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PLANNING A DECENTRALIZED CLINICAL TRIAL?

Three Site Engagement Recommendations to Maximize Your Success

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Decentralized clinical trials (DCTs) promise many benefits for Sponsors and CROs, including more available patient pools, faster enrollment, and greater patient retention. The engagement of the right sites, with the right approach, is equally important to achieving these results.

The pandemic forced sites to embrace elements of DCTs as a stopgap measure to keep patients safe and trials in compliance. However, not all sites will choose to work this way in the future. Sites that embrace DCTs need new operational frameworks and additional support from Sponsors and CROs as they navigate this new research environment.

To ease the transition, CROs and Sponsors will need to adapt their trial planning and management process, which begins with answering the following three questions:

1. How does my site selection approach need to change?

The days when Sponsors could choose sites based primarily on access to patients are long over. Site selection will need to include sites that are willing and able to accommodate a decentralized design. This requires a new site evaluation approach that determines:

- Which telehealth platforms they use and whether they are open to using new solutions
- How they handle remote monitoring and uploading of documentation for clinical monitoring
- Whether they are willing to work with home health companies and new approaches such as direct IP shipments to patients

Sponsors and CROs should also talk with site staff about their comfort and concerns conducting a DCT. Do they feel confident treating patients virtually? Using technology throughout the care experience? Are they excited about the transition to DCT or grudgingly accommodating? How sites answer these questions will indicate their willingness to adapt.

2. How should PI/Site budgets and contracts be approached differently?

Sponsors and CROs often rely on industry benchmarking tools that use historical data to develop site budgets. However, there is almost no historical data around operating within a DCT. Further, site budget formats have not changed much in over 30 years – mostly because the way trials have been designed and managed has not changed.

We are now in the decade of change and that creates blind spots and opportunities for all parties.

Sponsors will need to develop new budget standards that consider the time and costs for sites related to remote monitoring, telemed visits, integration with home health companies, and other activities. Other factors include custom devices versus allowing patients to use mobile apps; and what additional partners, including home health service providers, require separate contracts. If the sites do not feel like they are part of the solution and well compensated, patient enrollment will suffer. Sponsors still need the sites to enroll the patients - unless it is a completely virtual trial, which are few and far between.

3. How will site management change?

DCTs change the way trials are run, which impacts almost every step in the research process. In order for trials to run smoothly, Sponsors need to rethink the logistics of each trial and how it affects sites, and what key touchpoints will ensure successful delivery.

Some issues to consider include what site visit make-up will be included (in-person, telemedicine and home health visits); how patients will access treatment; how sites will capture and share patient data; how CROs will monitor site performance; and what role sites will play in supporting patients digitally.

Since this is an unfamiliar research environment, every role and activity must be clearly defined to avoid it quickly devolving into confusion.

Worth the effort

COVID-19 may have forced the pharmaceutical industry to adopt to DCTs, but if we can help sites embrace this transition, everyone benefits. DCTs make it easier for more people to participate in trials, which can accelerate results for Sponsors and allow site staff to spend less time on patient recruitment activities.

The Sponsors and CROs that make the time now to help their favorite sites adopt a DCT mindset will be best positioned to generate these benefits and gain an edge over their less innovative peers.

For more information on decentralized trials, contact credeker@advancedclinical.com

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