

Section 3. Documentation Requirements

Study staff are responsible for proper collection, management, storage, quality control, and quality assurance of all study-related documentation. This section contains information on the Essential Documents that each study site must maintain throughout the study. It also contains information related to establishing adequate and accurate participant research records — commonly referred to as participant “case history records” — for MTN 001.

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 001. The DAIDS SOP for Essential Documents can be found at: <http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Regulatory.htm>. 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 001. Study sites are not required to adopt the suggested structure, but are encouraged to consider it when developing their filing approach for MTN 001. 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 Section Appendix 3-1 may be further subdivided, consolidated, and/or re-organized if desired.
- It is recommended that a contents sheet be maintained and inserted as the first page(s) of each file/binder. Within each file/binder, it is recommended that documents be filed in ascending date order (most recent documents in front).
- To 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 Section Appendix 3-1.
- To facilitate routine inspection by study monitors, certain laboratory-related essential documents should be stored in the main study essential documents files/binders (see items 26-28 in Section Appendix 3-1). Other lab-related essential documents (e.g., lab SOPs) may be filed in site laboratories.
- The suggested filing structure assumes that MTN 001 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 001 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

Study sites must maintain adequate and accurate participant case history records containing all information pertinent to MTN 001 for each study participant. Per Section 13.5 of the MTN 001 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 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. Participants' study information will not be released without their written permission, except as necessary for monitoring (see Section 12 of the MTN 001 Protocol).

3.2.1 Case History Contents

Participant case histories should contain all of the following elements:

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

In addition to the above, DAIDS requires that all protocol deviations be documented in participant records, along with reasons for the departures and/or attempts to prevent or correct the departures, if applicable. The MTN Protocol Deviation Report Form is posted on the MTN Web site. Site staff are encouraged to submit a draft form for review and comment by the CORE (FHI) Clinical Research Manager prior to broader distribution of the form, to help ensure that the form is complete and accurate prior to distribution. Once the form is finalized, it will be distributed to the Protocol Chair, CORE Clinical Research Manager, SDMC Project Manager, NL representative, and 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://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/ClinicalSite.htm>. 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.

MTN 001, it is expected that participant case history records will consist of the following source documents:

- Narrative chart notes
- Randomization envelopes, Randomization form, and prescriptions documenting participants' random assignments
- 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)

As a condition for study activation, each study site must establish an SOP for source documentation that specifies the use of the above-listed documents as source documents. Although it is the responsibility of each site to determine the most appropriate source document for each required case history element, Section Appendix 3-2 provides a guide that sites may follow 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 and enrollment 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. Further information on the SOAP note format and several sample notes in SOAP format are provided in Section Appendix 3-3.

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 Section Appendix 3-4 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; i.e., Screening, Enrollment (Period 1 Start), 3-Week Visit (Mid-Study-Period 1 Visit), 6-Week Visit (Period 1 End), 7-Week Visit (Period 2 Start), 10-Week Visit (Mid-Study-Period 2 Visit), 13-Week Visit (Period 2 End), 14-Week Visit (Period 3 Start), 17-Week Visit (Mid-Study-Period 3 Visit), 20-Week Visit (Period 3 End), 21-Week Visit (Termination

Visit). A packet of other “as needed” forms also will be provided. The packets will be produced at a US-based printing company, and will be shipped from the printing company to each study site. For non-US sites, forms will be printed on A4 paper and four-hole punched. For the US sites, forms will be printed on letter size paper and three-hole punched. For all sites, forms that are administered directly to participants will be available in local languages relevant to the site.

As shown in Section 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. 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 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.

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, 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 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 001 protocol
- Current Investigator's Brochures for Tenofovir Disoproxil Fumarate (TDF) and Tenofovir 1% Vaginal Gel (Tenofovir Gel) (if brochures on file in the clinic essential document files are not easily accessible to pharmacy staff)
- Current MTN 001 FDA Form 1572
- Current list of authorized prescribers and staff authorized to sign MTN 001 Study Product Request Slips (names and signatures)
- Pharmacy Establishment Plan
- MTN 001 pharmacy and product-related SOPs
- MTN 001 PTID list (provided by the MTN SDMC)
- MTN 001 product import documentation (if applicable)
- MTN 001 product shipping and receipt documentation
- MTN 001 product storage temperature logs
- MTN 001 investigational agent accountability records
- MTN 001 participant-specific records (including prescriptions, study product hold/resume/pK supply/re-supply slips, dispensing records, and DataFax forms as applicable)
- MTN 001 monitoring visit reports
- MTN 001 communications with site clinic staff
- MTN 001 communications with the DAIDS Pharmaceutical Affairs Branch (PAB), the NIAID Clinical Research Product Management Center, and MTN Research Pharmacist
- MTN 001 communications with the MTN Coordinating and Operations Center (CORE)
- MTN 001 communications with the MTN SDMC
- Other MTN 001 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., TDF and Tenofovir 1% Gel. Separate accountability records must be maintained for each product, per instructions provided in the MTN 001 Pharmacist Study Product Management Procedures Manual available from the DAIDS 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 001 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 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 assignments (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.

Section Appendix 3-1
Suggested Filing Structure for MTN 001 Essential Documents

<p>File/Binder #1: MTN 001 Protocol and Current Informed Consent Forms</p> <ol style="list-style-type: none"> 1. MTN 001 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 001 informed consent forms
<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 #3A: IRB/EC Documentation for [IRB/EC A]</p> <ol style="list-style-type: none"> 4. FWA documentation for IRB/EC A 5. Roster of IRB/EC A (if available) 6. Relevant IRB/EC A Submission Requirements/Guidelines/SOPs 7. IRB Correspondence for IRB/EC A: File complete copies of all correspondence to and from the IRB/EC; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere; include all approval documentation.
<p>File/Binder #3B: IRB/EC Documentation for [IRB/EC B]</p> <ol style="list-style-type: none"> 8. FWA documentation for IRB/EC B 9. Roster of IRB/EC B (if available) 10. Relevant IRB/EC B Submission Requirements/Guidelines/SOPs 11. IRB Correspondence for IRB/EC B: File complete copies of all correspondence to and from the IRB/EC; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere; include all approval documentation.
<p>File/Binder #4: Product Safety Information</p> <ol style="list-style-type: none"> 12. Investigator's Brochure for TDF: current version and any subsequent updates 13. Investigator's Brochure for Tenofovir 1% Gel: current version and any subsequent updates 14. 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 #3A and #3B).
<p>File/Binder #5: MTN 001 Study-Specific Procedures (SSP) Manual</p> <ol style="list-style-type: none"> 15. Final version 2.0 (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 001 Study-Specific Standard Operating Procedures</p> <ol style="list-style-type: none"> 16. Final approved version of each SOP, and any subsequent updates to each

Section Appendix 3-1
Suggested Filing Structure for MTN 001 Essential Documents

File/Binder #7: MTN 001 Staffing Documentation

17. FDA Form 1572 (copy of original and dated form submitted to the RCC for Protocol Registration, and any subsequent updates)
18. MTN 001 Investigator of Record CV (copy of CV submitted to the RCC for Protocol Registration; ensure that the CV is current prior to initiating MTN 001; it is recommended that CVs be signed and dated to document at least annual updating)
19. Financial Disclosure Forms (original signed and dated forms, and any subsequent updates)
20. Study Staff Roster (original submitted to MTN CORE for study activation, and any subsequent updates)
21. Study Staff Identification and Signature Sheet (if not combined with staff roster; original and any subsequent updates)
22. Study Staff Delegation of Duties (if not combined with staff roster; original and all updates)
23. CVs for Study Staff other than the IoR (ensure that all CVs are current prior to initiating MTN 001; it is recommended that CVs be signed and dated to document at least annual updating)
24. Study Staff Job Descriptions
25. Documentation of Study Staff Training

File/Binder #8: Local Laboratory Documentation

26. Local Laboratory Certification(s), Accreditation(s) and/or Validation(s): file documentation current at time of study activation and all subsequent updates
27. 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
28. 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

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

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

31. (Non-Monitoring) Site Visit Log
32. MTN CORE Site Visit Reports and Documentation of Response to Visit Findings
33. MTN SDMC Site Visit Reports and Documentation of Response to Visit Findings
34. MTN Network Lab Site Visit Reports and Documentation of Response to Visit Findings
35. Other Site Visit Reports and Documentation of Response to Visit Findings

File/Binder #11: Study-Related Sponsor Communications

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

Notes:

- Communications related to individual MTN 001 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.

Section Appendix 3-1
Suggested Filing Structure for MTN 001 Essential Documents

<p>File/Binder #12: Other Study-Related Communications</p> <p>38. Study-Related Communications to and from MTN CORE 39. Study-Related Communications to and from MTN SDMC 40. Study-Related Communications to and from MTN Network Lab 41. Other Study-Related Communications</p> <p>Notes:</p> <ul style="list-style-type: none"> • Communications related to individual MTN 001 study participants will be filed in individual participant study records. • Product-related communications with DAIDS PAB and MTN Research Pharmacist (and its contractors) will be stored in the study pharmacy.
<p>File/Binder #13: Study Site Staff Meeting Documentation</p> <p>42. MTN 001 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 001 Operational Walkthrough
<p>File/Binder #14: Conference Call Documentation</p> <p>43. MTN 001 Protocol Team and Protocol Co-Chairs Conference Call Summaries 44. MTN 001 Study Coordinators Group Conference Call Summaries 45. MTN 001 Community Educators Group Conference Call Summaries 46. Summaries of Other MTN 001 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 001 Protocol Development Call
<p>File/Binder #15: DAIDS and Other Reference Documentation</p> <p>47. DAIDS SOP for Source Documentation (Version 2.0 and any subsequent updates) 48. DAIDS SOP for Essential Documents (Version 2.0 and any subsequent updates) 49. DAIDS Protocol Registration Policy and Procedures Manual (August 2004 and any subsequent updates) 50. Manual for Expedited Reporting of Adverse Events to DAIDS 51. US Regulations Applicable to Conduct of MTN 001 (45 CFR 46; 21 CFR 50, 54, 56, and 312) 52. Any other relevant manuals or reference documents</p>
<p>File/Binder #16: Site-Specific Study Activation Documentation</p> <p>54. Site-Specific Study Activation Documents</p>

Section Appendix 3-2
Guide to Required Case History Elements and Source Documents for MTN 001

Required Case History Element	Source Documents*
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); Clinical Eligibility form (non-DataFax); Enrollment Eligibility form (non-DataFax); Baseline Genital Symptoms; Safety Laboratory Results form; Screening and Enrollment STI Laboratory Results form; HIV Test Results form; Baseline Medical History form (non-DataFax), Concomitant Medications Log form, Physical Exam form (non-DataFax), Pre-existing Conditions form; Screening and Enrollment Pelvic Exam form; Pelvic Laboratory Results; Pelvic Exam Diagrams (non-DataFax); local lab logs and result reports [§] ; signed and dated chart notes.
A record of the participant's random assignment.	MTN 001 Randomization Envelope Tracking Record; MTN 001 Randomization Envelope; MTN 001 Randomization Document (or MTN 001 Replacement Randomization Document, if a replacement participant).
A record of the participant's exposure to the investigational study products.	MTN 001 Prescription,, MTN 001 Study Product Hold/Resume/pK supply/Re-supply Slip, MTN 001 participant pharmacy dispensing records; 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; Screening Summary (non-DataFax); Enrollment form; Enrollment Behavior Assessment form, Follow-up Visit form; Study Product Adherence and Behavior Assessment; Acceptability Assessment form; Final Acceptability Assessment form; Product Sharing Assessment form; Follow-up Medical History Log (non-DataFax); Follow-up Genital Symptoms; Genital Bleeding Assessment form (non-DataFax); Follow-up Pelvic Exam form (non-DataFax); Pelvic Laboratory Results form; STI Laboratory Results form; Adverse Experience Log; Family Planning Methods form; Pharmacokinetics-Intensive form; Pharmacokinetics-Non-Intensive form; Product Hold/Discontinuation 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; Flow Cytometry 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 Guidelines and Examples on the SOAP Format for Chart Notes

Guidelines

The SOAP Format: The benefits of the SOAP format are that it can be tailored to any type of study or study visit and that, if done properly, will satisfy both the medical record needs for the continuing care of the client and the source documentation requirements for the study. Below is a broad definition of the components of the SOAP format and then three examples of how it might be used in specific scenarios.

• **S (SUBJECTIVE):** The subjective component is the client’s report of how he or she has been doing since the last visit, and this includes the current visit. Subjective comments made by client may range from no complaints (“I feel great”) to specific current complaints (“I’ve had a headache for 3 days”) to complaints that took place in the interim but have resolved (“3 weeks ago I had diarrhea for a couple of days”). For an infant’s record, the subjective component would include the mother’s (or caretaker’s) observations. Again, these may range from no complaints (“The baby is happy and healthy”) to a specific current complaint (“the baby’s been fussy lately”) to a complaint that has resolved (“the baby had a nappy rash, but it’s all better now”). The client should be asked directed questions about any complaints – current or reportedly resolved -- and ask appropriate follow-up questions and document all responses.

Reports of compliance with specific treatment regimens – whether study-related or not – should also be included here: “How much of your study medication did you take since your last visit? Did you miss any doses? Why?” or “At the last visit, you were given antibiotics for pneumonia. Do you have any pills left?”

• **O (OBJECTIVE):** The objective component is straightforward and includes vital signs (temperature, blood pressure, pulse, respiration), documentation of the physical examination that was done, and results of laboratory or other studies that may be done during the course of this visit. For a client with no complaints, the physical exam may be limited to meet study specific needs. For a client with a complaint, an appropriate focused physical exam should be completed in addition to or instead of the study-specific exam.

• **A (ASSESSMENT):** For this component, the clinician pulls together the subjective information gathered during the interview with the client and the objective findings of the physical exam (and, possibly, laboratory or other study results) and consolidates them into a short assessment: “This is a 26-year old woman here for a routine MTN 001 study visit; there are no clinical problems today” or “This is a 22-year old pregnant woman, here for a non-study visit due to chief complaint of increased nausea for 1 week and vomiting for 2 days”

• **P (PLAN):** The plan should include anything that will be done as a consequence of the assessment and could include:

- The collection of study-specific labs or special studies
- The collection of labs or special studies to address an acute complaint
- Intention to admit to the hospital
- Study-specific medications dispensed (name of drug, amount dispensed and dosing instructions)
- Non-study medications prescribed or dispensed for a specific acute or chronic complaint (name of drug, amount dispensed and dosing instructions)
- Follow-up instructions to the client (for example: “return to the clinic if this problem does not resolve”)
- Date of next appointment

Section Appendix 3-3
Sample Chart Notes for MTN 001 in Subjective-Objective-Assessment-Plan (SOAP) Format

Sample Chart Note for Screening:

13 OCT 2008: Participant presented for MTN 001 screening. Obtained written informed consent for screening before initiating any procedures. Procedures were completed per protocol, visit checklist and SOPs.

S: Participant reported no current health problems.

O: Pregnancy test negative, participant behaviorally eligible per the Screening Eligibility form, tested HIV negative.

A: Participant is eligible for the study thus far.

P: Enrollment scheduled for 27 October 2008.

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Sample Chart Note for Screening:

13 OCT 2008: Participant presented for MTN 001 screening. Obtained written informed consent for screening before initiating any procedures. Procedures were completed per protocol, SOPs and visit checklist, with the additions listed here.

S: Participant complained of current genital itching and yellowish discharge, no other current health problems.

O: Participant behaviorally eligible per the Screening Eligibility form, tested negative for pregnancy and HIV.

A: Other than genital symptoms, participant appears eligible for the study thus far. Syndromic treatment provided [insert details here]; participant must be symptom free at next visit in order to enroll in study.

P: Enrollment scheduled for 28 OCT 2008, participant counseled to contact site if symptoms do not resolve in 5-7 days.

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Sample Chart Note for Enrollment:

27 OCT 2008: Participant presented for MTN 001 enrollment visit. Procedures completed per protocol, SOPs and visit checklist. Enrollment was discontinued at this visit due to ineligibility.

S: Participant reported no current health problems.

O: Screening GC and CT lab tests were negative, but today's pregnancy test was positive. Enrollment discontinued upon finding this result.

A: Participant is pregnant — not eligible for study.

P: Participant informed that she is pregnant and referred to [clinic name] for antenatal care.

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Sample Chart Note for Mid-Study Follow-up Visit:

4 NOV 2008: Participant presented for MTN 001 Week 10 visit. Procedures completed per protocol, visit checklist and SOPs.

S: No issues/problems reported since last visit.

O: Pregnancy test negative.

A: No issues of concern.

P: Week 13 visit scheduled for 25 NOV 2008.

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Sample Chart Note for Week-20 Follow-up Visit:

13 JAN 2009: Participant presented for MTN 001 Week 20 visit. Procedures completed per protocol, visit checklist and SOPs.

S: No issues/problems reported since last visit.

O: Participant tested negative for pregnancy and for HIV. Pelvic exam and wet mount normal (see test results and exam findings on DataFax forms).

A: No issues of concern.

P: Termination visit scheduled for 20 JAN 2009.

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Section Appendix 3-4
MTN 001 DataFax and Non-DataFax Forms

DataFax Forms	Non-DataFax Forms
Screening Consent	Clinical Eligibility (non-DataFax)
Demographics	Screening Summary (non-DataFax)
Screening and Enrollment Pelvic Exam	Enrollment Eligibility (non-DataFax)
Pelvic Laboratory Results	Genital Bleeding Assessment (non-DataFax)
Safety Laboratory Results	Follow-up Medical History Log (non-DataFax)
Screening and Enrollment STI Laboratory Results	Physical Exam (non-DataFax)
Concomitant Medications	Pelvic Exam Diagrams (non-DataFax)
Baseline Genital Symptoms	Screening Eligibility (non-DataFax)
Follow-up Genital Symptoms	Baseline Medical and Menstrual History (non-DataFax)
Pharmacokinetics-Intensive	
Pharmacokinetics-Non-intensive	
Product Sharing Assessment	
Flow Cytometry	
STI Laboratory Results	
Acceptability Assessment	
Family Planning Methods	
Enrollment Behavior Assessment	
Pre-Existing Conditions	
Enrollment	
Final Acceptability Assessment	
HIV Test Results	
Product Hold/Discontinuation	
Pregnancy Report and History	
Pregnancy Outcome	
Adverse Experience Log	
Follow-up Visit	
Study Product Adherence and Behavior Assessment	
Interim Visit	
Missed Visit	
Participant Transfer	
Participant Receipt	
Follow-up Pelvic Exam	
Termination	
End of Study Inventory	

Section Appendix 3-5
Use of MTN 001 DataFax Forms as Source Documents
(Forms listed in alphabetical order)

Form Name	Is form source?	Comments
Acceptability Assessment	Mixed	MTN 001 Randomization Document (or MTN 001 Replacement Randomization Document, if a replacement participant) is source for item 1. Form is source for the rest of the items on the form, as participant responses are recorded directly onto the form.
Adverse Experience Log	Yes	Form and/or participant chart notes may be source for all items.
Baseline Genital Symptoms	Yes	Form is interviewer-administered; participant responses are recorded directly onto this form.
Concomitant Medications	[Yes]	[It is expected that sites will record concomitant medication information directly and initially on to this form. If, instead, other documents such as the participant chart notes routinely will serve as the source documents for this information, then this form is not considered a source document and the actual source document should be specified here.]
Demographics	Yes	Form is interviewer-administered; participant responses are recorded directly onto the form.
End of Study Inventory	No	All items are based on source data recorded on other forms.
Enrollment	No	The Enrollment Informed Consent form is source for item 1. The Specimen Storage Informed Consent form is source for items 2 and 2a. The MTN 001 Randomization Envelope Tracking Record is source for items 3-5. The MTN 001 Randomization Document (or MTN 001 Replacement Randomization Document, if a replacement participant) is source for items 6-8. The SCHARP-provided list of participants requiring replacement should serve as source for item 9. The participant pharmacy dispensing record is source for items 10-12. The non-DataFax Physical Exam form is source for item 13.
Enrollment Behavior Assessment	Yes	Form is interviewer-administered; participant responses are recorded directly onto this form.
Family Planning Methods	No	The non-DataFax Baseline Medical and Menstrual History form will serve as the source document at the Screening and Enrollment Visits. The participant chart notes will serve as the source document at follow-up visits.
Final Acceptability Assessment	Mixed	The MTN001 Randomization Document (or MTN 001 Replacement Randomization Document, if a replacement participant) is source for item 1. Form is source for the rest of the items on the form, as participant responses are recorded directly onto the form.
Flow Cytometry	[No or Yes (site to choose one)]	[Form is not source if all items are based on data recorded on a local laboratory report or assay result data output. Form is source if results are read and recorded directly onto the form].

Form Name	Is form source?	Comments
Follow-up Genital Symptoms	Yes	Form is interviewer-administered; participant responses are recorded directly onto this form.
Follow-up Pelvic Exam	[Yes]	[It is expected that this form routinely will serve as a source document, with supplemental information recorded on the Pelvic Diagrams, and in the participant chart notes if needed. If, instead, other documents such as participant chart notes routinely will serve as the source documents for pelvic exam information, this should be specified here.]
Follow-up Visit	[Mixed]	[Form may serve as source for item 1 if result is not documented on a local laboratory report or clinic log, but is recorded directly onto the form. Form may also serve as source for item 1a. Participant chart notes and/or AE Log forms are source for items 2-2a. Form or pharmacy record may serve as source for items 3-4. Participant pharmacy dispensing record is source for items 5-6.]
HIV Test Results	[Mixed]	Local laboratory report (and network laboratory report, if needed) is source for items 1-4. [Form may serve as source for item 5.]
Interim Visit	Mixed	Participant chart notes and/or form may serve as source for items 1-1f, 2a, and 3. Form may serve as source for item 2 if result is not documented on a local laboratory report or clinic log, but is recorded directly onto the form. Form or pharmacy record may serve as source for items 4-5. Participant pharmacy dispensing record is source for items 6-7.
Missed Visit	[Yes]	[Form and/or participant chart notes may be source to document that the visit was missed and the reason why the visit was missed.]
Participant Receipt	No	Participant Transfer form may be source for items 1-2. Informed Consent forms are source for items 3-4a.
Participant Transfer	Yes	Form may be source for all items.
Pelvic Laboratory Results	[Mixed]	[For items 1a-1f, the form may serve as source in cases where results are not documented on a local lab report, but are recorded directly onto the form. Otherwise, the local laboratory report may serve as source. Local laboratory report is source for items 2 and 3.]
Pharmacokinetics-Intensive	Mixed	The non-DataFax Physical Exam form is source for item 1. Form may be source for items 2-14.
Pharmacokinetics- Non-Intensive	Mixed	The non-DataFax Physical Exam form is source for item 1. Form may be source for items 2-10.
Pre-Existing Conditions	No	All items are based on source data recorded on the non-DataFax Baseline Medical and Menstrual History form, non-DataFax Physical Exam form, Screening and Enrollment Pelvic Exam forms, Baseline Genital Symptoms form, non-DataFax Pelvic Exam Diagrams, and participant chart notes.
Pregnancy Outcome	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.
Pregnancy Report and History	Mixed	Form may be source for item 2. All other items are based on source data recorded on the non-DataFax Baseline Medical and Menstrual History form and non-DataFax Follow-up Medical History Log.

Form Name	Is form source?	Comments
Product Hold/Discontinuation	Mixed	Form may be source for all items EXCEPT item 3. Participant chart notes, the Pregnancy Report and History form, the STI Laboratory Results form, the HIV Test Results form, and/or AE Log form may serve as source for item 3.
Product Sharing Assessment	Yes	Form is interviewer-administered; participant responses are recorded directly onto the form.
Safety Laboratory Results	[Mixed]	[Form may serve as source for items 1a-1c in cases where results are not documented on a local lab report or log, but are recorded directly on the form. Otherwise, the local laboratory report or log may serve as source. Local laboratory report is source for items 1d-3d. Form may serve as source for item 4.]
Screening and Enrollment Pelvic Exam	[Yes]	[It is expected that this form routinely will serve as a source document, with supplemental information recorded on the Pelvic Diagrams, and in the participant chart notes if needed. If, instead, other documents such as participant chart notes routinely will serve as the source documents for pelvic exam information, this should be specified here.]
Screening and Enrollment STI Laboratory Results	No	Local laboratory report (and network laboratory report, if needed) will serve as source.
Screening Consent	[Mixed]	Form [may be] source for item 1. Items 2 and 2a are based on source data recorded in the participant chart notes and on the screening informed consent form.
STI Laboratory Results	No	Local laboratory report (and network laboratory report, if needed) is source for items 1-3c.
Study Product Adherence and Behavior Assessment	Mixed	The MTN001 Randomization Document (or MTN 001 Replacement Randomization Document, if a replacement participant) is source for item 1. Documentation from the participant or the form (if participant does not provide documentation) is source for items 2-3c. Form is source for remaining form items, as participant responses are recorded directly onto the form.
Termination	No	All items are based on source data recorded on other documents.

Section Appendix 3-6
Use of MTN 001 Non-DataFax Forms as Source Documents
(Forms listed in alphabetical order)

Form Name	Is form source?	Comments
Baseline Medical and Menstrual History	Yes	Form is source for all items. Data recorded on this form is based on participant self-report, and may also be supplemented with data recorded on other source documents (e.g., non-study medical records).
Clinical Eligibility	No	All items are based on data recorded on other documents as source.
Enrollment Eligibility	Mixed	Enrollment informed consent form is source for item 1. Form is source for items 2-15; items are interviewer-administered. [Form may be source for item 16 if result is not documented on a local laboratory report or clinic log, but is recorded directly onto the form. Form or participant chart notes may be source for item 17.]
Follow-up Medical History Log	Yes	Form may be source for all items.
Genital Bleeding Assessment	Mixed	[Form or participant chart notes may be source for items 1-11g and 13a-14a.] The Concomitant Medications Log may be source for items 12-13. The AE Log form is source for item 14b.
Pelvic Exam Diagrams	Yes	Form may be source for all items.
Physical Exam	Yes	Form may be source for all items.
Screening Eligibility	Mixed	Screening informed consent form is source for item 1. The local participant locator form is source for item 2. The Screening and Enrollment Log is source for item 3. Form may serve as source for item 4 if documentation of a normal Pap result (in the 12 calendar months prior to screening) is NOT available. Form is source for items 5-25; these items are interviewer-administered. [Form may be source for item 26 if result is not documented on a local laboratory report or clinic log, but is recorded directly onto the form. Form or participant chart notes may be source for item 27.]
Screening Summary	No	All items are based on data recorded on other documents as source.