

eCOA: Keep It Simple, Exec Argues

By William Myers

Clinical trials have not yet fully entered the digital age. Despite a revolution in consumer electronics that has built libraries of real-time personal health data, sites and sponsors seem to regard digital technology the same way Saint Augustine prayed for chastity and continence: “Grant them to me, O Lord — but not yet.”

Nearly half of all clinical trials still use paper as the primary — or even sole — source of records while barely a quarter of trials use electronic clinical outcome assessments (COA) or patient-reported outcomes (PRO).

On Monday, CTTI will unveil new recommendations for adopting mobile technology into clinical trials at an all-day event at the FDA’s main campus in Maryland.

One leading eCOA executive said that the problem among sites, sponsors and eCOA leaders may be less of an Augustinian problem and more of a “Cool Hand Luke” problem. What we have here, Sue Vallow argues, is failure to communicate.

“We still have issues with misaligned expectations between sponsors and sites as to how to make eCOA successful,” said Vallow, vice president of eCOA solutions at MedAvante-ProPhase. “It seems like we’re not understanding each other very well.”

It can take between seven and 14 weeks for an eCOA provider to build a robust digital records “ecosystem,” Vallow said. Any application has to be easy to use for sites, sponsors and patients but also has to protect privacy, be transparent, auditable and reliable.

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time to actually pull together a system for them. Maybe the roles and responsibilities are unclear, the sponsor’s not clear about what the eCOA provider is offering, maybe the eCOA provider is not clear about what they can do,” Vallow said. “When the system is asked to do a lot of things and it’s not entirely streamlined, we’re asking the system to do a lot of things that we’re not asking the paper system to do.”

Vallow spent the early part of her career working for sponsor companies, so she understands how easily expectations can be misaligned.

“People’s expectations around technology have come from their experiences as consumers. The electronics consumers use have gotten a lot better than the technology we use for work,” she said.

So, how can the parties manage each other’s expectations more easily? Vallow suggests that the first step is to agree to keep it simple.

“Some studies are just a mish-mash of different assessments loaded into a protocol and hoping that something sticks,” she said. “Mapping out how long it might take a patient to get through a typical visit might be really helpful. I worked in a trial where the expectation was that

the patient would take about four hours per visit. Who’s going to volunteer for that?”

Sponsors don’t have to do all the work themselves, though, Vallow said. An eCOA provider who says something like, “We see that you’re interested in using this kind of instrument and we believe that you want to measure this concept but we think this instrument is more streamlined and concise and it’s something we can implement swiftly,” for instance, is telling a sponsor that they’re proactive and care about getting the trial done right.

Once goals are clear and the process is simplified, it can be really important for sites, sponsors and eCOA providers to sit down and outline the roles and expectations for each phase of a trial, Vallow said. “When you’re building the solution, when you’re testing and designing it — who’s doing what? And how is all that communication taking place? The project manager is really important as the facilitator of all communication,” she said.

Sites can help by “keeping an open mind” but also by bringing the eCOA provider in early and testing and pushing back on any technology solution from the beginning. It can help eCOA staff understand how a site works and to “make sure we’re striving for project management and operational excellence,” Vallow said.

“Oftentimes we hear about devices not working or data being lost. Those problems still happen, unfortunately, after the fact,” she said.

Sites also shouldn’t be shy about making sure their staff is well trained on any technology, Vallow said. “I know they have a lot of different demands they’re bombarded with. They should also demand that sponsors and eCOA providers provide the correct training for it, as well,” she said. 