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 005.

3.1 Essential Documents

The *DAIDS Policy for Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-RA-03.00)* and *ICH E6 Good Clinical Practice: Consolidated Guidance* specify the administrative and regulatory documents that MTN study sites must maintain for DAIDS-sponsored studies. Based on this DAIDS Policy, the documentation listed below must be maintained for MTN 005. When required documents are modified or updated, the original and modified/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 005. Study sites are not required to adopt the suggested structure, but are encouraged to consider it when developing their filing approach for MTN 005. 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).

- 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 005 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 005 Screening and Enrollment Log, Participant Name-ID Number Link Log, and Clinic Randomization Envelope Tracking Record (which are described in Section 4 of this manual) will be stored in the study clinic or data management area, and not necessarily with the other essential documents listed in Section Appendix 3-1.

3.2 Participant Case History Documentation

Study sites must maintain adequate and accurate participant case history records containing all information pertinent to MTN 005 for each study participant.

3.2.1 Case History Contents

Participant case histories should contain all of the following elements:

- Basic participant identifiers.
- Documentation that the participant provided written informed consent to screen for and participate in the study prior to the conduct of any screening or study procedures, respectively.
- Documentation that the participant met the study's selection (eligibility) criteria.
- A record of the participant's random assignment.
- A record of the participant's exposure to the investigational study product.
- 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. MTN-005 study sites also must report reportable protocol deviations per Section 15.4 of the MTN Manual of Operations. The MTN Protocol Deviation Report Form is posted on the MTN Web site. Site staff should 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, MTN Pharmacist, IPM Representative, OCSO Program Officer, and DAIDS Medical Officer (mtn005protocoldeviations@mtnstopshiv.org).

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. Study sites must adhere to the standards of source documentation specified in the *DAIDS Policy for Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-CL-04.00)* and the standards outlined in this manual. The DAIDS policy specifies both requirements and recommendations. Study sites must comply with all requirements and are encouraged, but not required, to comply with all recommendations.

In MTN 005, 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
- 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/deviations/violations 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 Appendices 3-4, 3-5, and 3-6 for a listing of all DataFax and non-DataFax forms to be used for this study.

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 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. To maximize participant confidentiality, the PTID should be used whenever possible, and records that bear names or other personal identifiers, such as locator forms and informed consent forms, should be stored separately from records identified by PTID. Any documents transferred or transmitted to a non-study site location — including DataFax forms and Expedited Adverse Event Forms — must be identified by PTID only.

Regardless of whether the identifier on a particular document consists of the participant name or PTID, the original identifier may not be obliterated or altered in any way, even if another identifier is added. When necessary to maintain confidentiality, identifiers may be obliterated on <u>copies</u> of original source documents. For example, if medical records obtained from a non-study health care provider bear the participant's name, the original documents bearing the name 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 PITD. 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 005 protocol
- Current MTN 005 FDA Form 1572
- Current list of authorized prescribers and staff authorized to sign MTN 005 Study Product Request Slips (names and signatures)
- Pharmacy Establishment Plan
- MTN 005 Pharmacy Policy and Procedures Manual
- MTN 005 product import documentation
- MTN 005 product shipping and receipt documentation
- MTN 005 product storage temperature logs
- MTN 005 investigational product accountability records
- MTN 005 participant-specific records (including prescriptions, product supply slips, dispensing records, and DataFax forms as applicable)

- MTN 005 monitoring visit reports
- MTN 005 communications with site clinic staff
- MTN 005 communications with the MTN Research Pharmacist and the IPM Clinical Supply Coordinator
- MTN 005 communications with the MTN Coordinating and Operations Center (CORE)
- MTN 005 communications with the MTN SDMC
- Other MTN 005 communications
- Other locally-required administrative, operational, and/or regulatory documentation

Pharmacy staff will document the receipt, dispensing, and final disposition of the investigational product used in the study, i.e., IVR. 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 005 Pharmacy Policy and Procedure 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.

3.4 Record Retention Requirements

All study records must be maintained for at least two years following the date of marketing approval for each of the two study products for the indication in which they were studied. If no marketing application is to be filed, or if the application is not approved, the records must be retained until two years after the investigation is discontinued and the US Food and Drug Administration (FDA) is notified. All records must be retained on-site throughout the study's period of performance, and for at least three years after completion or termination of the study. Study product records must be stored in the study 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 005 Essential Documents

File/Binder #1: MTN 005 Protocol and Current Informed Consent Forms

1. MTN 005 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 005 informed consent forms

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

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)

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

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

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

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

File/Binder #4: Product Safety Information

12. Investigator's Brochure for IVR: current version and any subsequent updates
13. Product Safety Information/Reports/Memos

Notes:

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

File/Binder #5: MTN 005 Study-Specific Procedures (SSP) Manual

14. Final version 1.0 (when available) 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 005 Study-Specific Standard Operating Procedures

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

Section Appendix 3-1
Suggested Filing Structure for MTN 005 Essential Documents

File/Binder #7: MTN 005 Staffing Documentation

16. FDA Form 1572 (copy of original and dated form submitted to the RSC for Protocol Registration, and any subsequent updates)
17. MTN 005 Investigator of Record CV (copy of CV submitted to the RSC for Protocol Registration; ensure that the CV is current prior to initiating MTN 005; it is recommended that CVs be signed and dated to document at least annual updating)
18. Financial Disclosure Forms (original signed and dated forms, and any subsequent updates)
19. Study Staff Roster (original submitted to MTN CORE for study activation, and any subsequent updates)
20. Study Staff Identification and Signature Sheet (if not combined with staff roster; original and any subsequent updates)
21. Study Staff Delegation of Duties (if not combined with staff roster; original and all updates)
22. CVs for Study Staff other than the IoR (ensure that all CVs are current prior to initiating MTN 005; it is recommended that CVs be signed and dated to document at least annual updating)
23. Study Staff Job Descriptions
24. Documentation of Study Staff Training

File/Binder #8: Local Laboratory Documentation

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

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

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

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

File/Binder #11: Study-Related Sponsor Communications

35. Study-Related Communications to and from DAIDS
36. 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)

Notes:

- Communications should be filed beginning from the date of the MTN 005 site specific training.
- Communications related to individual MTN 005 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 005 Essential Documents

File/Binder #12: Other Study-Related Communications

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

Notes:

- Communications should be filed beginning from the date of the MTN 005 site specific training.
- Communications related to individual MTN 005 study participants will be filed in individual participant study records.
- Product-related communications with the MTN Research Pharmacist will be stored in the study pharmacy.

File/Binder #13: Study Site Staff Meeting Documentation

41. MTN 005 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries

Note:

- Meeting documentation should be filed beginning from the date of the MTN 005 Operational Walkthrough

File/Binder #14: Conference Call Documentation

42. MTN 005 Protocol Team and Protocol Co-Chairs Conference Call Summaries
43. Summaries of Other MTN 005 Conference Calls

Note:

- Conference call summaries will be filed beginning from the date of the MTN 005 site specific training.

File/Binder #15: DAIDS and Other Reference Documentation

44. DAIDS Policy for Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-CL-04.00)
45. DAIDS Policy for Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-RA-03.00)
46. DAIDS Protocol Registration Policy (26 March 2010) and Protocol Registration Procedures Manual (March 2010) along with any subsequent updates
47. Manual for Expedited Reporting of Adverse Events to DAIDS (Version 2.0 dated January 2010 and any subsequent updates)
48. US Regulations Applicable to Conduct of MTN 005 (45 CFR 46; 21 CFR 50, 54, 56, and 312)
49. Any other relevant manuals or reference documents

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

50. Site-Specific Study Activation Documents

Section Appendix 3-2
Guide to Required Case History Elements and Source Documents for MTN 005

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 eligibility criteria.	Demographics form; Locator form; Pelvic Exam form; Vaginal Test Results form; ; Baseline Pregnancy/Contraceptive History form; Menstrual History form; Physical Exam form; Pelvic Exam Diagram; Screening Behavioral Eligibility form; (Repeat) Pelvic Exam form; (Repeat) Vaginal Test Results form; Concomitant Medications Log; Pre-existing Conditions form; Eligibility Criteria form; Enrollment Behavioral Eligibility form; (Repeat) Physical Exam form; (Repeat) Pelvic Exam Diagram; local lab logs and result reports[§]; signed and dated chart notes.
A record of the participant's random assignment.	MTN 005 clinic randomization envelope tracking records; MTN 005 clinic randomization envelope; MTN 005 prescription; MTN 005 participant-specific pharmacy dispensing record.
A record of the participant's exposure to the investigational study products (Participants in Group A).	MTN 005 Study Product Request Slip, MTN 005 participant-specific pharmacy dispensing record; 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; Pelvic Exam Ring Assessment form; Follow-Up Visit form; Ring Adherence form; Follow-up Medical history log; Adverse Experience log; HIV test results form; Product hold/discontinuation form; Pregnancy Report form; Pregnancy Outcome form; Social Harm long; Genital Bleeding Assessment 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 005 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" or "This is a 44-year old HIV-infected woman here for routine study visit with increased fatigue and pallor; blood smear is positive for malaria."

• **P (PLAN):** The plan should include anything that will be done as a consequence of the assessment and could include:
- **o** The collection of study-specific labs or special studies
- **o** The collection of labs or special studies to address an acute complaint
- **o** Intention to admit to the hospital
- **o** Study-specific medications dispensed (name of drug, amount dispensed and dosing instructions)
- **o** Non-study medications prescribed or dispensed for a specific acute or chronic complaint (name of drug, amount dispensed and dosing instructions)
- **o** Follow-up instructions to the client (for example: "return to the clinic if this problem does not resolve")
- **o** Date of next appointment

Section Appendix 3-3
Sample Chart Notes for MTN 005 in Subjective-Objective-Assessment-Plan (SOAP) Format

Sample Chart Note for Screening:

16 JUN 2008: Participant presented for MTN 005 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 30 JUN 2008.

{staff signature}

Sample Chart Note for Screening:

16 JUL 2008: Participant presented for MTN 005 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 30 JUL 2008, participant counseled to contact site if symptoms do not resolve in 5-7 days.

{staff signature}

Sample Chart Note for Enrollment:

5 AUG 2008: Participant presented for MTN 005 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.

{staff signature}

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

3 SEP 2008: Participant presented for MTN 005 Week 12 visit. Procedures completed per protocol, visit checklist and SOPs.

S: No issues/problems reported since last visit.

O: Pelvic exam and wet mount normal (see test results and exam findings on DataFax forms).

A: No issues of concern.

P: Week 16/Termination Visit scheduled for 24 SEP 2008.

{staff signature}

Section Appendix 3-4
Listing of MTN-005 DataFax and Non-DataFax Forms

MTN-005 DataFax Forms	MTN-005 Non-DataFax Forms
Adverse Experience Log	Baseline Pregnancy/Contraceptive History
Concomitant Medications Log	Enrollment Behavioral Eligibility
Demographics	Follow-up Medical History Log
Demographics – India	Genital Bleeding Assessment
Demographics – United States	Menstrual History
Eligibility Criteria	MTN-005 LDMS Specimen Tracking Sheet
End of Study Inventory	Physical Exam
Enrollment	Pelvic Exam Diagrams
Follow-up Visit	Screening Behavioral Eligibility
HIV Test Results	
Interim Visit	
Local Laboratory Results	
Missed Visit	
Pelvic Exam	
Pelvic Exam Ring Assessment	
Pre-Existing Conditions	
Pregnancy Report	
Pregnancy Outcome	
Product Hold/Discontinuation Log	
Ring Adherence	
Social Harm Log	
Specimen Storage	
Termination	
Vaginal Test Results	

Section Appendix 3-5
MTN-005 DataFax Forms Used as Source Documents
(Forms listed in alphabetical order

Form Name	Acronym	Is Form Source?	Comments
Adverse Experience Log	AE-1		Form may be source for all items.
Concomitant Medications	CM-1		Form may be source for all items.
Demographics	DEM-1-2	Yes	Form is source for all items as participant responses are recorded directly onto the form.
Demographics – India	DMI-1	Yes	Form is source for all items as participant responses are recorded directly onto the form.
Demographics – United States	DMU-1	Yes	Form is source for all items as participant responses are recorded directly onto the form.
Eligibility Criteria	ECI-1		Form may be source for item 1. Specimen Storage Informed Consent form is source for item 2.
End of Study Inventory	ESI-1	No	All items are based on source data recorded on other documents.
Enrollment	ENR-1		Form may be source for item 4. The Screening Informed Consent form is source for item 1. The Enrollment Informed Consent form is source for item 2. The MTN-005 Randomization Envelope Tracking Record is source for items 3-3c. The prescription is source for item 3d. The Enrollment Visit checklist is source for item 5.
Follow-up Visit	FV-1		Form may be source for items 3, 5 and 5a. All other items are based on source data recorded on other forms/documents.
HIV Test Results	HTR-1		Local laboratory report(s) are source for items 1-3. Form may be source for item 4.
Interim Visit	IV-1		Form may be source for items 1, 5, and 6. Form is source for item 2. All other items are based on source data recorded on other forms/documents.
Local Laboratory Results	LLR-1	No	Local laboratory reports are source for all items.
Missed Visit	MV-1		Form may be source for all items.

Section Appendix 3-5
MTN-005 DataFax Forms Used as Source Documents
(Forms listed in alphabetical order

Form Name	Acronym	Is Form Source?	Comments
Pelvic Exam	PE-1, PE-2		Pelvic Exam Diagrams is source for items 1 and 1a. Form may be source for items 2-7. Visit checklist and Pelvic Exam Diagrams are source for item 8. Form may be source for items 8a, 9, and 9a.
Pelvic Exam Ring Assessment	PER-1		Form may be source for all items.
Pre-Existing Conditions	PRE-1	No	Form may be source for severity grade item. All other items are based on source data recorded on the Baseline Medical History form, Baseline Medical History Chart Sheet, Menstrual History form, Physical Exam form, Pelvic Exam Diagrams form, Pelvic Exam form, Local Laboratory Results form, and/or participant chart notes.
Pregnancy Report	PR-1		Form may be source for all items..
Pregnancy Outcome	PO-1, :PO-2		Form may be source for all items if medical records are not available (and data are based on participant self-report). If medical records are obtained, then they will be source for as many items as possible.
Product Hold Discontinuation Log	PH-1		Form may be source for all items.
Ring Adherence	RA-1	Yes	Form may be source for items 1 and 2 when the 005 Ring Diary is not available. Form is source for items 2a-4e as these are based on participant self-report (using the diary as a memory aid).
Social Harm Log	SH-1		Form may be source for all items.
Specimen Storage	SS-1		Form may be source for all items.
Termination	TM-1	No	All items are based on source data recorded on other documents.
Vaginal Test Results	VTR-1		Form may be source for any items not documented on local laboratory results reports.

Note: For forms where the site indicates that they will use the form as source, site should update "Comments" as needed to indicate which form items will be used as source. Site should replace all "may be used as source"

to “will be used as source” or “will not be used as source” as applicable, to match the previous column. IF blank, site should complete to indicate whether form will be used as source at their site.

Section Appendix 3-6
MTN-005 Non-DataFax Forms Used as Source Documents
(Forms listed in alphabetical order)

Form Name	Is Form Source?	Comments
Baseline Pregnancy/Contraceptive History		Form may be source for all items.
Enrollment Behavioral Eligibility	Yes	Form is source for all items (based on participant self-report).
Genital Bleeding Assessment		Form may be source for all items.
Follow-up Medical History Log		Form may be source for symptoms/diagnoses reported by the participant. Some items may have other forms as source (for example, the Pelvic Exam Diagrams form).
Menstrual History		Form may be source for all items.
MTN-005 LDMS Specimen Tracking Sheet		Form may be source for all items.
Physical Exam		Form may be source for all items.
Pelvic Exam Diagrams		Form may be source for all items.
Screening Behavioral Eligibility	Yes	Form is source for all items (based on participant self-report).