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Revisiting the “Do It” Button

I was reminiscing recently about one of my past consulting assignments at a local biotechnology company. A woman who was the director of data management there at the time was talking with me about the frustrations we had with program specifications. She laughed, saying, “What I want is a big red button in the middle of the screen that says ‘Do It,’ and all I have to do is click on the button and everything is done properly!”

I remember replying something along the lines of “That would be very advanced technology, otherwise known as mind reading!” However, as I thought about it more, the “Do It” button is easier to implement if you have standard electronic records, standard data items, standard screens, standard edit checks, and other standardizable processes. So the discussion of the “Do It” button fits in well with the theme of this issue of *The Monitor*.

In my experience, specifications are always the hardest part of a software development process. However, the more standards one has in a library, the easier the specification process becomes; consequently, the easier the development and validation become, as well.

Unfortunately, many companies have problems with standards. It seems that everything needs to be continually tweaked—that we are never completely satisfied with the way a particular data entry screen works, or how the edit checks work, or any of a number of other items. As scientists and professionals, many of us have a

drive to learn new things and improve upon how things are done. This propensity is at odds with standards.

Getting Specific About Specifications

I have worked recently with two companies that are still changing their adverse experience (AE) data entry screens after being in business for more than 10 years. Although there are occasional legitimate reasons to update AE information—most noticeably when the Food and Drug Administration changed the definitions of race and ethnicity, these reasons did not apply to my last two clients. They just did not like the behavior of the data entry screens.

In the absence of using standard building blocks such as data items, data tables, data entry screens, and so on, the specifications become more important, and more challenging. The reason they become more challenging is that most people do not think of everything when they are writing specifications. Even more important, the people that review the specifications do not really think about what they are reviewing.

I believe most people review documents assuming they are reviewing the document to determine if it sounds reasonable. They need to go beyond that. They need to review the document to determine if it is correct and complete. This level of document review is a much more difficult and time-consuming task.

In fact, I would go further and say that if the programmer finds problems

with the specifications, not only the author of the document, but all the reviewers of the document should study what issue the programmer found and aim seriously to prevent such occurrences in the future. I believe if the programmer finds specification issues, it is often very late in the process, and the cost of making a corrective change is always higher the later in the process a change is required.

How Standard are Your Standards?

With the quest for specific specifications in mind, the importance of using standards becomes more apparent. With the proper use of standards, not only is an item, data table, or data entry screen already programmed and tested, we also know how well it works. If there are problems with the screen, perhaps data managers and programmers should spend time experimenting with possible modifications and updating standards as a separate task. This

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way, the team can focus on the specific problem and (hopefully) do a good job of updating the standard. In this manner, ongoing clinical trial data entry development can stick to using the approved, standard data entry screens.

Although all clinical trials will have study-specific data collection needs that are not standard, the more standard data items, screens, and edit checks a company has, the closer a clinical trial data entry development “Do It” button becomes a reality. In fact, if a clinical protocol is written in a standard way, much of the standard data collection screens can be “automatically” specified. The clinical study team can then focus its energy

and time on specifying the study-specific data collection requirements.

Just Do It

While there are technologies available for rapid application development (see http://en.wikipedia.org/wiki/Rapid_application_development for more information), in which multiple prototype solutions are developed in an iterative fashion, such technologies are not easy to implement in a regulated environment where validation requires mapping the feature being validated against a specification. Maybe we can start with a “Do It” button that helps develop complete specifications and go from there? **ACRP**

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