentation released from the pharmacy include participants' product dispensing records or other information related to participants' random assignments.

Figure 3-1
MTN-003 Essential Documents Maintained in Study Site Pharmacies

- Current MTN-003 protocol
- Current Package Inserts for Viread and Truvada
- Current Investigator's Brochure for Tenofovir Gel
- Current MTN-003 FDA Form 1572
- Current list of authorized prescribers and staff authorized to sign MTN-003 Study Product Request Slips (names and signatures)
- PAB-approved MTN Pharmacy Establishment Plan
- MTN-003 pharmacy and product-related SOPs
- MTN-003 pharmacy randomization envelopes
- MTN-003 pharmacy randomization envelope tracking record
- MTN-003 PTID list
- MTN-003 product import documentation
- MTN-003 product shipping and receipt documentation
- MTN-003 product storage temperature logs
- MTN-003 investigational product accountability records
- MTN-003 participant-specific records (including prescriptions, pharmacy randomization envelopes, documentation of unused product returns, product dispensing and re-issuing records)
- MTN-003 monitoring visit reports
- MTN-003 communications with site clinic staff
- MTN-003 communications with the DAIDS Pharmaceutical Affairs Branch and the NIAID Clinical Research Product Management Center
- MTN-003 communications with the MTN CORE (PITT), including the MTN Pharmacist
- MTN-003 communications with the MTN CORE (FHI)
- MTN-003 communications with the MTN SDMC
- Other MTN-003 communications
- Other locally-required administrative, operational, and/or regulatory documentation

3.4 Record Retention Requirements

All study records must be maintained for at least two years following the date of marketing approval for each of the three study products for the indication in which they were studied. If no marketing application is filed, or if the application is not approved, records must be retained for two years after the US Food and Drug Administration is notified that the Investigational New Drug application for the product(s) is discontinued.

All records must be retained on-site throughout the study's period of performance, and for at least three years after completion or termination of the study. Study product records must be stored in site pharmacies, with access limited to authorized study pharmacy staff only, until the study is unblinded. DAIDS will provide further instructions for long-term storage of study records after the study is completed. Study records should not be re-located to an off-site location or destroyed without prior approval from DAIDS.

Section Appendix 3-1
Suggested Filing Structure for MTN-003 Essential Documents

File/Binder #1: MTN-003 Protocol and Current Informed Consent Forms

1. MTN-003 Protocol (including signed and dated protocol signature page): Version 1.0 and any subsequent protocol Clarification Memos, Letters of Amendment, and Amendments issued after Version 1.0.
2. Currently-approved (blank) MTN-003 informed consent forms

File/Binder #2: Regulatory Authority Documentation (if applicable)

3. Regulatory Authority Correspondence/Authorization/Approval/Notification of the MTN-003 Protocol (if applicable; if more than one regulatory authority has oversight responsibility for research performed at the study site, include subsections for each authority)

File/Binder #3A: IRB/EC Documentation for [IRB/EC A]

4. FWA documentation for IRB/EC A
5. Roster of IRB/EC A (if available)
6. Relevant IRB/EC A Submission Requirements/Guidelines/SOPs
7. IRB Correspondence for IRB/EC A: File complete copies of all correspondence to and from the IRB/EC; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere; include all approval documentation.

File/Binder #3B: IRB/EC Documentation for [IRB/EC B]

8. FWA documentation for IRB/EC B
9. Roster of IRB/EC B (if available)
10. Relevant IRB/EC B Submission Requirements/Guidelines/SOPs
11. IRB Correspondence for IRB/EC B: File complete copies of all correspondence to and from the IRB/EC; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere; include all approval documentation.

File/Binder #4: Product Safety Information

12. Investigator's Brochure for Tenofovir Gel: current version and any subsequent updates
13. Package Insert for Viread: current version and any subsequent updates
14. Package Insert for Truvada: current version and any subsequent updates
15. Product Safety Information/Reports/Memos

Notes:

- It is assumed that expedited adverse event reports will be stored in participant study notebooks.
- It is assumed that documentation of IRB/EC submission of above-listed documents (if applicable) will be maintained in the relevant IRB/EC Files/Binders (i.e., File/Binder #3A and #3B).

File/Binder #5: MTN-003 Study-Specific Procedures (SSP) Manual

16. Version 1.0 and any subsequent updates

Notes:

- For this reference copy of the SSP Manual, do not discard out-dated pages or sections when updates are issued; retain all versions of all pages as a complete historical record.
- The SSP Manual contains reference versions of all study case report forms, therefore additional (blank) copies of the case report forms need not be stored elsewhere in the essential document files.

File/Binder #6: MTN-003 Study-Specific Standard Operating Procedures

17. Final approved version of each SOP, and any subsequent updates to each

File/Binder #7: MTN-003 Staffing Documentation

18. FDA Form 1572 (copy of original form submitted to the DAIDS Protocol Registration Office (PRO), and any subsequent updates)
19. MTN-003 Investigator of Record CV (copy of CV submitted to the DAIDS PRO; ensure that the CV is current prior to initiating MTN-003; it is recommended that CVs be signed and dated to document at least annual updating)
20. Financial Disclosure Forms (original signed and dated forms, and any subsequent updates)
21. Study Staff Roster (original submitted to FHI for study activation, and any subsequent updates)
22. Study Staff Identification and Signature Sheet (if not combined with staff roster; original and any subsequent updates)
23. Study Staff Delegation of Duties (if not combined with staff roster; original and all updates)
24. CVs for Study Staff other than the IoR (ensure that all CVs are current prior to initiating MTN-003; it is recommended that CVs be signed and dated to document at least annual updating)
25. Study Staff Job Descriptions
26. Documentation of Study Staff Training

Section Appendix 3-1
Suggested Filing Structure for MTN-003 Essential Documents

File/Binder #8: Local Laboratory Documentation

27. Local Laboratory Certification(s), Accreditation(s) and/or Validation(s): file documentation current at time of study activation and all subsequent updates
28. Local Laboratory Normal Ranges: file documentation of relevant normal ranges for all protocol-specified tests current at time of study activation and all subsequent updates
29. Laboratory Manager CV (or cross-reference to CV contained in File/Binder #7)

Note:

- It is recommended that a cross-reference be included in this file/binder specifying the storage location(s) of other lab-related essential documents filed in the local lab(s).

File/Binder #9: Monitoring Visit Documentation

30. Monitoring Visit Log
31. Monitoring Visit Reports and Documentation of Response to Visit Findings

File/Binder #10: Documentation of Other MTN Site Visits

32. MTN CORE Site Visit Reports and Documentation of Response to Visit Findings
33. MTN SDMC Site Visit Reports and Documentation of Response to Visit Findings
34. MTN Network Lab Site Visit Reports and Documentation of Response to Visit Findings
35. Other Site Visit Reports and Documentation of Response to Visit Findings

File/Binder #11: Study-Related Sponsor Communications

36. Study-Related Communications to and from DAIDS
37. Communications to and from DAIDS RCC (includes copies of all submissions to the DAIDS PRO)

Notes:

- Communications should be filed beginning from the date of the MTN-003 Central Investigators Meeting.
- Communications related to individual MTN-003 study participants will be filed in individual participant study records.
- As needed to preserve blinding, product-related communications with DAIDS PAB (and its contractors) will be stored in the study pharmacy.

File/Binder #12: Other Study-Related Communications

38. Study-Related Communications to and from MTN CORE
39. Study-Related Communications to and from MTN SDMC
40. Study-Related Communications to and from MTN Network Lab
41. Other Study-Related Communications

Notes:

- Communications should be filed beginning from the date of the MTN-003 Central Investigators Meeting.
- Communications related to individual MTN-003 study participants will be filed in individual participant study records.
- As needed to preserve blinding, product-related communications with DAIDS PAB (and its contractors) will be stored in the study pharmacy.

File/Binder #13: Study Site Staff Meeting Documentation

42. MTN-003 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries

Note:

- Meeting documentation should be filed beginning from the date of the MTN-003 Central Investigators Meeting.

File/Binder #14: Conference Call Documentation

43. MTN-003 Protocol Team Conference Call Summaries
44. MTN-003 Study Coordinators Group Conference Call Summaries
45. MTN-003 Laboratory Group Conference Call Summaries
46. MTN-003 Community Working Group Conference Call Summaries
47. Summaries of Other MTN-003 Conference Calls

Note:

- Conference call summaries will be filed beginning from the date of the MTN-003 Central Investigators Meeting.

Section Appendix 3-1
Suggested Filing Structure for MTN-003 Essential Documents

File/Binder #15: DAIDS and Other Reference Documentation
48. DAIDS Protocol Registration Policy and Procedures Manual
49. Manual for Expedited Reporting of Adverse Events to DAIDS
50. DAIDS Adverse Experience Reporting System Reference Guide for Site Reporters and Study Physicians
51. US Regulations Applicable to Conduct of MTN-003 (45 CFR 46; 21 CFR 50, 54, 56, and 312)
52. Any other relevant manuals or reference documents
File/Binder #16: Site-Specific Study Activation Documentation
53. Site-Specific Study Activation Notice and supporting documentation

Section Appendix 3-2
Guide to Required Case History Elements and Source Documents for MTN-003

Required Case History Element	Source Documents*
Basic participant identifiers.	Locator form, Demographics form.
Documentation that the participant provided written informed consent to screen for and participate in the study.	Signed and dated informed consent forms; signed and dated chart notes stating that informed consent was obtained prior to initiating study procedures; informed consent coversheet.
Documentation that the participant met the study selection (eligibility) criteria.	Demographics form, locator form; Screening Part 1 Eligibility form; Participant-reported Baseline Medical and Menstrual History form; Concomitant Medications Log form; Physical Exam form; Pelvic Exam Diagrams form; Screening and Enrollment Pelvic Exam form; Screening Part 2/Enrollment Behavioral Eligibility form; Screening Part 2 Medical Eligibility form; Enrollment Medical Eligibility form; local lab logs and result reports[§]; signed and dated chart notes.
A record of the participant's random assignment.	Clinic randomization envelope tracking record; clinic randomization envelope; study product prescription; pharmacy randomization envelope tracking record; pharmacy randomization envelope; participant-specific pharmacy dispensing record(s).
A record of the participant's exposure to the investigational study products.	Study product prescription; study product returns documentation; study product request slip; participant-specific pharmacy dispensing record(s); dispensed product chain of custody logs; interviewer-administered case report forms and ACASI questionnaires that collect participant-reported product use data; Specimen Storage/PK form.
A record of all contacts, and all attempted contacts, with the participant.	Signed and dated chart notes and/or other worksheets or site-specific documents if designated in site SOPs.
A record of all procedures performed by study staff.	Completed visit checklists; signed and dated chart notes detailing (i) procedures performed in addition to those contained on the checklist and/or (ii) the reason why procedures contained on the checklist were not performed.
Information on the participant's condition before, during, and after the study.	All documents listed above; all interviewer-administered case report forms, Participant-reported Follow-up Medical and Menstrual History form; Follow-up Pelvic Exam form; Genital Bleeding Assessment form; HIV Test Results form; AE Log form; Product Hold/ Discontinuation Log form; Pregnancy Report and History form; Pregnancy Outcome form; Missed Visit form; Participant Transfer form; Participant Receipt form; local lab logs and result reports[§]; signed and dated chart notes; medical records and other documents bearing information pertinent to the study obtained from non-study sources; other designated site-specific source documents.

*Other site-specific source documents also may be used.

[§]A clinician must review all local laboratory reports and document this review by signing and dating all reports.

Section Appendix 3-3
MTN-003 DataFax and Non-DataFax Forms

MTN-003 DataFax Forms
Screening Consent
Demographics
Screening and Enrollment HIV Test Results
STI Laboratory Results
Safety Laboratory Results
Concomitant Medications Log
Contraceptives Log
Screening and Enrollment Pelvic Exam
Vaginal Test Results
Pap Test Result
Specimen Storage/PK
Enrollment
Pharmacy Randomization
Pre-existing Conditions
Baseline Family Planning
Baseline Behavior Assessment
Follow-up Visit
Product Returns and Dispensations
Monthly Symptoms
Follow-up Family Planning
Follow-up Pelvic Exam
Follow-up HIV Rapid Test Results
HIV Western Blot Test Results
Seroconverter Laboratory Test Results
Monthly Product Adherence and Behavior Assessment
Oral Product Adherence and Behavior Assessment
Vaginal Product Adherence and Behavior Assessment
Menstrual Practices and Study Disclosure Assessment
Interim Visit
Adverse Experience Log
Product Hold/Discontinuation Log
Pregnancy Report and History
Pregnancy Outcome
Missed Visit
Participant Transfer
Participant Receipt
Product Use End Visit
Study Exit Visit
Study Exit Behavior Assessment
Perceived Product Assessment
Termination
End of Study Inventory

MTN-003 Non-DataFax Forms
Screening Part 1 Eligibility
Participant-reported Baseline Medical and Menstrual History
Physical Exam
Pelvic Exam Diagrams
Screening Part 2/Enrollment Behavioral Eligibility
Screening Part 2 Medical Eligibility
Enrollment Medical Eligibility
Participant-reported Follow-up Medical and Menstrual History
Genital Bleeding Assessment
LDMS Specimen Tracking Sheet

Section Appendix 3-4
Use of MTN-003 DataFax Forms as Source Documents

MTN-003 DataFax Forms	Source?	Comments
Screening Consent	Mixed	Form may be source for items 1-2. All other items should be completed based on source data recorded on other source documents.
Demographics	Yes	Items 1-17 are interviewer-administered; participant responses must be recorded directly onto the form. Form may be source for item 18.
Screening and Enrollment HIV Test Results	No	All items should be completed based on laboratory source documents.
STI Laboratory Results	No	All items should be completed based on laboratory source documents.
Safety Laboratory Results	Mixed	All items except item 3d should be completed based on laboratory source documents. Form may be source for item 3d (weight); other documents, including the non-DataFax Physical Exam form, also may serve as source for item 3d.
Concomitant Medications Log	Yes	Form may be source for all items.
Contraceptives Log	Mixed	Contraceptive names and dates of use should be source documented on medical history source documents and then transcribed onto this form. Form may be source for frequency, dose/units, and route.
Screening and Enrollment Pelvic Exam	Mixed	Items 1 and 1a should be completed based on source data recorded on the Pelvic Exam Diagrams form. Form may be source for items 2-4. Other documents, including the non-DataFax Physical Exam form, may serve as source for item 4 (weight). Items 5 and 6 should be completed based on source data recorded on medical history source documents.
Vaginal Test Results	Mixed	Form may be source for item 1b. All other items should be completed based on laboratory source documents.
Pap Test Result	No	Form should be completed based on laboratory source documents.
Specimen Storage/PK	Yes	Form may be source for all items. Other documents, including the non-DataFax Physical Exam form, may serve as source for item 5 (height). Items 6-8 will be source when participants do not bring other source documents (e.g., appointment cards) on which they have recorded the date and time of last product use.
Enrollment	Mixed	Form may be source for items 4, 5, and 5a. All other items should be completed based on source data recorded on other source documents.
Pharmacy Randomization	No	All items should be completed based on source data recorded on other source documents.
Pre-existing Conditions	No	All items should be completed based on source data recorded on other source documents.

Section Appendix 3-4
Use of MTN-003 DataFax Forms as Source Documents

MTN-003 DataFax Forms	Source?	Comments
Baseline Family Planning	No	Form should be completed based on source data recorded on baseline medical history source documents.
Baseline Behavior Assessment	Mixed	Items 1-6e are interviewer-administered; participant responses must be recorded directly onto the form. Items 7-9a should be completed based on source data recorded on the Screening Part 1 Eligibility form.
Follow-up Visit	Mixed	Form may be source for items 4, 4a, 5, and 5a. All other items should be completed based on source data recorded on other source documents.
Monthly Symptoms	Yes	Form is interviewer-administered; participant responses must be recorded directly onto the form.
Follow-up Family Planning	No	Form should be completed based on source data recorded on follow-up medical history source documents.
Follow-up Pelvic Exam	Mixed	Items 1 and 1a should be completed based on source data recorded on the Pelvic Exam diagrams form. Form may be source for items 2-5.
Product Returns and Dispensations	No	All items should be completed based on source data recorded on other source documents.
Follow-up HIV Rapid Test Results	No	All items should be completed based on laboratory source documents.
HIV Western Blot Test Results	Mixed	Form may be source for item 4. All other items should be completed based on laboratory source documents.
Seroconverter Laboratory Test Results	No	All items should be completed based on laboratory source documents.
Monthly Product Adherence and Behavior Assessment	Yes	Form is interviewer-administered; participant responses should be recorded directly onto the form.
Oral Product Adherence and Behavior Assessment	Mixed	Items 1-20 are interviewer-administered; participant responses must be recorded directly onto the form. Items 21-21a should be completed based on source data recorded on other source documents.
Vaginal Product Adherence and Behavior Assessment	Mixed	Items 1-17 are interviewer-administered; participant responses must be recorded directly onto the form. Items 18-18a should be completed based on source data recorded on other source documents.
Menstrual Practices and Study Disclosure Assessment	Yes	Form is interviewer-administered; participant responses must be recorded directly onto the form.
Interim Visit	Mixed	Form may be source for items 1, 4, and 4a. Items 2 and 3 should be completed based on source data recorded on other source documents.
Adverse Experience Log	Mixed	Form may be source for items 4-5 and 8-11. All other items should be completed based on source data recorded on other source documents.
Product Hold/Discontinuation Log	Yes	Form may be source for all items.

Section Appendix 3-4
Use of MTN-003 DataFax Forms as Source Documents

MTN-003 DataFax Forms	Source?	Comments
Pregnancy Report and History	Mixed	Form may be source for items 2 and 3. All other items should be completed based on source data recorded on medical history source documents.
Pregnancy Outcome	Mixed	Form should be completed based on medical records whenever possible. When medical records are not available, form may be source for items 1-8, based on participant report. Items 9-10 must be completed based on medical records (if medical records are not available, these items will not be completed.
Missed Visit	Yes	Form may be source for all items.
Participant Transfer	Mixed	Form may be source for items 1, 2, and 4.
Participant Receipt	Mixed	Form may be source for items 1 and 2.
Product Use End Visit	Mixed	Form may be source for all items except item 1.
Study Exit Visit	Mixed	Form may be source for items 4, 4a, 5, and 5a. All other items should be completed based on source data recorded on other source documents.
Study Exit Behavior Assessment	Mixed	Items 1-6 are interviewer-administered; participant responses must be recorded directly onto the form. Items 7-7a should be completed based on source data recorded on other source documents.
Perceived Product Assessment	Yes	Form is source for all items.
Termination	No	All items should be completed based on source data recorded on other source documents.
End of Study Inventory	No	All items should be completed based on source data recorded on other source documents.

Section Appendix 3-5
Use of MTN-003 Non-DataFax Forms as Source Documents

MTN-003 DataFax Forms	Source?	Comments
Screening Part 1 Eligibility	Mixed	Items 1-19 are interviewer-administered; participant responses must be recorded directly onto the form. Form may be source for item 20. Item 21 (pregnancy test result) should be completed based on source data recorded on another source document. Item 22 is a numerical transformation of item 12.
Participant-reported Baseline Medical and Menstrual History	Yes	Form may be source for all items.
Physical Exam	Yes	Form may be source for all items.
Pelvic Exam Diagrams	Yes	Form may be source for all items.
Screening Part 2/Enrollment Behavioral Eligibility	Mixed	Items 1-6 are interviewer-administered; participant responses must be recorded directly onto the form. Item 7 should be completed based on source data recorded on other source documents.
Screening Part 2 Medical Eligibility	Mixed	Form may be source for items 4a and 6. All other items should be completed based on source data recorded on other source documents.
Enrollment Medical Eligibility	Mixed	Form may be source for items 4a and 7. All other items should be completed based on source data recorded on other source documents.
Participant-reported Follow-up Medical and Menstrual History	Yes	Form may be source for all items.
Genital Bleeding Assessment	Mixed	Form may be source for items 7-11, 13a, 13b, 13c, 14, and 14a. Items 1-6, 12, 12a, 12b, and 13 should be based on source data recorded on medical history source documents.
LDMS Specimen Tracking Sheet	No	All items based on source data recorded on other source documents.