SPONSORED

A unified, connected foundation is transforming the future of digital trials

Life science companies see the benefits of moving to a unified clinical operating model

Published Nov. 21, 2022

By Jodi Helmer

Permission granted by Veeva Systems

Sponsored content
By Veeva Systems

The number of clinical trials has increased from 2,119 in 2000 to more than 409,000 (and counting) in 2022. It's not just the number of trials that has increased; the amount of data has, too.

The average phase III clinical trial generates 3.6 million data points—three times more data than late-stage trials generated a decade ago—and that data is often collected in

different formats, making it difficult for sites, sponsors and contract research organizations (CROs) to manage and understand the influx of information.

“Many clinical operations processes are more time-consuming today than they were five to 10 years ago, which is largely due to increased complexity and information overload,” explains Jason Methia, vice president of Vault Clinical Operations Strategy at Veeva Systems. “With the rapid adoption of decentralized trials, you have this extreme proliferation of technology, but it’s all disconnected.”

During the pandemic, 87% of trial sponsors and CROs rapidly deployed decentralized trials1. Despite progress in moving to more digital ways of working, a fragmented technology landscape has created additional challenges in study speed, quality and collaboration.

Moving away from this fragmented landscape and unifying clinical technologies is critical to seamlessly connect trial stakeholders, improve data quality and speed development.

The need for digital transformation in clinical trials

The current lack of interoperability creates silos that negatively impact data integrity and slow down trial execution.

“A majority of the patient data, operational data and documents that a pharma company manages must be shared between several study partners,” says Methia. “You need complete and accurate information to monitor trial progress and make informed decisions based on a holistic view of the trial.”

A unified platform provides a single interface to manage the entire clinical trial process. When sponsors, CROs and investigators adopt common processes for tracking and managing data and documents, organizations can mitigate risks and run faster, more

cost-effective trials. Enabling this connected approach is why 95% of sponsors and CROs who adopted decentralized trials are also establishing a unified digital foundation to support sites and patients and improve data sharing and collaboration2.

“Bringing together applications such as eTMF, CTMS, study start-up and site payments eliminates functional silos,” Methia says. “You need a single source of truth to have a complete picture of what’s happening in the trial from an execution and compliance standpoint.”

Better data leads to improved decision-making

Data stored in multiple systems must be manually entered and then re-entered into different file formats to suit the needs of users, increasing errors and inconsistencies, ultimately eroding confidence in the data.

“Normalizing the data takes time, it reduces efficiency and it causes processes to grind to a halt,” says Chris McSpiritt, senior director of clinical strategy at Veeva Systems.

The lag also hinders access to real-time data that CROs and sponsors need for informed decision-making. A unified clinical operating model offers full visibility across clinical trial processes, enabling greater oversight and better decision-making that’s needed for high-quality trial execution.

Having accurate, up-to-date data means decisions can be made earlier in the study, which could have important implications for patient safety, risk and issue mitigation and the overall operational timeline, according to McSpiritt. “Visibility allows us to make the right decision faster,” he adds.

Optimizing digital trial execution

There is an industry-wide shift toward a digital trial environment that connects patients, sites, sponsors and CROs to drive seamless execution and flow of data across stakeholders3.

Researchers at the Tufts Center for the Study of Drug Development found that a phase II decentralized clinical trial that resulted in a time savings of one to three months was linked to a net benefit up to five times greater than the investment in the technologies needed to run decentralized trials; in phase III studies, the net savings was up to 14 times greater than the upfront investment.

As the industry progresses toward this vision, clinical trials will become more patient-centric and speed access to medical treatments. A unified clinical operating model drives higher levels of efficiency by streamlining study execution and simplifying information sharing and collaboration for faster, higher-quality trials.

Methia believes a holistic approach allows stakeholders to adapt to the ever-increasing number of clinical trials and data points, adding, “It’s the foundation for a broader expansion and enables the industry to tackle some of the biggest challenges holding back digital transformation. A clinical trial operating model on a single platform drives the efficiency and interoperability that’s needed to support digital trials.”