From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, July 05, 2006 11:17 AM
To: [Redacted]
Cc: CDER DRUG INFO
Subject: RE: Clinical trials - source data

Dear [Redacted]:

Your e-mail was forwarded to our office for a response.

Neither FDA regulations nor FDA guidance documents contain specifications for the percentage of source data that should be verified during an audit. FDA's regulations and guidance documents are general in order to provide sponsors and clinical investigators the flexibility they need to develop appropriate procedures and practices at their own sites or for specific studies. For example, FDA's official guidance for the conduct of clinical trials, the ICH E6, "Good Clinical Practice: Consolidated Guidance," states in Section 5.18.3 (Extent and Nature of Monitoring):

"The sponsor should ensure that the trials are adequately monitored. The sponsor should determine the appropriate extent and nature of monitoring. The determination of the extent and nature of monitoring should be based on considerations such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial...Statistically controlled sampling may be an acceptable method for selecting the data to be verified."

If you are trying to develop procedures for your organization, you might find it helpful to contact a clinical data management organization for information or recommendations about acceptable industry standards or "best practices." For example, the Association for Clinical Data Management [http://www.acdm.org.uk/] may be able to direct you to one or more such organizations that operate in [Redacted].

I hope this is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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Rockville, MD 20857

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [Redacted]
Sent: Friday, June 30, 2006 2:34 PM
To: CDER DRUG INFO
Subject: Clinical trials - source data

Name: [Redacted]

E-Mail: [Redacted]

Comments: During a clinical trial Sponsors frequently determine what is considered an acceptable percentage of the original source data that needs to be 100% verified. Does the FDA have a set percentage that would be acceptable during an audit, e.g., 20%?, 30%, 45%?

Thank you for your reply,
[Redacted]