

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-016.

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-016. 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-016. The study site is not required to adopt the suggested structure, but is encouraged to consider it when developing their filing approach for MTN-016. 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).
- To facilitate routine inspection by study monitors, certain laboratory-related essential documents should be stored in the main study essential documents files/binders (see items 23-25 in 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 and incorporated into the master file at the close of the study.
- The suggested filing structure assumes that MTN-016 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-016 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 of appropriate written informed consent for the participation of each woman and infant in the study prior to the conduct of any study procedures.
- Documentation that the participant/infant met the study's selection (eligibility) criteria.
- A record of all contacts, and attempted contacts, with the participant/infant.
- 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 on the website at www.mtnstopshiv.org/node/187.

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).

Certified Copies: Copies of documents, with manual documentation that all material included on the copy is accurate and complete based on the source document. The note is then dated and signed by the copier. This is not ideal given that corrections, clarifications, or additional material may later be added to a source document, rendering the certified copy accurate and complete only as of the date it was copied.

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
- 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, approved by FHI, 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). The site may elect to create source worksheets to ensure full documentation for all data points is collected for study visits and for study visits involving data collection for multiple protocols. FHI should approve these alternate source worksheets prior to implementation. Use of source worksheets should be referenced in the site-specific Source Documentation SOP.

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 an initial supply of all CRFs to each site. Additional supplies will be printed at each site, and the CRFs will be available via the ATLAS web portal.

As shown in Appendices 3-4 and 3-5, many of the DataFax and non-DataFax forms provided by the SDMC have been designed to serve as source documents. The study site must document the forms that 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 is 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, if site policy permits. If site policy does not permit, either a note to file documenting location of source or a certified copy of the source document should be made and filed with the 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 is 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 must be identified by PTID only, with the exception of medical information being forwarded to a participant's outside-study physician for the purpose of medical history or for referral for follow-up care.

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 Record Retention Requirements

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. 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-016 Essential Documents

<p>File/Binder #1: MTN-016 Protocol and Current Informed Consent Form</p> <ol style="list-style-type: none"> 1. MTN-016 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-016 informed consent form(s), plus all previously IRB-approved forms, with a version control log listing dates of all approved ICFs with a summary of updates
<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, including updates throughout course of site participation in study (if available) 6. Relevant IRB/EC A Submission Requirements/Guidelines/SOPs, including updates throughout course of site participation in study 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, including updates throughout course of site participation in study (if available) 10. Relevant IRB/EC B Submission Requirements/Guidelines/SOPs, including updates throughout course of site participation in study 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: MTN-016 Study-Specific Procedures (SSP) Manual</p> <ol style="list-style-type: none"> 12. 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 #5: MTN-016 Study-Specific Standard Operating Procedures</p> <ol style="list-style-type: none"> 13. Final approved version of each SOP, and any subsequent updates to each
<p>File/Binder #6: MTN-016 Staffing Documentation</p> <ol style="list-style-type: none"> 14. DAIDS Investigator of Record Form (copy of original and dated form submitted to the RCC for Protocol Registration, and any subsequent updates) 15. MTN-016 Investigator of Record CV (copy of CV submitted to the RCC for Protocol Registration; ensure that the CV is current prior to initiating MTN-016; it is recommended that CVs be signed and dated to document at least annual updating) 16. Financial Disclosure Forms (original signed and dated forms, and any subsequent updates) 17. Study Staff Roster (original submitted to MTN CORE for study activation, and any subsequent updates) 18. Study Staff Identification and Signature Sheet (if not combined with staff roster; original and any subsequent updates) 19. Study Staff Delegation of Duties (if not combined with staff roster; original and all updates) 20. CVs for Study Staff other than the IoR (ensure that all CVs are current prior to initiating MTN-016; it is recommended that CVs be signed and dated to document at least annual updating) 21. Study Staff Job Descriptions 22. Documentation of Study Staff Training and refresher training

Section Appendix 3-1
Suggested Filing Structure for MTN-016 Essential Documents

<p>File/Binder #7: Local Laboratory Documentation</p> <p>23. Local Laboratory Certification(s), Accreditation(s) and/or Validation(s): file documentation current at time of study activation and all subsequent updates</p> <p>24. Copy of local laboratory normal sheets, dated, and updated as required through dates of site study activity.</p> <p>25. Laboratory Manager CV (or cross-reference to CV contained in File/Binder #7)</p> <p>Note:</p> <ul style="list-style-type: none"> • 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 #8: Monitoring Visit Documentation</p> <p>26. Monitoring Visit Log, if applicable.</p> <p>27. Initiation and Monitoring Visit Reports and Documentation of Response to Visit Findings, if applicable.</p>
<p>File/Binder #9: Documentation of Other MTN Site Visits</p> <p>28. (Non-Monitoring) Site Visit Log</p> <p>29. MTN CORE Site Visit Reports and Documentation of Response to Visit Findings</p> <p>30. MTN SDMC Site Visit Reports and Documentation of Response to Visit Findings</p> <p>31. MTN Network Lab Site Visit Reports and Documentation of Response to Visit Findings</p> <p>32. Other Site Visit Reports and Documentation of Response to Visit Findings</p>
<p>File/Binder #10: Study-Related Sponsor Communications</p> <p>33. Study-Related Communications to and from DAIDS</p> <p>34. 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> <p>Notes:</p> <ul style="list-style-type: none"> • Communications related to individual MTN-016 study participants will be filed in individual participant study records.
<p>File/Binder #11: Other Study-Related Communications</p> <p>35. Study-Related Communications to and from MTN CORE</p> <p>36. Study-Related Communications to and from MTN SDMC</p> <p>37. Study-Related Communications to and from MTN Network Lab</p> <p>38. Other Study-Related Communications</p> <p>Notes:</p> <ul style="list-style-type: none"> • Communications related to individual MTN-016 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, and may be incorporated into Master Regulatory Files for archival at completion of study.
<p>File/Binder #12: Study Site Staff Meeting Documentation</p> <p>39. MTN-016 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries</p>
<p>File/Binder #13: Conference Call Documentation</p> <p>40. MTN-016 Protocol Team and Protocol Co-Chairs Conference Call Summaries if applicable</p> <p>41. MTN-016 Study Coordinators Group Conference Call Summaries if applicable</p> <p>42. MTN-016 Laboratory Group Conference Call Summaries if applicable</p> <p>43. MTN-016 Community Educators Group Conference Call Summaries if applicable</p> <p>44. Summaries of Other MTN-016 Conference Calls</p>
<p>File/Binder #14: DAIDS and Other Reference Documentation</p> <p>45. DAIDS SOP for Source Documentation (Version 2.0 and any subsequent updates)</p> <p>46. DAIDS SOP for Essential Documents (Version 2.0 and any subsequent updates)</p> <p>47. DAIDS Protocol Registration Policy and Procedures Manual (August 2004 and any subsequent updates)</p> <p>48. US Regulations Applicable to Conduct of MTN-016 (45 CFR 46; 21 CFR 50, 54, 56, and 312)</p> <p>49. Any other relevant manuals or reference documents</p>
<p>File/Binder #15: Site-Specific Study Activation Documentation</p> <p>50. Site-Specific Study Activation Documents</p>

Section Appendix 3-2
Guide to Required Case History Elements and Source Documents for MTN-016

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.	Woman Enrollment Form, Woman Demographics form, Parent Protocol Participation, Woman Medical History Log, Infant Medical History Log, signed and dated chart notes.
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; Woman Concomitant Medications Log form, Woman Demographics, Genetic Screening History form (women), Pregnancy Report and History form, Pregnancy Outcome, Woman Missed Visit form, Woman Medical History form, Infant Concomitant Medications Log form, Infant Visit form, Infant Physical Exam form, Infant Developmental Screening form, Infant Missed Visit form; local lab logs and result reports from the local lab (infants); 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. Note: CRFs listed may not be used as source if information is first reported elsewhere and then transcribed to the form. Site-specific source documentation will be described in detail in each site's Source Documentation SOP.

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 woman'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 should also be included here: "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. Note that, for MTN-016, no physical exams are required for the woman; a full physical exam should be done on the infant at every scheduled clinic visit (a problem focused exam may be done on interim visits).

• **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-016 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 6 month old infant here for routine study visit; mother reports no ongoing or current complaints."

• **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
- 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-016 in Subjective-Objective-Assessment-Plan (SOAP) Format

Woman
<p>Sample Chart Note Screening and Enrollment Visit (Woman): 16 JUN 2009: S: Pregnant woman, participant in VOICE, presents for MTN-016 screening and enrollment visit. Her pregnancy was confirmed by 2 consecutive urine qualitative hCG during VOICE visits. LMP was mid-March per maternal report. This 28 year old woman has been pregnant 3 times and has 2 living children (one baby died as an infant of “malaria”). Written informed consent for maternal and infant participation was obtained before initiating any procedures. As part of the informed consent process, participant agreed that photos may be taken of her infant. A: 12 week pregnant woman eligible for MTN-016 per the protocol eligibility criteria. P: Procedures were completed per protocol, visit checklist and SOPs. Participant scheduled to return to clinic in 3 months: 15 Sept 2009. Participant was given copy of signed consent. {staff signature and date}</p>
<p>Sample Chart Note Quarterly Visit (Woman): 15 SEPT 2009: S: Well nourished, healthy appearing 28 yo pregnant woman presents for MTN-016 quarterly visit. Participant reports no issues related to her pregnancy; her health has been “okay.” She continues to take multivitamins; she is taking no other medications. She reports no change in her living situation. A: Pregnant woman, 25 weeks gestation per US, completed quarterly 016 study visit. P: Procedures, including ultrasound, were completed per protocol, visit checklist and SOPs. Participant advised to contact study staff on arrival to L&D or in the event that something arises before her delivery date. Contact information provided to her. {staff signature and date}</p>
<p>Sample Chart Note Pregnancy Outcome Visit (Woman; data obtained at L&D): 23 DECEMBER 2009: S: Visited with mother in the nursery following her vaginal delivery of a live born baby boy on 22 December 2009. Per L&D records, baby’s birth weight: 6.6 kg; length: 50 cm; head circumference: 34.5 cm. Apgar of 9 at 5 minutes. Per maternal report and medical records, no complications with the delivery. A: Healthy woman s/p delivery of a healthy infant boy. P: Procedures were completed per protocol, visit checklist and SOPs. Mother to return to clinic in one month (22 January) for the infant’s month 1 appointment. {staff signature and date}</p>
<p>Sample Chart Note Quarterly Visit/Pregnancy Outcome Visit (Woman): 15 SEPT 2009: S: Well nourished, healthy appearing pregnant woman presents for MTN-016 quarterly visit. Mother reports that “the baby is too quiet” for the past 24 hours. She is concerned that something is wrong with her baby. O: Procedures, including ultrasound, were completed per protocol and for standard medical care, visit checklist and SOPs. A: Ultrasound confirms fetal demise. P: Participant is counseled re the loss of her pregnancy. She is advised to continue with maternal health care. {staff signature and date}</p>

Infant**Sample Chart Note Newborn Visit (data obtained at L&D):****23 DECEMBER 2009:****S:** New born male infant examined 6 hours following uncomplicated vaginal delivery.**O:** Vitals: Wt: 3.0 kg; Length: 50 cm; Head Circumference: 34.5 cm; Abdominal Circumference: 31 cm

General: infant crying at the start of the exam; easily consolable. Good color and tone.

HEENT: Mild bruising and edema of the scalp. Fontanelles open; neither bulging nor flat. Eyes: no discharge or erythema. Pupils equally round and responsive to light. Ears: normal set and rotation. Nose: nares patent. Mouth: palate intact by exam and palpation; tongue is freely mobile.

Neck: Symmetric with full range of motion.

Chest: Normal contour. Mild breast budding bilaterally (L>R).

Heart: Regular rhythm; rate 140 bpm. No murmur. Femoral pulses strong and equal.

Lungs: Bilaterally clear. Respiratory rate 45 bpm.

Abdomen: Soft, no masses. Umbilical cord clean and dry. Liver edge palpable 2 cm below r costal margin. Normal bowel sounds.

Genitalia: Intact foreskin; testicles descended bilaterally.

Anus: visibly patent

Back: symmetric. No skin tags, lesions, masses.

Extremities: Arms and legs symmetric with full range of motion. No hip clip.

Hands and feet: no extra digits.

A: Healthy newborn infant, enrolled in MTN-016.**P:** Procedures were completed per protocol, visit checklist and SOPs. Baby is scheduled for newborn vaccinations prior to discharge. Mother to return to clinic in one month (22 January) for an appointment for her infant.

{staff signature and date}

Sample Chart Note Month 1 Infant Visit:**9 JANUARY 2010:****S:** 3-week old male infant in for first MTN-016 study visit. The baby has been well since birth; the baby is being breastfed. Baby had first series of immunizations in the hospital. Will be returning to the clinic for the next set in one month.**O:** Vitals: Wt: 3.6 kg; Length: 52 cm; Head Circumference: 36.0 cm.

General: awake and alert infant

HEENT: Fontanelles open; neither bulging nor flat. Eyes: no discharge or erythema. Pupils equally round and responsive to light. Ears: normal set and rotation. Nose: nares patent. Mouth: palate intact by exam and palpation; tongue is freely mobile.

Neck: Symmetric with full range of motion.

Chest: Normal contour. No breast budding.

Heart: Regular rhythm; rate 100 bpm. No murmur. Femoral pulses strong and equal.

Lungs: Bilaterally clear. Respiratory rate 35 bpm.

Abdomen: Soft, no masses. Liver edge palpable 1 cm below r costal margin. Normal bowel sounds.

Genitalia: Intact foreskin; testicles descended bilaterally.

Anus: visibly patent

Back: symmetric. No skin tags, lesions, masses.

Extremities: Arms and legs symmetric with full range of motion. No hip clip.

Hands and feet: no extra digits.

A: Healthy 3 week old male infant, enrolled in MTN-016.**P:** Procedures were completed per protocol, visit checklist and SOPs. Mother to return to clinic in 5 months (22 June) for her infant's six month study visit.

{staff signature and date}

Sample Chart Note Month 6 Infant Visit:

11 JUNE 2010:

S: Well developed well nourished 6 month old here for scheduled MTN-016 visit. Mother provided immunization record: baby is up-to-date on immunizations. Mother reports that the baby was “sick” about 2 months ago or so. He fussed and cried and did not eat well. He started to get better before she could get him to the clinic. He is on no medications.

O: Vitals: Wt: 7.2 kg; Length: 66.1 cm; Head Circumference: 42.8 cm. Developmental assessment was completed per protocol.

General: awake and alert infant

HEENT: Pupils equally round and responsive to light. Ears: no effusion, redness or bulging of the TMs.

Nose: no discharge. Mouth: no lesions.

Heart: Regular rhythm; rate 100 bpm. No murmur.

Lungs: Bilaterally clear. Respiratory rate 35 bpm.

Abdomen: Soft, no masses. Normal bowel sounds.

Genitalia: Testicles descended bilaterally.

Extremities: Symmetric with full range of motion.

A: Healthy 6 month old male infant, enrolled in MTN-016. Per Denver II, developmental age consistent with chronologic age.

P: Procedures were completed per protocol, visit checklist and SOPs. Developmental assessment was completed per protocol. Mother to return to clinic in 6 months (23 December) for her infant’s final study visit.

{staff signature and date}

Screening and Enrollment/Pregnancy Outcome Visit: Woman

Initial Visit: Infant

Sample Chart Note Screening and Enrollment Visit/Pregnancy Outcome Visit (Woman):

16 MARCH 2011:

S: Healthy appearing 21 year old woman, participant in VOICE, presents for MTN-016 screening and enrollment visit following the birth of a baby girl 6 weeks ago. She has now moved back to this area. Her pregnancy had been confirmed by a urine qualitative hCG and the report of missed menses during participation in VOICE (per maternal report, LMP was “late April” 2010). She had been referred to MTN-016 but missed her visits because she had returned to her home village for the duration of her pregnancy. This was her first pregnancy. Written informed consent for mother’s participation in MTN-016 was obtained before initiating any study-specific procedures. Per the mother, her delivery was overseen by a local midwife. Her “waters came suddenly” and preceded delivery by about 3 hours. Placenta was delivered “soon after.” The baby cried on delivery and began suckling within 45 minutes. The midwife said that “all was good.” Since then the baby has been “very fine.” Mother is breastfeeding exclusively.

A: 21 yo woman s/p home vaginal delivery of a baby girl 6 weeks ago.

P: Mother advised to return to clinic for Month 6 Infant Visit (3 August 2011).

{staff signature and date}

Sample Chart Note Initial Visit (Infant):**16 MARCH 2011:**

S: Well developed, well nourished 6 week old female baby brought to MTN-016 clinic for enrollment. Baby's mother became pregnant while a participant in VOICE. She recently returned to the area after returning to her home village for duration of pregnancy and delivery. Baby was delivered vaginally; there were reportedly no complications with the delivery. Mother reports no problems with the baby since delivery. Baby is being breastfed. Written informed consent for baby's participation was obtained before initiating any procedures. Permission has been granted to take photos of the baby.

O: Vitals: Wt: 4.0 kg; Length: 54 cm; Head Circumference: 36.2 cm.

General: awake and alert Good color and tone.

HEENT: Fontanelles open; neither bulging nor flat. Eyes: no discharge or erythema. Pupils equally round and responsive to light. Ears: normal set and rotation. Nose: nares patent. Mouth: palate intact by exam and palpation; tongue is freely mobile.

Neck: Symmetric with full range of motion.

Chest: Normal contour. Mild breast budding bilaterally.

Heart: Regular rhythm; rate 135 bpm. No murmur. Femoral pulses strong and equal.

Lungs: Bilaterally clear. Respiratory rate 40 bpm.

Abdomen: Soft, no masses. Liver edge palpable 2 cm below r costal margin. Normal bowel sounds.

Genitalia: Labia majora and minora visualized; unable to appreciate hymenal tissue. No discharge.

Anus: visibly patent

Back: symmetric. No skin tags, lesions, masses.

Extremities: Arms and legs symmetric with full range of motion. No hip clip.

Hands and feet: no extra digits.

A: Healthy appearing 6 week old infant girl here for enrollment to MTN-016.

P: Tasks were completed per protocol, visit checklist and SOPs. Mother advised to return to clinic for Month 6 Infant Visit (3 August 2011).

{staff signature and date}

**Section Appendix 3-4
MTN-016 DataFax and Non-DataFax Forms**

MTN-016 DataFax Forms	
Woman Demographics	Woman End of Study Inventory
Woman Enrollment	Woman Termination
Woman Subsequent Consent	Infant Enrollment
Parent Protocol Participation	Infant Visit
Genetic Screening History	Infant Physical Exam
Ultrasound Results	Infant Developmental Screening
Woman Follow-up Visit	Infant HIV Test Results
Woman Interim Visit	Infant Interim Visit
Woman Concomitant Medications Log	Infant Concomitant Medications Log
Pregnancy Report and History	Infant Missed Visit
Pregnancy Outcome	Infant Participant Transfer
Woman Missed Visit	Infant Participant Receipt
Woman Participant Transfer	Infant End of Study Inventory
Woman Participant Receipt	Infant Termination
Woman End of Study Inventory	Social Harms Assessment Log
MTN-016 Non-DataFax Forms	
Woman Medical History Log	Infant Medical History Log

Section Appendix 3-5
Use of MTN-016 DataFax Forms as Source Documents

In some cases the parent protocol CRF may serve as source via certified copy, however note that some MTN-016 CRFs require more detail than the parent protocol forms provide.		
MTN-016 DataFax Forms	Source?	Comments
Woman Demographics	Yes	Form is interviewer-administered; participant's responses are recorded directly onto the form.. Questions should NOT be certified copied from MTN-003, but updated by verbal participant report.
Woman Enrollment	No	All items are based on parent protocol or participant informed consent form.
Woman Subsequent Consent	No	All items are based on parent protocol or participant informed consent form.
Parent Protocol Participation	No	All items are based on parent protocol or other study documents.
Genetic Screening History	Yes	Form may be source for all items.
Ultrasound Results	No	All items are based on ultrasound report
Woman Follow-up Visit	No	All items are based on data recorded on other source documents.
Women Interim Visit	No	All items are based on data recorded on other source documents.
Woman Concomitant Medications Log	Yes	Form is completed primarily based on participant self-report; participant responses are recorded directly onto the form. If medical records are available to document participants' use of medications, these records also will be used as source. If available medical records do not agree with participant reports of use of medications, the medical records will be used as source and any discrepancies with participant report will be documented in chart notes.
Pregnancy Report and History	Mixed	Items 1, 2 and 3 may be based on source data from parent protocol, May be source for items 4 and 5.
Pregnancy Outcome	Mixed	Medical records ideally will be obtained to document pregnancy outcomes. When such records are obtained, they will serve as source for data recorded on this form. Otherwise, the form will serve as source for recording participant-reported pregnancy outcome data.
Social Harms Assessment Log	Yes	Form is interviewer-administered; participant responses may be recorded directly onto the form.
Woman 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.
Woman Participant Transfer	No	All items are based on data recorded on other source documents.
Woman Participant Receipt	No	All items are based on data recorded on other source documents.
Woman End of Study Inventory	No	All items are based on data recorded on other source documents.

Section Appendix 3-5
Use of MTN-016 DataFax Forms as Source Documents

In some cases the parent protocol CRF may serve as source via certified copy, however note that some MTN-016 CRFs require more detail than the parent protocol forms provide.		
MTN-016 DataFax Forms	Source?	Comments
Woman Termination	No	All items are based on data recorded on other source documents.
Infant Enrollment	Mixed	Item 4 may be source. All other items are based on source data recorded on participant informed consent form or Pregnancy Outcome Form.
Infant Visit	Mixed	May be source for items 1-4. Items 5-8 are based on data recorded on other source documents.
Infant Physical Exam	Yes	May be source for all items.
Infant Developmental Screening	Mixed	Item 1 is based on source data recorded on the visit checklist. May be source for item 3. However, this form may not be used as source if results of the testing are first reported elsewhere and then transcribed to this form.
Infant HIV Test	No	All items are based on data recorded on other source documents.
Infant Interim Visit	No	All items are based on data recorded on other source documents.
Infant Concomitant Medications Log	Yes	May be source for all items.
Infant 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.
Infant Participant Transfer	No	All items are based on data recorded on other source documents.
Infant Participant Receipt	No	All items are based on data recorded on other source documents.
Infant End of Study Inventory	No	All items are based on data recorded on other source documents.
Infant Termination	No	All items are based on data recorded on other source documents.

Section Appendix 3-6
Use of MTN-016 Non-DataFax Forms as Source Documents

MTN-016 DataFax Forms	Source?	Comments
Woman Medical History	Yes	Form is source for all items; chart notes also will be used as needed to further document the details of condition recorded on this form. For co-enrolled participants, certified copies of parent study medical history source documents may be used as source.
Infant Medical History	Yes	All items based on verbal report from mother/guardian.