MTN Good Documentation Policy

Creation and Maintenance of Records Documenting Study Development, Management, Conduct, Analysis and Reporting

Network records documenting clinical (biomedical and/or behavioral) research study development, management, conduct, analysis and reporting will be created and maintained by each element and investigator of the MTN according to the following standards. Specifically, this will include those network elements listed in Table 9.1.

Table 9.1: MTN Elements Required to Create and Maintain Source Documentation

• MTN Executive Committee
• Leadership & Operations
• Operations Support Core
• Statistical Data Management Center
• Pharmacy Operations
• Laboratory Center
• Protocol Support Core
• Virology Core
• Pharmacology Core
• Endpoint Adjudication Committee
• Clinical Research Sites
• Working Groups
• Behavioral Research
• Biomedical Research
• Community
• Resource Committees
• Manuscript Review
• Network Evaluation
• Study Monitoring
• Protocol and Study Management Teams
• Protocol Safety Physicians

MTN Leadership & Operations Center will assist each element and investigator, as needed, determine which records are critical to this process; but, in general, they can be described as those original documents, data, recordings and certified copies of original records necessary for the reconstruction and evaluation of clinical (biomedical and/or behavioral) research studies. The following Table 9.2 provides a partial listing:

Table 9.2: Clinical Research Study Records (partial listing)

• Internal Policies & Procedures
• Personnel Qualification &Training Records
• Regulatory Submissions
• Regulatory Approvals (FDA, DAIDS, IRB, IEC)
• All Communication with Regulatory Bodies[1]
• All Communications with Product Sponsors[1]
• Contracts (all)
• All Communications with Non-Network Sub-Contractors[1]
• Investigator Brochures & Notices of Receipt
• Protocols
• Letters of Amendment
• Clarification Memos
• Statistical Analysis Plans (all)
• MTN Pharmacy Guidelines and Instructions Manual for MTN Clinical Trials
• Study-Specific Pharmacist Study Product Management and Procedures Manual
• Study Specific Procedures Manuals
• Network/Site Communications[1]
• All Relevant Documentation Pertaining to Site Trainings Provided by Network Staff
• Summary Reports of All Network/Site Visits
• Minutes of Working Group Meetings
• Minutes of Resource Committee Meetings
• Protocol Team & Management Meeting Minutes
• Protocol Safety Physician Decisions
• Protocol Safety Review Team (PSRT) Teleconference/Meeting Minutes
• All Data, including any test, repeat or reanalysis performed for a test sample[2]
• Reports Prepared for Data Safety Monitoring Boards
• Reports Prepared for Study Monitoring Committee (SMC) Reviews and Interim Study Reviews
• Reports Resulting from Study Monitoring Committee Reviews and Interim Study Reviews

[1] Relevant to study development, management, conduct, analysis and reporting.
[2] Especially applicable to MTN Laboratories and Clinical Research Sites

Each Clinical Research Site will continue to follow the documentation requirements set forth in the *ICH E6, Guideline for Good Clinical Practice*.

The use of electronic systems/software to create, sign, date, track and/or store study records is not permitted without the written permission of the leadership of the applicable Network organizational unit (SDMC, LC or MTN LOC.) All electronic systems which are relevant to the rights, safety and wellbeing of study participants and/or the quality and integrity of study data and results will be validated before use and comply with the requirements of 21 CFR Part 11 and CPMP/ICH/135/95. Each proposed system will be individually evaluated and approved.

In the absence of electronic systems approved for use by the relevant Network leadership (SDMC, LC, LOC), the procedure for creating, collecting and storing study records will be as follows:

- Records will be collected and stored in paper and electronic form, in a timely manner
- Records (source documents) may be electronically generated initially but must be printed and hand-signed and hand-dated by the author and in some cases by the person under whose authority the information has been generated
    - If factual information has been verified by a second individual, this person also needs to hand-sign and hand-date
    - All roles (authorship, authority, verification) should be specified
- Electronic records will be created by scanning source documents into limited access files
- Certified, paper copies of electronic or paper source documents will be created, as necessary, by having the person making the copy write a circled “C” on the copy, hand-sign and hand-date
    - Documents consisting of more than one page may be certified by—
        - Writing a circled “C” on each page of the copy
        - Hand-signing, initialing and hand-dating the first page and
        - Initialing and hand-dating each subsequent page (marked with a circled “C”).
    - A “Certified” stamp may be used in place of the circled “C”
- Both paper and electronic files will be maintained in secure, limited access files, protected to the extent possible from physical damage and loss
- Electronic files will be routinely backed up and original date/time stamps will be maintained
- MTN LOC (Pitt) will return to sender as unacceptable all study documentation it receives that has not been provided as a scanned, properly hand-signed and hand-dated record

The objective of this procedure is that all study documentation will be attributable, legible, contemporaneous, original, accurate and unquestionably reliable.

In accordance with the requirements of MTN Manual of Operational Procedures (MOP) section, “Study Close-Out”, all study records, including paper files, electronic study data, electronic documents and audio files of interviews, will be maintained on site for the entire period of study implementation and for an extended period after study completion or

discontinuation. During such time, study records must be available and accessible for possible DAIDS, MTN, product sponsor or regulatory authority inspection or review. Guidance for long-term record storage will be provided by the LOC (FHI 360) CRM in consultation with DAIDS and the MTN Executive Committee. See MOP section 18 for additional details.