# Good Documentation Practice

## Source Data recording guidance

### Source data

Source data is the "*information in original records and certified copies of original records of clinical findings, observations, or any other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies)*" [1]. All data that are collected for a clinical study must have a source to allow independent verification of the accuracy of the reported study [2].

### Source documents

A clear understanding of the purpose of source data is necessary as a lack of control over the documentation could result in an inability to reconstruct the trial and the trial data being labelled as unreliable.

Source documents are "*original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial)*" [1]. This includes certified copies of original records, laboratory results, prescription forms, ECGs, and records at the laboratories.

It is important to establish which documents will provide source data for the study. This is obviously study specific, and types of source documentation to be utilised should be detailed at the start of the trial. A source data list should be created to detail this; this may be within a Standard Operating Procedure (SOP), Data Management Plan (DMP), or other document.

The importance of good documentation practice needs to be emphasized to investigator sites to ensure that the data and study results can be reconstructed, and can therefore be considered credible.

### ALCOA (EACCCC)

Original principles of Good Documentation practice are described by the FDA using the acronym ALCOA: attributable, legible, contemporaneous, original and accurate [3] [4].

**A**ttributable: It should be clear who has documented the data.
**L**egible: Readable and signatures identifiable in a form that is meaningful to an independent reviewer.
**C**ontemporaneous: The information should be documented in the correct time frame along with the flow of events. If a clinical observation cannot be entered when made, chronology should be recorded. Acceptable amount of delay should be defined and justified prior to trial recruitment [5].

**O**riginal: The first record made by the appropriate person. If not original it should be an exact copy. The investigator should have the original source document.
**A**ccurate: Accurate, consistent and real representation of facts.

The EMA advise additional principles (and letters):
**E**nduring: Long-lasting and durable.
**A**vailable and accessible: Easily available for review of treating physicians and during audits/inspections. The documents should be retrievable in reasonable time.
**C**omplete: Complete to that point in time.
**C**onsistent: Demonstrate the required attributes consistently.
**C**redible: Based on real and reliable facts.
**C**orroborated: The data should be backed up by evidence.

## Responsibility

The PI is responsible for all data produced, entered or filed at a site level. The PI needs to ensure they are involved and that they supervise source data documentation throughout the duration of the study. The PI should ensure systems are in place that allow for regular data review and timely resolution of issues.

The PI may and should delegate to adequately trained staff (trained in the protocol and GCP, at a minimum). Training of site staff should be repeated at defined frequency. New staff must be adequately trained before trial participation.

Medical decisions should be clearly delegated to medically qualified staff. Medical decisions include eligibility, adverse event assessment, IMP prescribing and/or dose calculations or modifications.

Sponsors/CI and coordinating groups should allow ample time to be spent during study set-up on source documentation, as this will help a great deal to minimize documentation issues later. The source data and their respective capture methods should be clearly defined prior to trial recruitment, i.e. in the protocol or study specific source data agreement.

Site electronic health records should be assessed as per *JRMO SOP 38a Use of Computerised equipment in clinical research* and deemed fit for purpose before use.

## Detailed guidance regarding source documentation

Prior to recruitment to a study, the individual taking consent must explicitly record in the source documents which inclusion and exclusion criteria are satisfied; it is not sufficient to include a statement that all criteria have been met. This is particularly important when the criteria rely on investigator judgement (e.g. that the individual has the capacity to consent) or where the absence of a condition is required (e.g. that there is no history of mental health conditions, or no history of drug abuse).

Each visit should be recorded in the source documentation and should include**:**

- Patient's name,
- Name of trial,

- Visit number/day and date,
- All data to be collected for that visit, including explanations if it has not been possible to collect any required data.

All entries should be signed and dated allowing for clear identification of the person recording the information and their role.

Test results should be evaluated by an appropriately trained research team member (NB. this is frequently a medical decision) and after assessment should be signed and dated. The purpose of this assessment is to ascertain if any out of range results are clinically significant or not.

Study drug compliance (if applicable):

Source documentation should contain clear information on the Investigational Medicinal Product (IMP) dispensed to the patient.

The following information should be recorded:

- Date IMP was dispensed,
- Batch numbers of IMP dispensed,
- Numbers of all containers dispensed (bottles, boxes, syringes) or volume given,
- Date and time of first dose of dispensed drug,
- Information on amount of IMP the patient is taking home (if applicable),
- Start and finish time of infusions (if applicable).

If the IMP can be administered in different ways, route of IMP administration should also be stated.

All changes of the dose of IMP should be included in the source documentation, not only to track patient's compliance, but also to assess possible connection of the study drug to any Adverse Events.
More information and guidance can be obtained from the JRMO, GCP team.

## References and Guidance

## Bibliography

[1] International Conference for Harmonisation, *Good Clinical Practice,* 1996.

[2] UK Statutory Instrument, *Schedule 1, Part 2 (9).*

[3] Food and Drug Administration, *Guidance for Industry: Electronic Source Data in Clinical Investigations,* 2013.

[4] C. Bargaje, *Good documentation practice in clinical research,* vol. 2, Perspectives in Clinical Research, 2011, pp. 59-63.

[5] European Medicines Agency, *Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials,* 2010.

## Guidance

MHRA Position Statement and Guidance Electronic Health Records Version 1.0 (16 September 15)

Access to Electronic Health Records by Sponsor representatives in clinical trials

EMA Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials (01 August 2010)

Bargaje C, Good documentation practice in clinical research, Perspect Clin Res, v.2 (2): 59-63; Apr-Jun 2011, PMC3121265