Title: CP-CTNet Source Record Guide

Version: 4.0

Version Date: November 03, 2025

REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
4.0	NOV-03-2025	Updated the term “source document” to “source record” throughout the document to align with E6(R3) *Good Clinical Practice*. Added significant clarifying updates and made minor editorial changes throughout the document.
3.0	MAY-01-2024	Minor clarifications throughout document.
2.0	FEB-21-2023	Added section 3 *Definitions*, reformatted section 12 *References*, and made minor clarifications throughout document.
1.0	AUG-05-2020	Original version of document.

1. INTRODUCTION AND PURPOSE

The Cancer Prevention Clinical Trials Network (CP-CTNet) Source Record Guide provides clinical trial staff conducting CP-CTNet studies with information on source records in the following areas:

- Defining source records,
- Examples of source records,
- What constitutes a complete set of source records,
- Creating worksheet templates for use as source records,
- Using an electronic Case Report Form (eCRF) as a source record,
- Maintaining accurate source records,
- Correcting errors on source records,
- Reconciling conflicting source data,
- Signing source records, and
- Storing and retaining source records.

This reference guide provides information about the requirements for maintaining source records for CP-CTNet studies in a manner that ensures data integrity, accuracy, consistency, and traceability for all clinical research activities.

Note: The Principal Investigator (PI) retains overall responsibility for the study and delegating study tasks, which includes ensuring that study personnel are appropriately trained on good source record practices.

2. SCOPE

This document details information regarding source records for Lead Academic Organizations (LAOs), accruing LAOs, and Affiliated Organizations (AOs) that are participating in CP-CTNet studies.

3. DEFINITIONS

Term	Definition
AE	Adverse Event
ALCOA-C	An abbreviation of a few crucial concepts in the field of clinical trials and good source records, which researchers need to implement and follow: Attributable, Legible, Contemporaneous, Original, Accurate-Complete
AO	Affiliated Organization
CFR	Code of Federal Regulations
CP-CTNet	Cancer Prevention Clinical Trials Network
DCP	Division of Cancer Prevention
eCRF	Electronic Case Report Form; eCRFs for CP-CTNet studies are located within Medidata Rave
EMR	Electronic Medical Record
ePROs	Electronic Patient-Reported Outcomes
FDA	Food and Drug Administration

Term	Definition
ICF	Informed Consent Form
ICH	International Council for Harmonization
LAO	Lead Academic Organization
M-SOP	Manual of Standard Operating Procedures
NCI	National Cancer Institute
PI	Principal Investigator
SAE	Serious Adverse Event
SOP	Standard Operating Procedure

4. DEFINING SOURCE RECORDS

Source records are “original documents or data (which includes relevant metadata) or certified copies of the original documents or data, irrespective of the media used. This may include trial participants’ medical/health records/notes/charts; data provided/entered by trial participants (e.g., electronic patient-reported outcomes (ePROs)); healthcare professionals’ records from pharmacies, laboratories and other facilities involved in the clinical trial; and data from automated instruments, such as wearables and sensors” (see E6(R3) *Good Clinical Practice Integrated Addendum to ICH E6(R1)* for more information). Source records, also known as source data or source documents, are necessary for reconstructing and evaluating a clinical trial. They describe or record the methods, conduct, and/or results of a clinical trial, the factors affecting a clinical trial, and the actions taken during a clinical trial. A clinical trial is reconstructed and evaluated during reviews for quality assurance, monitoring, and auditing. The purpose of a source record is to:

1. Provide proof of a participant’s existence,
2. Confirm that protocol-required procedures were completed and conducted as per the protocol, and
3. Verify that data reported on the study eCRFs are accurate and have not been intentionally or unintentionally modified after entry into an electronic medium.

5. EXAMPLES OF SOURCE RECORDS

Source records at a clinical trial site may include the participant’s research, clinical, hospital, institutional, and/or medical office records. These records may be maintained in paper or electronic format and typically contain the following types of information:

1. Notes from clinicians, nurses, study coordinators, and other healthcare staff.
2. Reports of procedures and tests (e.g., radiology, laboratory, surgery, and pathology).
3. Flow sheets, checklists, and worksheets.
4. Participant questionnaires.
5. Pill diaries/calendars.
6. Prescriptions and pharmacy records (e.g., accountability logs and shipping receipts).
7. Participant registration documents.
8. Study notes or memos to file.
9. Documented communication with participants, including face-to-face interviews, telephone conversations, portal communication, emails, and faxes.

10. Hospital admission forms and discharge summaries.
11. Obituaries, autopsy reports, and birth/death certificates.

6. WHAT CONSTITUTES A COMPLETE SET OF SOURCE RECORDS

Source records must be complete to ensure that data from a clinical trial are valid. Source records for CP-CTNet studies typically consist of the following:

1. Original ICF, signed by the participant and appropriately designated study staff who have been authorized by the PI to consent participants.
2. Description of the informed consent process.
3. Source records (e.g., original paper, printed and certified copy, or ready access to the information in the EMR) to support (or in the case of screen failures, to deny) all eligibility criteria, including medical/surgical history, screening/laboratory test results, eligibility worksheets, and clinician/research notes.
4. Participant registration documents.
5. Symptoms and diagnoses present at baseline, or a statement that there are none.
6. Current physical condition based on clinical observation, laboratory tests, and/or medical procedures.
7. Current medications, or a statement that there are none (and recent medication history if applicable per study requirements).
8. Method of birth control used, or reason if none, if applicable per study requirements.
9. Progress notes as well as dates and descriptions/summaries of study visits, including unplanned visits.
10. Records of out-of-window and missed study visits, including the reason(s) and attempt(s) to contact the participant.
11. Reports of procedures and tests (e.g., radiology, laboratory, surgery, and pathology).
12. Participant questionnaires (e.g., quality of life assessments).
13. Completion of the procedures required at each study visit, or non-completion and reason.
14. Improvement of baseline symptoms.
15. New or worsening symptoms, illnesses, and/or injuries occurring since baseline (e.g., AEs, SAEs).
16. Deviations from the protocol requirements, regardless of cause.
17. Study agent randomization and prescriptions.
18. Study agent instructions, dispensation, and return.
19. Study agent administration/record of intake (e.g., pill diaries/calendars), including any interruptions or changes in dosing.
20. Calculations to determine study agent compliance.
21. Documented communication with participants, including face-to-face interviews, telephone conversations, portal communication, emails, and faxes.
22. Date and reason that study participation ended.

Note: All data collected and reported in accordance with the protocol must be verifiable through corresponding source records.

7. CREATING WORKSHEET TEMPLATES FOR USE AS SOURCE RECORDS

Source record worksheet templates help clinical trial staff record source data and research visit activities in a standardized manner across all accruing LAOs and AOs participating in a CP-CTNet study. Templates are developed according to the requirements of the protocol. The LAO may create templates for use as source record worksheets and distribute them to accruing LAOs and AOs to encourage consistent data collection. The LAO must ensure that any source record worksheet templates are kept up-to-date and align with the most current version of the protocol.

A source record worksheet template for a CP-CTNet study may be developed as follows:

1. Using the protocol and relevant eCRFs from Medidata Rave for reference, add required data fields to a new blank document (e.g., the worksheet template).
2. Add appropriate titles such as “Eligibility Worksheet” or “Worksheet for Month 3 Visit.”
3. Add prompts for Participant ID, visit type and date, and a signature and date.
4. Add additional prompts as needed to:
    4.1. Capture the completion of visit activities as outlined in the protocol Schedule of Events.
    4.2. Remind users to update the cumulative eCRFs (e.g., Adverse Events, Concomitant Medications, and Study Treatment) when changes in symptoms, medication use, or study treatment are reported.
    4.3. Refer to other source records to avoid redundancy in reporting. For example, after an eligibility worksheet prompt to record whether the participant’s screening laboratory results met inclusion criteria, add a reference to the laboratory report for relevant results.
5. Ensure that negative responses are included as needed, for example, to document when a participant has no symptoms or when all visit evaluations were not completed.
6. Include space for supporting comments, with a reminder to enter them in the Comments field on the corresponding eCRF. The comments section should not capture data necessary for analysis.

If the completed worksheet is maintained as part of the medical record, local policies may direct an individual site to add an institutional header or footer or other such additions to comply with records requirements.

8. USING AN ECRF AS A SOURCE RECORD

An eCRF may be used as a source record, but in limited circumstances and only with DCP approval. An eCRF may be approved for use as a source record under these conditions:

1. The information is originally recorded on the eCRF, and
2. The protocol has specified that the eCRF is to be used as a source record.

The Investigator’s signature on the Verification eCRF at the end of the study serves as evidence of Investigator review of an eCRF used as a source record.

The FDA’s guidance on *Electronic Source Data in Clinical Investigations* promotes capturing source data in electronic form and addresses source data used to complete an eCRF.

9. MAINTAINING ACCURATE SOURCE RECORDS

Whether recorded and maintained on paper or in an electronic format, source records must meet the six fundamental principles of data quality. They must be attributable, legible, contemporaneous, original, accurate, and complete:

1. **Attributable:** The source record must clearly identify the data originator (and amender, as applicable) who created or modified the data, using a signature or initials, along with the date and time. Attribution should always be clear, consistent, and verifiable.

    1.1. Dates should be formatted with written months (e.g., 24Apr2025) instead of numbers to avoid confusion due to international differences in recording dates. Using the 24-hour clock (i.e., military time) without colons or units (e.g., 1345 for 1:45 PM) to format times is preferred, but not required.

    1.2. Electronic systems must use unique logins and passwords for traceability.

    1.3. The source record must also include relevant identifiers (e.g., Participant ID and NCI protocol number).

2. **Legible:** The source record must be readable, understandable, and clearly outline the order of steps or events included in the record. Signatures must be recognizable. If handwritten, the writer must use permanent, dark ink (e.g., black or blue) to prevent fading. Handwritten entries should never be in pencil.

3. **Contemporaneous:** The record must be signed and dated when the information is first recorded, with any updates or corrections noted in real-time as well. Late entries should be clearly labeled with the actual date of entry and an explanation for the delay. Backdating is not permitted.

4. **Original:** The source record must be the first place the information is recorded. Any transcribed or copied information on the source record must be clearly marked.

    4.1. Any copies must be made directly from the original source record, not from other copies. Each copied source record must be clearly marked (e.g., stamped or handwritten) with the word “copy” on each page and the first page must be initialed and dated by the person that made the copy. Copied records should not be altered or added to, as the original record is always the authoritative version when available.

5. **Accurate:** The information on the source record must be an error-free, truthful, valid, reliable, and consistent reflection of the data. The specifics of all procedures (e.g., time, site, route, participant response, etc.) and units of measure, as applicable, should be recorded on the source record. Any conflicts with data recorded elsewhere must be reconciled and recorded. See section 11 *Reconciling Conflicting Source Data* below for more information.

6. **Complete:** The source record must be thorough and capture all required details necessary to fully describe an event or action (e.g., information to answer the who, what, when, where, why, and how) to an outsider. All fields should be completed, and any missing information must be explained and added as necessary. See *Computerized Systems Used in Clinical Investigations* for more information.

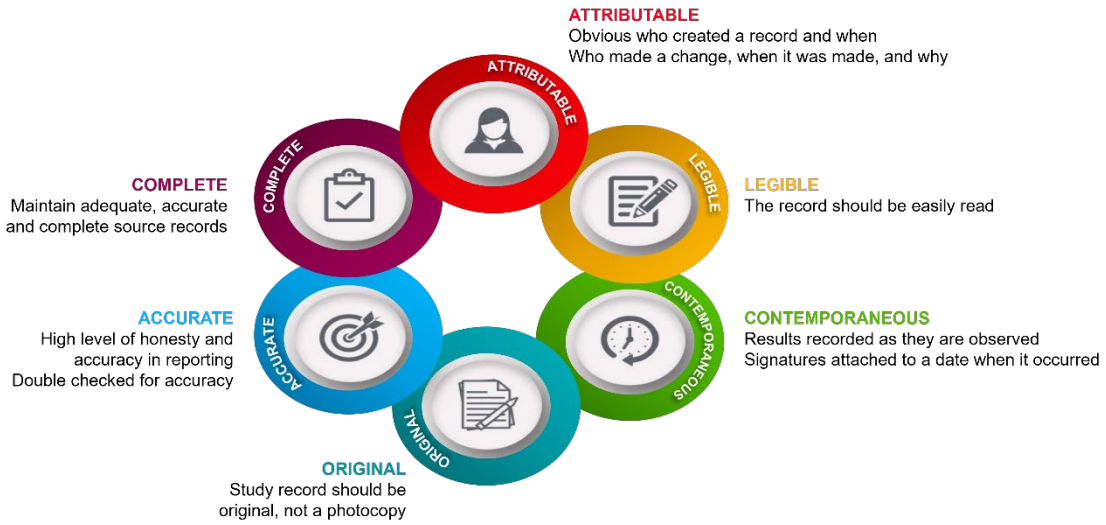

Figure 1: ALCOA-C in Clinical Trial Electronic Record Management.

Note: Electronic source record systems should be verified for accuracy, completeness, reliability, validation, controlled access, audit trail, appropriate SOPs on their use, and availability of data backup procedures.

10. CORRECTING ERRORS ON SOURCE RECORDS

Source data must be maintained in its original form, with corrections clearly indicated in accordance with the principles stated above. If a source record needs to be corrected, then the reason(s) should be clearly documented. Common source documentation errors include missing or incorrect data, missing signatures or dates, erased or obscured entries, and undocumented changes. These errors must be corrected promptly by either the original author or an authorized individual without obscuring the original entry. The following procedures apply to source data recorded on paper (e.g., a participant chart):

1. Draw a single line through the error without obscuring it, add the correct data next to or above it, include a reason for the correction, and then initial and date the correction.

    1.1. Acceptable reasons for corrections include data entry errors, late entries, technical issues, transcription or calculation mistakes, and clarity improvements. All corrections should explain what happened and why it happened. If the error involves a protocol deviation, then it must be documented and reported accordingly. See SOP 02-02 *Reporting Protocol Deviations* for more information.

2. Never erase, “black out,” or “white out” incorrect information with an ink eraser, marker, tape, or correction fluid.

3. Never write entries on scrap paper, skin, or other mediums with the intent of transferring the data to the permanent source record later.

4. Never overwrite and obscure errors with correct entries, predate or postdate entries, make corrections on behalf of others (unless authorized and documented when the original author is unavailable), or leave uncorrected mistakes.

5. Do not destroy original records even if the number of errors necessitates the creation of a new record. Indicate on the old record that a new one was created.

6. When an error is found in a clinician note, add a new note, signed and dated, to state the error and resolve the discrepancy. Do not alter the past note.

While specific procedures for correcting electronic source data may vary according to the system in use, the principles of data quality still apply. Electronic study systems should have adequate controls and logs (i.e., audit trails) to show which information has been added to, or changed from, the original information, the user that made the change, and the date and time that the change was made.

11. RECONCILING CONFLICTING SOURCE DATA

Conflicts in multiple source records must be reconciled before data are entered into the database. Efforts to identify the most authoritative source data should include consultation with relevant clinicians as appropriate. Knowledge of the site's standard clinic flow and procedures may also help inform the data reconciliation. The resolution of conflicting source data should be noted in the participant chart for quality assurance, monitoring, and auditing purposes.

12. SIGNING SOURCE RECORDS

Handwritten signatures must include the signer's printed name and the date of signing. Electronic signatures must comply with *Title 21 CFR Part 11, Electronic Records; Electronic Signatures - Scope and Application*, ensuring they include the signer's printed name, the date and time of signing, and the purpose of the signature (e.g., review, approval, responsibility, or authorship). Controls must be in place to maintain the security and integrity of electronic signatures. Each handwritten or electronic signature must be permanently linked to its corresponding source record to prevent tampering or misuse.

13. STORING AND RETAINING SOURCE RECORDS

Source records must be stored using methods that ensure that they remain readable, easily accessible, and safeguarded against damage, deterioration, or loss. Paper records must be kept in secure, controlled locations such as locked cabinets or designated filing rooms. Electronic records must be maintained on secure servers with proper access controls and regular backups to protect against data loss. Access to data should be carefully managed, particularly during staff transitions.

All source records must be retained for the period required by relevant regulatory, network, and institutional policies. See SOP 04-02 *Study Closeout* for more information.

14. REFERENCES

Note: All CP-CTNet SOPs are included in the *CP-CTNet Manual of Standard Operating Procedures (M-SOP)*, which is available on the CP-CTNet DMASC public website.

Resource	ID	Location
How ALCOA-C Impacts Clinical Trial Electronic Document Management	Reference	florencehc.com
Computerized Systems Used in Clinical Investigations	Reference	FDA.gov
Electronic Source Data in Clinical Investigations	FDA-2010-D-0643	FDA.gov
Good Clinical Practice Integrated Addendum to ICH E6(R1)	E6(R3)	FDA.gov
Reporting Protocol Deviations	SOP 02-02	Program Resources
Study Closeout	SOP 04-02	Program Resources

Resource	ID	Location
Title 21 CFR Part 11, Electronic Records; Electronic Signatures - Scope and Application	FDA-2003-D-0143	FDA.gov

15. APPENDICES

None