

Section 3. Documentation Requirements

Study site staff is responsible for the collection, storage, timely submission, and quality assurance of study data collected at their site. In addition, the site is responsible for maintaining all administrative and regulatory documentation critical to the conduct of the study, known as Essential Documents. This section contains a listing of required Essential Documents that each site must maintain and keep current throughout the study, as well as procedures for establishing adequate and accurate participant research study records.

3.1 Essential Documents

The Division of AIDS (DAIDS) policy on *Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials* specifies the essential documents that study sites must maintain for DAIDS-sponsored studies, including HPTN 057.

When required essential 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. In its policy on *Requirements for Manual of Operational Procedures*, DAIDS requires study sites to establish a standard operating procedure (SOP) for maintaining essential documents.

Table 3-1 presents a suggested essential documents filing structure for HPTN 057. The suggested structure incorporates guidance previously received from the DAIDS Prevention Sciences Branch and the DAIDS Clinical Site Monitoring Group. Study sites are not required to adopt the suggested structure, but are strongly encouraged to consider it when developing their filing approach for HPTN 057. All sites also are encouraged to establish a SOP to document their filing approach. Further clarifications of the suggested filing structure are as follows:

- Essential Documents may be stored in files or in binders. The files/binders listed in Table 3-1 may be further divided, consolidated, or otherwise reorganized if desired.
- It is recommended that a contents sheet be 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.
- Study drug related Essential Documents (not listed here) will be filed in the study pharmacies. A listing of Essential Documents to be maintained in the pharmacies is provided in Section 8.
- Certain lab related Essential Documents will be stored with the other Essential Documents listed here to facilitate routine inspection of these documents by study monitors. Other lab related Essential Documents (e.g., lab SOPs not listed here) may be filed in the lab.

The suggested filing structure assumes that:

- Individual HPTN 057 participant study records, including signed and dated informed consent forms, will be stored separately in the study clinic(s) or data management area, not necessarily with the other Essential Documents listed here.

- The HPTN 057 Screening and Enrollment Log and participant identification number -Name Link Log will be stored in the study clinic(s) or data management area, not necessarily with the other Essential Documents listed here.
- Site- and study-specific quality management documentation will be maintained separately from study-specific Essential Documents.

3.2 Participant Research Records

Study sites must maintain adequate and accurate participant case history records containing all information pertinent to HPTN 057 for each study participant.

3.2.1 Participant Research Record Content

Mother and infant research records should contain all of the following elements:

- basic participant identifiers
- documentation that mothers provided written informed consent to participate in study screening and enrollment prior to the conduct of any study procedures
- documentation that mothers met the study's eligibility criteria
- a record of the cohort assignment
- a record of the mother and infant's exposure to study drug, if applicable
- a record of all contacts and attempted contacts with the participants, including all clinic visits, off-site contacts (e.g., at home), and all verbal and written contacts
- a record of all procedures performed by study staff during the study
- complete source documents; e.g., notes recorded by attending nurse or record of any visits to referral physicians, if available (certified copy of notes)
- a record of any adverse events (AEs) and serious adverse events (SAEs) including onset and resolution dates, severity grading and relationship to study product
- study-related information on the participant's condition before, during, and after the study, including:
 - ◆ subjective data obtained directly from the participant (e.g., interview responses)
 - ◆ objective data ascertained by study staff (e.g., exam and lab findings)
 - ◆ objective data obtained from non-study sources (e.g., medical records)

In addition to the above all protocol departures/deviations/violations be documented in participant's study records, along with reasons for the departures and attempts to prevent or correct the departures, if applicable.

3.2.2 Concept of 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 upon which source data are first recorded. All study sites must comply with the standards of source documentation specified in the DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials*. The DAIDS policy specifies both requirements and recommendations. Study sites must comply with all requirements and are encouraged, but not required, to comply with all recommendations.

For each HPTN study, participant case history records typically consist of some or all of the following:

- narrative chart notes
- visit checklists or flow sheets
- laboratory reports
- medical records or clinic charts
- DataFax case report forms
- randomization log or other documentation (when applicable)
- investigational product dispensing and accountability records (when applicable)
- other source documents and non-DataFax study forms/questionnaires

As a condition for study activation, each site must establish an SOP for source documentation that specifies the use of these documents as source documents. Study staff must follow the specifications of this SOP consistently for all study participants throughout the study. It is the responsibility of the study site to determine the most appropriate source document for each required case history element listed in Section 3.2.1. Table 3-2 at the end of this section provides example source documents for each case history element for this study. Each site must complete a site-specific version of this table. In the event that study staff is not able to record source 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 case report form (CRF)
- enter a chart note stating the reason why an alternative source document was used.

Supplemental information on the use of chart notes and DataFax and non-DataFax forms as source documents is provided below.

3.2.3 Document Organization

Study staff must make every effort to keep all research records – individual participant records as well as logs and documents pertaining to all participants – confidential and secure. All records should be securely stored in an area with access limited to authorized staff only.

All study-specific documents that are transmitted to an off-site location, including DataFax case report forms, x-ray reports, expedited adverse event/experience EAE Report Forms and all biological specimens processed in any way by non-study staff or transferred to an off-site location must be identified only by the participant's study identification number (PTID) to maintain confidentiality. Inclusion of more than one identifier on other study records that are accessible only to authorized study staff is not prohibited by DAIDS; however, such records must be stored securely with limited access.

Study records must be stored in the same manner for all participants. Study records that contain participant names or other personal identifiers, such as locator forms and informed consent forms, should generally be stored separately from study records identified by PTID. Regardless of whether the participant identifier on a particular document is the participant's 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 or altered on *copies* of original source documents. For example, if medical records obtained from a non-study medical provider bear the participant name, the original document must remain unaltered and should be stored with other study documents bearing the participant's name. A copy of the document could be added to the participant's chart, with the participant's name obliterated from the copy and his/her PTID entered onto the document. Likewise, if supporting documentation for an EAE Report that is to be submitted to DAIDS, such as x-rays or lab reports, contains a participant's name, this should be obliterated on the copy transmitted off-site, but not on the original.

All local databases will be secured with password-protected access systems. Log books, appointment books, and any other listings that link PTID numbers to participant names or other personal identifiers should be stored securely in a location separate from records identified by either PTID or name. These documents should never be left unattended or accessible to unauthorized individuals.

It is strongly recommended that each site designate a single place where completed DataFax forms will be stored prior to transmission and a single place where transmitted forms will be stored prior to filing in participant charts. A similar system should be established for EAE Forms and other records (e.g., laboratory results forms) that are transmitted to off-site locations and then returned to the participant's file. 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 PTID numbers, linking PTID numbers to participant names, and storing the name-number link log
- Procedures for establishing participant files/charts/notebooks
- During-visit participant chart and case report form (CRF) 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 (QC) notes sent from the SDMC
- Procedures for handling and filing field workers logs, worksheets, etc.
- Storage locations for blank case report forms
- Procedures for back-up of electronic study data
- Handling of participant study records for off-site contacts and visits
- Confidentiality protections
- Other ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- Staff training requirements
- Quality Control/Quality Assurance (QC/QA) procedures related to the above (if not specified elsewhere)

3.2.4 Chart Notes

Chart notes may be used to document the following:

- 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 the protocol deviation form or other source documents

All chart notes or other tools used as source documentation must document the PTID number and/or name of the study participant to whom they pertain, the identity of the study staff member who entered information, and the date of the entry. 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.

3.2.5 DataFax and Non-DataFax Forms Provided by the SDMC

CRFs are designed for use with the DataFax data management system described in Section 12. The SDMC will provide these forms to each site taking part in the study. The SDMC may also provide some non-DataFax forms to each participating site.

3.3 Record Retention Requirements

All study records must be maintained for at least two years following the date of marketing approval of the study product for the indication in which it was studied. If no marketing application is filed, or if the application is not approved, records must be retained for two years after the US Food and Drug Administration is notified that the Investigational New Drug application for the product is discontinued.

The sponsor will provide further instructions for long-term storage of study records after the study is completed.

3.4 Product Dispensing and Accountability Records

The receipt, dispensing, and final disposition of all study drug supplies used must be documented by designated study site staff in accordance with the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks*, as well as any supplemental instructions provided by DAIDS Pharmacy Affairs Branch (PAB), the study protocol, and/or Section 8 of this SSP Manual.

3.5 Protocol Deviation Reporting

The HPTN has developed a policy to cover the reporting of protocol deviations, defined as individual incidents or omissions in study conduct that result in:

- Significant added risk to the participant
- Non-adherence to significant protocol requirements
- Significant non-adherence to the International Conference on Harmonization E6: Guidelines for Good Clinical Practice

Examples of protocol deviations that will require formal documenting are as follows:

- Enrollment of an ineligible participant
- Informed consent not obtained prior to performing protocol-specified procedures
- Significant protocol-specified procedures not followed. (*Note: Participant non-compliance with the study protocol, including missed visits, is not considered a reportable protocol deviation.*)
- Breach of participant confidentiality

All protocol deviation reports should be sent to the following distribution list and a copy kept at the site:

- Protocol Chair
- Investigator of Record at site
- Site Study Coordinator
- DAIDS Medical Officer
- NICHD Medical Officer
- Member of the DAIDS Clinical Operations Group
- DAIDS Protocol Pharmacist
- CORE Protocol Specialist
- SDMC Project Manager
- HPTN NL Representative

Refer to the HPTN Manual of Operations, Section 16.2 available at: <http://www.hptn.org/HPTNMOP2007/HPTNMOP2007.htm> for a full description.

3.6 Ancillary Studies

Ancillary studies or “sub-studies” are defined as secondary investigations conducted in conjunction with a primary or “main” study. The investigator proposing the ancillary study is responsible for ensuring that all necessary approvals are obtained and that all relevant IMPAACT and DAIDS procedures are followed. All ancillary studies using IMPAACT funding and/or data or biological specimens from a primary HPTN study are subject to HPTN administrative approval and, if applicable, to DAIDS regulatory approval. The purpose of the review and approval process is to ensure that site and central network resources are being used appropriately and that the rights and well being of human subjects are protected in accordance with

45 CFR 46. The administrative and regulatory requirements for the conduct of ancillary studies can be found on the IMPAACT website.

3.7 Study Publications

All manuscripts, abstracts, posters or presentations based on the results or conduct of HPTN 057 must be prepared in accordance with the IMPAACT and DAIDS Publication policy and the Clinical Trials Agreement (CTA). The CTA specifies that Gilead Sciences Inc. shall receive copies of any abstract, poster, presentation, or manuscript prior to its submission for publication with sufficient time for review and comment. Recognizing that Gilead Sciences Inc. staff play an important role in the design, analysis, and interpretation of the findings of HPTN 057, reasonable consideration shall be given by the investigators and DAIDS to include appropriate individuals from Gilead Sciences in the authorship of publications.

Table 3-1. Suggested Filing Structure for HPTN 057 Essential Documents

<p>File/Binder #1: HPTN 057 Protocol and Current Informed Consent Forms</p> <ol style="list-style-type: none"> 1. HPTN 057 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 site-specific HPTN 057 informed consent forms
<p>File/Binder #2: Regulatory Authority Documentation (if applicable)</p> <ol style="list-style-type: none"> 3. Regulatory Authority Correspondence/Authorization/Approval/Notification of Protocol (if applicable; if more than one regulatory authority has oversight responsibility for research performed at the study site, include subsections for each authority)
<p>File/Binder #3A: IRB/EC Documentation for (IRB/EC A)</p> <ol style="list-style-type: none"> 4. FWA documentation for IRB/EC A 5. Roster of IRB/EC A (if available) 6. Relevant IRB/EC A Submission Requirements/Guidelines/SOPs 7. IRB Correspondence for IRB/EC A: File complete copies of all correspondence to and from the IRB/EC; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere 8. IRB approval documentation; include stamped consents if approval letter does not reference which version of the consents were approved and designation of children risk/benefit category
<p>File/Binder #3B: IRB/EC Documentation for (IRB/EC B)</p> <ol style="list-style-type: none"> 9. FWA documentation for IRB/EC B 10. Roster of IRB/EC B (if available) 11. Relevant IRB/EC B Submission Requirements/Guidelines/SOPs 12. 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 13. IRB approval documentation; include stamped consents if approval letter does not reference which version of the consents were approved
<p>File/Binder #4: Product Safety Information</p> <ol style="list-style-type: none"> 14. Investigator’s Brochure for Tenofovir Disoproxil Fumarate (as provided by DAIDS): current version and any subsequent updates 15. Product Safety Information/Reports/Memos (as provided by DAIDS) 16. Tenofovir Disoproxil Fumarate: current version and any subsequent updates <p><i>Notes:</i></p> <ul style="list-style-type: none"> • Expedited adverse event reports will be stored in participant study notebooks. • 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: HPTN 057 Study-Specific Procedures (SSP) Manual</p> <ol style="list-style-type: none"> 17. Final version 1.0 and any subsequent updates <p><i>Notes:</i></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 DOCUMENTS files.
<p>File/Binder #6: HPTN 057 Study-Specific Standard Operating Procedures</p> <ol style="list-style-type: none"> 18. Final approved version of each SOP, and any subsequent updates to each

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<p>File/Binder #7: HPTN 057 Staffing Documentation</p> <ol style="list-style-type: none"> 19. FDA Form 1572 (copy of original and dated form submitted to FHI for Protocol Registration, and any subsequent updates) 20. HPTN 057 Investigator of Record CV (copy of CV submitted to FHI for Protocol Registration; it is recommended that CVs be updated as needed and signed and dated at least annually) 21. Financial Disclosure Forms (original signed and dated forms, and any subsequent updates) 22. Study Staff Roster (original submitted to FHI for study activation, and any subsequent updates) 23. Study Staff Identification and Signature Sheet (if not combined with staff roster; original and any subsequent updates) 24. Study Staff Delegation of Duties (if not combined with staff roster; original and all updates) 25. CVs for key study staff other than the IoR including all subinvestigators, clinicians, the study coordinator(s), and Pharmacist of Record (ensure that all CVs are current prior to initiating HPTN 057; it is recommended that CVs be updated and signed and dated at least annually) 26. Study Staff Job Descriptions 27. Documentation of Study Staff Training
<p>File/Binder #8: Local Laboratory Documentation</p> <ol style="list-style-type: none"> 28. Local Laboratory Certification(s), Accreditation(s) and/or Validation(s): File documentation current at time of study activation and all subsequent updates 29. 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 30. Laboratory Manager CV (or cross-reference to CV contained in File/Binder #7) <p><i>Note:</i></p> <ul style="list-style-type: none"> • <i>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).</i>
<p>File/Binder #9: Monitoring Visit Documentation</p> <ol style="list-style-type: none"> 31. Monitoring Visit Log 32. Initiation and Monitoring Visit Reports and Documentation of Response to Visit Findings
<p>File/Binder #10: Documentation of Other HPTN Site Visits</p> <ol style="list-style-type: none"> 33. (Non-Monitoring) Site Visit Log 34. HPTN CORE (FHI) Site Assessment Reports and Documentation of Response to Visit Findings 35. HPTN SDMC (SCHARP) Site Visit Reports and Documentation of Response to Visit Findings 36. HPTN Network Lab Site Visit Reports and Documentation of Response to Visit Findings 37. 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"> 38. Study-related communications to and from DAIDS 39. Communications to and from the DAIDS RCC (includes emails acknowledging receipt or approving protocol registration from the DAIDS Protocol Registration Office) <p><i>Notes:</i></p> <ul style="list-style-type: none"> • <i>Communications related to individual study participants will be filed in participant study records.</i> • <i>Product-related communications with DAIDS PAB (and its contractors) will be stored in the study pharmacy.</i>
<p>File/Binder #12: Other Study-Related Communications</p> <ol style="list-style-type: none"> 40. Key study-related communications to and from HPTN CORE (FHI) 41. Key study-related communications to and from HPTN SDMC (SCHARP) 42. Key study-related communications to and from HPTN Network Lab 43. Other Key study-related communications <p><i>Notes:</i></p>

Table 3-1. Suggested Filing Structure for HPTN 057 Essential Documents

<ul style="list-style-type: none">• <i>Any documentation of agreements or significant discussions regarding study conduct, protocol violations, or adverse event reporting should be filed.</i>• <i>Communications related to individual HPTN 057 study participants will be filed in individual participant study records.</i>• <i>Product-related communications with DAIDS PAB (and its contractors) will be stored in the study pharmacy.</i>
File/Binder #13: Study Site Staff Meeting Documentation 44. HPTN 057 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries
File/Binder #14: Conference Call Documentation 45. HPTN 057 Protocol Team Conference Call Summaries 46. HPTN 057 Laboratory Group Conference Call Summaries 47. HPTN 057 Protocol Safety Review Team Call Summaries 48. Summaries of Other HPTN 057 Conference Calls, such as site-specific calls
File/Binder #15: Reference Documentation 49. DAIDS Protocol Registration Policy and Procedures Manual (August 2004 and any subsequent updates) 50. Manual for Expedited Reporting of Adverse Events to DAIDS (Version 1.0, May 6, 2004 and any subsequent updates) 51. US Regulations Applicable to Conduct of HPTN 057 (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 including Activation Notice

Table 3-2. Sample HPTN 057 Required Case History Element and Source Document Guide

HPTN 057 Required Case History Element	HPTN 057 Source Documents – [EXAMPLE TEXT]
Basic mother and infant participant identifiers.(e.g. name, date of birth)	<i>Locator form; screening and enrollment logs; Medical records.</i>
Documentation that the mother provided written informed consent for screening study prior to initiation of study screening procedures.	<i>Signed and dated Screening Informed Consent Form; signed and dated Informed Consent Coversheet.</i>
Documentation that the mother provided written informed consent to participate in the study prior to initiation of study procedures.	<i>Signed and dated Enrollment Informed Consent Form; signed and dated Informed Consent Coversheet.</i>
Documentation that the mother met the study inclusion/exclusion criteria:	
Age	<i>Mother’s Medical Record</i>
HIV status	<i>Laboratory Records¹</i>
Stated intent to deliver at the study site	<i>Chart Note or Mother’s Medical Record</i>
Stated willingness to be contacted or visited at home	<i>Chart Note or Mother’s Medical Record</i>
Stated willingness to be admitted to and remain in delivery facility through Day 3 postpartum (Cohort 1)	<i>Chart Note or Mother’s Medical Record</i>
Stated willingness to be admitted to and remain in delivery facility through Day 7 postpartum (Cohorts 2, 3 and 4)	<i>Chart Note or Mother’s Medical Record</i>
No prior treatment with TDF	<i>Mother’s Medical Record</i>
No active opportunistic infection and/or serious bacterial infection	<i>Mother’s Medical Record</i>
Did not have laboratory values as follows on the most recent test prior to study entry: hemoglobin < 8 gm/dL, alanine aminotransferase (ALT [SGPT]) > 3 x upper limit of normal (ULN), serum creatinine > 1.5 mg/dL	<i>Laboratory Records¹</i>
No chronic malabsorption or diarrhea during current pregnancy, according to WHO definitions	<i>Mother’s Medical Record</i>
No evidence of clinically significant disease or condition that would compromise the ability of the participant to complete the study or the study requirements as determined by the study clinician	<i>Mother’s Medical Record</i>
No known multiple gestation this pregnancy (prior to enrollment)	<i>Mother’s Medical Record</i>
No participation in any other therapeutic or vaccine trial during the current pregnancy	<i>Mother’s Medical Record</i>
Did not use atazanavir or lopinavir/ritonavir (Katra [®]) within 2 weeks of anticipated delivery date (Cohorts 1, 2 and 3)	<i>Mother’s Medical Record</i>
Did not use of any of the following disallowed medications within two weeks of anticipated delivery date: investigational agents, heparin, highly nephrotoxic drugs (such as amphotericin B, cidofovir, ganciclovir, or valganciclovir), or dideoxyinosine	<i>Mother’s Medical Record</i>

¹ A study clinician must review all laboratory reports and document this review by signing and dating the reports

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HPTN 057 Required Case History Element	HPTN 057 Source Documents – [EXAMPLE TEXT]
No other condition or situation that, in the opinion of the investigator, would interfere with study participation or interpretation.	<i>Mother’s Medical Record</i>
Documentation that the infant met the Infant Inclusion Criterion	
Born to an HIV infected mother enrolled in the study	<i>Medical Birth Record</i>
For Cohorts 2, 3 and 4 documentation that the infant met the Exclusion Criteria for Initial Infant Dosing	
Birth weight of at least 2000 gm	<i>Medical Birth Record</i>
No severe congenital malformation or other medical condition not compatible with life or that would interfere with study participation or interpretation, as judged by the examining clinician	<i>Infant’s Medical Record</i>
No Grade 2 or higher serum creatinine level or any other Grade 3 or higher toxicity known prior to dosing (Note: test results not required prior to dosing)	<i>Laboratory Records¹</i>
No multiple birth	<i>Infant Medical Record</i>
Documentation of the assignment of the study cohort	<i>Mother’s Medical Record</i>
Study Drug Dispensation	<i>Study Drug Accountability Records; Study Product Receipt/Return Records</i>
A record of all contacts, and all attempted contacts, with the participant (e.g. home visits, telephone contacts, etc.).	<i>Chart notes (signed and dated), and/or other worksheets or local documents if designated in local SOPs. Home visitor records.</i>
A record of all procedures performed by study staff.	<i>Chart notes (signed and dated) detailing (a) procedures performed in addition to scheduled procedures and/or (b) the reason why scheduled procedures were not performed. Medical Records, Lab Records, Study-specific Source Documents</i>
Information on the participant’s condition before, during, and after the study.	<i>Medical Records; Laboratory Records², Study-specific Source Documents; Reports of information pertinent to the study obtained from non-study sources; chart notes (signed and dated).</i>

¹ A study clinician must review all laboratory reports and document this review by signing and dating the reports