

Good Clinical Practice Q&A: Focus on Source Documents

Do GCP standards require that 100% of the information recorded on a case report form (CRF) be recorded in a medical record/chart first?

Not necessarily. The ICH GCP guideline specifically acknowledges that data may, in some cases, be recorded directly on case report forms, and FDA GCP standards also permit this practice. "The trial design should include the identification of any data to be recorded directly on the CRFs (i.e., no prior written or electronic record of data), and to be considered source data," the ICH guideline states.

The FDA has discussed situations in which such a practice is permitted. In the preamble to a November 1996 final rule entitled "Protection of Human Subjects; Informed Consent Verification," the FDA states that "if the case report form is made a permanent part of the subject's medical record, then the medical record may not need to contain information that is contained in that case report form. In most instances, the agency thinks that information is typically entered into the subject's medical record first; then, it is entered onto the case report form for transmittal to the research sponsor."

According to ICH guidance, if sections of the CRF are to be considered source documents, these sections or pages should be identified in the protocol prior to study inception (6.4.9). Ideally, in such cases, the documents should be signed and dated.¹

If raw study data are entered directly into a computer system rather than kept on a medical record-chart, what is considered to be the source document?

Section III (General Principles) of the FDA's April 1999 industry guidance entitled, "Computerized Systems Used in Clinical Trials" states that, "when original observations are entered directly into a computerized system, the electronic record is the source document." The same statement appears in the FDA's September 2004 draft revision of the April 1999 guidance.

Raw data entered into a clinical computer system are considered to be the source data, regardless of whether they are immediately printed out as a hard copy following entry or simply stored as computer files. All rules and conventions regarding the validity and adequacy of source documents apply to electronic transcription.²

What are the rules governing the use of a signature stamp in clinical studies?

Some clinical settings permit the use of a rubber stamp on medical records. When it is used, however, the impression should be initialed in script, and there must be supporting documentation matching the stamp signature with an original signature.

Rubber stamps may be used in clinical studies in a very limited manner – that is, on hospital medical records if permitted by the hospital and if initialed and dated. As part of the site selection process, the sponsor should evaluate the site's methods for creating and maintaining medical records. If a rubber stamp is routinely used at the investigator's office/clinic or participating hospital, then the rules regarding its use should be discussed with site staff prior to the study's initiation at that site.³

References

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2005, pg. 112
2. ibid, pg. 114-115
3. ibid, pg. 120-121

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"Good Clinical Practice: A Question & Answer Reference Guide 2005," is available for \$39.95 at <http://www.barnettinternational.com/>