Delivering on the Promise of Digital Trials: Simplified Experiences for Sites and Patients

The shift toward decentralised trials (DCTs) was not caused by COVID-19 but has certainly been accelerated by it. Research indicates that just 28% of sponsors and CROs ran DCTs before the pandemic.[1] Now, 87% run DCTs, with estimates of an increase to 95% in years to come.

DCTs should result in a more patient-centric experience. Since they do not need to travel to clinical research sites to participate in studies, patients are empowered to share clinical data from varied caregiving settings. Remote clinical trials are enabled through the use of digital applications, which are the how of DCTs. But such a rapid shift has introduced challenges, with patients juggling multiple technologies during a trial.

Patients are not the only ones facing challenges. Sites also find it difficult to realise the operational benefits of DCTs. As one sponsor at a recent Veeva roundtable noted: "Decentralised trials burden sites with more technology and processes. We need to provide a helping hand for more efficient execution."

Patient Effort Still High

New processes and technology (including patient-facing applications) were introduced rapidly at sites during the pandemic so ongoing trials could continue. This included wearables, digital patient diaries, electronic monitoring, and electronic consent (eConsent) forms, which are now standard tools for patients and site teams.

But, if introduced as separate applications, they shift the burden onto patients, who become responsible for downloading apps to document their progress and communicate with study teams. Some struggle with the day-to-day experience of multiple logins and passwords. Others, particularly in Europe, need reassurance around privacy implications, such as how their health data is being stored and accessed.

Greater Capabilities, More Complexity

Digital transformation has also increased operational complexity for sites, particularly those running large numbers of trials. Without close coordination with sponsors, it's difficult to cultivate technology expertise at sites. Instead, clinical research sites spend disproportionate time training their teams to navigate dozens of platforms introduced by different sponsors.

Site staff, who thrive on patient interaction, are instead troubleshooting technology issues for patients. Some sites have even hired platform managers and technology liaisons to free up research nurses to focus on patients. Lacking standardised or connected systems, many sites struggle to operate efficiently.

At a recent Veeva roundtable of clinical operations leaders, Joana Claverol, who leads the clinical research unit at Barcelona Children's Hospital SJD, depicted the scale of the challenge: "Every year, we conduct roughly 200 trials, and we use the sponsor's technology for each. A trial can require us to use different platforms for feasibility, documentation, electronic data capture, patient randomisation, travel expenses, imaging, invoicing, and others."

Sponsors acknowledge the heavy burden on sites of multiple siloed applications: 99% of those surveyed agreed that technology adoption is a major barrier to decentralised trials.1 As the systems are disconnected and lack interoperability, this can result in data access and quality issues for site teams and CROs: for example, if the same data is manually entered into different systems.

Four Steps to Simplify the Experience

Sponsors should seize the opportunity to reduce the technology burden on patients and sites. Here are four steps to simplify the experience and deliver on the promise of digital trials:

1. **Build standard operating procedures (SOP).** Identify universal ways of working and standardise SOPs before introducing new technology. For example, develop a login pathway that minimises the number of times a team member or patient will have to log into applications.

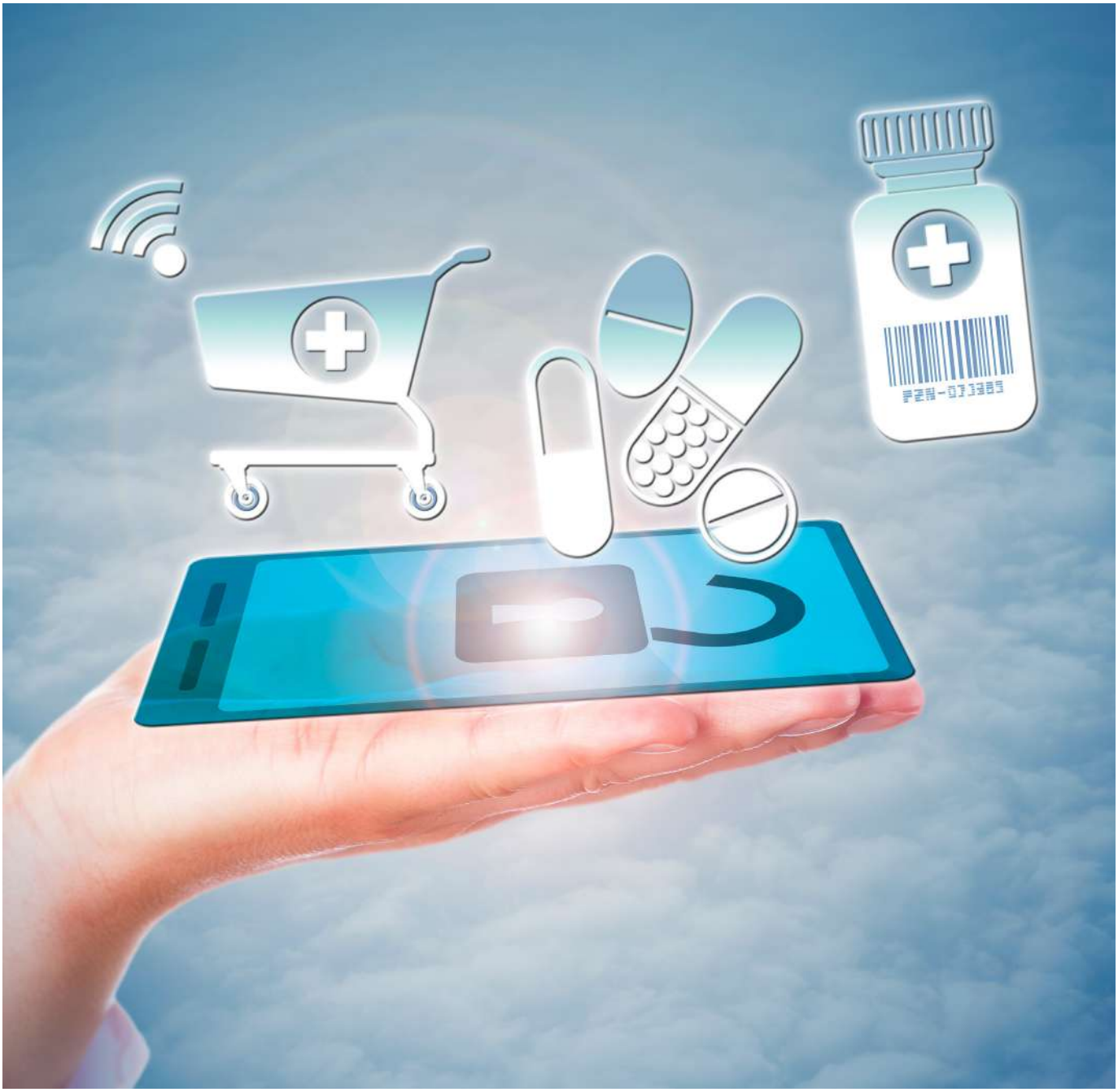
2. **Collaborate early and often with users.** Before adding a new resource, widen the conversation to teams, sponsors, and patients. This will help incorporate new criteria in software decisions that could boost user adoption, including functionality, user-friendliness, and workload.

3. **Identify dedicated resources for site support.** Create a digital support team as a single point of contact for sites. Make sure they work directly with new technology vendors and are trained to troubleshoot for sites.

4. **Improve the patient experience.** Making trial participation more accessible and convenient will improve patient enrollment and retention. Innovative patient-facing applications could be used to keep patients informed and connected through a single application for all their trial activities. Study information should flow seamlessly between sponsors, CROs, sites, and patients, eliminating paper and manual processes.

Effective Data Management at the Core

An emerging priority is gaining access to a system that aggregates real-time data in one place. This would address sites' data quality concerns by ensuring all uploaded data from multiple applications are brought into one platform. Investigators would benefit by being able to make decisions quickly. Site leaders pinpoint the potential impact on efficiency: "We estimate that 20% of our time would be saved if we could use one platform to simplify our work," Claverol said.



With paperless trials now the norm, sites increasingly see the need for flexible, modern electronic data capture (EDC). One sponsor observed that this is underestimated by teams when they move from paper to electronic processes. "People can do whatever they want with paper, but when you try to do something electronically all your decisions have to be made upfront. This can slow down implementation."

Collaborate and Consolidate

The shift to decentralised clinical trials was already underway but has been accelerated by the pandemic. As a result, patients are more empowered to participate in studies and contribute data from different settings. DCTs also offer great potential to improve collaboration between patients, sites, sponsors, and CROs, for better trial and patient outcomes.

There is a significant opportunity to convert willingness to use new tools into improved operational efficiency at sites, and a seamless patient experience. It requires a more collaborative approach and a willingness to consolidate existing systems. Only then will digital trials start to deliver on their huge potential.

REFERENCES

1. Veeva, Digital Clinical Trials Survey Report, 2021
2. Veeva, Digital Clinical Trials Survey Report, 2021

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