Changes needed for EDC to show true efficiency

By Suz Redfearn

Three quarters of clinical trial managers report challenges loading data into their EDC systems, which in turn increases the time it takes to build study databases and then delays trials.

Eighty-three percent of life sciences organizations release a clinical database after the first patient, first visit. It takes an average of 68 days to build and release a clinical study database, which contributes to an increase of nearly a month downstream in the completion of a trial.

These are some of the results of new research from the Tufts Center for the Study of Drug Development (CSDD) and Veeva Systems, a cloud computing company focused on pharmaceutical and life sciences industries. The two teamed up to look at whether or not the huge efficiency gains promised by EDC when it first hit the market were in fact being delivered. About 250 clinical trial managers were queried for the 2017 eClinical Landscape Study, which the researchers say is one of the largest, most in-depth surveys of clinical data management professionals ever done.

Over the last 30 years, EDC systems have become engrained into the fabric of the drug development process, in an effort to replace paper. New guidelines and laws such as the PUDFA IV Section 12 mandate that all new drug submissions comply with CDISC electronic data standards. But the benefits of EDC systems have yet to be fully realized.

The main culprit isn’t necessarily the EDC systems themselves, but rather the increasing level of complication seen in study protocols, said Ken Getz, director of sponsored research programs and research associate professor at Tufts.

“We believe the major root cause is the complexity of our protocols and how that translates into the execution of the study as it’s supported by various functions,” he said. “We’ve shown that the more complex the protocol, the worse the recruitment and retention, and overall timelines. Now we look at data management and we see so much of the burden and challenge that protocol complexity is presenting there, too.”

Getz continued, “The protocols require a high volume of data coming from a variety of sources—wearable devices, patient-reported devices, real-word evidence—and all of this is creating data management challenges. The results of our study are yet another manifestation of the impact the growth in the clinical trial community is having on different critical operating functions.”

Even so, current eClinical offerings aren’t all they need to be. Current industry-standard solutions have not been built with the necessary flexibility to handle these changes, which are unavoidable in today’s clinical trial environment, wrote the study authors, adding that it’s also one of the reasons why modern clinical trials aren’t much faster or more efficient than they were 20 or 30 years ago, despite new technologies.

EDC is the most widely adopted clinical application, used by all respondents to the survey, followed by randomization and trial supply management (77%), electronic master file (70%) and safety (70%) systems.

A majority (58%) of respondents use either Medidata Rave or Oracle Inform as their primary EDC system.

At least one big player in the space takes umbrage to the study. Mike Capone, chief operating officer of Medidata, said the study didn’t factor protocol complexity into its survey.

“It’s difficult to draw a correlation between the time it takes for a trial to complete without factoring in measures of complexity,” he said. “For example, treating the perception of those who have focused on early phase studies in therapeutic areas with few end points, such as pain management, the same as the perceptions of those who have worked on complex, adaptive-arm oncology studies that utilize a variety of biomarkers could be considered confounding.”

Richard Young, vice president of Veeva Systems, which just entered the EDC market in April of this year, said complexity didn’t yet need to come into play for what Tufts and Veeva were measuring.

“This survey was very much about trying to establish a baseline of how long data management activities take, and we interestingly found there are correlations between them,” he said. “The standard timeline to get a study operational is 60 days, but the industry on average is not hitting that milestone. We know study complexity plays a role, but the goal of the survey was to quantify how long these tasks are currently taking across all studies.”

When asked about the type of data managed in their EDC, all CROs and sponsors
surveyed cited electronic case report form (eCRF) data, followed by local lab and quality of life data (60% each). However, respondents say eCRF data is the highest volume of data they manage in their EDC system (at an average of 78% of the total data managed). The next highest data volumes reported are central lab data and local lab data at 5% each. This demonstrates the need for processes and systems to support the industry’s vision to have complete study data in their EDC, said the study’s authors.

What lies ahead? Getz said the survey results raise questions about what the industry will need to do to continue to meet its goals of getting to a higher level of efficiency and speed while maintaining quality.

“The results of the study are a new baseline assessment measuring the role of the data management function as a strategic asset, because it’s being tasked with having to manage too much—not just data from CRFs but also data from so many different applications and sources,” said Getz. “We think this points to the real premium that needs to be placed on solving the protocol complexity issue.”

Getz said he’s heartened, though, by initiatives taking place across the industry, such as committees that review protocol feasibility, use of patient and professional advisories to give second opinions on protocols before they launch and the increasing use of adaptive designs and pragmatic trials, which require more upfront planning before the protocol is unveiled.

“There is a lot happening to impact this area, and the benchmark data we’re providing may get organizations to focus more on their data management function and what changes they need to make to meet their own timeline requirements,” said Getz.