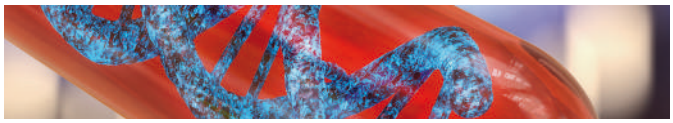
Digital Clinical Trials: Time to Throw Out the Old Rule Book

Unless we create a new rule book with user experience at the forefront, operational excellence will remain a distant dream.



Traditional industries are regularly disrupted by new technologies, and the life sciences industry is no exception. Electronic data capture (EDC) arrived on the scene decades ago. It has now become the de facto tool for data management and collection, and over time it has bought with it several important benefits. Where previously it would take 8 to 16 weeks for data recorded during a patient's visit to appear in the data management workstream, EDC has reduced that lag time from weeks to days, even hours in some cases.

However, these changes did bring trade-offs with them. Traditional EDC, for example, transferred the responsibility of data entry from sponsors to sites. This fragmented the data model whilst ignoring the underlying challenges around data collection. The pandemic saw another crucial change, with the industry introducing new processes and technology that allowed organisations to oversee and execute trials remotely. Patients now had new methods of participating in studies, however, it meant site users were left juggling trial data originating from multiple sources.

These trade-offs that prioritise the needs of one set of users (e.g.sites, patients, regulators, etc.) over equally important stakeholder groups can have a detrimental effect. Ultimately, there needs to be a realignment between operational efficiency and scientific rigour. Rather than having to choose between trial execution and scientific excellence, we instead need a fresh approach to these challenges. If we're ever to deliver on the potential of digital clinical trials, we need to place the user experience at the centre of our efforts.

Refocusing on Speed and Simplicity

At a recent Veeva event for more than 500 European R&D and quality leaders, the discussion topics were surprisingly consistent. The industry is increasingly frustrated with the silo-driven approach suppressing operational efficiency. Obstacles include fragmented data, inefficient processes, and the heavy demands of manual tasks, not to mention the difficulty of breaking long-established ways of working.

It's easy to see how disjointed technology and processes could hinder progress in areas that should be advancing faster. In data management, for example, the complexity of today's clinical trials means it is far more challenging to be efficient. Trials that were linear at the start of my career are now four-dimensional. We've morphed into an era of platform, bucket, and umbrella trials that require amendments after almost every visit. Tanya du Plessis, chief data and solutions officer at CRO Bioforum, summarizes the challenge: "We've gone from linear to almost circular [in data management]. It's hard to determine where one step starts and the other ends, and that's not even accounting for the volume or veracity of data."

It's fairly common now to see studies with 15 or more data sources or types. Yet, as an industry, we are not at the point where our systems and processes can easily manage non-conventional data at scale. The outcome is patchwork solutions that require complex data integrations. Instead of more automation, we rely heavily on manual solutions (such as emails and spreadsheets) to track data queries and cleanliness. This makes the data manager's job harder and does nothing to boost productivity.

Even more troubling, a siloed approach to complex trials raises the risk of poor decision-making. Companies have introduced technology to collect data from sources that did not exist (nor were accepted) by regulators until a few years ago. Millions of new data points have had a huge impact, slowing data cleaning and reviews. It has become critical to gain central oversight of these tasks that are now undertaken in a decentralized manner.

How can we create a more connected approach? First, we need to focus more on the total experience in clinical trials across stakeholders. I believe today's clinical trials are like a complex Rubik's Cube, with each side representing an important user group. Each time you try to solve a problem for one set of users, you need to specifically review the experience of other users to determine the overall impact. Just as you can't solve a Rubik's Cube with one move, the challenges we face in clinical trials are too big to address with one phase of digital transformation. Instead, we need to take incremental steps and focus our innovation efforts on eliminating daily time-consuming tasks.

For instance, data managers need better tools to aggregate, clean, and provide data with less manual effort. We can automate activities like data cleaning, medical coding, safety signals, and predictive analyses, which are all too often still on paper or in spreadsheets. Technology can also eliminate manual processes to simplify the data manager's job, like end-of-study data or serious advance-event reconciliation.

Having a holistic view of clean and concurrent data is important. Not only does our database need to scale to match today's complex clinical trials, but we also need the capability to harmonize data from multiple sources without custom coding. The data model we require needs to be simultaneously flexible to adjust to future trial requirements and robust enough to handle today's complexity.

Simplifying the User Experience

There are more tools available than ever before and greater opportunities to run studies more efficiently. However, by introducing an avalanche of new systems, we have significantly increased the burden on users with seemingly few efficiency gains.

If we are to make a real difference in productivity, the priority should be to work with sites to understand their frustrations and burdens. On the patient side, simplifying the number of tools patients use could improve participation and choice. Then, we can move on to offering them a consumer-grade experience that meets specific

needs, like easy methods of reminder management or dispensing and travel support.

The life sciences industry must recapture the essence of its goal, which is ensuring that patients can participate in the right clinical studies – to do this, they need to be enrolled as quickly and as seamlessly as possible. To deliver medicines and therapies to the broader patient population in a timely manner, we must take responsibility for speeding this process up. It's time to embrace different ways of working, and through a mix of pragmatism, optimism, and enthusiasm, we can draft a new rule book that brings truly effective change.

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Richard Young is Vice President, Vault CDMS, at Veeva Systems. With over 25 years of experience in life sciences, Richard is known for his executive vision and proven operational experience in data management, eClinical solutions, and advanced clinical strategies. His role at Veeva is helping to transform the way we approach clinical data, unifying every contributor and consumer in a single platform.