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3 GOOD DOCUMENTATION PRACTICE

3.1 Introduction to Good Documentation Practices within the IMPAACT Network

Good Documentation Practices (GDP) play an important role to ensure effective communication between all IMPAACT Network members, clearly illustrate document histories, and demonstrate compliance with Good Clinical Practice (GCP) guidelines (International Council on Harmonisation Good Clinical Practices, ICH E6(R2)). This section sets minimum standards for GDP compliance within the IMPAACT Network. Each Network organization (Leadership and Operations Center (LOC), Laboratory Center (LC), Statistical and Data Management Center (SDMC), and Clinical Trials Unit/Clinical Research Site (CTUs/CRSs)) may have additional, specific requirements.

Documentation includes all records—in any form—that describe or record the methods, conduct, and/or results of a study, the factors affecting a study, and the actions taken. They are created throughout the protocol lifespan, from protocol development through publication and close-out. Applicable documents may include, but are not limited to, the following:

- Regulatory submissions and approvals
- Protocol documents (protocols, Letters of Amendment, Clarification Memoranda, Full Protocol Amendments, Summaries of Changes)
- Site selection documents
- Training materials, attendance sheets, and presentations
- Study-specific Manuals of Procedures
- Laboratory Processing Charts
- Study Progress, Data, and Safety Monitoring Plans
- Statistical Analysis Plans
- Site-specific Study Activation Checklists
- Data collection instruments
- Call summaries
- Monitoring reports
- Operational guidance documents (e.g., fact sheets, Frequently Asked Questions (FAQs), infographics)
- Monitoring Committee (SMC or DSMB) reports and responses
- Notes to file and other study memoranda
- Personnel qualification and training records

Documents must be accurate and written in a manner that ensures both internal document consistency and consistency with other applicable reference documents. If documents are to be used together, then each should clearly reference the other.

The use of electronic systems/software to create, sign, date, track and/or store study records is permitted by the applicable Network organization or CTU/CRS. Division of AIDS (DAIDS) guidance and recommendations for electronic systems to be used in the conduct of IMPAACT studies is provided in the Electronic Information Systems (EIS) Policy, which is available at https://www.niaid.nih.gov/research/daids-clinical-site-implementation-operations.

Throughout this Manual, guidance is provided on the assigned primary author(s), required Network or protocol team member reviews, and the associated review and approval steps of various Network and protocol documents. It is the assigned primary author's responsibility to ensure timely updates, distribution, maintenance, version and change control, and record management. Each primary author must comply with applicable policies, guidelines, and/or standard operating procedures (SOPs) for their organization. Additionally, all documents developed for IMPAACT studies should follow the guidelines included in this section.

This section outlines the principles and guidelines for good documentation practices. These guidelines apply to all site and central resource staff working on IMPAACT studies. For additional guidance, the DAIDS Good Documentation Policy and job aid are available at: https://www.niaid.nih.gov/research/daids-clinical-research-protocol-informed-consent.

3.2 General Guidelines for Document Creation, Review, and Management

Consistent with good documentation practices, all study documents should meet the ALCOA+ elements, as shown in Figure 3.1.

Figure 3.1. ALCOA+ Elements to Ensure Good Documentation Practices

A	**Attributable**	It should be obvious who created a document and when it was created. Similarly, if any changes were made, it should be obvious who made the change, when the change was made, and why.
L	**Legible**	The document should be easy to read.
C	**Contemporaneous**	Information should be recorded as it was observed. When signatures are required, all signatures/initials should be attached to a date indicating when the signature was added to the document.
O	**Original**	Records should be original and not a photocopy.
A	**Accurate**	Study records should have a high level of integrity and honesty to what was truly observed. Records should be thorough and correct and checked for unintentional errors.
+		Complete: Documentation should be thorough and free from losses and omissions of key information. Consistent: Information should be recorded and presented in the expected manner and sequence. Enduring: Records must be maintained throughout the entire lifecycle of a study and in accordance with all applicable laws and regulations. Available: Information should be accessible whenever needed or requested.

3.2.1 Document Identifiers

Every controlled document, tool, template, etc., should contain unique identifiers. "Controlled document" refers to any document, either digital or paper, that must be managed in a way that protects the integrity of the document's content through revisions. If a document is not final, it should be clearly marked as a draft.

Documents should include a title to allow for rapid identification of the document; in general, the following identifiers should also be included:

- Brief title of the document (For study-specific documents, the study number, e.g., "IMPAACT ####", should be included in the title)
- Page numbers, following the standard of "X of Y", with Y indicating the total number of pages, for multipage documents (Note: For PowerPoint or other presentation slides, page numbers may be excluded)
- Date (using unambiguous formatting, e.g., 12 APR 2023 rather than 04/12/23)
- Version number (if applicable; Note: For PowerPoint or other presentation slides, version numbers may be excluded)
- Roles (author and approver, as applicable)

A table of contents is recommended for long documents to facilitate finding specific sections within the document. (Note: Per Electronic Common Technical Document [eCTD] requirements, any protocol document that is five or more pages must include a table of contents.)

3.2.2 Document Review and Approval

Document review and approvals follow standard procedures as outlined in other sections of this Manual. To assist with compliance to good documentation practices, documents should generally be reviewed by a secondary author or designated Network or protocol team member to ensure that the information is correct and accurate.

Confirmation that a review has taken place and approval from required members should be documented and include the approval date. The primary author should follow their organization's guidelines and/or SOPs on obtaining approvals. If the organization does not have established procedures, approval may be obtained through written electronic communications (e.g., an email or scanned wet signature) unless a signature is required pursuant to FDA predicate rules. Any confirmation of review and approval must include the approval date, based on receipt of the email, electronic signature, or handwritten date on a wet signature approval form.

The following signature best practices are encouraged when obtaining necessary approvals:

- Include a printed or typed name along with the signature on documents requiring sign-off, using blue ink if handwritten. (If using a 21 CFR Part 11 compliant system, the typed name and date of signature will automatically be generated by the signature software.)
- When using a 21 CFR Part 11 compliant electronic platform, select the appropriate reason for sign-off from the software options (e.g., "I am the document author," "I am the document approver," "I have read and understand this document," or "I have trained on this document").
- Optional: A person's title or role on the study may also be included.
- Ensure, to the extent possible, that a handwritten date accompanies a handwritten signature and is in an unambiguous format (e.g., 12 APR 2023 rather than 04/12/23).

DAIDS has provided guidance outlining signature requirements for documents submitted to the DAIDS Protocol Registration Office, which may be used as guidance for additional documents: https://rsc.niaid.nih.gov/resources/signature-requirement-guidance.

3.2.3 Document Distribution

Once finalized, all documents that are not to be altered or used as tools should be saved in portable document format (PDF) prior to distribution. The PDF helps to prevent inadvertent changes in the document post finalization. Document distribution should occur as efficiently as possible post document finalization to ensure the document remains contemporaneous and up-to-date. The primary author is responsible for ensuring the document is distributed to the required and/or most appropriate persons. Electronic distribution by email is the preferred method of the IMPAACT Network to distribute finalized documents.

3.2.4 Reviews, Updates, and Management

Documents are reviewed and updated, as applicable, per procedures as outlined in relevant sections of this Manual. A periodic review of documents may be completed to ensure documents are kept current; this review is the responsibility of the primary author(s).

When modifications must be made to finalized documents, the revised version must be saved with indicators reflecting the revised nature of the document; for example, a new version number and/or date that follows the logical sequence of the prior distribution. Edits affecting content should be reviewed, and confirmation of the review and approval of the edited document should be obtained. Unless otherwise required, minor grammatical edits or small corrections do not require a formal review and approval.

Once the revised document is finalized, the document should be distributed with a summary of changes, including (when appropriate) the reason for the correction(s). The summary of changes may be communicated within the text of an email; however, a cover page, separate summary of changes document, or a version control and document history table within the document are preferred.

To ensure the most up-to-date version is used, all prior versions of documents should be archived and individuals receiving the updated document should be notified as such.

3.2.4.1 Corrections

Any correction or modification to any applicable documents that does not result in issuance of an updated document should include a single line through the original entry, with initial and date. If needed (e.g., source document), an explanation of the change should be included.

3.2.5 Document Storage

Documents should be filed in a consistent and logical way for easy retrieval upon request. To the extent possible, files should be maintained in a secure manner with limited access and be protected from physical damage and loss. All study documents should be stored through study implementation, study closeout and as required by the study protocol, study sponsor, Institutional Review Board/Ethics Committee (IRB/EC), and regulatory authorities. See Section 14 for additional details related to document retention.

3.2.6 Trial Master Files

The Trial Master File (TMF) is a collection of documents that individually and collectively permit the evaluation of the conduct of a study and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with GCP standards, as well as with other applicable regulatory requirements.

As of May 2021, DAIDS utilizes a decentralized approach for new TMFs. TMF documents will be stored in multiple DAIDS-approved electronic systems maintained by Electronic System Owners. DAIDS is responsible for communicating which IMPAACT Network studies require creation and maintenance of a TMF. Individual IMPAACT Network groups are responsible for maintaining sponsor-delegated documents in study TMFs, according to their applicable organizational policies and as assigned by DAIDS. The study sponsor is ultimately responsible for the full TMF for all IMPAACT studies after study closure and ensuring suitable archive is available.