Good Clinical Practice Q&A

Given that a site might maintain records off-site and may not have immediate access to them, how does the FDA interpret the requirement that an FDA inspector be provided with "prompt access" to required study-related records that will be inspected?

Although the FDA’s Compliance Program Guidance 7348.811 traditionally used the phrase “prompt access,” the agency’s regulations do not specify a time within which FDA inspectors must be provided access to study-related records. FDA regulations at 21 CFR 312.68 (Inspection of investigator’s records and reports) state that “An investigator shall, upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to, and copy and verify records or reports made by the investigator.”

Given that the FDA generally provides clinical investigators and sites with advance notification of a few days or more for routine inspections and that the agency even identifies the records that it wants to inspect, clinical sites will have time to locate and assemble the records in advance of the inspection itself. Agency inspectors contacted on this question noted their expectation that these pre-identified records be available at the start of an inspection. If such records are not available upon an inspector’s arrival or within a brief period following that arrival (e.g., a reasonable period to permit site staff to immediately retrieve the records from a nearby office and bring them to the inspector), this could raise suspicions that the site has not maintained adequate access to its own records. The relevant circumstances (e.g., the nature of the records sought, degree of delay) will determine if the delay in access will justify further investigation or even a citation in a Form 483 – Inspectional Observations.

Even with advance notification, FDA inspectors sometimes request raw data or other information that the site may not have anticipated and that the site staff has not collected for the inspection. While there is no regulation or guideline that establishes a timeframe within which access to such records must be provided, several present and former FDA inspectors contacted regarding this question suggested that 24 hours is a reasonable timeframe, if there are justifiable reasons for such a delay. For example, the specific records may be stored at a distant facility, and the volume of records being requested makes faxing/scanning/emailing impractical. Alternatively, the records may exist only in microfilm/microfiche format, and printouts of these records may be blurry when faxed. In such cases, a site should be able to use an overnight courier service to provide access to the records on the following business day.

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