Good Clinical Practice Q&A: Focus on Site Monitoring

Do GCP regulations require that a site establish and maintain a monitor visit log? If so, what happens if a monitor forgets to sign it during a visit? And should a clinical auditor sign the monitor visit log?

Neither the FDA GCP regulations nor the ICH GCP guideline identify the need for a “monitor signature log.” However, the FDA, in its December 2008 Compliance Program Guide 7348.811, instructs agency field staff, during study site inspections, to “determine if the study records include a log of on-site monitoring visits, written reports, or other communications provided to the clinical investigator. Obtain a copy of the log (if any) and examples of monitor reports and communications.”

Since site monitoring reports are not maintained at sites, a visit log may provide the only site-maintained evidence, with the exception of correspondence, to “prove” that a CRA made routine monitoring visits. In some cases, the study coordinators also sign the monitoring log to further attest to the visit. The log provides a chronological review of the frequency of visits, such that an auditor or inspector can quickly comprehend the intensity of monitoring activity.

In addition, a monitor visit log is an excellent means of establishing that monitoring frequency was appropriate, given enrollment rates for specific periods of time. The monitoring log can be compared with the enrollment log to evaluate the adequacy of monitoring visit frequency.

If a monitor forgets to sign the log, he or she should sign it at a later date, noting the actual date of the visit and the date of the late entry. The fact that this is a late entry should be made readily apparent.

Clinical auditors do not sign the monitor log unless there is an institutional or sponsor standard operating procedure that requires them to do so. The only evidence that an auditor made a visit might be an auditing certificate placed in the study binder, as well as related correspondence.

Originals of the monitor log should remain at the site. Copies should be forwarded to the sponsor central files. Sponsor staff should be alert to discrepancies between dates on the monitor log and dates of visits listed on monitoring reports. Discrepancies should be brought to the monitor’s attention and resolved. It is acceptable to annotate explanations of unusual events (e.g., earthquakes, hurricanes) on the log to help explain why a visit was cut short. Also, it is acceptable to explain that one of the visitors was co-monitoring or in training or present more as an observer, rather than as an “official” monitor.

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