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 the 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-014.

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-014. 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-014 and should be followed for MTN-014.

Section Appendix 3-1 presents a suggested essential documents filing structure for MTN-014. The suggested structure incorporates guidance received from the DAIDS Prevention Science Program and the DAIDS Clinical Site Monitoring Group. The study site is not required to adopt the suggested structure, but is encouraged to consider it when developing their filing approach for MTN-014. 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).

- 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 pharmacies is provided in Figure 3-1, 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 Section Appendix 3-1). Other lab-related essential documents (e.g., lab SOPs) may be filed in the site laboratory.

- The suggested filing structure assumes that MTN-014 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-014 Screening and Enrollment Log, Participant Name-ID Number Link Log, and 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

The study site must maintain adequate and accurate participant case history records containing all information pertinent to MTN-014 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 study procedures.
- 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)

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. The study site 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. The study site must comply with all requirements and are encouraged, but not required, to comply with all recommendations.

For MTN-014, it is expected that participant case history records will consist of the following source documents:

- Narrative chart notes
- Randomization envelopes and prescriptions documenting participants' random assignments
- 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., eligibility checklists, site-specific worksheets, non-study medical records)

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, Section Appendix 3-2 provides a guide that the site 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, 5, and 7 of this manual. Detailed information on proper completion of DataFax and non-DataFax forms provided by the MTN SDMC is provided in Section 10 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 informed consent processes (see also Section 4)
- 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
- Reason(s) why protocol-specified procedures were not performed
- Contact attempts to follow up on participants who missed a scheduled study visit
- Notes taken on participants' responses during the DOD Assessment Interviews (see Section 5)

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 Good Clinical Practice standards. Sample notes in SOAP format are available from the MTN Leadership and Operations Center (LOC; FHI 360) upon request.

Visit Checklists: The checklists posted on the MTN-014 Study Implementation Materials webpage 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 10 of this manual. See Section Appendix 3-3 for a listing of all DataFax and non-DataFax forms for this study.

The SDMC will post all forms individually and in pre-assembled packets for each protocol-specified study visit on the MTN-014 ATLAS webpage. Packets of other "as needed" forms and translated, interviewer-administered forms also will be provided.

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. The 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 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 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 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, the study site must have a site 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
- 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
- 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 Protocol Deviations

In addition to the above, DAIDS requires that all protocol deviations be documented in participant records, along with efforts made to correct the deviations, and efforts made to prevent similar deviations in the future. The MTN policy on protocol deviations and the MTN Manual of Operational Procedures should be referenced for complete guidance on protocol deviations.

The Protocol Deviation Log CRF will be used to document each protocol deviation. The Protocol Deviation Log CRF is completed and faxed to the SDMC for each reportable deviation identified. Like all CRFs, completed Protocol Deviation Log CRFs will be filed in the participant's study binder. Missed visits are considered protocol deviations per the MTN policy, however these will *not* be captured on the Protocol Deviation Log CRF (the Missed Visit CRF will capture this information instead).

If there is any question as to whether a deviation has occurred, or how it should be documented, MTN Regulatory should be contacted at mtnregulatory@mtnstopshiv.org. Once the potential protocol deviation has been confirmed by the MTN Regulatory Department, the site will be contacted with this confirmation and the 3 day reporting requirement will begin. Once the CRF is faxed, the MTN Regulatory department will follow up with the site if any clarifications or additional information on the CRF is needed. The study management team will follow up with the site regarding any next steps as needed.

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

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

Pharmacy staff will document the receipt, dispensing, return, 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-014 Pharmacist Study Product Management 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-014 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, 5, and 7 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.

Figure 3-1
MTN-014 Essential Documents Maintained in Study Site Pharmacies

- Current MTN-014 protocol
- Current Investigator's Brochure for Tenofovir Gel
- Current MTN-014 FDA Form 1572
- Current list of authorized prescribers to sign MTN-014 prescriptions
- MTN Pharmacy Establishment Plan
- MTN-014 pharmacy and product-related SOPs
- MTN-014 PTID list
- MTN-014 product shipping and receipt documentation
- MTN-014 product storage temperature logs
- MTN-014 investigational product accountability records
- MTN-014 participant-specific and site-specific records (including study prescriptions, participant-specific dispensing record, documentation of product dispensing)
- MTN-014 monitoring visit reports
- MTN-014 communications with site clinic staff
- MTN-014 communications with the MTN LOC (PITT), including the MTN Pharmacist
- MTN-014 communications with the MTN LOC (FHI 360)
- MTN-014 communications with the MTN SDMC
- Other MTN-014 communications
- Other locally-required administrative, operational, and/or regulatory documentation

3.5 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 it was 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. 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-014 Essential Documents

File/Binder #1: MTN-014 Protocol and Current Informed Consent Forms

1. MTN-014 Protocol (including signed and dated protocol signature page): Version 1.0 and any subsequent protocol Clarification Memos, Letters of Amendment, and Amendments
2. Currently-approved (blank) MTN-014 informed consent forms

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

3. Regulatory Authority Correspondence/Authorization/Approval/Notification of the MTN-014 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 #3: IRB/EC Documentation

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.

File/Binder #4: Product Safety Information

8. Investigator's Brochure for Tenofovir Gel: current version and any subsequent updates
9. 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 #3).

File/Binder #5: MTN-014 Study-Specific Procedures (SSP) Manual

10. Version 2.0 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-014 Study or Site-Specific Standard Operating Procedures

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

File/Binder #7: MTN-014 Staffing Documentation

12. FDA Form 1572 (copy of original form submitted to the DAIDS Protocol Registration Office (PRO), and any subsequent updates)
13. MTN-014 Investigator of Record CV (copy of CV submitted to the DAIDS PRO; ensure that the CV is current prior to initiating MTN-014; 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 (copy of original submitted to FHI 360 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-014; 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-014 Essential Documents

File/Binder #8: Local Laboratory Documentation

21. Local Laboratory Certification(s), Accreditation(s) and/or Validation(s): file documentation current at time of study activation and all subsequent updates
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
23. 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

24. Monitoring Visit Log
25. Monitoring Visit Reports and Documentation of Response to Visit Findings

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

26. MTN CORE Site Visit Reports and Documentation of Response to Visit Findings
27. MTN SDMC Site Visit Reports and Documentation of Response to Visit Findings
28. MTN Network Lab Site Visit Reports and Documentation of Response to Visit Findings
29. Other Site Visit Reports and Documentation of Response to Visit Findings

File/Binder #11: Study-Related Sponsor Communications

30. Study-Related Communications to and from DAIDS
31. Communications to and from DAIDS Regulatory Support Center (includes copies of all submissions to the DAIDS PRO)

Notes:

- Communications should be filed beginning from the date of DAIDS Protocol Registration
- Communications related to individual MTN-014 study participants will be filed in individual participant study records.

File/Binder #12: Other Study-Related Communications

32. Study-Related Communications to and from MTN LOC
33. Study-Related Communications to and from MTN SDMC
34. Study-Related Communications to and from MTN LC
35. Other Study-Related Communications

Notes:

- Communications related to individual MTN-014 study participants will be filed in individual participant study records.
- Product-related communications with the MTN Pharmacist will be stored in the study pharmacy.

File/Binder #13: Study Site Staff Meeting Documentation

36. MTN-014 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries

Note: Meeting documentation should be filed beginning from the date of Version 1.0 of the protocol

File/Binder #14: Conference Call Documentation

37. MTN-014 Protocol Team Conference Call Summaries
38. Summaries of Other MTN-014 Conference Calls

Note: Conference call summaries will be filed beginning from the date of Version 1.0 of the protocol

File/Binder #15: DAIDS and Other Reference Documentation

39. DAIDS Protocol Registration Policy and Procedures Manual
40. Manual for Expedited Reporting of Adverse Events to DAIDS
41. DAIDS Adverse Experience Reporting System Reference Guide for Site Reporters and Study Physicians
42. US Regulations Applicable to Conduct of MTN-014 (45 CFR 46; 21 CFR 50, 54, 56, and 312)
43. Any other relevant manuals or reference documents

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

45. Site-Specific Study Activation Notice and supporting documentation

Section Appendix 3-2
Guide to Required Case History Elements and Source Documents for MTN-014

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.	Eligibility Checklists; Behavioral Eligibility Worksheet; Eligibility Criteria form, Demographics form, locator form; Baseline Medical History Questions Sheet; Concomitant Medications Log form; Screening Visit Physical Exam form; Pelvic and Anorectal Exam forms; local lab logs and result reports[§]; signed and dated chart notes.
A record of the participant's random assignment.	Randomization envelope tracking record;; randomization document;
A record of the participant's exposure to the investigational study products.	Study product prescription; study product returns/dispensation documentation; participant-specific pharmacy dispensing record(s); dispensed product chain of custody logs; participant-reported product use data (DOD-1 CRF); study product request slip
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; AE Log form; Product Hold/ Discontinuation Log form; Missed Visit 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-014 DataFax and Non-DataFax Forms

MTN-014 DataFax Forms
Abbreviated Physical Exam
Anorectal Exam
Adverse Experience Log
Biopsy Specimens
Clinical Product Hold/Discontinuation Log
Concomitant Medications Log
Demographics
Directly Observed Dosing
DOD Experience Assessment
Eligibility Criteria
Enrollment
Enrollment DOD Experience Assessment
Follow-up Visit Summary
HIV Confirmatory Results
HIV Results
Missed Visit
Directly Observed Dosing
Pelvic Exam
Pharmacokinetics
Pre-existing Conditions
Pregnancy Outcome
Pregnancy Report and History
Product Dispensation and Returns
Protocol Deviation Log
Safety Laboratory Results
Screening Visit Physical Exam
Specimen Storage
STI Test Results
Termination
Vaginal and Rectal Practices

MTN-014 Non-DataFax Forms
Pelvic Exam Diagrams
Screening Menstrual History

Section Appendix 3-4
Use of MTN-014 DataFax Forms as Source Documents

MTN-014 DataFax Forms	Source?	Comments
Abbreviated Physical Exam	Yes	Form may be source for all items.
Anorectal Exam	Yes	Form may be source for all items.
Adverse Experience Log	Yes	Form may be source for all items.
Biopsy Specimens	Yes	Form may be source for all items.
Clinical Product Hold/Discontinuation Log	Yes	Form may be source for all items.
Concomitant Medications Log	Yes	Form may be source for all items.
Demographics	Yes	Form is source for all items as participant responses are recorded directly onto the form.
Directly Observed Dosing	Yes	Form may be source for all items. Visit checklist may be source for items 2a-2c dosing times.
DOD Experience Assessment	Mixed	Form is source for study treatment period, Items 1, 5, 8 and 11. Chart notes are source for all other items.
Eligibility Criteria	Mixed	Form may be source for item 1.Eligibility Checklist and/or Screening and Enrollment Log may be source for all items.
Enrollment	Mixed	Source for Item 1 is Informed Consent form, source for items 2-5 is randomization envelope tracking record, Visit checklist/chart notes source for Item 6.
Enrollment DOD Experience Assessment	Mixed	Form is source for study treatment period and item 3. Chart notes are source for all other items.
Follow-up Visit Summary	No	All items should be completed based on source data recorded on other source documents.
HIV Confirmatory Results	No	All items should be completed based on source data recorded on other source documents.
HIV Results	No	All items should be completed based on source data recorded on other source documents.
Missed Visit	Yes	Form may be source for all items.
Pelvic Exam	Mixed	Form may be source for items all items except #2. AE Log should be source for item 2.
Pre-existing Conditions	No	All items should be completed based on source data recorded on other source documents.
Pharmacokinetics	Yes	Form may be source for all items.
Pregnancy Outcome	Yes	Source if relevant medical records are not available (and data are based on participant self-report).
Pregnancy History and Report	Yes	Form may be source for all items.
Product Dispensation and Returns	Mixed	Form may be source for item 2, 2a and 4, 4a. Other items based on pharmacy dispensing records.
Protocol Deviation Log	Yes	Form may be source for all items.
Safety Laboratory Results	Mixed	All laboratory value items should be completed based on laboratory source documents. Form may be source for any other non-laboratory value items.
Screening Visit Physical Exam	Yes	Form may be source for all items.
Specimen Storage	Yes	Form may be source for all items (or lab requisition form).

Section Appendix 3-4
Use of MTN-014 DataFax Forms as Source Documents

MTN-014 DataFax Forms	Source?	Comments
STI Test Results	Mixed	This form or lab testing logs may be source for items 1-2. Items 3-4 should be based on laboratory source documents.
Termination	Yes	Form may be source for all items.
Vaginal and Rectal Practices	Yes	All items are interviewer-administered; participant responses must be recorded directly onto the form

Section Appendix 3-5
Use of MTN-014 Non-DataFax Forms as Source Documents

MTN-014 Non-DataFax Forms	Source?	Comments
Pelvic Exam Diagrams	Yes	Form may be source for all items.
Screening Menstrual History	Yes	Form may be source for all items.