

Section 3. Documentation Requirements

Study staff is 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 the 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-008.

3.1 Essential Documents

The Division of AIDS (DAIDS) Standard Operating Procedure (SOP) for Essential Documents specifies the essential documents that study site must maintain for DAIDS-sponsored studies, including MTN-008. When required documents are modified or updated, the original and all modified or 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.

Section Appendix 3-1 presents a suggested essential documents filing structure for MTN-008. The suggested structure incorporates guidance received from the the DAIDS Clinical Site Monitoring Group (CSMG). The study site is not required to adopt the suggested structure, but is encouraged to consider it when developing their filing approach for MTN-008. The study site also is encouraged to establish an SOP to document their filing approach. 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 table of contents be developed and maintained in the front page(s) of each file/binder. Within each section of the file/binder, it is recommended that documents be filed in ascending date order (most recent documents in front).
- Certain documents related to the investigational study products will be stored in the site pharmacy. A listing of essential documents to be maintained in the pharmacy is provided in Section 3.3. The list of documents to be kept in the pharmacy should be included in the master table of contents.
- 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 21-23 in Section Appendix 3-1). Other lab-related essential documents (e.g., lab SOPs) may be filed in site laboratories. The list of documents to be kept in the lab should be included in the master table of contents.
- The suggested filing structure assumes that MTN-008 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-008 Screening and Enrollment Log and Participant Name-ID Number Link Log (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

The study site must maintain adequate and accurate case history records 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 exposure to the investigational product (as directed in the protocol).
- 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 departures/deviations/violations be documented in participant records, along with reasons for the departures/deviations/violations and/or attempts to prevent or correct the departures/deviations/violations, if applicable. The study site also must report protocol deviations to DAIDS and others per guidelines provided in the MTN Manual of Operating Procedures Section 15.4 available at: <http://mtnstopshiv.org/node/187>

3.2.2 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. The study site must adhere to the standards of source documentation specified in the DAIDS SOP for Source Documentation. The DAIDS SOP specifies both requirements and recommendations. The study site must comply with all requirements and is encouraged, but not required, to comply with all recommendations.

It is expected that participant case history file will consist of the following source documents:

- Narrative chart notes
- Clinic prescriptions (“original” kept in the pharmacy)
- Pharmacy records for investigational product dispensing and chain of custody records
- 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)
- Behavioral questionnaires provided by RTI
- Other source documents (e.g., site-specific worksheets, non-study medical records)

Additionally, electronic source documentation will be captured through web-based CASI instruments. These data will be stored and managed by the SDMC.

As a condition for study activation, the 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 the site to determine the most appropriate source document for each required case history element, Appendix 3-2 provides a guide that the site may follow for this study. 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 of DataFax and Non-DataFax forms provided by the MTN SDMC is provided in Section 13 of this manual.

3.2.3 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. The time the contact takes place, any specific procedures conducted, and, when necessary, adherence to protocol requirements should also be documented. Chart notes also must be used to document the following:

- The study informed consent process (see also Section 5)
- Procedures performed that are not recorded on other source documents

- Pertinent data about the participant that are not recorded on other source documents
- Protocol departures/deviations/violations that are not otherwise captured on other source documents
- Explain why procedures in addition to those listed on a checklist were performed.
- Explain why procedures listed on a checklist were not performed.
- Document procedures performed at interim visits.
- Document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements).

The study site is 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 GCP standards. Other approaches also are acceptable so long as all necessary information is present. For any issues reported (whether or not an adverse event), necessary information would include at a minimum:

- Diagnosis or Symptom
- Severity
- Onset
- Resolution
- Impact on daily or social activities
- Grade
- Treatments
- Relationship to study drug
If relevant, include description of the symptom, e.g., location of the pain, nature of the pain, does anything relieve the pain, etc.
- Is there a cause or association the participant offers as explanation?

3.2.4 Visit Checklists

The sample 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 are not sufficient for documenting all procedures. For example, chart notes are 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).

3.2.5 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 13 of this manual. The SDMC will provide the initial supply of these forms to the site. Additional supplies of DataFax and non-DataFax forms can be printed at the site using the MTN-008 Atlas webpage. The SDMC also will provide several study-specific non-DataFax forms to the site. See Section Appendix 3-3 for a listing of all DataFax and non-DataFax forms to be provided for this study.

The SDMC will provide all forms in pre-assembled visit packets for each study cohort. (i.e., Screening Visit, Enrollment (Day 0) Visit, Day 1 Phone Call, Day 3 Phone Call, Day 6 Visit,

Day 14 Phone Call, and Delivery and Post-delivery Visits (Pregnancy Cohort only). A small supply of other “as needed” forms also will be provided. The notebooks will be produced by SCHARP and shipped to the study site. Forms will be printed on letter size paper and three-hole punched.

As shown in Appendices 3-5 and 3-6, many of the DataFax and non-DataFax forms provided by the SDMC have been designed to serve as source documents. The study site must document the forms that it will routinely use as source documents for this study in its Source Documentation SOP, and they must follow the specifications of this SOP consistently for all study participants. In the event that study staff is 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
- Enter a chart note stating the relevant study visit date and the reason why an alternative source document was used

3.2.6 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 is 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. For participants who enroll in the study, their 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 records that bear names or other personal identifiers, such as locator forms and informed consent forms, should be stored separately from records identified by PTID. Any documents transferred or transmitted to a non-study site location — including DataFax forms and Expedited Adverse Event 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 certified copies 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 must be stored unaltered with other study documents bearing the name. However, a certified copy of the original documents could be made, the PTID could be entered onto the certified 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 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 either participant name or PTID. When in use, these documents 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, the 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
- Data transmission procedures, including timeframes, case report form storage locations before and after faxing, and mechanisms for identifying when forms have been transmitted
- CASI data collection, back-up, and transmission procedures, including timeframes, CASI 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. (if applicable)
- 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 (if applicable)
- Confidentiality protections
- Other ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- Staff training requirements (if not specified elsewhere)
- QC/QA procedures related to the above (if not specified elsewhere)

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

Pharmacy staff will document the receipt, dispensing, 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-008 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-008 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.

The following essential documents should be maintained in the study site pharmacy:

- Current MTN-008 protocol
- Current Investigator's Brochures for Tenofovir 1% Vaginal Gel.
- Current MTN-008 FDA Form 1572
- Authorized prescribers signature list
- PAB approved Pharmacy Establishment Plan
- MTN-008 pharmacy and product-related SOPs
- MTN-008 PTID list (provided by the MTN SDMC)
- MTN-008 product shipping and receipt documentation
- MTN-008 product storage temperature logs
- MTN-008 investigational agent accountability records
- MTN-008 participant-specific records (including prescriptions)
- MTN-008 monitoring visit reports
- MTN-008 communications with site clinic staff
- MTN-008 communications with the DAIDS Pharmaceutical Affairs Branch (PAB) and the NIAID Clinical Research Product Management Center
- MTN-008 communications with the MTN Coordinating and Operations Center (PITT), including the MTN Pharmacist
- MTN-008 communications with the MTN Coordinating and Operations Center (FHI)
- MTN-008 communications with the MTN SDMC
- Other MTN-008 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 the study product for the indication in which they were studied. If no marketing application is to be filed, or if the application is not approved, the records must be retained until two years after the investigation is discontinued and the US Food and Drug Administration (FDA) is notified. 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 the study pharmacy, with access limited to authorized study pharmacy staff only. DAIDS will provide further instructions for long-term storage of study records after the study is completed.

Section Appendix 3-1
Suggested Filing Structure for MTN-008 Essential Documents

<p>File/Binder #1: MTN-008 Protocol and Current Informed Consent Form</p> <ol style="list-style-type: none"> 1. MTN-008 Protocol (including copy of 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 MTN-008 informed consent form
<p>File/Binder #2: Regulatory Authority Documentation (if applicable)</p> <ol style="list-style-type: none"> 3. Regulatory Authority Correspondence/Authorization/Approval/Notification of Protocol (if applicable; if more than one regulatory authority has oversight responsibility for research performed at the study site, include subsections for each authority)
<p>File/Binder #3: IRB/EC Documentation</p> <ol style="list-style-type: none"> 4. FWA documentation for IRB/EC 5. Roster of IRB/EC (if available) 6. Relevant IRB/EC Submission Requirements/Guidelines/SOPs 7. IRB Correspondence for IRB/EC: 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.
<p>File/Binder #4: Product Safety Information</p> <ol style="list-style-type: none"> 8. Investigator's Brochure for Tenofovir 1% Gel: current version and any subsequent updates 9. Product Safety Information/Reports/Memos <p>Notes:</p> <ul style="list-style-type: none"> • 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 #3).
<p>File/Binder #5: MTN-008 Study-Specific Procedures (SSP) Manual</p> <ol style="list-style-type: none"> 10. Final version 1.0 (when available) and any subsequent updates <p>Notes:</p> <ul style="list-style-type: none"> • 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.
<p>File/Binder #6: MTN-008 Study-Specific Standard Operating Procedures</p> <ol style="list-style-type: none"> 11. Final approved version of each SOP, and any subsequent updates to each
<p>File/Binder #7: MTN-008 Staffing Documentation</p> <ol style="list-style-type: none"> 12. FDA Form 1572 (copy of original and dated form submitted to the RSC for Protocol Registration, and any subsequent updates) 13. MTN-008 Investigator of Record CV (copy of CV submitted to the RSC for Protocol Registration; ensure that the CV is current prior to initiating MTN-008; it is recommended that CVs be signed and dated to document at least annual updating) 14. Financial Disclosure Forms (original signed and dated forms, and any subsequent updates) 15. Study Staff Roster (original submitted to MTN CORE for study activation, and any subsequent updates) 16. Study Staff Identification and Signature Sheet (if not combined with staff roster; original and any subsequent updates) 17. Study Staff Delegation of Duties (if not combined with staff roster; original and all updates) 18. CVs for Study Staff other than the IoR (ensure that all CVs are current prior to initiating MTN-008; it is recommended that CVs be signed and dated to document at least annual updating) 19. Study Staff Job Descriptions 20. Documentation of Study Staff Training

Section Appendix 3-1
Suggested Filing Structure for MTN-008 Essential Documents

<p>File/Binder #8: Local Laboratory Documentation</p> <p>21. Local Laboratory Certification(s), Accreditation(s) and/or Validation(s): file documentation current at time of study activation and all subsequent updates</p> <p>22. 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</p> <p>23. Laboratory Manager CV (or cross-reference to CV contained in File/Binder #7)</p> <p>Note:</p> <ul style="list-style-type: none"> • 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).
<p>File/Binder #9: Monitoring Visit Documentation</p> <p>24. Monitoring Visit Log</p> <p>25. Initiation and Monitoring Visit Reports and Documentation of Response to Visit Findings</p>
<p>File/Binder #10: Documentation of Other MTN Site Visits</p> <p>26. (Non-Monitoring) Site Visit Log</p> <p>27. MTN CORE Site Visit Reports and Documentation of Response to Visit Findings</p> <p>28. MTN SDMC Site Visit Reports and Documentation of Response to Visit Findings</p> <p>29. MTN Network Lab Site Visit Reports and Documentation of Response to Visit Findings</p> <p>30. Other Site Visit Reports and Documentation of Response to Visit Findings</p>
<p>File/Binder #11: Study-Related Sponsor Communications</p> <p>31. Study-Related Communications to and from DAIDS</p> <p>32. Communications to and from DAIDS RSC (includes copies of all submissions to the DAIDS Protocol Registration Office, which will be prepared by the site, as well as the current monthly DAIDS IB/PI listing and year-end and current monthly DAIDS Comprehensive Safety Distribution Report)</p> <p>Notes:</p> <ul style="list-style-type: none"> • Communications should be filed beginning from the date of the MTN-008 site protocol registration. • Communications related to individual MTN-008 study participants will be filed in individual participant study records. • Product-related communications with DAIDS PAB and prescriptions (and its contractors) will be stored in the study pharmacy.
<p>File/Binder #12: Other Study-Related Communications</p> <p>33. Study-Related Communications to and from MTN CORE</p> <p>34. Study-Related Communications to and from MTN SDMC</p> <p>35. Study-Related Communications to and from MTN Network Lab</p> <p>36. Other Study-Related Communications</p> <p>Notes:</p> <ul style="list-style-type: none"> • Communications should be filed beginning from the date of the MTN-008 site protocol registration. • Communications related to individual MTN-008 study participants will be filed in individual participant study records. • Product-related communications with DAIDS PAB (and its contractors) will be stored in the study pharmacy.
<p>File/Binder #13: Study Site Staff Meeting Documentation</p> <p>37. MTN-008 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries</p> <p>Note:</p> <ul style="list-style-type: none"> • Meeting documentation should be filed beginning from the date of the MTN-008 site protocol registration
<p>File/Binder #14: Conference Call Documentation</p> <p>38. MTN-008 Protocol Team Conference Call Summaries if applicable</p> <p>39. MTN-008 Community Educators Group Conference Call Summaries if applicable</p> <p>40. Summaries of Other MTN-008 Conference Calls</p> <p>Note:</p> <ul style="list-style-type: none"> • Conference call summaries will be filed beginning from the date of the MTN-008 site protocol registration

Section Appendix 3-1
Suggested Filing Structure for MTN-008 Essential Documents

File/Binder #15: DAIDS and Other Reference Documentation

41. DAIDS SOP for Source Documentation (Version 2.0 and any subsequent updates)
42. DAIDS SOP for Essential Documents (Version 2.0 and any subsequent updates)
43. DAIDS Protocol Registration Policy and Procedures Manual (March 2010 and any subsequent updates)
44. Manual for Expedited Reporting of Adverse Events to DAIDS (January 2010 and any subsequent updates)
45. US Regulations Applicable to Conduct of MTN-008 (45 CFR 46; 21 CFR 50, 54, 56, and 312)
46. Any other relevant manuals or reference documents

File/Binder #16: Site-Specific Study Activation Documentation

47. Site-Specific Study Activation Documents

Section Appendix 3-2
Guide to Required Case History Elements and Source Documents for MTN-008

Required Case History Element	Source Documents*
Basic participant identifiers.	Locator form; MTN-008 PTID-Name Link Log
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.
Documentation that the participant met the study selection (eligibility) criteria.	Demographics form, locator form; Participant-reported Baseline Medical and Menstrual History, (if verbally reported by participant and not obtained through medical records), Infant Medical History Log, non-Datafax Enrollment Eligibility Forms; non-Datafax Pelvic Exam Diagrams form; local lab logs and result reports [§] ; signed and dated chart notes.
A record of the participant's exposure to the investigational study products.	MTN-008 Pharmacokinetics forms (mother and infant); study product prescription; visit checklists, Study Product Returns 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; Feeding Record, Missed Visit form, 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; MTN-008 Study Visit forms; Participant Evaluability and Replacement form; Targeted Physical Exam form; Participant-reported Baseline Medical and Menstrual History (and...Follow-Up...) forms; Concomitant Medications Log form; Adverse Experience Log form; Missed Visit form; Termination form; End of Study Inventory form; local lab logs and result reports from the local lab [§] ; results of information pertinent to the study obtained from non-study sources; signed and dated chart notes.

*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-008 DataFax and Non-DataFax Forms

MTN-008 DataFax Forms
Demographics
Enrollment
Pelvic Exam
Pelvic Laboratory Results
STI Laboratory Results
Safety Laboratory Results
Maternal Pharmacokinetics
Infant Pharmacokinetics
Feeding Record
Flow Cytometry
Follow-up Visit
Pregnancy Outcome (Pregnancy Cohort only)
Participant Evaluability and Replacement
Study Product Returns
Pre-existing Conditions
Adverse Experience Log
Concomitant Medications Log
Missed Visit
Interim Visit
Product Hold/Discontinuation Log
Termination
End of Study Inventory
Pharmacy Randomization (pharmacy staff only)
Pregnancy Report and History (Lactation Cohort only if needed)

MTN-008 Non-DataFax Forms
Enrollment Eligibility-Pregnancy Cohort
Enrollment Eligibility-Lactation Cohort: Mother
Enrollment Eligibility-Lactation Cohort: Infant
Mother: Participant-reported Baseline Medical and Menstrual History
Mother: Participant-reported Follow-up Medical and Menstrual History
Mother Targeted Physical Exam
Pelvic Exam Diagrams
MTN-008 Maternal PK- LDMS Specimen Tracking Sheet
Infant Medical History Log (Lactation Cohort only)
MTN-008 Infant PK- LDMS Specimen Tracking Sheet

Section Appendix 3-4
Use of MTN-008 DataFax Forms as Source Documents

MTN-008 DataFax Forms	Source?	Comments
Demographics	Yes	Form may be used as source for all items.
Enrollment	Mixed	The signed informed consent form is source for item 1. Items 2 and 2a based on data recorded on other source documents. The Specimen Storage Informed Consent form is source for items 4 and 4a. The Enrollment Visit checklist is source for item 5. The Clinic Randomization Envelope Tracking Record is source for items 6-6c.
Pelvic Exam	No	All items should be completed based on data recorded on other source documents (i.e. visit checklists, laboratory source documents, and non-DataFax Pelvic Exam Diagrams form).
Pelvic Laboratory Results	Mixed	Form may be source for item 1b. All other items should be completed based on data recorded on laboratory source documents.
STI Laboratory Results	No	All items should be completed based on data recorded on laboratory source documents.
Safety Laboratory Results	No	All items should be completed based on data recorded on laboratory source documents.
Maternal Pharmacokinetics	Mixed	Form may be used as source for all items except specimen (serum and PBMC) storage.
Infant Pharmacokinetics	Yes	Form may be used as source for all items.
Feeding Record	Yes	Form may be used as source for all items.
Flow Cytometry	No	Laboratory report will be source.
Follow-up Visit	No	All items should be completed based on data recorded on other source documents (i.e. visit checklists and Adverse Experience Log forms).
Pregnancy Outcome (Pregnancy Cohort only)	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 9-11a must be completed based on medical records (if medical records are not available, these items will not be completed).
Participant Evaluability and Replacement	Yes	Form may be used as source for all items.
Study Product Returns	Yes	Form may be used as source for all items.
Pre-existing Conditions	No	All items are based on source data recorded on the non-DataFax Mother: Participant-reported Baseline Medical and Menstrual History form, non-DataFax Mother Targeted Physical Exam form, non-DataFax Pelvic Exam Diagrams form, and/or participant chart notes.
Adverse Experience Log	Mixed	Form may be source for items 1-10. Item 11 should be completed based on data recorded on other source documents.
Concomitant Medications Log	Yes	Form may be used as source for all items.
Missed Visit	Yes	Form may be source for the fact that the visit was missed; source data on the reason why the visit was missed also may be recorded on this form.

Section Appendix 3-4
Use of MTN-008 DataFax Forms as Source Documents

MTN-008 DataFax Forms	Source?	Comments
Interim Visit	No	All items should be completed based on data recorded on other source documents.
Product Hold/Discontinuation Log	Yes	Form may be source for all items.
Termination	No	All items should be completed based on data recorded on other source documents.
End of Study Inventory	No	All items should be completed based on data recorded on other source documents.
Pharmacy Randomization (pharmacy staff only)	No	All items should be completed based on data recorded on other source documents.
Pregnancy Report and History (Lactation Cohort only if needed)	Mixed	Form is source for item 2. All other items are based on data recorded on other source documents (i.e. the non-DataFax Mother: Participant- reported Baseline Medical and Menstrual History form and the non-DataFax Mother: Participant-reported Follow-up Medical and Menstrual History form.)

Section Appendix 3-5
Use of MTN-008 Non-DataFax Forms as Source Documents

MTN-008 DataFax Forms	Source?	Comments
Enrollment Eligibility-Pregnancy Cohort	No	All items should be completed based on data recorded on other source documents.
Enrollment Eligibility-Lactation Cohort: Mother	No	All items should be completed based on data recorded on other source documents.
Enrollment Eligibility-Lactation Cohort: Infant	No	All items should be completed based on data recorded on other source documents.
Mother: Participant-reported Baseline Medical and Menstrual History	Yes	Form may be used as source for all items though may be supplemented with other source documents as needed (e.g. medical records).
Mother: Participant-reported Follow-up Medical and Menstrual History	Yes	Form may be used as source for all items though may be supplemented with other source documents as needed (e.g. medical records).
Mother Targeted Physical Exam	Yes	Form may be used as source for all items.
Pelvic Exam Diagrams	Yes	Form may be used as source for all items.
MTN-008 Maternal PK- LDMS Specimen Tracking Sheet	No	All items should be completed based on data recorded on laboratory source documents.
Infant Medical History Log (Lactation Cohort only)	Yes	Form may be used as source for all items though may be supplemented with other source documents as needed (e.g. medical records).
MTN-008 Infant PK- LDMS Specimen Tracking Sheet	No	All items should be completed based on data recorded on laboratory source documents.