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IECRN Findings: Data Management**

Presenter:

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DR. SMITH: I want to move on for the last few minutes here to another area, and that is data management, which is closely related to IT. It is, obviously, not one and the same thing.

There is the moving bubble again. You know, if I reverse this, we can watch that twice. Are we ready for lunch?

Okay. This is the outline of what I am going to say, so I will just say it. What is data management? This is about all that stuff that captures, processes, stores the information.

And let me say here that there is a focus in this that is on protocol or about protocols and CFR type data, not all information that could be dealt with. That gives a little more focus to the research on this. And exchange and presentation of the data can be included in that.

Data management, dispersion, as it is called here, what that really means is how much centralized data management is being used. About two-thirds of the CRNs report centralized data management and that is probably encouraging. It would seem like there are significant efficiencies in centralization, with

security and backup and process management and QC, QA type things.

Any time the cup is two-thirds full, it is a third empty. So we need to look at that from both angles.

Is there a data management committee? Yes. There are more data management committees than IT type committees out there. So I suppose that is encouraging, too.

And general findings on data management, most, almost two-thirds, have a dedicated data management director. I will just skip through a couple of these.

Let me point here that the clinical trials and NIH-funded CRNs, again, come out as a special group that are more likely to use private contractors for data management. And then for others, academic centers are their predominant data management organizations.

I guess the significance of that would be up to groups this afternoon to see if that is just a fact or whether that has particular significance in where things are and where things should go.

On data capture, which is part of data management, by our definition here, the most common data transfer methods are hard copy that was referred to this morning by a couple people.

Electronic transmission is used, but these are,

obviously, overlapping percents. Multiple methods are used by organizations. And direct data entry.

But if we try to get down and focus in on the hard copy and say what is the predominant method in the network, hard copy does come up as the most common predominant method.

So to the extent that we believe, can show and can show value in electronic data capture, and then there are quite a ways that things can go in that arena and that is probably worth looking at seriously.

Some other important general findings in the data management area overlap with other things I said about standards, and, that is, about 61 percent have developed some kind of common data standards related to their data management practice. Only about 18 percent are using CDISC.

Presumably, that would reflect that -- and, actually, some of the other data suggests that this 61 percent means that we are pretty good, whatever 61 percent means at internal standards. CDISC is one indicator of several that we are not as focused on external standards.

So, again, that theme kind of resurrects here on standards and how they are used and external versus internal process and collaboration.

But real good news, standards are viewed positively

and they are generally seen as improving data quality and increasing operations and shortening time lines.

Those aren't overwhelmingly high percentages, but they are substantial enough to mean that there is some recognition out there and looking at those organizations and what they are doing helps inform others, I think.

While using these kind of external standards is fairly low, it is also encouraging that 42 percent of CRNs report they are participating in some kind of standards development efforts; 62 percent, or nearly two-thirds, plan to participate in additional standards development efforts; and, again, the NIH-funded networks are more likely to say they plan to participate, for probably obvious reasons.

The barriers, staffing and defining common data elements and standards are barriers to data management, based on the interviews and studies there.

One of the more important factors in this, if we get down to a little bit of the detail, is just believing there is value and having a vision of the value of the data management standards and common data elements.

Let's see. Finally, some facilitators in data management are electronic data capture. It is valued as a solution to labor shortages in a number of organizations. Maybe

shortages, I don't know if that is exactly the right word. It would be difficulties of getting labor of the right kind, in some cases; in some cases, maybe just sheer shortages.

And facilitators are, of course, common data elements. It does seem that adopting standards, at least internally, is a great facilitator of data management success.

Let's see. Conclusions. Standards are coming and data management, but external have a way to go. There are some gaps in data transfer. That is referring to the electronic data capture. And it would be good to consider building more commitment to external interactivity.

That is really about what I have. I will finalize with a comment on variations.

Obviously, I haven't represented all the kinds of variations here. I have pointed out a little bit. Flexibility and diversity of approaches is part of what IT should support. IT should not just become a box and say everybody do this. I think we all know that in research organizations.

We don't have time to delve into it, but there are approaches to IT that support flexibility and diversity, not just saying here is the one way or the one system, and those will be interesting to look at as time goes on.

Thanks. [Applause.]