ARE DECENTRALISED TRIALS THE SOLUTION TO OUR CLINICAL TRIAL WOES?

Branding Science Group

From participant recruitment and retention to ensuring diversity and minimising patient burden, the world of clinical trials faces a unique set of challenges.

Decentralised clinical trials (DCTs) have emerged as a potential solution, promising to address some of these longstanding issues. But are they truly the solution we've been waiting for, or do they bring new challenges of their own?

At a recent webinar, Branding Science Director, Chris Recaldin, explored the true impact of decentralising clinical trials.

Take a look at our article below to dive into their key insights, or for a more in-depth look, click here to watch the webinar in full on demand.

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What are decentralised clinical trials?

Decentralised clinical trials shift away from the traditional brick-and-mortar model of trials, offering more flexibility through telemedicine, mobile technology, and local healthcare providers.

The concept spans a spectrum, from partially decentralised trials, where only certain elements are conducted remotely (like e-consent or telemedicine visits), to fully decentralised models where every aspect of the trial takes place away from a centralised site.

The excitement around DCTs, which in more recent years has been accelerated by the COVID-19 pandemic, has led to estimates that the market for decentralised solutions could reach **$17 billion by 2027**. But while the potential is clear, the actual benefits and challenges of implementing DCTs warrant a closer look.

The benefits of decentralisation

Improved participant experience

One of the most significant benefits of decentralisation is the improved participant experience. By reducing the need for travel, DCTs can alleviate one of the major burdens of traditional trials. A 2021 study revealed that 70% of participants lived more than two hours away from a trial site. For many, decentralisation could significantly reduce the strain of travel, particularly for those from lower income backgrounds.

Telemedicine and other remote trial elements can make trials more accessible to a broader range of participants. This is especially valuable for patients with conditions where physical exams are less critical, such as chronic kidney disease, where patient assessments are primarily based on blood tests rather than in-person evaluations.

Enhanced diversity

Increasing diversity in clinical trials has become a critical focus for regulatory bodies like the FDA, which now requires sponsors to create diversity action plans.

Decentralisation can help sponsors reach underrepresented populations by reducing the barriers to participation. Older adults, those from racial and ethnic minority groups, and people in rural areas may find it easier to join trials with decentralised components.

While data on the direct impact of DCTs on diversity is still evolving, early studies indicate positive trends. For example, a 2019 study from the Centre for the Study of Drug Development found that trials incorporating DCT elements recruited more participants from lower income brackets, reducing the barrier of time off work and travel.

Better recruitment and retention

Recruitment and retention are notorious challenges for clinical trials, with up to 80% of trials failing to meet their enrolment timelines. Decentralisation offers some promise here. A systematic review of 13 scientific papers found that 11 of them showed improved recruitment when decentralised methods were used, such as online recruitment tactics. However, the same review found mixed results when it came to retention, with only seven papers showing an improvement in keeping participants engaged.

Challenges of decentralised trials

Despite the benefits, decentralised trials also come with their share of challenges. Two of the most significant are accessibility and integration.

Digital divide and accessibility

Not all participants have equal access to technology, and this can become a barrier in decentralised trials. While decentralisation can help reach lower income populations, these same groups may struggle with access to reliable internet or lack the necessary devices for digital participation. A report by the Journal of Internet Research noted that between 20-30% of trial participants failed to engage with digital tools due to these limitations.

Complexity and integration

As clinical trials become more complex, incorporating decentralised elements can add another layer of difficulty. A recent benchmarking report highlighted that trial complexity is increasing, partly due to the addition of digital tools like home health visits and remote data capture. Some of these tools have even been abandoned mid-trial due to issues with regulatory approval or concerns about data integrity.

A survey by Clinical Trials Arena found that while 70% of sponsors intended to use decentralised components, only 30% successfully implemented them. This underscores the challenge of integrating these tools smoothly into trial protocols.

Are decentralised trials the solution?

Decentralised trials are not a one-size-fits-all solution. While they offer real benefits, particularly in improving participant experience and recruitment, they also introduce new complexities. The decision to decentralise a trial should be based on the specific needs of the patient population and the condition being studied. For some conditions, decentralisation makes perfect sense, while for others, in-person visits remain essential.

> To ensure success, trial teams must carefully consider which decentralised solutions to implement, ensuring they address real patient needs. Moreover, testing these solutions in a safe environment before full implementation is critical to avoid unnecessary complications.

Decentralisation may not be a silver bullet, but with thoughtful integration, it can be a valuable tool in the future of clinical trials.

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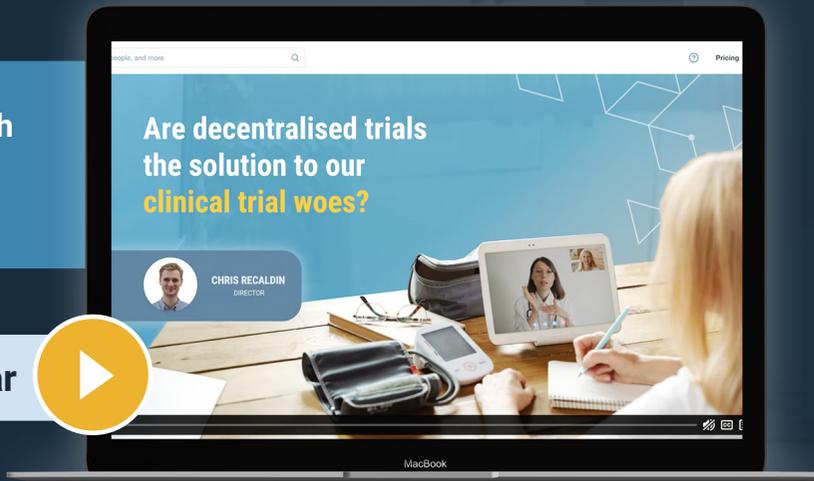
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