From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, May 23, 2006 3:48 PM
To: [purged]
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear [purged]:

Neither the Food and Drug Administration's regulations nor guidance documents use or define the term "double data entry." It's my understanding that double data entry refers to the practice of having the same data entered by two different individuals and using a computer program to compare the entries and identify discrepancies, which are then resolved. If a site were to use such a system to verify its data, it would make sense for the site to resolve all discrepancies that were identified in the system check (presumably by checking the source documents, and ensuring that the data that was entered matches the information in the source documents).

Neither FDA's regulations or guidance nor guidance contain a numeric accuracy standard. However, FDA's official guidance, the ICH E6 "Good Clinical Practice, Consolidated Guidance," provides the following recommendations:

Section 4.9.1: "The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports."

Section 4.9.2: "Data reported on the CRF, which are derived from source documents, should be consistent with the source documents or the discrepancies should be explained."

Section 4.9.3: "Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained..."

If you wish to read the ICH E6 guidance in its entirety, you may find it on FDA's Good Clinical Practice website at http://www.fda.gov/oc/gcp .

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)
5600 Fishers Lane, Room 14-B17
Rockville, MD 20857

Phone: 301/827-3340
Fax: 301/827-1169

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: [purged]
Sent: Wednesday, May 10, 2006 3:57 AM
To: CDER DRUG INFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Please note the change in my e-MAIL Domain from [purged]
All future correspondence to me should be addressed to firstname.lastname@[purged]
Sir/Madam,

Thank you for the reply. I am looking for any documented standard for data accuracy percentage (i.e. 100% or 99.96% accuracy) for double data entry in clinical data management setup. Could you please help me with this.

Regards,

[purged]

"CDER DRUG INFO" <DRUGINFO@cder.fda.gov> 10/05/2006 12:49 AM

To [purged]

cc

Subject RE: DrugInfo Comment Form FDA/CDER Site

Dear [purged]:

Thank you for your message to the Center for Drug Evaluation and Research (CDER), one of the five centers within the Food and Drug Administration (FDA).

Can you provide more information in regards to your question so we can try to help you.

Sincerely,

Division of Drug Information

D202D

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents our best judgment at this time but does not constitute an advisory opinion, 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: [purged]
Sent: Monday, May 08, 2006 10:46 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]
Comments: Is there any recommended standard data accuracy for double entry data?