



EDC Help Text or No EDC Help Text: That is the Question

There is debate today about whether or not EDC applications should contain completion instructions and/or help texts associated with individual fields or eCRFs. Some believe that if the questions are worded clearly, the cursor control is logical and helpful, the layout is clear and uncluttered, and appropriate data capture structures are used (e.g., radio buttons, dropdown lists), then there should be no need for additional instructions or help as the form should stand on its own. To address differences between sponsors in layout, cursor control and question wording, a study conventions document can be prepared that contains general information regarding entering data and the like.

I believe that this is only part of the picture. Without question, EDC prompts should be very clear, use appropriate field structure, and so forth. These characteristics are tightly related to defining and capturing high quality data. It is also not necessary to create help texts that only restate the prompts, e.g., a help text of "Please enter the subject's weight"



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Cutting Edge Education

Kestrel is pleased to offer you four new webinars for March 2010. Part five and six of our very popular Standards Management 101 series, part one of our Risk Management series, followed by a webinar in Data Quality. All kestrel webinars are 90 minutes long. They consist of 75 minutes of intense learning, plus 15 minutes for Q&A. Please register at www.kestrelconsulting.com/registration.php

"Great job presenting the webinar, Kit. A lot of useful information. Special thanks for posting the recording for those of us who missed it."
-Tatyana Doroshenko, Independent Data Manager

Database Audits Today

Monday, March 8, 2010 11:30 am - 1:00 pm EST



Database audits have been a staple of the clinical data manager's quality arsenal for decades, and they persist even in the face of persistent nagging questions about their validity and usefulness. These questions are even more relevant now that adoption of EDC, ePRO and other electronic data capture media is accelerating. This webinar examines the traditional database audit and demonstrates why it did not answer the question we thought it was asking. It also suggests a better approach for paper-based studies and an equivalent process for studies where there is no "CRF", such as EDC. The content is based upon work done by the Data Quality Research Institute.

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Downloadable Webinars

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*Cutting Edge Education cont.**(Continued from page 1)*This webinar will benefit heads and colleagues in:

- Standards management
- Process improvement
- Clinical data management
- EDC design and programming
- Clinical operations
- Clinical monitoring



Risk Assessment in Cleaning Clinical Data Part 1: Understanding the Concepts

Monday, March 22, 2010 11:30 am - 1:00 pm EDT

The FDA has recognized in recent years that the idea of trying to deliver "perfect" data is neither cost-effective nor feasible, and is embracing a risk-based approach to data quality. This pair of webinars challenges the idea that all data should be cleaned equally. It explores the question of "risk to what/whom" and what "quality" means in this context. The first webinar covers the conceptual material and the second presents the practical application. Based in part on work by the Data Quality Research Institute, this two-part webinar:

- Identifies a two-tiered approach to risk management in data quality
- A decision model for deciding what types of errors are low, medium or high risk
- A mechanism for applying those decisions systematically and objectively to specific data points
- Demonstrates how to use the model when the same domain is implemented in different ways (e.g., blood pressure as safety vs. efficacy)
- Suggests a documentation approach for making the strategy transparent internally and to the regulator agencies

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Standards Management 101

Register Now for "Managing Standards" and "Standards in Contracted Clinical Development" parts 5 and 6 of the *Standards Management 101 series*.

Ongoing clinical data standards management requires a specialized and dedicated knowledge set that does not exist in other functional areas. This webinar series provides the insights and skills necessary for ongoing development, management, maintenance, tracking and retirement of standards in today's industry. Register now at www.kestrelconsulting.com to maximize the quality, efficiency, and cost-effectiveness of your clinical data standards.

Part 5: Managing Standards: Standards are valuable only if they are used, but typically, the standards manager has little to no formal authority to ensure compliance. How can they achieve standards adoption? Standards implementation must also be monitored, their uptake in the organization tracked and their metrics measured. This section discusses the rationale, processes, methods and tools for handling these tasks.

Wednesday, March 10, 2010 11:30 am - 1:00 pm EST

Part 6: Standards in Contracted Clinical Development: Conventional wisdom is that CROs cannot use standards as each client has different requirements. To some degree that is true, but there are many elements that can be adopted to ease clinical trials conduct and reporting. From a sponsor's perspective, adopting standards when contracting out data activities brings many bene-

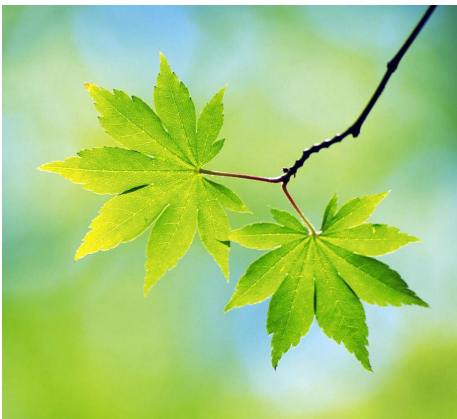
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That is the Question cont.

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on a field with the prompt “Weight.” Finally, a study conventions document can provide valuable information about navigation, handling individual fields with missing data (e.g., put a note in the pop-up query window), and the like.

On the other hand, such a document does not educate the sites with respect to many of the sponsor’s other expectations for data quality and consistency, which can be thought of as the scientific or business rules. For example, the study conventions document does not provide specific information on the edit check ranges used on the fields, nor why those ranges were chosen. It doesn’t usually alert the site to data relationships the sponsor expects to see, such as AEs corresponding to each new concomitant therapy started during the study. In fact, virtually everything that the sponsor expects check and that could result in a query should be communicated to the site in some way. Otherwise, how is the site supposed to know how the data should be captured and recorded? It is like requiring them to take a test on material that they have never been taught!



Some of the information mentioned above could be drawn from the protocol, but many protocols do not go to this level of detail, and given that study coordinators often run many studies with different sets of rules, it would seem safer to add the rules to the tool they use to prompt them for those data. The information is also in the Data Management Plan, but most sites do not see that. Given the amount of disagreement there is on chat forums such as LinkedIn, it is clear that there is no consensus on many of these practices, so how can we expect the sites to “just know” what to do?

Here are some more examples of scientific or business rules that I have seen vary either on discussion forums or between clients:

- When in a study to start capturing AEs and SAEs?
- How far from the protocol-defined visit day can a visit occur and still be “compliant”?
- Over how many days can a visit occur and still be “compliant”? E.g., bloods one day, physical exam the next, ECG the following.
- How should open AEs and concomitant therapies be handled if the subject dies during the study (i.e., should they be closed out with date of death as the end date, or left open)?
- What conditions should be recorded on the medical history screen? I.e., starting at what time point, or “clinically significant” ones only (though that definition is not always clear)?
- Should symptoms or diagnoses be recorded on AE eCRFs?

If these questions and many more like them are not defined for the sites in a way that is clear, accessible and user-friendly, then the data will be less comparable and uniform (i.e., lower quality), and we may not even know it.

By Kit Howard, MS, CCDM, CRCP

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This webinar is the first half of the Risk Assessment series and should be taken with Part 2, offered on April 19th.

This webinar will benefit those who define organizational strategy and implementation for clinical data quality, including heads and colleagues in:

- Standards management
- Process improvement
- Clinical data management
- EDC design and programming
- Database programming
- Biostatistics
- Clinical science/study management
- Clinical Operations
- Clinical monitoring

With every Kestrel webinar, you will receive:

- 75 minutes of lecture
- Slide deck with all materials used during the webinar
- Spreadsheet with decision trees and tools for implementation
- Q&A opportunity with an industry standards expert
- Post-webinar quiz (voluntary) to check your understanding of the material



Standards Management 101 cont.

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fits. This webinar explores different approaches to using standards in contracting environments, including the quality, risk management, financial and competitive advantages of their adoption. Wednesday, March 24, 2010 11:30 am - 1:00 pm EDT

Each of the 7 webinars is an intense 75 minute lecture, plus 15 minutes Q&A

Kestrel's own expert presenter is Kit Howard, MS, CCDM, CRCP

These webinars will benefit:

- Leaders exploring process improvement and standards implementation
- Heads and colleagues in
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 - Process improvement
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