

Good Clinical Practice Q&A: Focus on Subject Diaries

The reliability of data recorded in subject diaries is often questioned, given subjects' propensity for losing the diaries, forgetting to complete them, and falsifying information. Still, given that diaries can be a good source of data on adverse experiences, drug compliance, and daily activities, what steps can clinical research sites take to ensure that the data and information provided in subject diaries will comply with GCP standards?

At the beginning of a study, site staff should explain to each subject (or parent) the importance of the diary and how the subject should record data within it. Site staff should review the diary at each visit; deficiencies and attempts to correct these deficiencies should be noted in source records. Site staff must ensure that the diaries are returned at the time designated in the trial protocol. If a patient diary is not returned, the site should make several attempts to retrieve it. These attempts should be documented in the subject's medical record.

Although clinical auditors and FDA inspectors recognize that diaries often pose a source documentation problem, they expect to see documented efforts to minimize these problems. Diaries that are too neat, all look the same, or have been rewritten by the study coordinator are sure to raise suspicions.¹

Should extraneous information scribbled by the subject in pencil in the margins of the diary (e.g., "left work early") be recorded in the diary case report form page?

All the data and information that the subject records in the margins of diaries should be reviewed by site staff with the subject. These data should not automatically be considered extraneous until site staff conduct a thorough discussion with the subject. What may appear to be superfluous information may be, upon further examination and subject input, quite meaningful.

A subject entry such as "left work early" requires clarification and follow up. Why did the subject leave work early—was he/she ill? If the subject was ill, then it could be that the event should be considered an adverse event and be recorded in the case report form's adverse event page as well as the case report form's diary page. A note to explain the subject's margin entry should be made in the subject's source record.²

What should a study coordinator do if she/he observes a subject completing the diary in the office waiting room or parking lot just prior to a study visit?

Assuming that the subject is observed entering data that should have been entered in the diary during the previous week or even a day earlier, then the subject was not adhering to the protocol and this behavior should be considered and handled as a protocol violation. As such, the principal investigator or study coordinator should counsel the subject regarding his/her obligations as a study subject. The protocol violation and the discussion with the subject should be documented in the subject's source record.

If the subject's noncompliance continues, site staff should contact the sponsor for advice as to how to proceed. The sponsor may decide that this subject should be dropped from the study because of protocol noncompliance.²

References

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2005, pg. 265
2. *ibid*, pg. 266

Source

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