Impact Assessment of Decentralized Clinical Trials (DCT)

Awareness in the Clinical Research Industry

SCRS
Society for Clinical Research Sites
Our Voice | Our Community | Your Success

SCRS WHITE PAPER
May 2020

Clinical research sites continually strive to improve patient recruitment and engagement practices for clinical trials in an effort to provide sponsors with the critical data they need to bring new medications to market safely. In addition, it is an ongoing challenge to retain the number of patients needed to successfully complete and validate the integrity of a study. As the Food and Drug Administration's (FDA) Commissioner of Food and Drugs, Scott Gottlieb, said when addressing barriers between clinical trials and clinical care, we "see great potential in using digital technologies to bring clinical trials to the patient, rather than always requiring the patient to travel to the investigator. This is an FDA priority."[1] While the industry continues to search for new solutions that simplify the process and reduce the burden on patients, there is a gap between available solutions and the adoption of those solutions by sites. The relevant questions here are: how long it will take for the majority of sites to adopt new solutions, and what is holding them back?

To better understand the obstacles to industry-wide adoption, VirTrial, in collaboration with the Society for Clinical Research Sites (SCRS), surveyed clinical research site professionals (clinicians) worldwide to discover:

> The most prominent challenges in enrollment and retention when conducting trials;
>
> Site awareness of decentralized clinical trials (DCTs);
>
> Alignment between the two preceding points, and;
>
> The level of education available on telemedicine solutions.

The term decentralized clinical trials (DCTs) was coined by the Clinical Trials Transformation Initiative (CTTI), an organization that was established in 2007 through a partnership between the US Food and Drug Administration (FDA) and Duke University. CTTI developed a white paper which provides guidance around DCTs entitled "CTTI Recommendations: Decentralized Clinical Trials" in September 2018.[2] The white paper includes standardized industry terminology to encourage consistency and minimize confusion regarding DCTs. Within the paper, DCTs are described as trial visits "executed through telemedicine and mobile/local healthcare providers (HCPs), using procedures that vary from the traditional clinical trial model (e.g., the investigational medical product [IMP] is shipped directly to the trial participant)."[2] DCTs can be conducted as 100% decentralized or as a hybrid study in which the DCT offers the additional flexibility of incorporating both in-person visits and virtual visits into the study as appropriate.

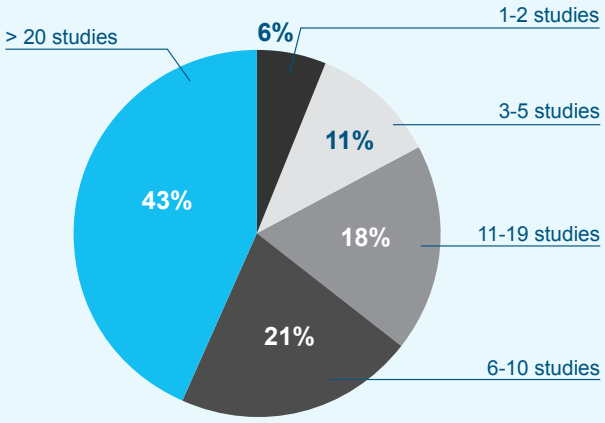


Figure 1
Average Number of Studies Conducted/Year

METHODOLOGY

The survey, completed in July 2019, included 340 site professionals worldwide, with 80% based in the US. The participants primarily represented private practices, freestanding research centers, practice groups, and research institutions. Most held titles of Principal Investigator (PI), Clinical Research Coordinator (CRC) or Site Director. Slightly less than half were part of a site network, and more than 43% of respondents reported conducting more than 20 studies per year followed by over 18% who reported that they conduct 11 - 19 studies per year (Figure 1).

KEY FINDINGS

- Respondents' primary concerns regarding DCTs were patient safety, study quality, and fewer sites receiving trials as DCTs become more prevalent.
- The majority of sites have not received adequate training and education on DCTs, and few have experience actually conducting a DCT.
- Priorities listed by survey respondents that would help with enrollment and retention are well-aligned with the benefits DCTs provide.
- Multiple examples of how both clinicians and patients spend unnecessary time completing study-related tasks that could be saved by adopting decentralized visits were identified.
- One-quarter of sites have not taken the steps necessary to prepare for DCT adoption and implementation.

SURVEY RESULTS

As expected, clinicians' concerns regarding the adoption of DCTs centered around patient safety and the quality of studies. However, many clinicians also reported that they were not well-educated about DCTs and that their respective sites had done little to prepare to adopt the new technology. The latter finding indicates that further training and investigation of DCTs is warranted to determine whether or not the core concerns are justified.

When asked to prioritize the variables that would increase enrollment and retention, survey respondents listed time as most important. Nearly half of survey respondents indicated that patients regularly spend as much as a quarter of their time involved in non-study-related activities such as traveling to and from the site and waiting in the lobby to be seen. 79% of respondents indicated that they believed patients would be likely or very likely to use their personal devices for trial-related activities if given the option, ranking it above their likelihood to use a secondary device or take-home equipment such as a blood pressure cuff.

With access to basic technology and a strong internet connection, any site can quickly work toward enabling themselves to perform DCTs. Overall, nearly 37% of clinicians reported that they have conducted a hybrid DCT, while 60% said they have only conducted traditional trials, and a mere 3% had participated in a completely virtual trial, where all visits are conducted remotely (Figure 3).

When asked about concerns regarding DCTs, 60% of sites said patient safety was their number one concern, followed by 37% who are concerned that fewer sites will be needed to conduct a study, and 30% with concerns about the quality of study data. The next highest ranked concerns were quality of study data, less personnel being needed to conduct a study and additional complexity for sites. These data indicate that sites are primarily concerned with patient safety and the quality of their data, followed by the fear that less sites will be needed for a study (Figure 3).

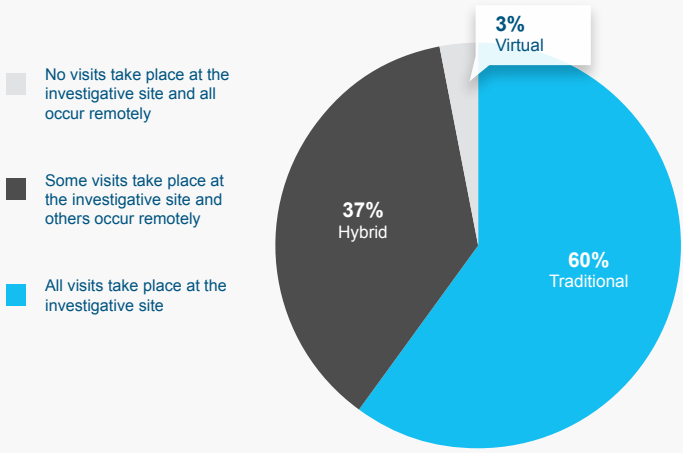
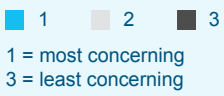
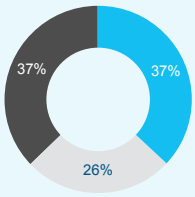


Figure 2
Type of Patient Visits Conducted by Site

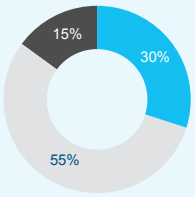
Figure 3
Top 3 Concerns for Virtual Trials



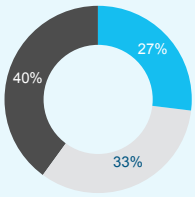
1 = most concerning
3 = least concerning



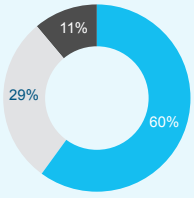
Less study sites will be needed to conduct a study



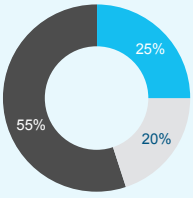
Quality of study data will be at risk



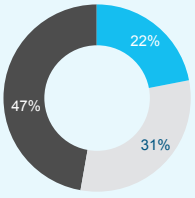
Less study personnel will be needed to conduct a study



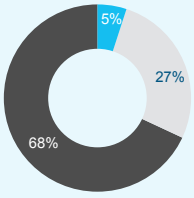
Safety of the patient will be at risk



Being a user of study related systems will become more complex



Being a study site will become more complex



Cost of conducting studies will increase

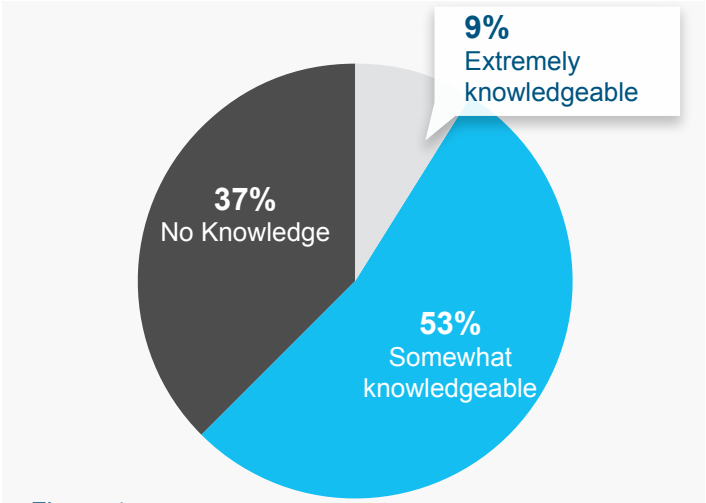


Figure 4

Knowledge of Virtual Trials & Their Potential Implications on Site Suistainability

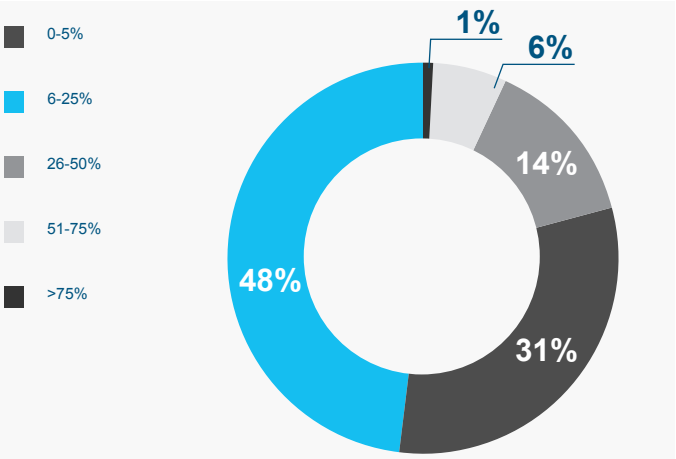


Figure 5

Time Patients Spend on Non Study-Related Activities

(i.e. Traveling to the site or waiting at the office to be seen)

More than half of participants responded that they are only somewhat knowledgeable about DCTs. Alarmingly, 37% stated they have no knowledge about DCTs. This correlates with findings that the majority of sites have not yet invested in training on DCTs or telemedicine platforms (Figure 4).

79% of respondents reported that patients spend up to a quarter of their time on non-study related activities such as traveling to the site or waiting in the office to be seen. Patients could consider committing this much excess time to a clinical trial burdensome, which may result in patient non-compliance and drop-out prior to study completion (Figure 5).

The distance for a patient to travel to participate in a clinical trial is often a barrier to recruitment or a factor in a patient's decision not to complete a study. 82% of survey respondents indicated that patients are either not willing to enroll or are likely to drop out of a study after enrolling if travel over 20 miles is required. If a patient is required to attend six in-person visits to qualify for the trial and the site is 21 miles away, that means the patient must drive 126 miles simply for office visits (Figure 6).

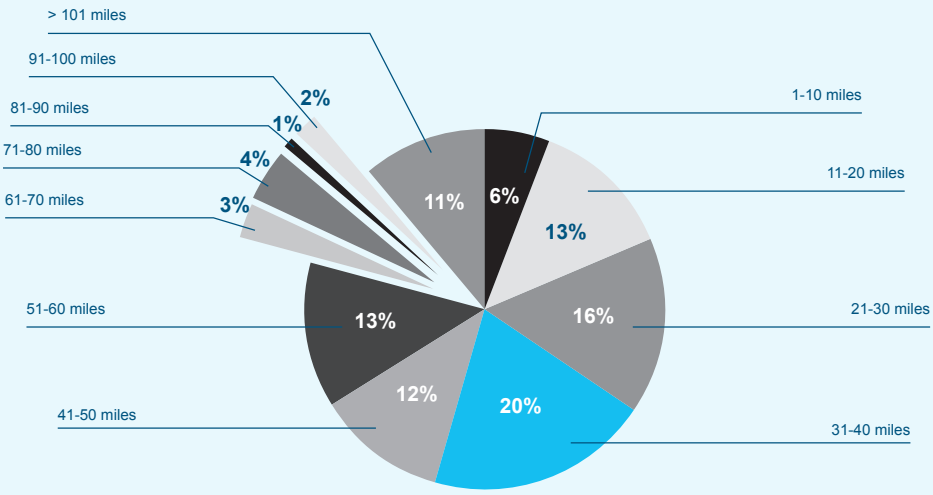


Figure 6

What Distance is too Far for Study Patients to Travel?

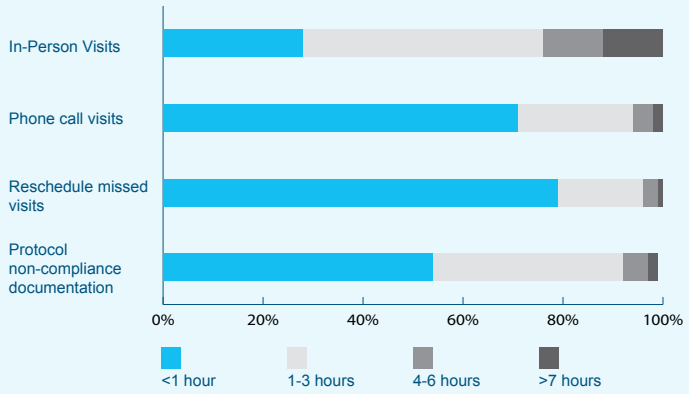


Figure 7

Approximate Time Sites Spend Per Patient on Activity

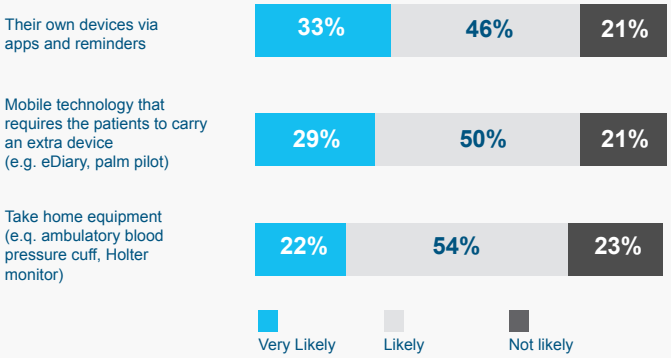


Figure 8

Likelihood of Patient Using Device Throughout Study

When asked how much time was spent on various activities per week, 48% of sites reported that they spend 1-3 hours per patient on in-person visits, and 38% spend the same amount of time working through protocol non-compliance documentation. Even more worrisome is that 12% of sites reported spending excess of 4 hours per patient during their week, with an additional 12% reporting spending more than 7 hours per patient for in-person visits. These data clearly indicate that sites are spending the majority of their time on in-person visits. Decreasing the frequency of in-person visits would be beneficial when time savings are needed.

The advantages of incorporating DCTs for routine visits could reduce in-clinic wait times and increase patient convenience. In addition, procedures such as simple blood draws could be conducted with traveling phlebotomy services or labs local to the patient. It would also enable sites to be more efficient, allowing PIs and other site personnel to spend more time focusing on in-person visits that require more complex procedures (Figure 7).

Creating as much ease of use as possible for patients and sites alike is an important component when introducing virtual elements to a clinical trial. 79% of survey respondents reported that in their experience, patients would be likely or very likely to consistently use personal devices, such as a cell phone, that they were already familiar with throughout a trial. This justifies a Bring Your Own Device (BYOD) model and technology applications that work on a patient's own device or any device patients are already comfortable using (Figure 8).

Mobile technology that requires patients to carry an extra device ranked second, presumably because it requires the patient to learn and carry a new device, adding to their burden. Take-home equipment ranked last as it is often not user-friendly and can be inconvenient for patients to use in their everyday lives.

When asked about the technology currently available at their sites, clinicians ranked telemedicine last in a list of eight options, indicating that site management has not yet made an investment in adopting the new technology (Figure 9).

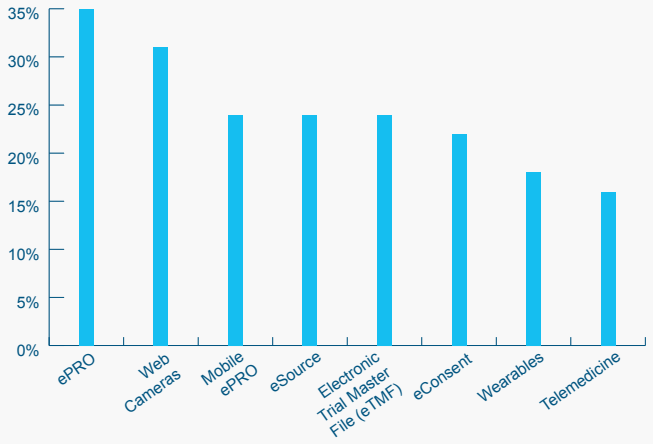


Figure 9

What Technologies are Currently Available at Your Site?

69% of respondents who have experience conducting DCTs said that compared to traditional trials, retention in DCTs was the same or higher, further substantiating the evidence that telemedicine and remote visits increase retention in clinical trials (Figure 10).

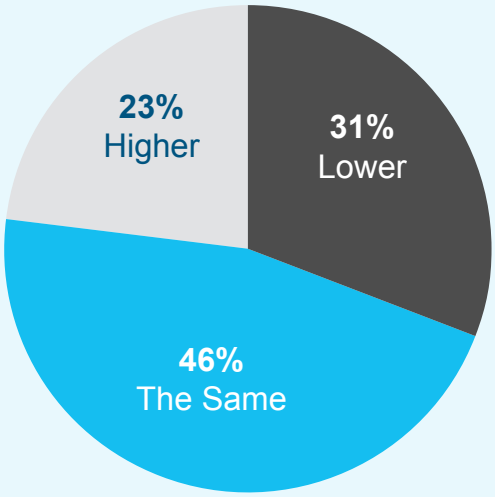


Figure 10
Compliance: Traditional vs. Virtual Trials

CONCLUSION

The survey results highlight an interesting fact: the key challenges cited by survey respondents can largely be solved by telemedicine platforms. The survey data shows that the clinical research industry can increase the pace of innovation by embracing new technologies that address current obstacles encountered by sites.

Sites that have conducted at least one DCT reported multiple benefits, including decreased workload and less time spent on administrative tasks, more patient interest due to less travel and increased flexibility, and having access to study data anywhere at any time. In addition, 69% of respondents reported that retention rates for DCTs were either the same or higher than for trials requiring 100% in-person visits. The majority of sites, however, have not invested in the education or technology needed to adopt a telemedicine platform and conduct DCTs.

Opportunities abound for the industry to address current challenges, increase enrollment and retention, and save significant time for both patients and clinicians. Solutions and training are available today that can help address the issues at hand. With additional education, a push to adopt technology, and a modification of current processes, great progress can be made quickly to advance the industry.

Consideration and support from sponsors and CROs can fast-track the adoption process. For example, adequate timelines and reimbursement for site training on how to conduct DCTs could enable more clinicians to become certified more quickly. When designing a protocol, confirming that the virtual elements that are incorporated will still enable sites to comply with local regulations and allow PIs to maintain oversight will ensure the ability to execute at the site level.

It is not often that big challenges have available solutions at their disposal, but the clinical research industry is currently in that rare and fortunate circumstance. Many of the most commonly reported challenges from clinicians are the precise issues that new telemedicine solutions aim to solve via DCTs.

REFERENCES

1. Food and Drug Administration (FDA). Gottlieb, S. Breaking Down Barriers Between Clinical Trials and Clinical Care: Incorporating Real World Evidence into Regulatory Decision Making. January 28, 2019. Accessed from: https://www.fda.gov/news-events/speeches-fda-officials/breaking-down-barriers-between-clinical-trials-and-clinical-care-incorporating-real-world-evidence

2. Clinical Trials Transformation Initiative (CTTI). CTTI Recommendations: Decentralized Clinical Trials. September 2018. Accessed from: https://www.ctti-clinicaltrials.org/sites/www.ctti-clinicaltrials.org/files/dct_recommendations_final.pdf

This paper was produced by SCRS in collaboration with

VIRTRIAL™
The Future of Decentralized Clinical Trials

Advocate

Educate

Mentor

Connect

SCRS
Society for Clinical Research Sites

Our Voice | Our Community | Your Success

7250 Parkway Drive. Suite 405 | Hanover, MD 21076 | 410.696.5080 | MySCRS.org