DCP Consortia Source Documentation Guide

The DCP Consortia Source Documentation Guide provides clinical site staff conducting DCP Consortia studies with basic information on source documentation. For ease of use, the guide is divided into six topics.

Contents

1. 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 case report forms (CRF) are accurate.

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

[1] *Guidance for Industry. Good Clinical Practice: Consolidated Guidance (ICH-E6)*; FDA, June 1996.

2. Complete Source Documentation

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

- Original informed consent form, signed by the participant and appropriate study staff
- Description of the informed consent process
- Documentation 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 (and recent medication history if applicable per study requirements)
- Method of birth control used, or reason if none
- 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 noncompletion and reason
- Improvement of baseline symptoms
- New or worsening symptoms, illnesses, and/or injuries occurring since baseline (i.e., adverse events)
- 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, emails, and faxes
- Date and reason that study participation ended

3. Creating Templates for Source Document Worksheets

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 Consortium Lead Organization (CLO) 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 DCP Prevention Consortia study may be developed as follows:

- Using the relevant case report form (CRF) for reference, copy the data fields from the CRF 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 CRFs (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 transcribe them to the Comments CRF. 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.

4. Using a Case Report Form as a Source Document

A case report form (CRF) may be used as a source document, but in limited circumstances and only with sponsor approval. A CRF may be approved for use as a source document under these conditions:

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

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

5. Maintaining Accurate Source Documents

Whether recorded and maintained on paper or in an electronic format, source documents must meet the five fundamental principles of data quality. They must be attributable, legible, contemporaneous, original, and accurate[1]:

- 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.

[1] *Guidance for Industry: Computerized Systems Used in Clinical Investigations*, May 2007. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf.

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:

- 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. The reason for the change may be written in a study note or memo to file.
- 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.
- 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.

Reconciling Conflicting Source Data

Conflicts in multiple sources of documentation must be reconciled before data are transcribed to the case report forms (CRF). 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.

6. Monitoring Source Documents

Source document verification is the process by which a study monitor confirms that source documents were transcribed accurately to the study case report forms (CRF). It is critical that the monitoring review begin with review of the source documents, as this practice prompts the monitor to note any omissions in the data transcribed to the CRFs.

The development and use of a protocol-specific monitoring worksheet helps to ensure efficient and thorough on-site monitoring review. Suggested content for a monitoring worksheet for a DCP Prevention Consortia study is shown below.

Suggested Content for a DCP Prevention Consortia Study Monitoring Worksheet

Area of Source Document Review	Prompts
Participant Number/Demographics	▪ Registration number and date ▪ Randomization number and date ▪ Gender ▪ Birth Year ▪ Race ▪ Ethnicity
Informed Consent	▪ Version date ▪ IRB approval date ▪ Date signed by participant ▪ Date signed by site ▪ Documentation of consent process in the chart
Eligibility Criteria	▪ Inclusion criteria (list each) ▪ Exclusion criteria (list each) ▪ Changes due to protocol amendments (if any)
Medical/Surgical History	▪ Start and stop dates
Visit Dates	▪ Visit windows
Evaluations Performed at Each Visit	▪ Protocol Schedule of Evaluations (or bring a separate copy of the relevant protocol page) ▪ Findings: Exclusionary, abnormal, out of range, or within normal limits ▪ Incomplete or missing evaluations
Baseline Symptoms	▪ Start date and grade (baseline visit only) ▪ Symptoms improved or worsened from baseline (subsequent visits only) ▪ Treated with medication or medical/surgical procedure
AEs	▪ Start and stop dates ▪ Changes from previous visit ▪ If treated with medication or medical/surgical procedure, is medication/procedure also reported? ▪ SAE ▪ Verbatim and CTCAE terms, attribution, and grade
Concomitant Medications	▪ Start and stop dates ▪ Changes from previous visit ▪ If used for new or worsening symptom, is the symptom also reported?
Study Agent(s)	▪ Date(s) agent(s) dispensed ▪ Amount dispensed ▪ Date agent(s) started ▪ Any interruptions in dosing or dose modifications? ▪ Agent returns–date(s) and amount ▪ Compliance
Section for Additional Notes or Details	▪ Unreported protocol deviations (or not applicable) ▪ Date off study and final study status (complete or early withdrawal with reason)