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December 21, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subject: **Docket No. 2004D 0440, CDER 2003195**
Comments on Computerized Systems Used in Clinical Trials
(DRAFT GUIDANCE)

Dear Dockets Management Branch:

Enclosed are comments, provided by Genentech, for the *Draft Guidance Computerized Systems Used in Clinical Trials*.

Thank you for providing us the opportunity to comment on this Draft Guidance. We hope that you will find our comments useful and constructive.

If you have any questions regarding this document, please contact Marc Baires, Associate, Regulatory Affairs at (650) 225-7959.

Sincerely,

Robert L. Garnick, Ph.D.
Senior Vice President
Regulatory Affairs, Quality,
and Compliance

for:

2004 D-0440

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Comment Matrix
Computerized Systems Used in Clinical Trials
Draft Guidance – September 2004
Docket No. 2004D-0440

Line No.	Proposed Change/Clarification Request	Justification/Clarification Question
Lines 54-57	<p>Please delete the sentence starting on Line 54 and ending on Line 57.</p> <p>This guidance addresses how Agency expectations and regulatory requirements regarding data quality might be satisfied where computerized systems are being used to create, modify, maintain, archive, retrieve, or transmit clinical data. Although the primary focus of this guidance is on computerized systems used at clinical sites to collect data, the principles set forth may also be appropriate for computerized systems belonging to contract research organizations, data management centers, and sponsors. Persons using the data from computerized systems should have confidence that the data are no less reliable than data in paper form.</p>	<p>There is no need to underscore the primary and secondary focus of this guidance, since many important recommendations apply to the “secondary focus.” This may lead to confusion of scope and over-interpretation.</p>
Line 107	<p>Replace the word “trials” with “trails.”</p> <p>We recommend that audit trials trails.</p>	<p>Grammatical.</p>
Line 213	<p>Replace the word “trials” with “trails.”</p> <p>We recommend that audit trials trails.</p>	<p>Grammatical.</p>

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214	Please replace the phrase “. . . who made the changes, when, and why changes were made to the electronic record” with “. . . what, when and by whom were changes made to the electronic record.”	The current phrasing requires why changes were made which is inconsistent with Part 11, Comment 74 which states “ <i>The agency does not believe part 11 needs to require recording the reason for record changes because such a requirement, when needed, is already in place in existing regulations that pertain to the record themselves.</i> ” Additionally, the current phrasing is inconsistent with the examples noted in the second and third bullet points, which only require the “who, what and when.”
258-259	Please clarify the following statement: “We recommend against the use of features that automatically enter data into a field when the field is bypassed.”	Some automatic data entry may enhance the value of the program, for example automatic entering of a current date stamp, without necessarily compromising the attributability of the data.
278-279	Please clarify the following sentence: “It is not necessary to reprocess data from a study that can be fully reconstructed from available documentation.”	In order to better follow the “therefore” (conclusion) in the next sentence, it would be useful to clarify, with the use of exemplars, what is meant by re-processing vs. re-construction.

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303	Please delete the following sentence: “We recommend that procedures and controls be implemented to prevent the data from being altered, browsed, queried, or reported via external software applications that do not enter through the protective system software.”	Genentech does not believe that companies should be prohibited from altering, browsing, querying or reporting data provided that adequate safeguards are in place to protect original data. This is consistent with Part 11 guidance where controls should be commensurate with record risk. If it can be demonstrated that an integration application can maintain the accuracy and security of the data (outside of the “protective system software”), there should be no issues with this architecture.