JOURNAL OF CLINICAL RESEARCH BEST PRACTICES
Vol. 13, No. 9, September 2017 "Happy Trials to You"

Good Clinical Practice Q&A: Focus on Study Records

We have an investigator site that had a fire. Initial information is that all source data records, charts, etc., along with remaining IMP on site, were destroyed. There were three subjects' worth of data. One subject was still active (and only requiring a couple of visits to complete the trial). All the data was source verified by the CRA at their last visit. What can be done? Can we recreate the source through the eCRF data already collected, include it in the analysis, and explain in the Clinical Trial Report? Must we exclude all data from this site due to no source data?

FDA would not consider the situation described as serious or continuing noncompliance and should only be reported as an unanticipated problem if subject safety is at risk. The PI, sponsor and IRB can determine this. All efforts should be made to recover documentation, and the attempts should be documented in writing, in case an FDA inspection should occur at your site; however, you can't recover documents that have been destroyed by a fire. FDA would use enforcement discretion in an unusual situation such as a fire. The sponsor should directly contact the FDA review division that is overseeing the study to get some guidance as to how they want you to retrieve the documentation that is in your electronic files. Anything that you do to retrieve the study related materials should be documented in detail.

Source

"Good Clinical Practice: A Question & Answer Reference Guide," Barnett International. The Guide is available at http://www.barnettinternational.com in electronic and paper form.