VANDERBILT UNIVERSITY

Vanderbilt's Advice for Sponsors: How to Make Working with Your EDC Easier for Sites

Modernizing electronic data capture (EDC) is critical for conducting more effective clinical trials. From improving the accuracy of electronic case report forms (eCRFs) to streamlining the entire site experience, running high-quality studies requires exceptional clinical trial data management.

Jill Janssen

Alesia Pruitt

At a recent Veeva Summit on R&D and Quality, Jill Janssen, director of Vanderbilt University Medical Center and Alesia Pruitt, research coordinator at Vanderbilt Clinical Trials Center, discussed how EDC systems impact their study start-up and training, data entry quality, operational reporting, and more.

Accelerating clinical trials by bringing together study start-up activities

Can you tell us about your experience with study start-up as it pertains to EDC in clinical trials?

Alesia Pruitt: As coordinators, we work with a few other teams during the study start-up process. Once we get access to start training in the EDC, we work with our navigator team to obtain eCRF guidelines and source worksheets to determine what information will be captured in the medical record and what we need to capture in our eSource. One challenge we run into is not having the guidelines and source worksheets, which can cause delays in starting a study. We use REDCap to record our participant information and use the protocol to tailor study-specific forms. If we don't receive the EDC guidelines early enough, we don't have time to create and test our source forms—hence the delay.

Other than delays, what are additional challenges you face when eCRF forms and worksheets are unavailable—especially when it comes to Vanderbilt developing its own source materials internally?

Alesia Pruitt: The most important part is knowing what information is needed. There is certain information—like demographic and procedure data—that's standard, but in some forms such as medication and vital signs we may not know what we need. If it's not standard of care information for the providers and nurses, we may not add it to our source and that can cause delays for sponsors in getting their data because we either need to

backfill the information or leave it as unknown. We can mitigate these challenges by working with the outside departments to find out what data they typically collect during a visit or procedure. That's the type of extra work we do if we aren't getting the EDC early enough.

When considering a study's timeline, how early in advance of Vanderbilt's first enrolled patient do you need this information?

Jill Janssen: The timeline typically depends on the acuity of the trial. The higher the acuity, the more lead time is needed. I would prefer to receive them at IRB submission, which is when we start to work on our source documents and workflow, leading up to site activation. We usually receive EDC guidelines or snapshots closer to site activation, which puts us behind the eight-ball trying to gather information. We don't want to be missing data points when we enroll that first patient.

Simplifying and streamlining training for EDC in clinical trials

Having the eCRF completion guidelines or being able to access the system is necessary for training. What has been your training experience with EDC systems, as well as other pieces that you need to more effectively use an EDC?

Alesia Pruitt: As I'm going through the protocol and looking at the schedule of events, I like to be able to have the eCRF guidelines available to know what I need to capture. Knowing what I'm looking at ahead of time helps during the EDC training process. When I trained on Veeva for the first time, I liked that we were able to enroll a practice patient before we got access to the live database for the study. That really helped me figure out the nuances of the EDC. Normally, the first time we ever actually enter information into the EDC is when we have a patient to screen. Also, being able to print PDFs of the database was great to know ahead of time in case we need to print those out prior to the patient visit.

In addition to being able to work out all your own kinks with the EDC system in advance so you can avoid a learning curve when you're screening a live patient, do you have any other thoughts on training that you want to add?

Jill Janssen: Having the sponsor train us on the EDC is important for more than the site initiation visit. We'd like those guidelines in place when working with other collaborators within Vanderbilt. It is important because additional training may be necessary on what data is needed. Again, the sooner we can have the data elements, the better, and Veeva really makes it faster, easier, and more streamlined.

When we ask sponsors for the guidelines we typically hear, "We haven't finalized the EDC yet." The assumption is that their timeline is based on first patient visit. If the EDC isn't ready until first patient visit, that really puts sites behind the eight-ball.

Alesia Pruitt: And just to echo what Jill mentioned, the coordination element with other departments is very important because if you're dealing with medical staff who are not involved in research, they'll just follow their standard of practice. We have to be able to provide the information on what's needed in advance so the team lead is prepared. It's important to align the sponsor's timeline with the preparation timeline of the sites and other stakeholders participating in the study.

Improving the accuracy and quality of data entry

Let's shift to entering data into the system. When you're working with the eCRFs, what's your experience in terms of data entry? What works and what doesn't work?

Alesia Pruitt: Dates are the most basic thing that we enter, but there can be challenges. If a procedure is associated with a visit, we can get stuck if there is only one date field. For example, a lot of times imaging can't be done on the same day as the actual clinical visit. Not being able to capture those as different dates—but then pair them—makes it hard to capture accurately or without triggering a query.

It's also helpful to have pre-designated options if your department has a specific way of coding things. Knowing on the sponsor side how things need to be coded is beneficial, because then we don't have to go back and change information—especially on pages where we've already had the provider lock certain information like adverse events.

Both of those areas lead to more consistent data entry and data quality. What eCRF improvements would help with the process?

Jill Janssen: Further clarification on study windows would be helpful, as there are numerous ways you can calculate them and it may not be clear within the protocol. A lot of EDCs will have calculations in place to alert the coordinator if a visit is out of a study window, but how that calculation is made is important. We usually don't find out until we put in a visit date that our calculation is not aligning with the EDC calculation. Having transparency behind what the sponsor is really wanting from a visit window is critical, especially when it's built as a check into the EDC.

Expanding reporting capabilities to enhance trial insights

If you have an audience full of sponsors, is there anything else you'd like to let them know or requests for things that would make your life easier?

Alesia Pruitt: Coordinators having access to reporting would be great, such as being able to look at the comment list and medications that we enter on different forms. Having a comprehensive list for each patient to be able to print from the EDC would be very helpful, especially when it comes to some patients who have their own medication list that they keep with them all the time. If I can give patients a list at the same time and say, "Okay, these are the medications that we have listed for you. If anything changes, just make sure you keep this with you so we can update as needed."

What other kinds of reports would you find useful in the work you do at the site?

Jill Janssen: We work with living, breathing source documents that change as we go through a trial, especially with adverse events and con-meds. Instead of having to go back and note that I updated con-meds and so I need to make sure the EDC matches, it would be beneficial to have reports to compare the two. If the EDC is utilizing visit windows, a report showing the visits across the study is helpful—as is what visits have been completed with dates so that you can see a true visit log within the system to make sure it's matching up.

Alesia Pruitt: And being able to pull these reports also helps our quality control so we won't be behind or have to wait for a full-scale audit to make sure things are done correctly. A drug accountability report would also be helpful, especially when we're not using investigational drug services and we are the pharmacy. Being able to

reconcile that information in the EDC rather than multiple different places is advantageous. All that information is already in the EDC, so having a way to better track that as the study progresses—especially when you have to do pill counts throughout the study—keeps everything consistent.

If those reports were to become available, how would you like to receive them?

Jill Janssen: They should be viewable within the system in real time. We usually have to wait for the monitor to check and balance our items, and it would be nice to be able to prevent some of that by reviewing them ourselves. Having those visualizations from an administrator standpoint in the system and in real time would be helpful. In fact, giving a site administrator or quality team manager view-only access to the EDC system would be very helpful. We've asked and are often told "no," but it would help us identify issues in a timely manner so we can proactively retrain our staff if there's an issue and not have to wait for a monitoring visit.

Watch the on-demand Veeva Summit on R&D and Quality webinar to learn how to run more patient-centric, efficient, and cost-effective clinical trials.