From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, February 13, 2006 3:53 PM
To: [purged]
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. [purged]:

Thank you for the clarification of what you meant by "data query response."

You said the sites use the "data query responses" to "answer [your] questions" or to clarify discrepancies in clinical trial data. In answer to your second question in your original e-mail, a "data query response" would not qualify as a source document or source data because a data query response is not an original document used BY THE SITE to capture clinical findings, observations, or other activities in the trial. [In some trials, clinical investigators may enter data directly onto a Case Report Form (CRF), in which case a CRF WOULD be a source document.]

In general, if a question arises about information that was entered onto a CRF, the answer to the question would be resolved by going back to the source data contained in source documents (e.g., medical records, progress notes of the physician, hospital chart(s), lab results, x-ray films, EKGs) to determine what the correct information is, and why it was incorrectly entered onto the CRF. If a CRF is changed as a result, there should be an audit trail, that clearly indicates who made the change, when, and for what reason. Any changes made to the CRFs should be endorsed by the CI

I am concerned about your statement that you "verify the site's data query responses against the source, and "EXPECT THE SOURCE TO BE UPDATED OR CORRECTED, IF NEEDED, IN RESPONSE TO A QUERY." [Emphasis added.] Perhaps I am not understanding you completely, but the suggestion that source documents should be updated or corrected "in response to a query" is NOT an acceptable practice.

Source data is all the information contained in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. The CRFs should report what is contained in the original source documents, and if the CRF does not agree with the source data, then the CRF (NOT the source data) should be corrected, and the correction should clearly show who made the change, when, and why.

FDA's investigators routinely compare the source data with the information reported on the CRFs. This is how they reconstruct the study and determine if the clinical investigator properly conducted the study (e.g., followed the study protocol; appropriately included or excluded subjects; accurately and completely reported his observations, any concomitant medications used by the subjects, adverse events; appropriately supervised his staff in the conduct of the study; etc.)

If you wish to obtain more insights into the standard procedures used by FDA's investigators during an inspection, you can access the Compliance Program Guidance Manual chapters for bioresearch monitoring establishments electronically from the Good Clinical Practices website: http://www.fda.gov/oc/gcp. Once there, click on "Bioresearch Monitoring Program" (the last item in the middle column).

You might find it helpful to review FDA's official guidance on clinical trials, the ICH E6, "Good Clinical Practice: Consolidated Guideline," which is also posted on the GCP website under "Guidances and Information Sheets." The E6 guidance defines both "source data" and "source documents," in case there is any confusion about what these terms mean. [See sections 1.51 and 1.52.]

I hope this answers your questions.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
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5600 Fishers Lane, Room 9C24
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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: [purged]
Sent: Wednesday, February 08, 2006 12:24 PM
To: 'OC GCP Questions'
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. Hommel,

When I review study data at a research site (as a site monitor), I issue written questions to the site staff to clarify discrepancies in data, or request that missing data is entered into the Case Report Forms. These questions are the "data queries." The site's answers to my questions are the "data query responses."
I hope this helps.

Thank you,
[purged]

-----Original Message-----
From: Hommel, Carolyn - OC [mailto:carolyn.hommel@fda.hhs.gov] On Behalf Of OC GCP Questions
Sent: Tuesday, February 07, 2006 2:51 PM
To: [purged]
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. [purged]:

Your inquiry was forwarded to me for a response, but I am not familiar with the term that you are using, specifically what you mean by "data query response." Could you clarify what you mean?

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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-----Original Message-----
From: [purged]
Sent: Wednesday, February 01, 2006 12:57 PM
To: CDER DRUGINFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: Hello -

I am a research study monitor and have a source documentation question:
On site, I always verify the site's data query responses against the source, and expect the source to be updated or corrected, if needed, in response to a query.

I have a site that disagrees, and says the query response IS the source.
I say that the data entered into the eCRF and query responses are all part of 'data collection.' The source is completely different from data collection.

Question: Can data query responses by the site ever be considered source?

Many thanks for your input to this question.

[purged]