Title: CP-CTNet Source Documentation Guide

Version: 1.0

Version Date: August 05, 2020

REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
1.0	AUG-05-2020	Original version of document

1. INTRODUCTION AND PURPOSE

The CP-CTNet Source Documentation Guide provides clinical site staff conducting CP-CTNet studies with information on source documentation in the following areas:

- Defining source documents
- Examples of source documents
- What constitutes a complete set of source documents
- Creating templates for source documents
- Using an electronic Case Report Form (eCRF) as a source document
- Maintaining accurate source documents
- Correcting errors on source documents
- Reconciling conflicting source data

2. DEFINING SOURCE DOCUMENTS

A source document is an original record of information, also known as source data, which is necessary for reconstructing and evaluating a clinical trial.[1] A clinical trial is reconstructed and evaluated during reviews for quality assurance, monitoring, and auditing. The purpose of source documents is to:

- Provide proof of a participant's existence,
- Confirm that protocol-required procedures were completed and conducted per protocol, and
- Verify that data reported on the study electronic case report forms (eCRFs) are accurate and have not been intentionally or unintentionally modified after entry into an electronic medium.

3. EXAMPLES OF SOURCE DOCUMENTS

Source documents 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:

- Notes from clinic physicians, nurses, and other study staff
- Reports of procedures and tests, e.g., radiology, laboratory, surgery, and pathology
- Flow sheets, checklists, and worksheets
- Participant questionnaires
- Pill diaries/calendars
- Prescriptions and pharmacy records, e.g., accountability logs and shipping receipts
- Participant registration documents
- Study notes or memos to file
- Documented telephone calls, emails, and faxes
- Hospital admission forms and discharge summaries
- Obituaries, autopsy reports, and birth/death certificates

4. COMPLETE SOURCE DOCUMENTATION

Source documentation must be complete to ensure that data from a clinical trial is valid. Complete source documentation for CP-CTNet studies typically consists of the following:

- Original informed consent form, signed by the participant and appropriate study staff
- Description of the informed consent process
- Source documentation (original paper, printed and certified copy, or ready access to the information in the electronic medical record (EMR)) to support (or in the case of screen failures, to deny) all eligibility criteria, including medical/surgical history, screening test results, eligibility worksheets, and clinician/research notes
- Symptoms present at baseline, or a statement that there are none
- Current physical condition based on clinical observation, laboratory tests, and/or medical procedures
- Current medications, or a statement that there are none (and recent medication history if applicable per study requirements)
- Method of birth control used, or reason if none, if applicable per study requirements
- Dates of study visits, including unplanned visits
- Documentation of out-of-window and missed study visits, including the documented reason(s) and attempts to contact the participant
- Completion of the procedures required at each study visit, or non-completion and reason
- Improvement of baseline symptoms
- New or worsening symptoms, illnesses, and/or injuries occurring since baseline (i.e., adverse events (AEs)).
- Deviations from the protocol requirements, regardless of cause
- Study agent randomization and prescriptions
- Study agent instructions, dispensation, and return
- Study agent administration/record of intake, including any interruptions or changes in dosing
- Calculations to determine study agent compliance
- Documented communication with participants, including face-to-face interviews, telephone conversations, portal communication, emails, and faxes
- Date and reason that study participation ended

5. CREATING TEMPLATES FOR SOURCE DOCUMENT

Source document worksheets help clinical trial staff record source data and research visit activities. Worksheet templates are developed according to the requirements of a protocol. The Lead Academic Organization (LAO) may create templates for source document worksheets and distribute them to enrolling sites to encourage consistent data collection.

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

- Using the relevant eCRF from Rave for reference, copy the data fields from the eCRF and add them to a new blank document (i.e., the worksheet template).
- Add an appropriate title such as “Eligibility Worksheet” or “Worksheet for Month 3 Visit.”

- Add prompts for participant number, visit identifiers and a signature and date.
- Add additional prompts as needed to:
  - Capture the completion of visit activities as outlined in the protocol Schedule of Events.
  - Remind users to update the cumulative eCRFs (e.g., Adverse Events and Concomitant Medications) when changes in symptoms or medication use are reported.
  - Refer to other source documents to avoid redundancy in reporting. For example, after an eligibility worksheet prompt to record whether the participant's screening labs met inclusion criteria, add a reference to the lab report for relevant results.
- Ensure that negative responses are included as needed, for example, to document when a participant has no symptoms at baseline or when all visit evaluations were not completed.
- Include space for supporting comments, with a reminder to enter them in the comments field on the eCRF. The comments section should not capture data necessary for analysis.

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

6. USING AN ELECTRONIC CASE REPORT FORM (eCRF) AS A SOURCE DOCUMENT

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

- The information will be originally recorded on the eCRF, and
- The protocol has specified the eCRFs to be used as source documents.

An eCRF used as a source document must be signed and dated when the data are collected.

The FDA's guidance on Electronic Source Data in Clinical Investigation promotes capturing source data in electronic form and provides recommendations for source data in clinical investigations used to fill an eCRF.[2]

7. MAINTAINING ACCURATE SOURCE DOCUMENTS

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

- Attributable: The data originator (and amender, as applicable) is identified.
- Legible: The source document must be readable. If handwritten, the writer must use ink (blue or black), never pencil.
- Contemporaneous: The document must be signed and dated when the information is first recorded, with any updates or corrections noted in real time as well.
- Original: The document must be the first place the information is recorded.
- Accurate: The information must be error-free, and any conflicts with data recorded elsewhere must be reconciled.

- Complete: Investigators and institutions should maintain adequate, accurate, and complete source documents.[3]

https://www.florencehc.com/aloca-c-in-clinical-trial-electronic-document-management/

8. ERROR CORRECTIONS

Source data must be maintained in its original form, with corrections clearly indicated in accordance with the principles stated above. The following procedures apply to source data recorded on paper (e.g., a patient chart):

- Draw a single line through the error without obscuring it, add the correct data next to or above it, then initial and date the change.
- Never “black out” or “white out” incorrect information with a marker, tape, or correction fluid.
- Do not destroy original documents even if the number of errors necessitates the creation of a new document. Record on the old document that a new one was created.
- 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.

9. RECONCILING CONFLICTING SOURCE DATA

Conflicts in multiple sources of documentation must be reconciled before data are entered in the eCRF. 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 documents should be noted in the study chart for quality assurance, monitoring, and audit purposes.

10. REFERENCES

- [1]*Guidance for Industry. Good Clinical Practice: Consolidated Guidance (ICH-E6 R2*; FDA, February 2018).
- [2]*Electronic Source Data in Clinical Investigations, September 2013.* Available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf
- [3]*Guidance for Industry: Computerized Systems Used in Clinical Investigations*, May 2007. Available at: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/fda-bioresearch-monitoring-information/guidance-industry-computerized-systems-used-clinical-trials

11. APPENDICES

- None