We have an investigator site that had a fire. Initial information is that all source data records, charts, etc., along with the remaining IMP on site, were destroyed. There were three subjects' worth of data, and one subject 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 re-create 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, so it should only be reported as 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 you do to retrieve the study related materials should be documented in detail. ICH E6(R2) 4.9.0 addendum states, “The investigator/institutions should maintain adequate and accurate documents and trial records that include all pertinent observations on each trial subject. Source data should be traceable, should not obscure the original entry, and should be explained, if necessary (e.g., via an audit trail).”

Source