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It's About Time We Get Serious About Paperless Clinical Research Sites

Ana Marquez, President of Marquez Clinical Site Partners, LLC, talks with Norman Goldfarb, Editor of the Journal

Ana, what do you think it's about time for the clinical research enterprise to start doing?

Norm, I say this with reservations, but it's time for clinical research sites to move to a 100% paperless system.

What are your reservations?

Paperless means software, probably on the cloud, and software usually means headaches of epic proportions. Software in theory is a lot easier to use than software in practice. There always seem to be implementation hassles, the transition from the old system can be problematic, and the new system probably has its own ideas on how you should run your business processes.

Sounds like a nightmare, so why do you think it's time for sites to go paperless?

Well, the increasing cost pressures and complexities of clinical research give us no choice. We have to become more efficient at handling more complex studies. When paperless systems work, they are much more efficient than paper, they streamline data entry and remote monitoring, they generate lots of metrics and reports, and they build SOPs into consistent, high-quality processes.

How do your study coordinators feel about going paperless?

The last thing a study coordinator wants is yet another software system to learn, yet another password to remember, and yet another technical support line that doesn't answer calls. On the other hand, study coordinators are frustrated with paper, too, especially all the scanning and faxing. Of course, they think entering data on a paper source document and then re-entering it in EDC system is a big waste of time. Very few study coordinators want to be early adopters. They want someone else to sort out all the problems.

How do your site managers feel about going paperless?

Site managers feel the study coordinators' pain. If they're smart, they are also very concerned about integration with other systems and compliance with HIPAA, Part 11, etc. When implementing a new software system, they feel very alone — nobody is happy with them and the software company suddenly seems to have other priorities. Of course, when it's the sponsor's or CRO's system, that's another layer of frustration. I might be exaggerating here, but these are definitely valid concerns.

On the other hand, they see the potential efficiencies of going paperless and hope it will make the study coordinators' job easier. That's important because the toughest challenge

for a lot of sites is finding, training and keeping good study coordinators. If going paperless expedites and simplifies the study coordinator's job, especially with complex studies, site managers will support it.

So, is there a missing ingredient that will ease the pain?

It's hard to say, but, like most challenges in clinical research, we need a lot more communication and collaboration. If we want paperless systems to work together for the site, we *all* need to work together with the site.

Well, Ana, it looks like we have our work cut out for us.

Yes, Norm, nothing new there.

Interviewer

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.