

## Section 3. Documentation Requirements

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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-007.

### 3.1 Essential Documents

The Division of AIDS (DAIDS) Standard Operating Procedure (SOP) for Essential Documents specifies the essential documents that study sites must maintain for DAIDS-sponsored studies, including MTN-007. The DAIDS SOP for Essential Documents can be found at:

<http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSCLinRsrch/Documents/essentialdocpolicy.pdf>.

Note: 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.

Table 3-1 presents a suggested essential documents filing structure for MTN-007. Study sites are not required to adopt the suggested structure, but are encouraged to consider it when developing their filing approach for MTN-007. Study sites also are 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 Table 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 ensure study integrity, 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 Table 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 23-25 in Table 3-1). Other lab-related essential documents (e.g., lab SOPs) may be filed at the site laboratories.
- The suggested filing structure assumes that MTN-007 participant case history records will be stored separately from the other essential documents listed in Table 3-1. Section 3.2 below provides information on the required contents of those records. The suggested filing structure also assumes that the MTN-007 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 Table 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-007 for each study participant.

### **3.2.1 Case History Contents**

Participant case histories for MTN-007 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 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 departures and/or attempts to prevent or correct the departures, if applicable. Study site staff are also responsible for reporting deviations using the MTN Protocol Deviation Report Form, which is posted on the MTN Web site:

Site staff will submit a draft form within 30 calendar days of site awareness of the occurrence to the study management team for review and comments to ensure that the form is complete and accurate prior to broader distribution. Once the form is finalized, it should be distributed to an e-mail group designated for MTN-007 Protocol Deviations which includes the following: Protocol Chair, FHI Clinical Research Manager, SDMC Project Manager, NL representative, and the DAIDS Medical Officer.

### **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 adhere to the standards of source documentation specified in the DAIDS SOP for Source Documentation, which can be found at:

[http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/source\\_docpolicy.pdf](http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/source_docpolicy.pdf).

The DAIDS SOP 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-007, 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, 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, Table 3-2 provides a guide that sites 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, 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 13 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. 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 must be used to document the following:

- The screening, enrollment and specimen storage informed consent processes (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 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 GCP standards.

**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 13 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 Table 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 packets for each protocol-specified study visit (Screening Visit, Enrollment Visit, Treatment 1 Visit, etc.). Packets of other “as needed” forms also will be provided. The packets will be produced and shipped from the printing company to each study site.

As shown in Tables 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
- 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. 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 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 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.

Per Section 13.5 of the MTN-007 Protocol, all study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with access limited to authorized study staff. Data collection process and administrative forms, laboratory specimens, and other reports will be identified by a coded number – PTID) only to maintain participant confidentiality. All local databases will be secured with password-protected access systems. Forms, lists, logbooks, appointment books, and any other listings that link participant ID numbers to other identifying information will be stored in a separate, locked file in an area with limited access. 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. Participants' study information will not be released without their written permission, except as necessary for monitoring (see Section 12 of the MTN-007 Protocol).

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
- Data transmission procedures, including timeframes, case report form storage locations before and after faxing, and mechanisms for identifying when forms have been transmitted
- Procedures for resolving data quality control notes from the SDMC
- Procedures for resolving/troubleshooting CASI questionnaire issues (accessing questionnaires, problems with the computers, etc.)
- 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
- Procedures for back up of electronic study data (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

The following essential documents should be maintained in study site pharmacies:

- Current MTN-007 protocol
- Current Investigator's Brochures for Tenofovir 1% Vaginal Gel (Tenofovir Gel), HEC Placebo gel and the Package Insert for Nonoxynol-9 (if brochures and package insert are on file in the clinic essential document files and are not easily accessible to pharmacy staff)
- Current MTN-007 FDA Form 1572
- Current list of authorized prescribers and staff authorized to sign MTN-007 Study Product Prescriptions (names and signatures)
- Pharmacy Establishment Plan
- MTN-007 pharmacy Chain of Custody SOP
- MTN-007 Pharmacy Policy and Procedures Manual
- MTN-007 PTID list (provided by the MTN SDMC)
- MTN-007 product shipping and receipt documentation
- MTN-007 product storage temperature logs
- MTN-007 investigational agent accountability records
- MTN-007 participant-specific records (including prescriptions, dispensing records, and DataFax forms as applicable)
- MTN-007 monitoring visit reports
- MTN-007 communications with site clinic staff
- MTN-007 communications with MTN CORE Pharmacist
- MTN-007 communications with the MTN Coordinating and Operations Center (CORE)
- MTN007 communications with the MTN SDMC
- Other MTN-007 communications
- Other locally-required administrative, operational, and/or regulatory documentation

Pharmacy staff will document the receipt, dispensing, and final disposition of the investigational products used in the study, i.e., Tenofovir 1% Gel, HEC Placebo and 2% Nonoxynol-9. Separate accountability records must be maintained for each product, per instructions provided in the *MTN-007 Pharmacy Policy and Procedures Manual* available from the MTN Pharmacist.

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-007 Pharmacy Policy and 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 study integrity, neither study clinic staff nor study participants will be provided access to product-related documentation maintained in the study pharmacies. Pharmacy staff may provide copies of some participant-specific documentation maintained in the study pharmacies (e.g., chart notes) to clinic staff for purposes of communication and operational coordination. However, decisions to provide such documentation to clinic staff will be made by pharmacy staff only, and under no circumstances will documentation released from the pharmacy include participants' product dispensing records or other information related to participants' random assignment (see also Section 9.1 of this manual).

### **3.4 Record Retention Requirements**

All study records must be maintained for at least two years after the investigation is discontinued and the US Food and Drug Administration (FDA) is notified. Study product records must be stored in the study pharmacies, 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. No records are permitted to be relocated off site, discarded, or destroyed without prior written authorization from DAIDS and CONRAD.

**Table 3-1  
Suggested Filing Structure for MTN-007 Essential Documents**

<p><b>File/Binder #1: MTN-007 Protocol and Current Informed Consent Forms</b></p> <ol style="list-style-type: none"> <li>1. MTN-007 Protocol (including copy of signed and dated protocol signature page): Version 2.0 and any subsequent protocol Clarification Memos, Letters of Amendment, and Amendments issued after Version 2.0</li> <li>2. Currently-approved MTN-007 informed consent forms</li> </ol>
<p><b>File/Binder #2: Regulatory Authority Documentation (if applicable)</b></p> <ol style="list-style-type: none"> <li>3. Regulatory Authority Correspondence/Authorization/Approval/Notification of Protocol (if more than one regulatory authority has oversight responsibility for research performed at the study site, include subsections for each authority)</li> </ol>
<p><b>File/Binder #3: IRB Documentation</b></p> <ol style="list-style-type: none"> <li>4. FWA documentation for IRB</li> <li>5. Roster of IRB (if available)</li> <li>6. Relevant IRB Submission Requirements/Guidelines/SOPs</li> <li>7. IRB Correspondence for IRB: File complete copies of all correspondence to and from the IRB; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere; include all approval documentation.</li> </ol>
<p><b>File/Binder #4: Product Safety Information</b></p> <ol style="list-style-type: none"> <li>8. Investigator's Brochure for Tenofovir 1% Gel: current version and any subsequent updates</li> <li>9. Investigator's Brochure for HEC Placebo gel: current version and any subsequent updates</li> <li>10. Package Insert for Nonoxynol-9: current version and any subsequent updates</li> <li>11. Product Safety Information/Reports/Memos</li> </ol> <p>Notes:</p> <ul style="list-style-type: none"> <li>• It is assumed that expedited adverse event reports will be stored in participant study notebooks.</li> <li>• It is assumed that documentation of IRB submission of above-listed documents (if applicable) will be maintained in the relevant IRB Files/Binders (i.e., File/Binder #3).</li> </ul>
<p><b>File/Binder #5: MTN-007 Study-Specific Procedures (SSP) Manual</b></p> <ol style="list-style-type: none"> <li>12. Final version 2.0 and any subsequent updates (when available)</li> </ol> <p>Notes:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul>
<p><b>File/Binder #6: MTN-007 Study-Specific Standard Operating Procedures</b></p> <ol style="list-style-type: none"> <li>13. Final approved version of each SOP, and any subsequent updates to each</li> </ol>
<p><b>File/Binder #7: MTN-007 Staffing Documentation</b></p> <ol style="list-style-type: none"> <li>14. FDA Form 1572 (copy of original and dated form submitted to the RSC for Protocol Registration, and any subsequent updates)</li> <li>15. MTN-007 Investigator of Record CV (copy of CV submitted to the RSC for Protocol Registration; ensure that the CV is current prior to initiating MTN-007; it is recommended that CVs be signed and dated to document at least annual updating)</li> <li>16. Financial Disclosure Forms (original signed and dated forms, and any subsequent updates)</li> <li>17. Study Staff Roster (submitted to MTN CORE (FHI) for study activation, and any subsequent updates)</li> <li>18. Study Staff Identification and Signature Sheet (if not combined with staff roster; original and any subsequent updates)</li> <li>19. Study Staff Delegation of Duties (if not combined with staff roster; original and all updates)</li> <li>20. CVs for Study Staff other than the IoR (ensure that all CVs are current prior to initiating MTN-007; it is recommended that CVs be signed and dated to document at least annual updating)</li> <li>21. Study Staff Job Descriptions</li> <li>22. Documentation of Study Staff Training</li> </ol>

**Table 3-1**  
**Suggested Filing Structure for MTN-007 Essential Documents**

<p><b>File/Binder #8: Local Laboratory Documentation</b></p> <p>23. Local Laboratory Certification(s), Accreditation(s) and/or Validation(s): file documentation current at time of study activation and all subsequent updates</p> <p>24. 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>25. Laboratory Manager CV (or cross-reference to CV contained in File/Binder #7)</p> <p>Note:</p> <ul style="list-style-type: none"> <li>• 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).</li> </ul>
<p><b>File/Binder #9: Monitoring Visit Documentation</b></p> <p>26. Monitoring Visit Log</p> <p>27. Initiation and Monitoring Visit Reports and Documentation of Response to Visit Findings</p>
<p><b>File/Binder #10: Documentation of Other MTN Site Visits</b></p> <p>28. (Non-Monitoring) Site Visit Log</p> <p>29. MTN CORE (FHI) Site Visit Reports and Documentation of Response to Visit Findings</p> <p>30. MTN SDMC Site Visit Reports and Documentation of Response to Visit Findings</p> <p>31. MTN Network Lab Site Visit Reports and Documentation of Response to Visit Findings</p> <p>32. Other Site Visit Reports and Documentation of Response to Visit Findings</p>
<p><b>File/Binder #11: Study-Related Sponsor Communications</b></p> <p>33. Study-Related Communications to and from DAIDS</p> <p>34. Communications to and from DAIDS RSC (includes copies of all submissions to the DAIDS Protocol Registration Office, which will be prepared by the sites with copies provided to the MTN CORE, 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"> <li>• Communications related to individual MTN-007 study participants will be filed in individual participant study records.</li> <li>• Product-related communications with MTN CORE Pharmacist will be stored in the study pharmacy.</li> </ul>
<p><b>File/Binder #12: Other Study-Related Communications</b></p> <p>35. Study-Related Communications to and from MTN CORE</p> <p>36. Study-Related Communications to and from MTN SDMC</p> <p>37. Study-Related Communications to and from MTN Network Lab</p> <p>38. Other Study-Related Communications</p> <p>Notes:</p> <ul style="list-style-type: none"> <li>• Communications related to individual MTN-007 study participants will be filed in individual participant study records.</li> <li>• Product-related communications with MTN CORE Pharmacist will be stored in the study pharmacy.</li> </ul>
<p><b>File/Binder #13: Study Site Staff Meeting Documentation</b></p> <p>39. MTN-007 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries</p> <p>Note:</p> <ul style="list-style-type: none"> <li>• Meeting documentation should be filed beginning from the date of the MTN-007 Operational Walkthrough</li> </ul>
<p><b>File/Binder #14: Conference Call Documentation</b></p> <p>40. MTN-007 Protocol Team Call Summaries</p> <p>41. MTN-007 Community Working Group Conference Call Summaries</p> <p>42. Summaries of Other MTN-007 Conference Calls including Operations Group Call Summaries</p> <p>Note:</p> <ul style="list-style-type: none"> <li>• Conference call summaries will be filed beginning from the date of the MTN-007 Protocol Development Call</li> </ul>

**Table 3-1**  
**Suggested Filing Structure for MTN-007 Essential Documents**

<p><b>File/Binder #15: DAIDS and Other Reference Documentation</b></p> <ul style="list-style-type: none"><li>43. DAIDS SOP for Source Documentation (Version 2.0 and any subsequent updates)</li><li>44. DAIDS SOP for Essential Documents (Version 2.0 and any subsequent updates)</li><li>45. DAIDS Protocol Registration Policy and Procedures Manual (March 2010 and any subsequent updates)</li><li>46. Manual for Expedited Reporting of Adverse Events to DAIDS (Version 2.0 dated January 2010)</li><li>47. US Regulations Applicable to Conduct of MTN-007 (45 CFR 46; 21 CFR 50, 54, 56, and 312)</li><li>48. Any other relevant manuals or reference documents</li></ul>
<p><b>File/Binder #16: Site-Specific Study Activation Documentation</b></p> <ul style="list-style-type: none"><li>49. Site-Specific Study Activation Documents</li></ul>

**Table 3-2  
Guide to Required Case History Elements and Source Documents for MTN-007**

<b>Required Case History Element</b>	<b>Source Documents*</b>
Basic participant identifiers.	Locator form; Demographics forms.
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.	Signed and dated informed consent forms; Demographics form, Locator form; Screening Consent form; Screening Eligibility form (non-DataFax); Enrollment Visit Eligibility form (non-DataFax); Medical Eligibility form (non-DataFax); Laboratory Results form; STI Laboratory Results form; HIV Test Results form; Baseline Medical and Menstrual History form (non-DataFax), Concomitant Medications Log form, Physical Exam form (non-DataFax), Pre-existing Conditions form; local lab logs and result reports <sup>§</sup> ; signed and dated chart notes.
A record of the participant's random assignment.	Clinic randomization envelope; Pharmacy randomization envelope; Clinic randomization tracking record; Pharmacy randomization tracking record; study product prescription; participant-specific pharmacy dispensing record(s)
A record of the participant's exposure to the investigational study products.	Study product prescription, participant-specific pharmacy dispensing record(s); study product returns documentation; study product request slip; dispensed product chain of custody logs, visit checklists.
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; Enrollment form; Follow-up Visit/Phone Call form; Follow-up Medical and Menstrual History form (non-DataFax); Rectal Exam form; Anoscopy and Sigmoidoscopy Results form; Adverse Experience Log form; Product Hold/Discontinuation Log form; Pregnancy Report and History form; Pregnancy Outcome form; Interim Visit form; Missed Visit form; Participant Transfer form; Participant Receipt form; Termination form; End of Study Inventory form; local lab logs and result reports from the local lab <sup>§</sup> ; 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.

<sup>§</sup>A clinician must review all local laboratory reports and document this review by signing and dating all reports.

**Table 3-3  
MTN-007 DataFax and Non-DataFax Forms**

<b>MTN 007 DataFax Forms</b>	<b>MTN 007 Non-DataFax Forms</b>
Adverse Experience Log	MTN 007 LDMS Specimen Tracking Sheet
Anoscopy and Sigmoidoscopy Results	Medical Eligibility
Concomitant Medications Log	Participant-reported Baseline Medical and Menstrual History
Demographics	Participant-reported Follow-up Medical and Menstrual History
End of Study Inventory	Physical Exam
Enrollment	Screening Visit Eligibility
Follow-up Visit/Phone Call	Enrollment Visit Eligibility
HIV Test Results	
Interim Visit	
Laboratory Results	
Missed Visit	
Participant Receipt	
Participant Transfer	
Pre-Existing Conditions	
Pregnancy Outcome	
Pregnancy Report and History	
Product Hold/Discontinuation Log	
Rectal Exam	
Screening Consent	
Specimen Storage	
STI Laboratory Results	
Study Product Returns	
Termination	

**Table 3-4**  
**Use of MTN-007 DataFax Forms as Source Documents**  
*(Forms listed in alphabetical order)*

Form Name	Acronym	Is Form Source?	Comments
Adverse Experience Log	AE-1	Yes	Form and/or participant chart notes may be source for all items.
Anoscopy and Sigmoidoscopy Results	ASR-1	Yes	Form is source for all items. Supplemental information will be recorded in the participant chart notes.
Concomitant Medications	CM-1	Yes	Form is source for all items.
Demographics	DM-1-2	Yes)	Form is source for all items, since participant responses are recorded directly onto the form.
End of Study Inventory	ESI-1	No	All items are based on source data recorded on other documents.
Enrollment	ENR-1	Mixed	A participant's chart notes, Baseline Medical and Menstrual History form, Screening Visit Eligibility form, and/or Medical Eligibility form is source for item 1. The Enrollment Informed Consent form is source for item 2. The Specimen Storage Informed Consent form is source for items 3 and 3a. The Clinic Randomization Envelope Tracking Record is source for items 4-6. The Enrollment Visit checklist is source for items 7 and 7a.
Follow-up Visit/Phone Call	FU-1	No	All items are based on source data recorded on other forms.
HIV Test Results	HTR-1	Mixed	Local laboratory report(s) are source for items 1-2. Form may be source for item 3.
Interim Visit	IV-1	Mixed	Form may be source for item 1. Form is source for item 2. Local laboratory reports/logs are source for item 3a.
Laboratory Results	LR-1	No	Local laboratory reports are source for all items.
Missed Visit	MV-1	Yes	Form may be source for all items. Supplemental information will be recorded in participant chart notes.
Participant Receipt	PRC-1	No	Participant Transfer form is source for items 1-2. Informed Consent forms are source for items 3-4a.
Participant Transfer	PT-1	Yes	Form is source for all items.
Pre-Existing Conditions	PRE-1	No	All items are based on source data recorded on the non-DataFax Participant-reported Baseline Medical and Menstrual History form, non-DataFax Physical Exam form, Rectal Exam form, Anoscopy and Sigmoidoscopy form, and/or participant chart notes.
Pregnancy Outcome	PO-1	Yes	Form may be source for all items if medical records are not available and the data recorded on the form are based on participant self-report. If medical records are obtained, then they will be source for as many items as possible.

Form Name	Acronym	Is Form Source?	Comments
Pregnancy Report and History	PR-1	Mixed	Form is source for item 2-3. All other items are based on source data recorded on the non-DataFax Participant-reported Baseline Medical and Menstrual History form (“Women Only” pages) and the non-DataFax Participant-reported Follow-up Medical and Menstrual History form (“Women Only” pages).
Product Hold Discontinuation	PH-1	Yes	Form is source for all items. Supplemental information may be captured on the PR-1 form, SLR-1, HTR-1 form, and/or AE Log form, depending on the reason for the permanent discontinuation.
Rectal Exam	RE-1	Yes	Form is source for all items. Supplemental information is recorded in the participant chart notes.
Screening Consent	SC-1	No	The source document for item 1 is the Demographics form. The source document for items 2-2a is the screening informed consent form.
Specimen Storage	SS-1	No	Visit checklists and/or participant chart notes will serve as source for all items.
STI Laboratory Results	STI-1	No	Local laboratory reports will serve as source for all items.
Study Product Returns	SPR-1	Yes	Form is source for all items.
Termination	TM-1	No	All items are based on source data recorded on other documents.

**Appendix 1 Part C**  
**MTN-007 Non-DataFax Forms Used as Source Documents**  
*(Forms listed in alphabetical order)*

<b>Form Name</b>	<b>Is form source?</b>	<b>Comments</b>
MTN 007 LDMS Specimen Tracking Sheet	No	Visit checklists and participant chart notes are source for all items.
Medical Eligibility	No	All items are based on source data recorded on other source documents
Participant-reported Baseline Medical and Menstrual History	Yes	Form is source for all items though may be supplemented with other source documents as needed (i.e. medical records).
Participant-reported Follow-up Medical and Menstrual History	Yes	Form is source for all items though may be supplemented with other source documents as needed (i.e. medical records).
Physical Exam	Yes	Form is source for all items.
Screening Visit Eligibility	Mixed	Form is source for items 1-16, as these items are interviewer-administered. The local participant locator form is source for item 17. Local laboratory pregnancy test log report is source for item 18.
Enrollment Visit Eligibility	Mixed	Form is source for item 1. The Participant-Reported Baseline Medical and Menstrual History form is source for item 2.