

Section 3. Documentation Requirements

Study staff is responsible for proper collection, management, storage, quality control, and quality assurance of all study-related documentation. This section contains information on the Essential Documents that the study site must maintain throughout the study. It also contains information related to establishing adequate and accurate participant research records — commonly referred to as participant “case history records” — for MTN 002.

3.1 Essential Documents

The Division of AIDS (DAIDS) Standard Operating Procedure (SOP) for Essential Documents specifies the essential documents that study site must maintain for DAIDS-sponsored studies, including MTN 002. 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 002. The suggested structure incorporates guidance received from the DAIDS Clinical Site Monitoring Group (PPD). The study site is not required to adopt the suggested structure, but is encouraged to consider it when developing their filing approach for MTN 002. The study site also is encouraged to establish an SOP to document their filing approach. Further clarifications of the suggested filing structure are as follows:

- Essential documents may be stored in files and/or in binders. The files/binders listed in Section Appendix 3-1 may be further subdivided, consolidated, and/or re-organized if desired.
- It is recommended that a table of contents be developed and maintained in the front page(s) of each file/binder. Within each section of the file/binder, it is recommended that documents be filed in ascending date order (most recent documents in front).
- Certain documents related to the investigational study products will be stored in the site pharmacy. A listing of essential documents to be maintained in the pharmacy is provided in Section 3.3. The list of documents to be kept in the pharmacy should be included in the master table of contents.
- To facilitate routine inspection by study monitors, certain laboratory-related essential documents should be stored in the main study essential documents files/binders (see items 26-28 in Section Appendix 3-1). Other lab-related essential documents (e.g., lab SOPs) may be filed in site laboratories. The list of documents to be kept in the lab should be included in the master table of contents.

- The suggested filing structure assumes that MTN 002 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 002 Screening and Enrollment Log and Participant Name-ID Number Link Log (which are described in Section 4 of this manual) will be stored in the study clinic or data management area and not necessarily with the other essential documents listed in Section Appendix 3-1.

3.2 Participant Case History Documentation

The study site must maintain adequate and accurate case history records for each study participant.

3.2.1 Case History Contents

Participant case histories should contain all of the following elements:

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

In addition to the above, DAIDS requires that all protocol departures/deviations/violations be documented in participant records, along with reasons for the departures/deviations/violations and/or attempts to prevent or correct the departures/deviations/violations, if applicable. The study site also must report protocol deviations to DAIDS and others per guidelines provided in the MTN Manual of Operating Procedures Section 15.4 available at <http://mtnstopshiv.org/downloads/core/manuals/MTN%20MOP%20Final%20All%20Section%20s.pdf>.

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

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

- Narrative chart notes
- Clinic prescriptions (“original” kept in the pharmacy)
- Pharmacy records for investigational product dispensing
- 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, the study site must establish an SOP for source documentation that specifies the use of the above-listed documents as source documents. Although it is the responsibility of the site to determine the most appropriate source document for each required case history element, Appendix 3-2 provides a guide that the site may follow for this study. Supplemental information on the use of chart notes, visit checklists, and forms provided by the MTN SDMC is provided below. Detailed information on proper completion of DataFax and Non-DataFax forms provided by the MTN SDMC is provided in Section 13 of this manual.

Chart Notes: Study staff must document every contact with a study participant in a signed and dated chart note specifying the date, type, purpose, and location of the contact, and the general status of the participant. The time the contact takes place, any specific procedures conducted and, when necessary, adherence to protocol requirements should also be documented. Chart notes also must be used to document the following:

- The study informed consent process (see also Section 5)
- Procedures performed that are not recorded on other source documents
- Pertinent data about the participant that are not recorded on other source documents
- Protocol departures/deviations/violations that are not otherwise captured on other source documents

The study site is strongly encouraged to adopt a common format — such as the Subjective-Objective-Assessment-Plan (SOAP) format — for all chart notes, to help ensure adequacy and consistency of note content and maximize adherence to GCP standards. 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 are not sufficient for documenting all procedures. For example, chart notes are required to document procedures performed at unscheduled study visits, and/or to explain why procedures in addition to those listed on a checklist may have been performed or why procedures listed on a checklist were not performed. Chart notes also may be required to document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements).

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 the site. The SDMC also will provide several study-specific non-DataFax forms to the 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 participant notebooks, with each notebook containing tabbed sections with case report forms required for each study visit; i.e., Screening and Enrollment Visit, Gel Administration Day, 24 Hour Evaluation, and Two Week Phone Call. A small supply of other “as needed” forms also will be provided. The notebooks will be produced by SCHARP and shipped to the study site. Forms will be printed on letter size paper and three-hole punched.

As shown in Appendices 3-5 and 3-6, many of the DataFax and non-DataFax forms provided by the SDMC have been designed to serve as source documents. The study site must document the forms that it will routinely use as source documents for this study in its Source Documentation SOP, and they must follow the specifications of this SOP consistently for all study participants. In the event that study staff 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. For participants who enroll in the study, their screening documentation should be transferred into large ring binders that will serve as participants' study notebooks for the duration of their participation in the study.

All documents contained in participant case history records must bear a participant identifier, which generally will consist of either the participant identification number (PTID) or the participant name. To maximize participant confidentiality, the PTID should be used whenever possible, and records that bear names or other personal identifiers, such as locator forms and informed consent forms, should be stored separately from records identified by PTID. Any documents transferred or transmitted to a non-study site location — including DataFax forms and Expedited Adverse Event Forms — must be identified by PTID only.

Regardless of whether the identifier on a particular document consists of the participant name or PTID, the original identifier may not be obliterated or altered in any way, even if another identifier is added. When necessary to maintain confidentiality, identifiers may be obliterated on 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 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, the study site must establish an SOP for data management. This SOP minimally should contain the following elements:

- Procedures for assigning PTIDs, linking PTIDs to participant names, and storing the name-PTID link log
- Procedures for establishing participant files/charts/notebooks
- During-visit participant chart and case report form review procedures
- Post-visit participant chart and case report form review procedures and timeframes
- Data transmission procedures, including timeframes, case report form storage locations before and after faxing, and mechanisms for identifying when forms have been transmitted
- Procedures for resolving data quality control notes from the SDMC
- Procedures for handling and filing field workers' logs, worksheets, etc. (if applicable)
- Storage locations for blank case report forms
- Storage locations for documents identified by participant names or other personal identifiers
- Storage locations for documents identified by PTID
- Procedures for back up of electronic study data (if applicable)
- Handling of participant study records for off-site contacts and visits (if applicable)
- Confidentiality protections
- Other ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- Staff training requirements (if not specified elsewhere)
- QC/QA procedures related to the above (if not specified elsewhere)

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

The following documents should be maintained in study site pharmacy:

- Current MTN 002 protocol and associated Letters of Amendment and/or Clarification Memos (if applicable)
- Current Investigator's Brochures for Tenofovir 1% Vaginal Gel.
- Copy of the current MTN 002 FDA Form 1572
- Most current Authorized prescribers' signature list
- PAB approved Pharmacy Establishment Plan
- MTN 002 PTID list (provided by the MTN SDMC, in the form of the MTN 002 PTID-Name Link Log)
- MTN 002 product receipt and return documentation
- MTN 002 product storage temperature logs
- MTN 002 investigational agent accountability records
- MTN 002 participant-specific records (including prescriptions)
- MTN 002 communications with site clinic staff
- MTN 002 communications with the DAIDS Pharmaceutical Affairs Branch (PAB) and the NIAID Clinical Research Product Management Center
- MTN 002 communications with the MTN Coordinating and Operations Center (CORE)
- MTN 002 communications with the MTN SDMC
- Other MTN 002 communications
- Other locally-required administrative, operational, and/or regulatory documentation

Pharmacy staff will document the receipt, dispensing, and return of the Tenofovir 1% Gel.

The specifications related to document security and participant confidentiality described in Section 3.2 also apply to records maintained in the study pharmacy. All records must be stored securely in the pharmacy with access limited to authorized 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 pharmacy. Pharmacy staff may provide copies of some participant-specific documentation maintained in the study pharmacy (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.

3.4 Record Retention Requirements

All study records must be maintained for at least two years following the date of marketing approval for the study product for the indication in which they were studied. If no marketing application is to be filed, or if the application is not approved, the records must be retained until two years after the investigation is discontinued and the US Food and Drug Administration (FDA) is notified. All records must be retained on-site throughout the study's period of performance, and for at least three years after completion or termination of the study. Study product records must be stored in the study pharmacy, with access limited to authorized study pharmacy staff only. DAIDS will provide further instructions for long-term storage of study records after the study is completed.

Section Appendix 3-1
Suggested Filing Structure for MTN 002 Essential Documents

<p>File/Binder #1: MTN 002 Protocol and Current Informed Consent Form</p> <ol style="list-style-type: none"> 1. MTN 002 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 002 informed consent form
<p>File/Binder #2: Regulatory Authority Documentation (if applicable)</p> <ol style="list-style-type: none"> 3. Regulatory Authority Correspondence/Authorization/Approval/Notification of Protocol (if applicable; if more than one regulatory authority has oversight responsibility for research performed at the study site, include subsections for each authority)
<p>File/Binder #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 Tenofovir 1% Gel: current version and any subsequent updates 13. 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 002 Study-Specific Procedures (SSP) Manual</p> <ol style="list-style-type: none"> 14. Final version 1.0 (when available) and any subsequent updates <p>Notes:</p> <ul style="list-style-type: none"> • For this reference copy of the SSP Manual, do not discard out-dated pages or sections when updates are issued; retain all versions of all pages as a complete historical record. • The SSP Manual contains reference versions of all study case report forms, therefore additional (blank) copies of the case report forms need not be stored elsewhere in the essential document files.
<p>File/Binder #6: MTN 002 Study-Specific Standard Operating Procedures</p> <ol style="list-style-type: none"> 15. Final approved version of each SOP, and any subsequent updates to each

Section Appendix 3-1
Suggested Filing Structure for MTN 002 Essential Documents

<p>File/Binder #7: MTN 002 Staffing Documentation</p> <ol style="list-style-type: none"> 16. FDA Form 1572 (copy of original and dated form submitted to the RCC for Protocol Registration, and any subsequent updates) 17. MTN 002 Investigator of Record CV (copy of CV submitted to the RCC for Protocol Registration; ensure that the CV is current prior to initiating MTN 002; 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 002; 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
<p>File/Binder #8: Local Laboratory Documentation</p> <ol style="list-style-type: none"> 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) <p>Note:</p> <ul style="list-style-type: none"> • It is recommended that a cross-reference be included in this file/binder specifying the storage location(s) of other lab-related essential documents filed in the local lab(s).
<p>File/Binder #9: Monitoring Visit Documentation</p> <ol style="list-style-type: none"> 28. Monitoring Visit Log 29. Initiation and Monitoring Visit Reports and Documentation of Response to Visit Findings
<p>File/Binder #10: Documentation of Other MTN Site Visits</p> <ol style="list-style-type: none"> 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
<p>File/Binder #11: Study-Related Sponsor Communications</p> <ol style="list-style-type: none"> 35. Study-Related Communications to and from DAIDS 36. Communications to and from DAIDS RCC (includes copies of all submissions to the DAIDS Protocol Registration Office, which will be prepared by the site with copies provided to the MTN CORE, as well as the current monthly DAIDS IB/PI listing and year-end and current monthly DAIDS Comprehensive Safety Distribution Report) <p>Notes:</p> <ul style="list-style-type: none"> • Communications related to individual MTN 002 study participants will be filed in individual participant study records. • Product-related communications with DAIDS PAB and its contractors will be stored in the study pharmacy.
<p>File/Binder #12: Other Study-Related Communications</p> <ol style="list-style-type: none"> 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 <p>Notes:</p> <ul style="list-style-type: none"> • Communications related to individual MTN 002 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 002 Essential Documents

File/Binder #13: Study Site Staff Meeting Documentation 41. MTN 002 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries
File/Binder #14: Conference Call Documentation 42. MTN 002 Protocol Team and Protocol Co-Chairs Conference Call Summaries if applicable 43. MTN 002 Study Coordinators Group Conference Call Summaries if applicable 44. MTN 002 Laboratory Group Conference Call Summaries if applicable 45. MTN 002 Community Educators Group Conference Call Summaries if applicable 46. Summaries of Other MTN 002 Conference Calls
File/Binder #15: DAIDS and Other Reference Documentation 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 002 (45 CFR 46; 21 CFR 50, 54, 56, and 312) 52. Any other relevant manuals or reference documents
File/Binder #16: Site-Specific Study Activation Documentation 53. Site-Specific Study Activation Documents

Section Appendix 3-2
Guide to Required Case History Elements and Source Documents for MTN 002

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.	Demographics form, locator form; Study Eligibility form. Concomitant Medications Log form, Targeted Physical Exam form, Pelvic Exam Diagrams; Pre-existing Conditions form, local lab logs and result reports [§] ; baseline medical history, signed and dated chart notes.
A record of the participant's drug assignment.	MTN 002 participant-specific pharmacy dispensing record.
A record of the participant's exposure to the investigational study products.	MTN 002 Study Product Request Slip, MTN 002 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; MTN 002 Study Visit form, C-section Delivery Information form, Flow Cytometry form, Pelvic Exam form; Pelvic Exam Diagrams form, Pre-existing Conditions form, Concomitant Medications Log form, Targeted Physical Exam form, Adverse Experience Log form; Missed Visit form;; End of Study Inventory form; local lab logs and result reports from the local lab [§] ; results of information pertinent to the study obtained from non-study sources; signed and dated chart notes.

*Other site-specific source documents also may be used.

[§]A clinician must review all local laboratory reports and document this review by signing and dating all reports.

Section Appendix 3-3 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 002 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:

- 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 002 in Subjective-Objective-Assessment-Plan (SOAP) Format

Sample Chart Note for Screening and Enrollment Visit:

16 JUN 2008: Participant presented for MTN 002 screening and enrollment visit. 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:** Participant eligible per the protocol eligibility criteria, tested HIV negative.
- A:** Participant is eligible for the study thus far.
- P:** Plan for PK measures visit, confirm the day planned for the C/S procedure.
 {staff signature}

Sample Chart Note for PK Measures Visit/Gel Administration Day:

3 SEP 2008: Participant presents for her scheduled C/S procedure. Procedures completed per protocol, visit checklist and SOPs.

- S:** No issues/problems reported during gel administration.
- O:** PK Procedures performed according to protocol with no problems.
- A:** No issues of concern.
- P:** Twenty-Four Hour Evaluation scheduled for 4 SEP 2008.
 {staff signature}

Section Appendix 3-4
MTN 002 DataFax and Non-DataFax Forms

MTN 002 DataFax Forms
Demographics
Enrollment
Pelvic Exam
Pharmacokinetics
Participant Evaluability and Replacement
Adverse Experience Log
Missed Visit
Interim Visit
Termination
End of Study Inventory

MTN 002 Non-DataFax Forms
Targeted Physical Exam
Pelvic Exam Diagrams
MTN 002 LDMS Specimen Tracking Sheet

**Section Appendix 3-5
Use of MTN 002 DataFax Forms as Source Documents**

MTN 002 DataFax Forms	Source?	Comments
Demographics	Yes	.
Concomitant Medications Log	Yes	Form may be source for all items.
Enrollment	Mixed	Item 1 is based on source data recorded on participant informed consent form. May be source for items 2 and 2a.
Pre-Existing Conditions	No	All items are based on data recorded on other source documents.
Interim Visit	Yes	. Form may be used as source for all items
Flow Cytometry	No	Lab report will be source.
C-section Delivery Information	No	Hospital chart will be source.
MTN 002 Study Visit	Yes	Form may be used as source for all items.
Pharmacokinetics	Yes	Form may be used as source for all items.
Participant Evaluability and Replacement	Yes	Form may be used as source for all items.
Missed Visit	Yes	Form may be source for the fact that the visit was missed; source data on the reason why the visit was missed also may be recorded on this form.
Pelvic Exam	No	Visit checklist is source for item 1, Pelvic Exam Diagrams may be source for item 1a.
Adverse Experience Log	Yes	Form may be source for all items.
Termination	No	All items are based on data recorded on other documents as source.
End of Study Inventory	No	

**Section Appendix 3-6
Use of MTN 002 Non-DataFax Forms as Source Documents**

MTN 002 DataFax Forms	Source?	Comments
Study Eligibility	Yes	Form may be source for all items.
Targeted Physical Exam	Yes	Form may be source for all items.
Pelvic Exam Diagrams	Yes	Form may be source for all items.
Maternal PK LDMS Specimen Tracking Sheet	No	All items are based on data recorded on other documents as source.
C-section LDMS Specimen Tracking Sheet	No	All items are based on data recorded on other documents as source.