

Impact Assessment of eClinical Technologies and Industry Initiatives on Sites

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RESEARCH REPORT
SEPTEMBER 2019

TABLE OF CONTENTS

Introduction	3
Research Methodology	4
Results	6
eClinical Technologies Use	6
Industry Initiatives	9
Consolidated Investigator Platforms	9
Site Networks	12
Other	13
Decentralized Clinical Trials	14
Conclusion	20

INTRODUCTION

Sponsors and contract research organizations (CROs) fight a continuous uphill battle to reduce complexity, streamline business processes and workflows, ensure compliance and increase efficiencies in the pursuit of bringing drugs to market. Fundamental to this goal is a site-centric approach to conducting clinical trials.

Sites are dynamic environments, and new technology and industry initiatives are important complements to the critical need for relationship-building and maintenance. But, are these technologies and initiatives helping improve site and sponsor-CRO collaboration and creating a competitive edge through improved clinical trial performance?

To explore these issues and their impact, the Society for Clinical Research Sites (SCRS) and Oracle Health Sciences surveyed clinical research site professionals around the world.

The research provided valuable insights into the perceived and actual benefits and challenges for sites related to technology used in clinical trials, site networks and the industry move along the continuum from traditional to hybrid studies.

Key findings from the research:

- **Increasingly negative sentiment toward disparate systems** – More than a third of respondents expressed dissatisfaction with current eClinical technologies, which represents a 65% increase from 2016. Too many systems with different processes and login credentials, combined with redundant training, was cited as the main cause of this negative sentiment. Also, not surprisingly, dissatisfaction was found to be higher for sites working with multiple sponsors/CROs that require separate systems and login credentials.
- **Single sign-on and point of entry cited as priorities** – Despite their dissatisfaction, 70% of respondents have no plans to use currently available technologies to address these concerns. Consolidated Investigator Platform usage remains low at 17%, with sites indicating the high cost of implementation (i.e., sunk cost) and lacking utilization of a common solution across sponsors/CROs as pain points for adoption.
- **Membership in site networks is growing** – 48% of respondents are or are planning to become a member of a site network – an increase from 17% reported in a 2016 study conducted by ACRP/CenterWatch.¹ Improved trial access and site profiles were cited as the top reasons for joining.

- **Competition among sites for studies is prompting sites to improve their profile and improve their chances of being selected** – 47% have contributed to public/private registries. Establishing direct contact with sponsors/CROs and focusing on performing well (i.e., quality and speed) were cited above improving staff quality (e.g., hiring experienced research staff and providing training).
- **Opportunities and challenges lay ahead as the industry moves from traditional to hybrid studies** – While respondents cited greater patient participation (82%) and patient access (71%) as positive anticipated benefits, they cited more systems to be trained in (69%), more usernames and passwords (62%), and fewer sites (47%) and staff (48%) as negative anticipated results. In addition, respondents indicated risk to overall study quality data as the number one concern with decentralized trials.

Continue reading for deeper insight into these key findings.

RESEARCH METHODOLOGY

This research was conducted between April and June 2019 by SCRS. The research methodology used conformed to accepted marketing research methods, practices and procedures and was conducted through an online survey sent to SCRS, ACRP and Clin-Edge subscribers via email and social media outreach. The target population was clinical researchers working at investigative sites globally. Respondents were screened to ensure they worked for a research site of any type, resulting in 97% of respondents being currently active in clinical trials.

Most of the questions in the survey were constructed so that the participant had to rank four answers. In presenting the data, we use the terms *popular* and *important* to describe the sentiment of the question. The definitions are as follows:

- Popular (Most popular, all ranks) – the percentage of participants picking an answer, independent of ranking
- Important (#1 rank) – the percentage of participants ranking an answer #1

The descriptive statistics of the respondents are outlined in **Figures 1-5** below:

Figure 1: Type of investigative site with which respondents were affiliated:

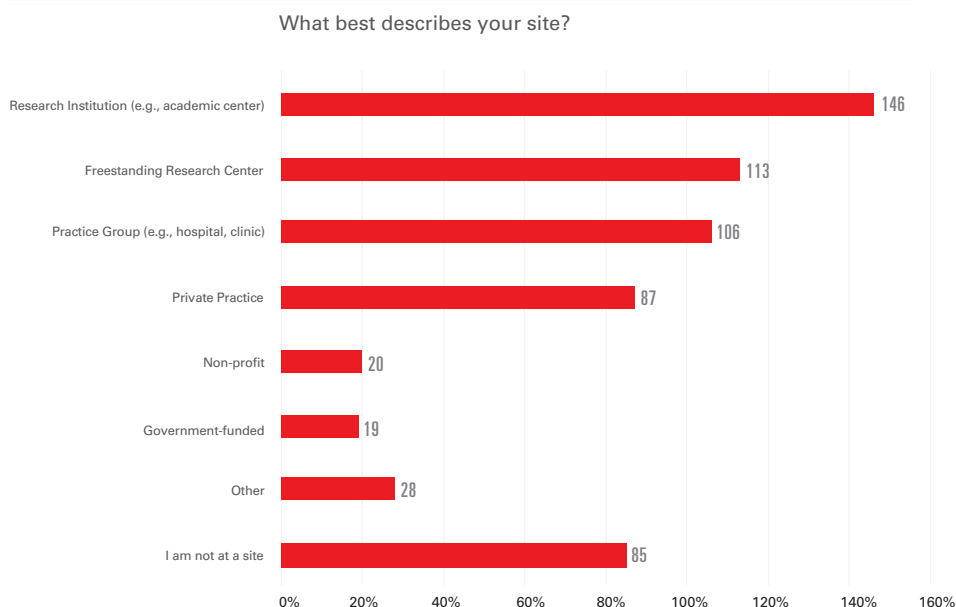


Figure 1

Figure 2: Respondent's role at the investigative site:

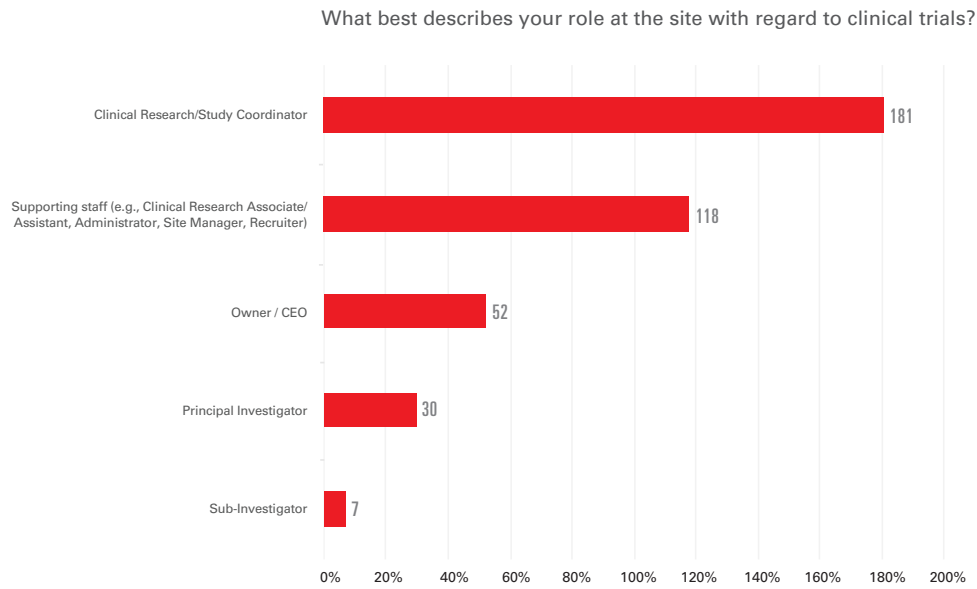


Figure 2

Figure 3: Type of community in which investigative sites worked:

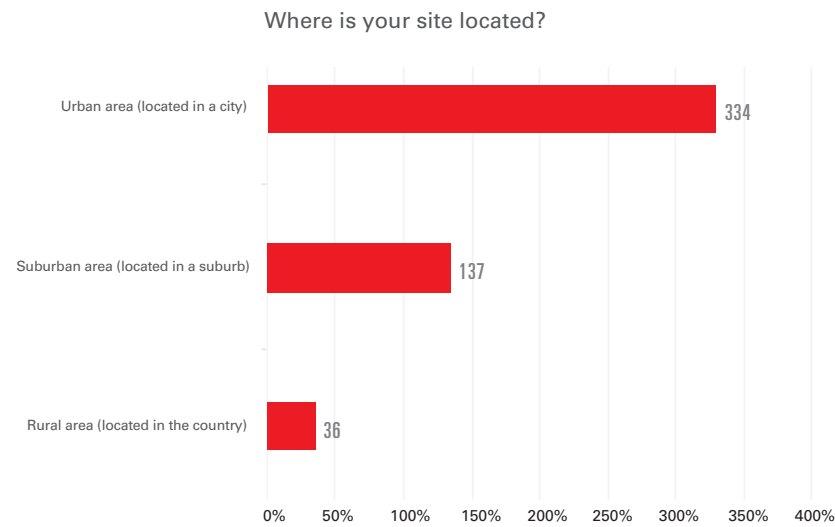


Figure 3

Figure 4: Average number of studies conducted per year by respondents:

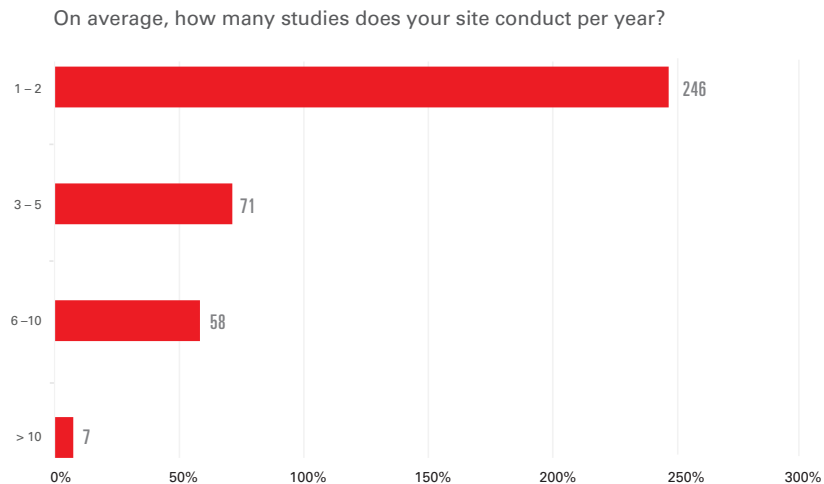


Figure 4

Figure 5: Average number of sponsors/CROs with whom the investigative site conducts studies per year:

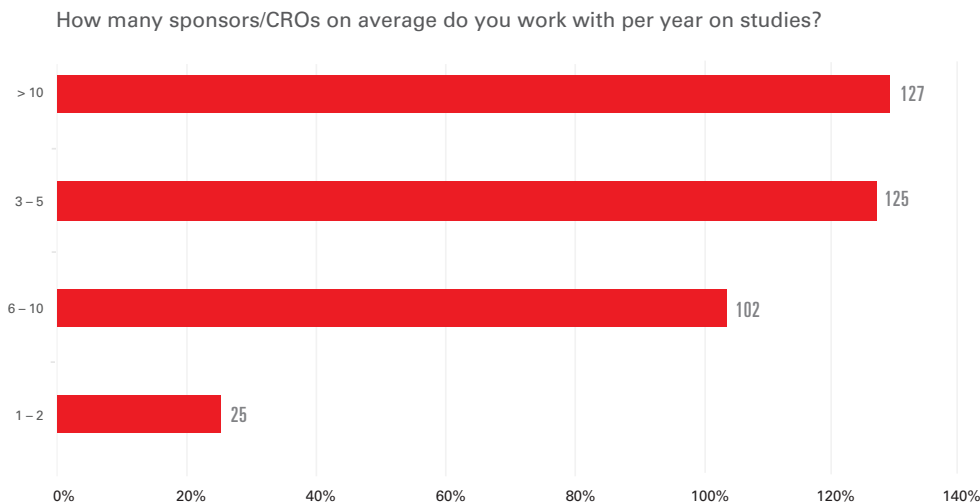


Figure 5

The survey garnered 505 qualified respondents with 85% from North America and 15% from other countries, representing a significant voice within the industry.

Oracle Health Sciences was not identified as the sponsor of the research.

RESULTS

eClinical Technologies Use

Changes since 2016 ACRP/CenterWatch Study

Figure 6 illustrates that there are no overall changes with regard to the clinical technology required to conduct a clinical trial (i.e., point solutions silo'ed along functional lines) in comparison to the results of the 2016 ACRP/CenterWatch study. The one noticeable change is the increase in mobile ePRO usage, which may indicate a move to more patient-centric approaches.

Which of the following software applications, typically supplied by Sponsors/CROs, are currently being used by your site to conduct a clinical trial? Select all that apply.

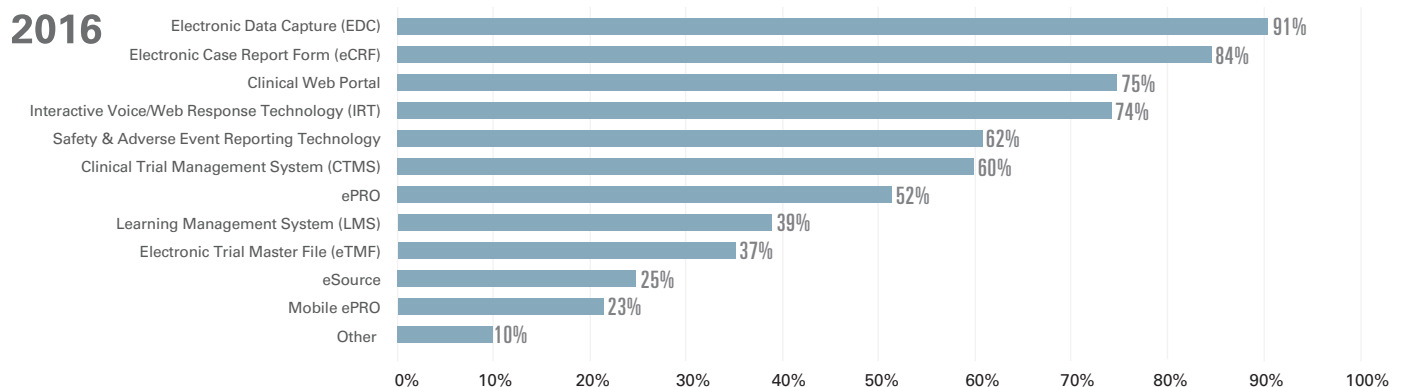


Figure 6

2019

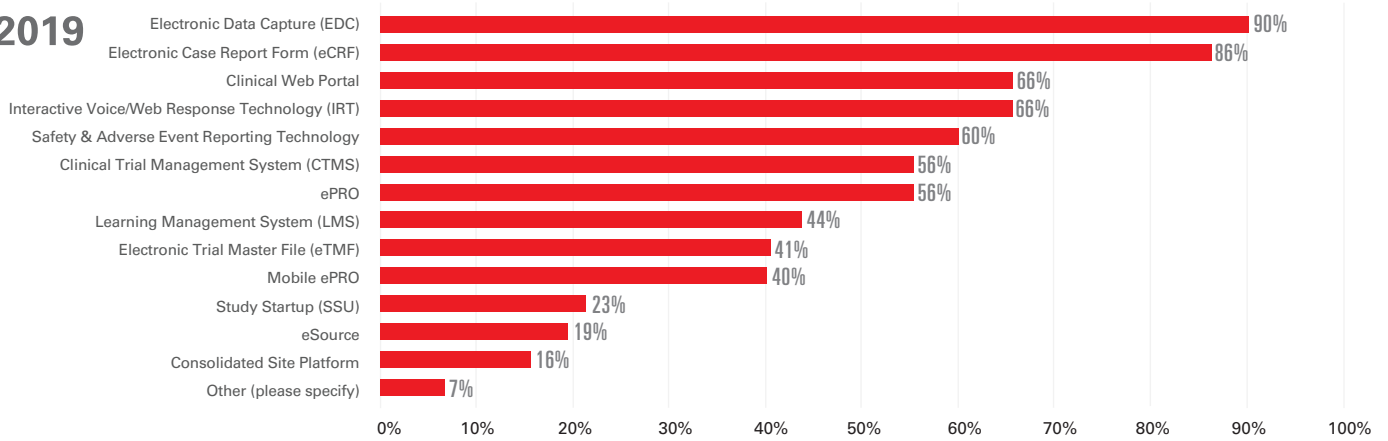


Figure 6

Challenges regarding the utilization of software applications

Figure 7 indicates that the two most significant challenges cited by respondents regarding using clinical technologies were (a) too many systems requiring different processes and login credentials and (b) the duplication of training requirements each time a new study is started. In addition, the top three most popular challenges all related to issues of duplicative, redundant activities required because of incompatible, silo'ed solutions.

What are the biggest challenges when it comes to using software applications to conduct a clinical trial? Rank your top 4 in order of importance. (1 = most important)

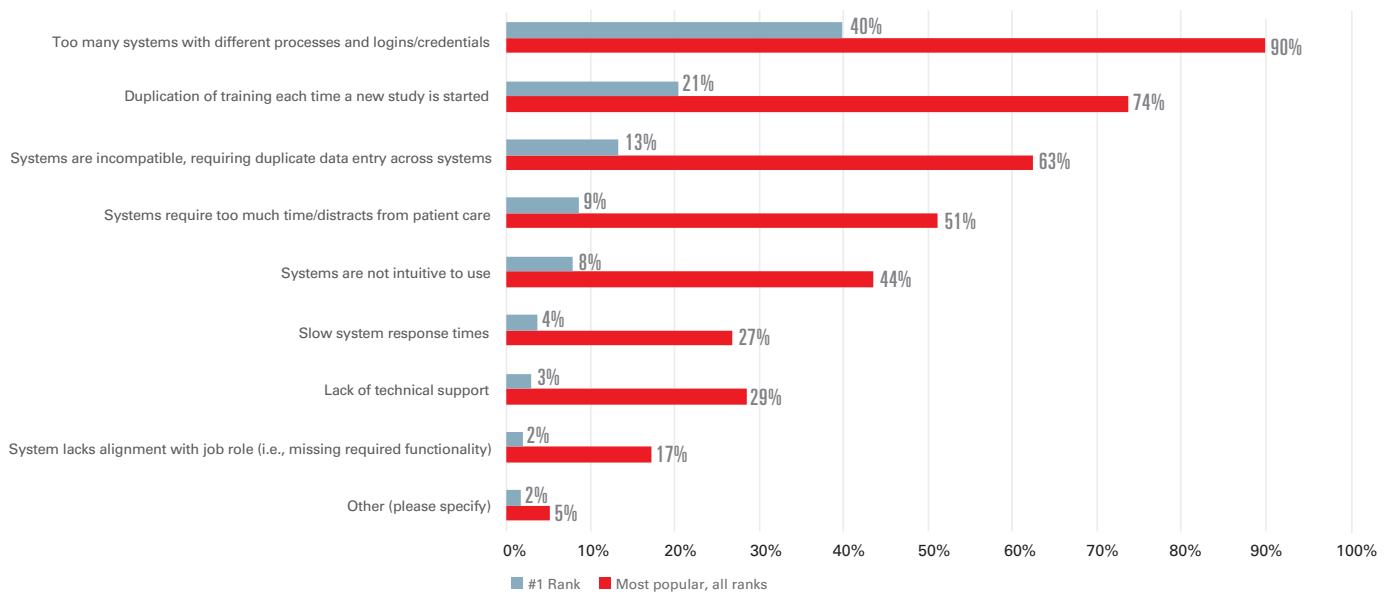


Figure 7

Desired clinical trial applications improvements cited by respondents

As it related to clinical trial software, the improvement cited most frequently by respondents (83%) was having a single point of data entry/elimination of repeated or duplicate data entry. The second-most popular improvement cited by respondents (74%) was having single sign-on (one login) across trials and applications **Figure 8**.

What future improvements to clinical trial software applications would you consider a priority? Rank your top 4 in order of importance. (1 = most important)

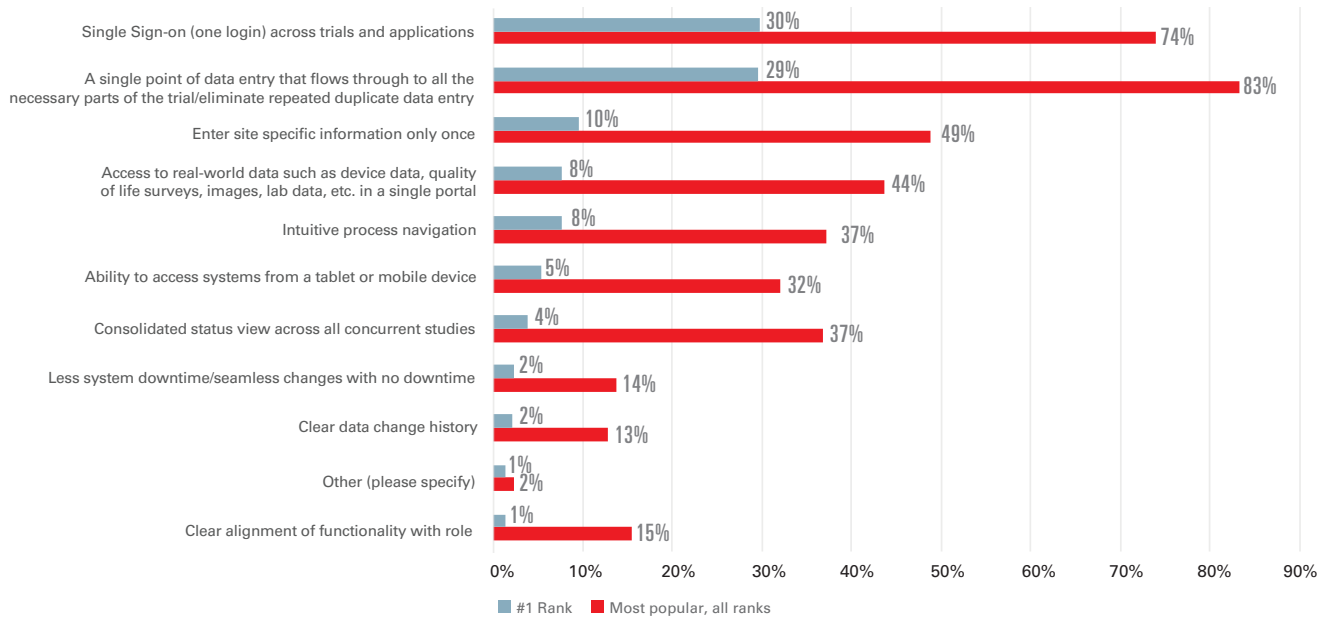


Figure 8

Do software applications meet sites' needs?

In comparison to the 2016 ACRP/CenterWatch study, respondents reported a remarkable increase (65%) in negative sentiment toward eClinical technologies **Figure 9**.

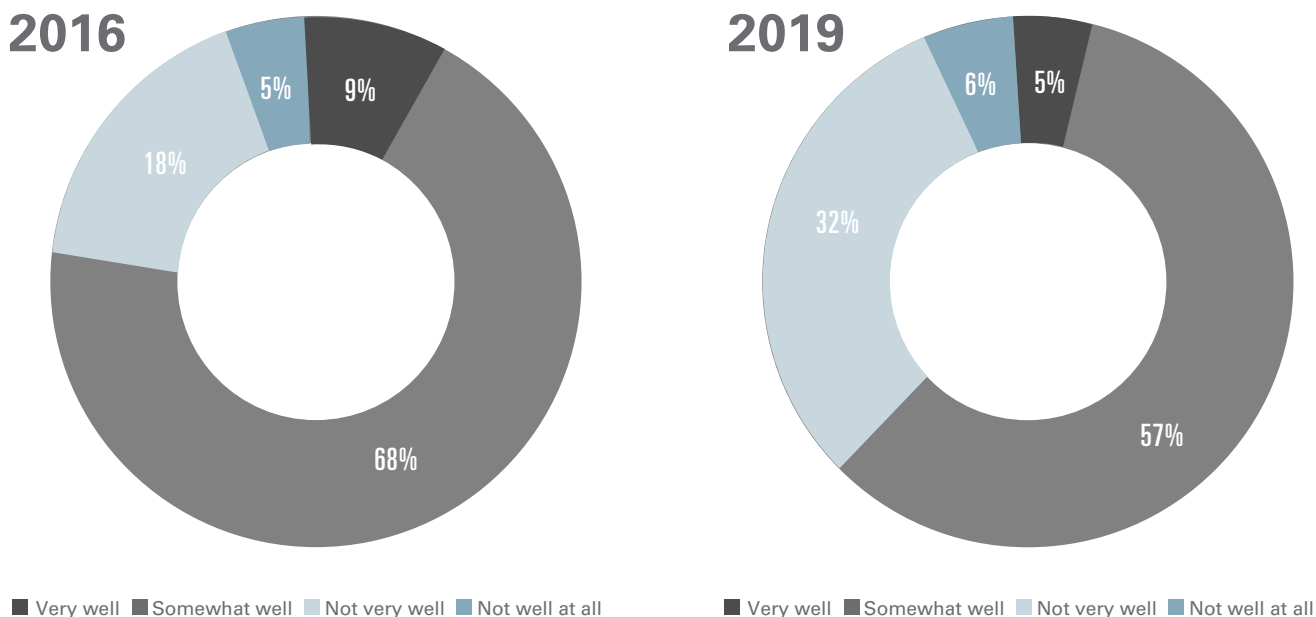
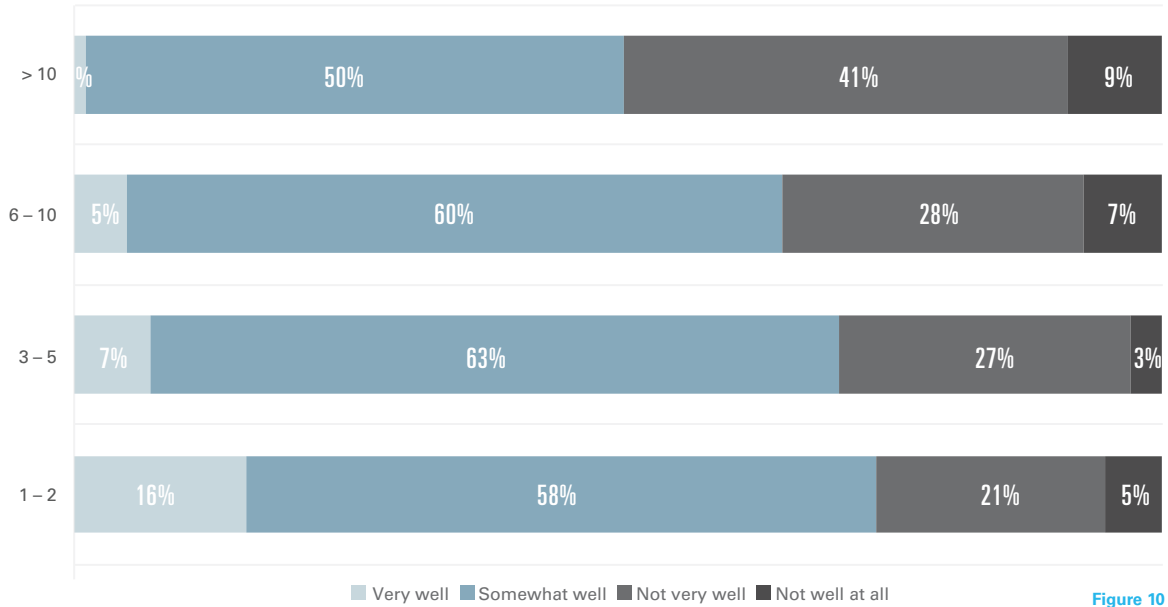


Figure 9

Impact of number of sponsors/CROs on sites' software applications sentiment

As **Figure 10** illustrates, there is a clear correlation between the increase in negative sentiment and the number of sponsors/CROs a site is engaged with on studies.

Feelings that software applications available are meeting operating needs by number of sponsors/CROs



No matter how beneficial an application may be, these benefits cannot be realized when inefficient and redundant training, data entry, and utilization practices are used. These findings indicate that sponsors/CROs should work toward streamlining training, sign-on requirements and data entry across applications to improve site sentiment toward eClinical technologies.

INDUSTRY INITIATIVES

Consolidated Investigator Platform

Using a Consolidated Investigator Platform

A Consolidated Investigator Platform offers single sign-on access to a site's library of content that can be used and reused in a study and the technology applications needed to conduct a study.

Despite the priorities indicated by respondents for future eClinical technologies and the current existence of technologies offering these capabilities, only 30% of respondents are using or are planning to use a Consolidated Investigator Platform. A remarkable 70% of respondents are not planning to use a Consolidated Investigator Platform **Figure 11**.

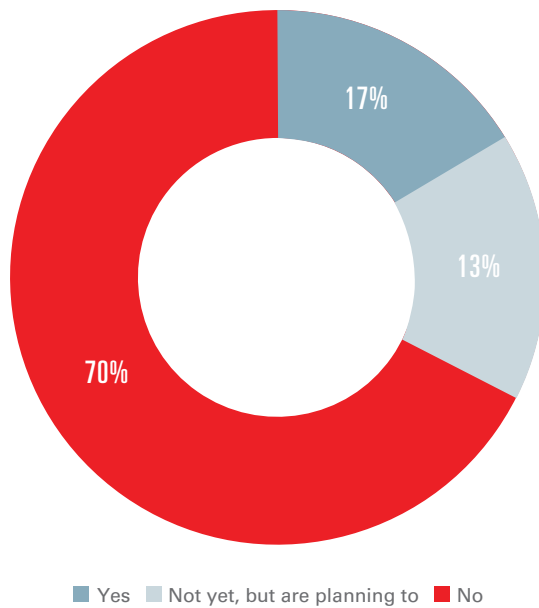


Figure 11

Sites indicate the high, uncompensated cost of implementation (i.e., training costs, procedural changes, etc.) and lacking utilization of a common solution across sponsors/CROs as pain points for adoption. These issues need to be addressed in order to encourage greater adoption of these technologies.

Realized vs. anticipated advantages of using a Consolidated Investigator Platform

In presenting the data, we use the terms realized and anticipated to describe the sentiment of the question. The definitions are as follows:

- Realized – the site has actually experienced these advantages
- Anticipated – the site anticipated that they will experience these advantages

Respondents using a Consolidated Investigator Platform reported realized advantages of increased efficiencies and reduced administrative burden (40%) over anticipated (30%) as the most important benefit. However, anticipated benefits associated with an increase in intra-company collaboration were not realized **Figure 12**.

Advantages from using a consolidated investigator platform in the conduct of clinical trials?
Rank your top 4 in order of importance. (1 = most important)

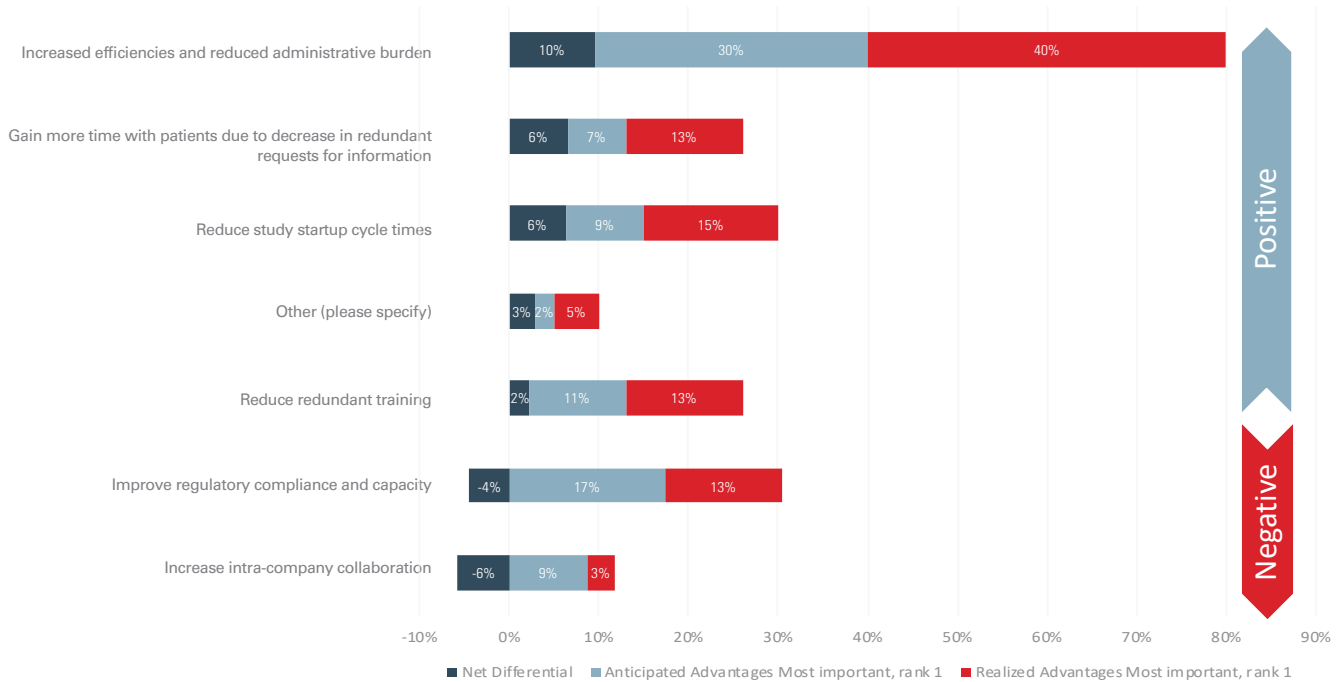


Figure 12

Realized vs. anticipated challenges from using a Consolidated Investigator Platform

Respondents using a Consolidated Investigator Platform reported realized challenges of acceptance of the Consolidated Investigator Platform by sponsors/CROs (19%) over anticipated (9%) as the most important challenge. However, anticipated challenges associated with integrating existing systems with a Consolidated Investigator Platform were not realized **Figure 13**.

Challenges from using a consolidated investigator platform in the conduct of clinical trials?
Rank your top 4 in order of importance. (1 = most important)

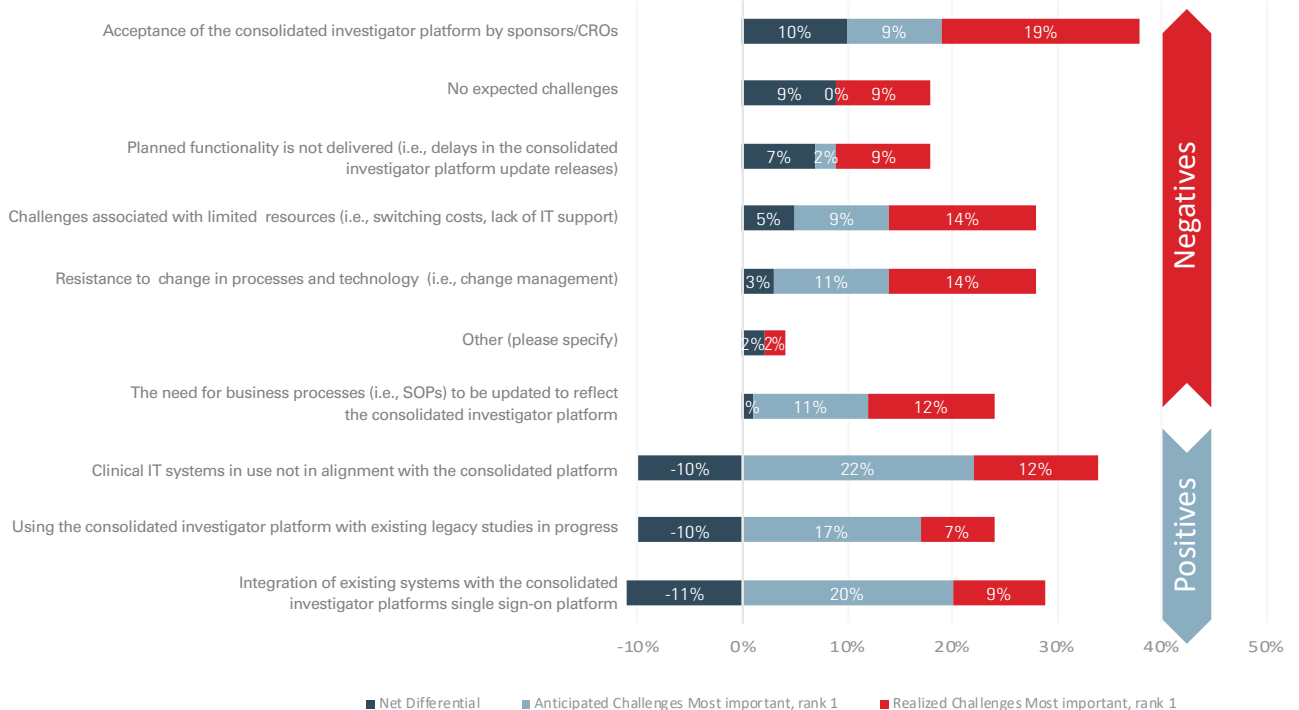
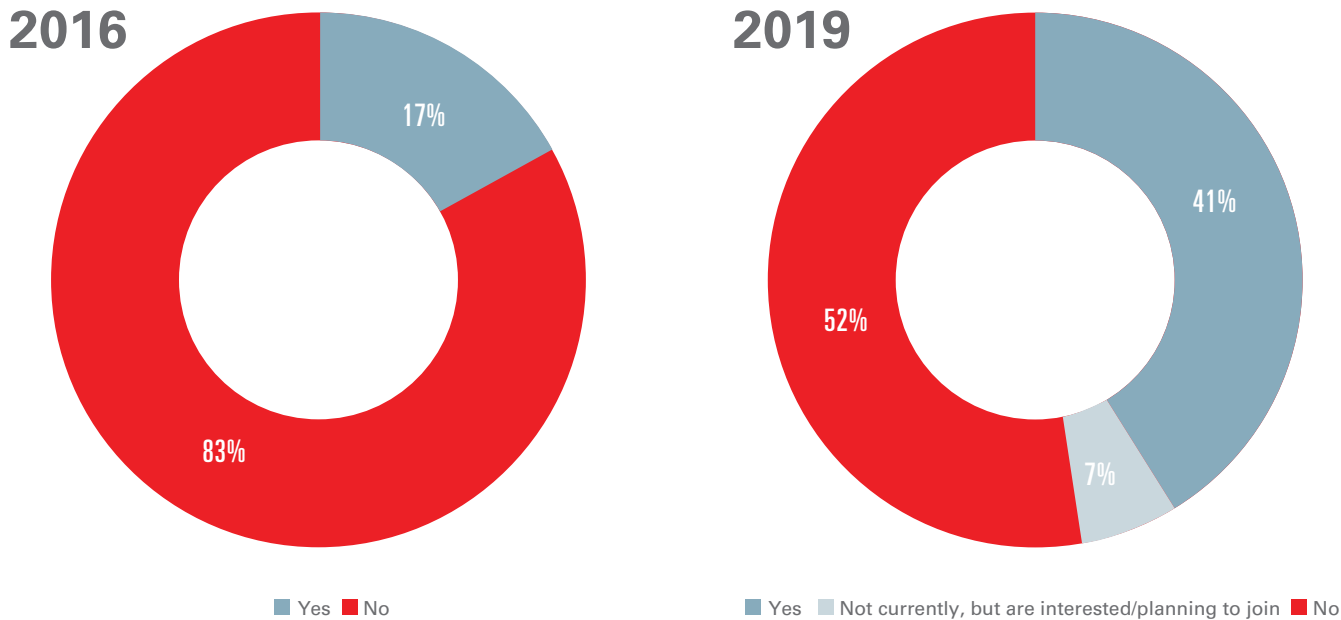


Figure 13

SITE NETWORKS

Interest in membership in a site network

Figure 14 shows that almost half of respondents (48%) indicated that their site is either a member or planning to become a member of a site network. This marks a significant increase over the three-year period since the 2016 ACRP/CenterWatch study.



Source: Oracle & SCRS study 2019 Figure 14

Site network member benefits (Expected vs. Actual)

There was agreement from respondents on perceived benefits and realized advantages of joining a site network, with improved access to clinical trials and improved site profiles as the top responses Figure 15.

How do you expect your site to benefit by joining a site network? Rank your top 4 in order of importance. (1 = most important)

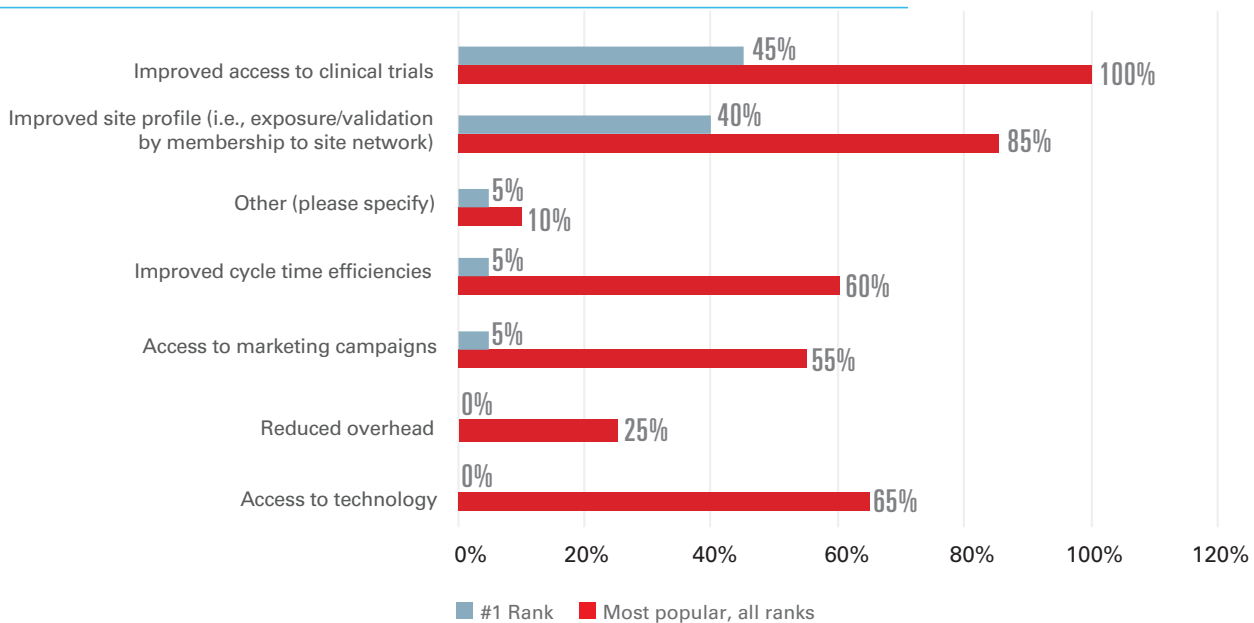


Figure 15

What have been the advantages of being associated with a site network?
Rank your top 4 in order of importance. (1 = most important)

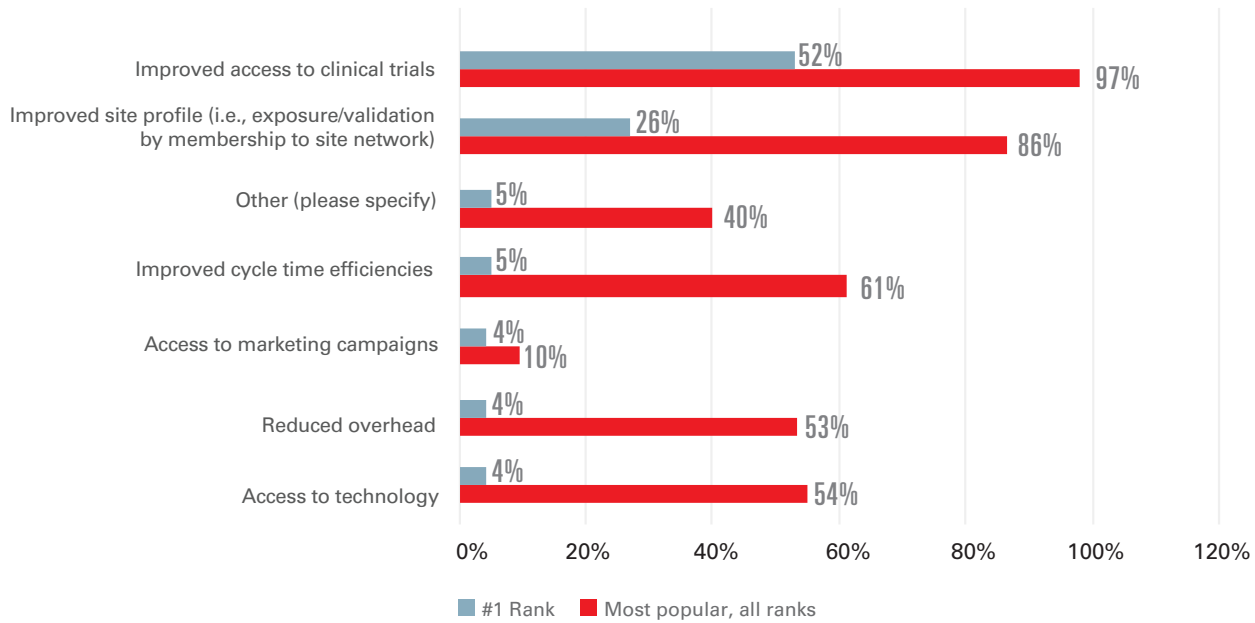


Figure 15

OTHER

What else have you done to improve your site profile?

Almost half of respondents (47%) have contributed to public/private registries to improve their site profile and increase their likelihood of being selected as a candidate of choice for a clinical trial. Interestingly, only 14% of respondents in the “other” category indicated that improved staff quality (hiring experienced research staff and providing training) was important to them in this regard **Figure 16**.

What else have you done to improve your site profile to become a candidate for a clinical trial? Select all that apply.

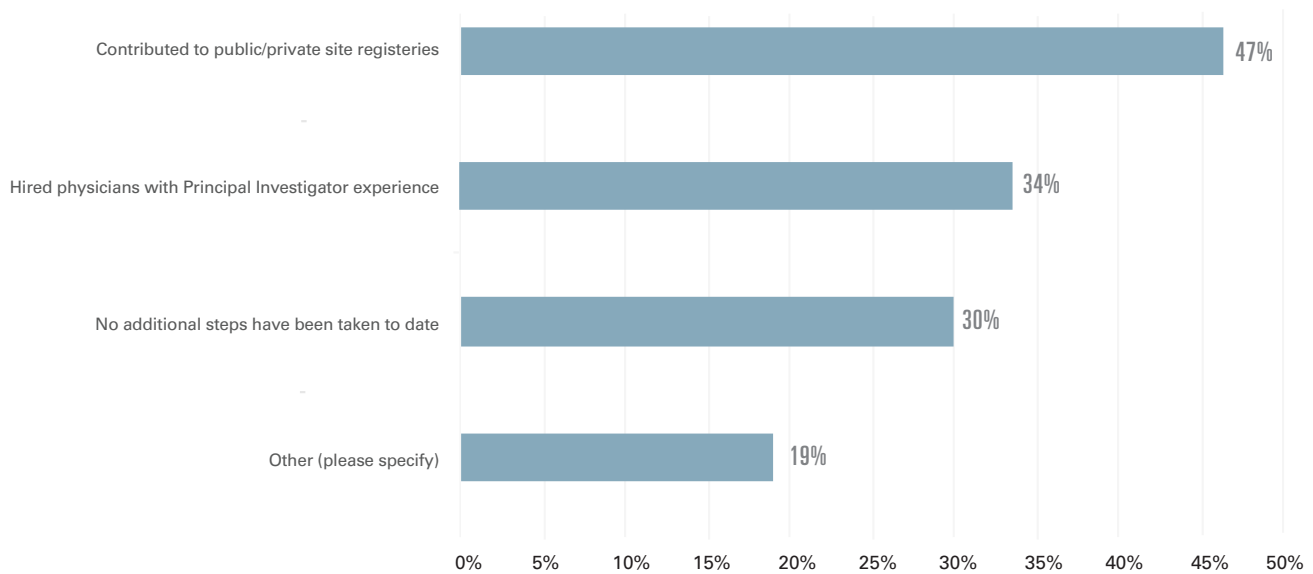


Figure 16

DECENTRALIZED CLINICAL TRIALS

The Avoca Quality Consortium definition of a Decentralized Clinical Trial (DCT)² was used for the purposes of conducting the research survey. That definition is: “Decentralized clinical trials (DCT) deploy a wide range of digital technologies to collect safety and efficacy data from study participants, normally from the comfort of the patients’ own home. The specific digital technologies used for data collection vary by study but can include telemedicine, wearable/sensor devices, eConsent, electronic clinical outcome assessments (eCOA), and electronic health (eHealth) records.”

Challenges in enrolling patients

The two most important challenges cited by respondents for enrolling patients in a study were (a) distance and frequency of visits required for a study and (b) perceived benefit of study doesn’t outweigh current standard of care available **Figure 17**.

When you have identified patients qualified for a study, what are the 3 biggest challenges in enrolling patients into a trial? Rank your top 3 in order of importance. (1 = most important)

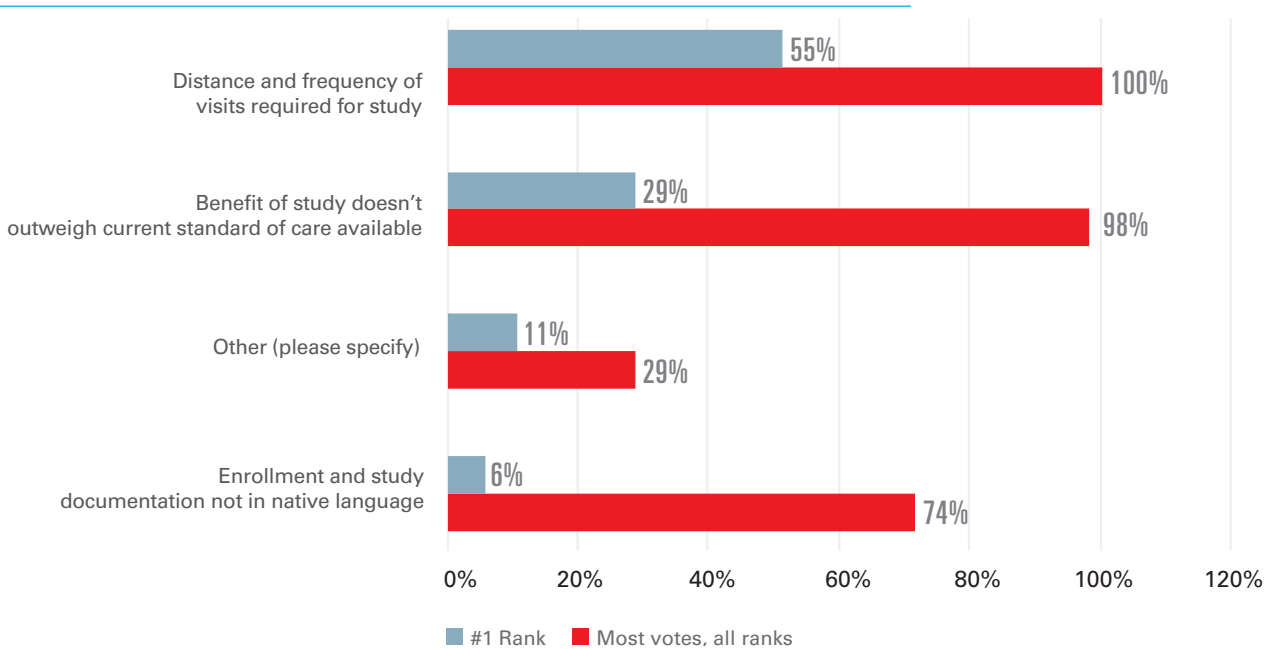


Figure 17

Patient enrollment – Distance vs. Location

When a research site is rural, the distance to the patient becomes more critical (93%) vs. when a site is located in an urban/suburban area (approximately 50%). This highlights a crucial limitation with traditional studies with the limitation emphasizing location over patient density **Figure 18**.

Distance and Frequency of Visits required for study ranked as a challenge based on Site Location

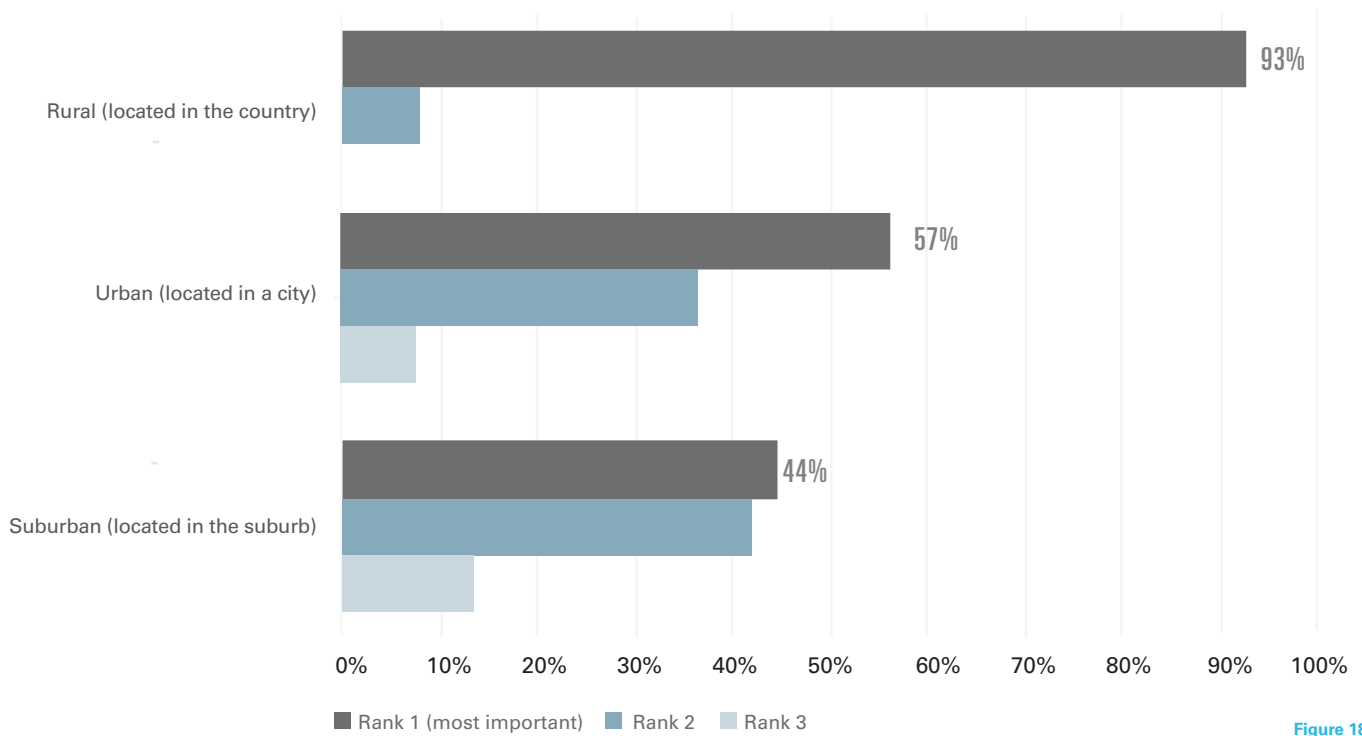


Figure 18

Challenges in patient retention

Figure 19 shows that the two most important challenges cited by respondents regarding patient retention were (a) too much time spent participating in a study and (b) requiring too much repetitive information from patients. This aligns with the biggest challenges sites have with clinical software, summarized in Figure 7, which was too many systems and redundant activity and data entry.

What are the biggest challenges in patient retention? Rank your top 4 in order of importance. (1 = most important)

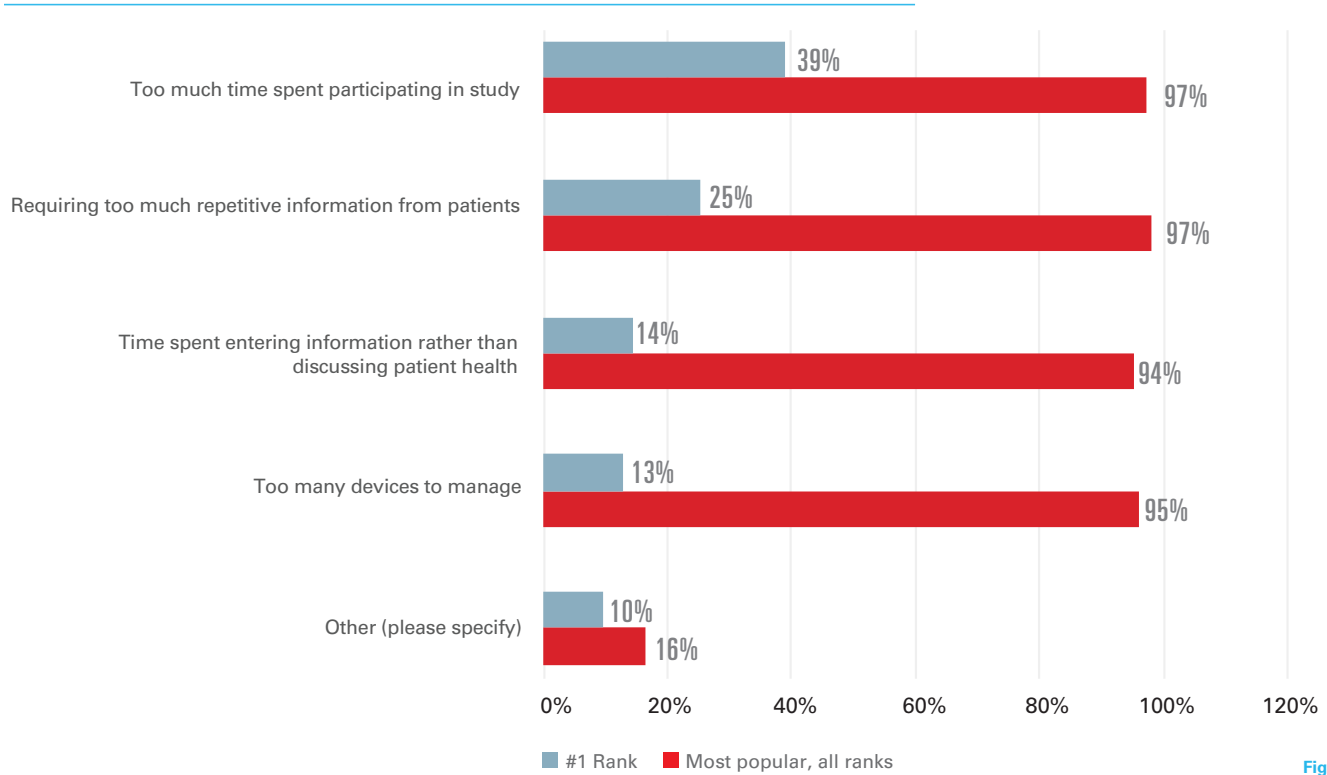


Figure 19

Potential benefits of a Decentralized Clinical Trial

Decentralized Clinical Trials (DCTs) offer a new opportunity to rethink the traditional approach to conducting clinical research, but they are not without challenges. Respondents cited (a) greater participation by patients in clinical trials and (b) improved access to suitable trial patients as the two most important potential benefits of participating in decentralized clinical trials **Figure 20**.

From your perspective, what are the biggest potential benefits from decentralized clinical trials?
Rank your top 4 in order of importance.

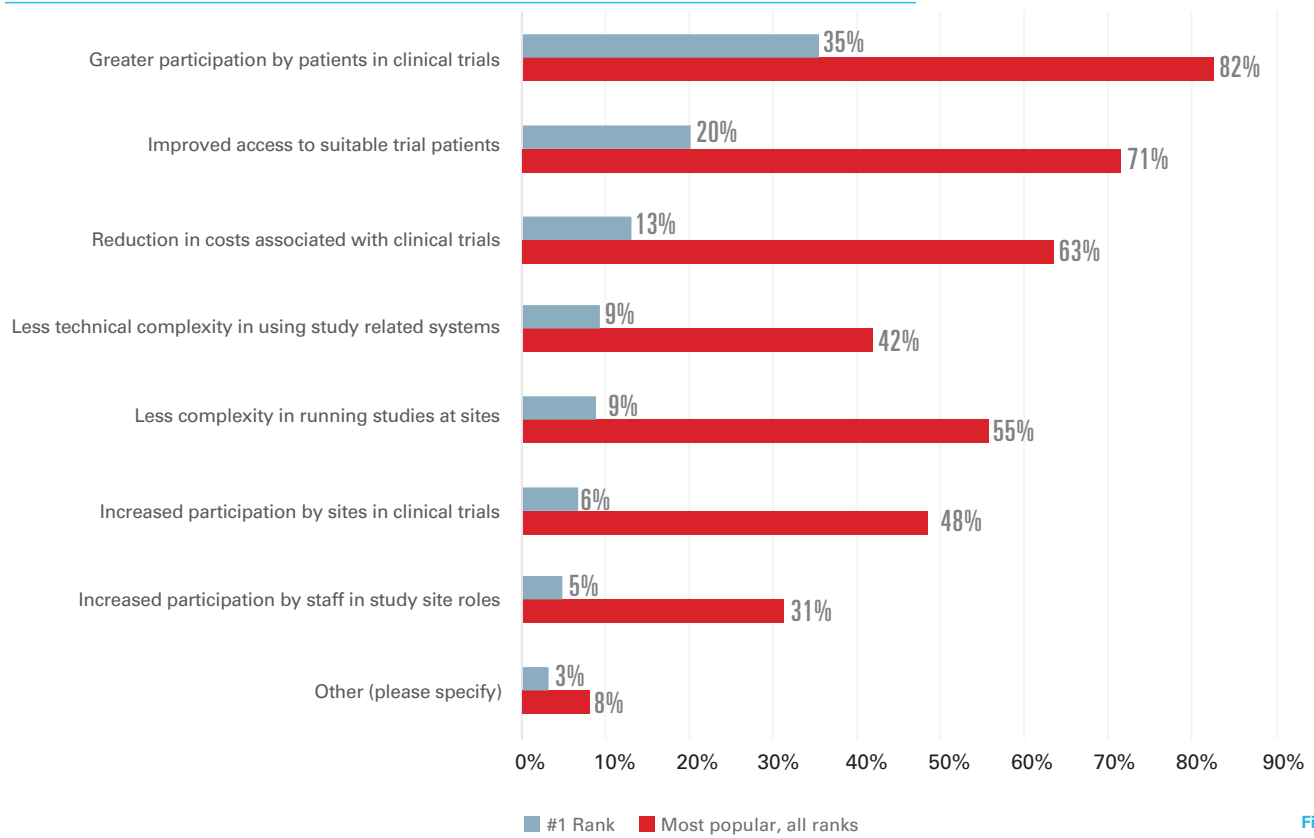


Figure 20

Challenges with running a Decentralized Clinical Trial

The two most popular perceived challenges of running DCTs were (a) placing the quality of study data at risk and (b) increased complexity for clinical researchers due to new systems **Figure 21**.

From your perspective, what are the biggest challenges facing decentralized clinical trials?
Rank your top 4 in order of importance. (1 = most important)

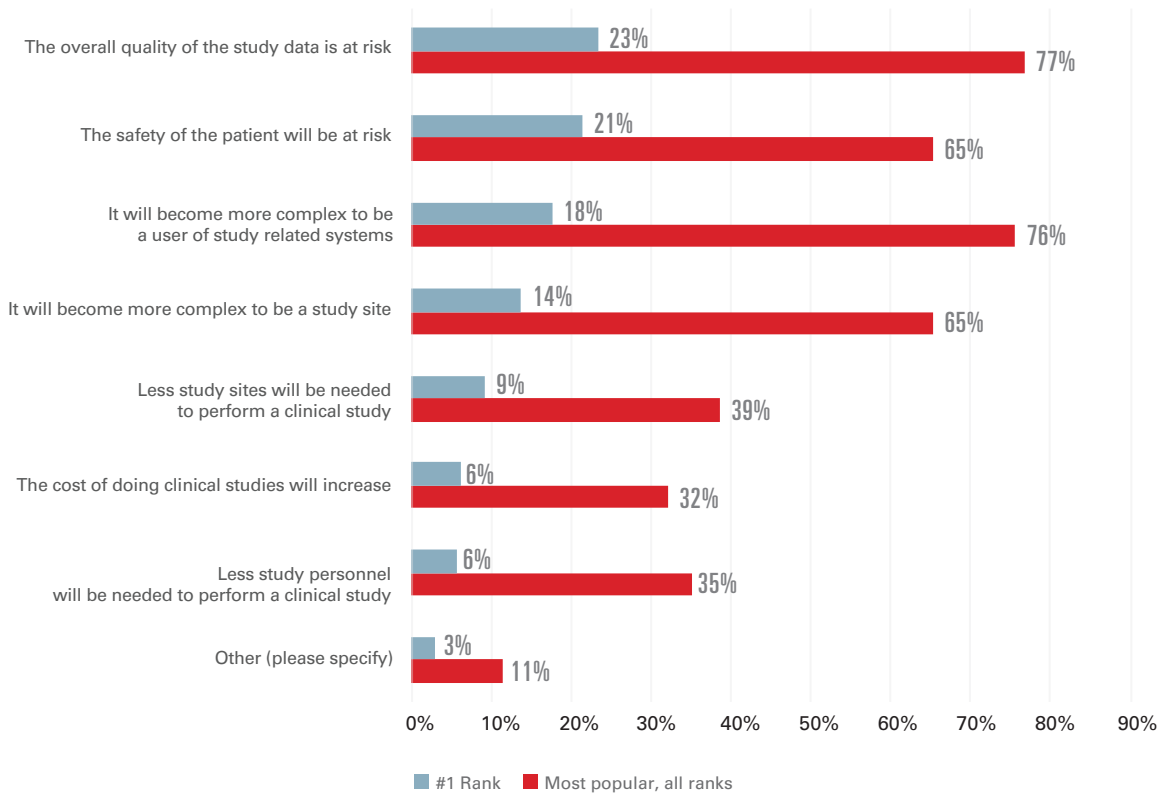


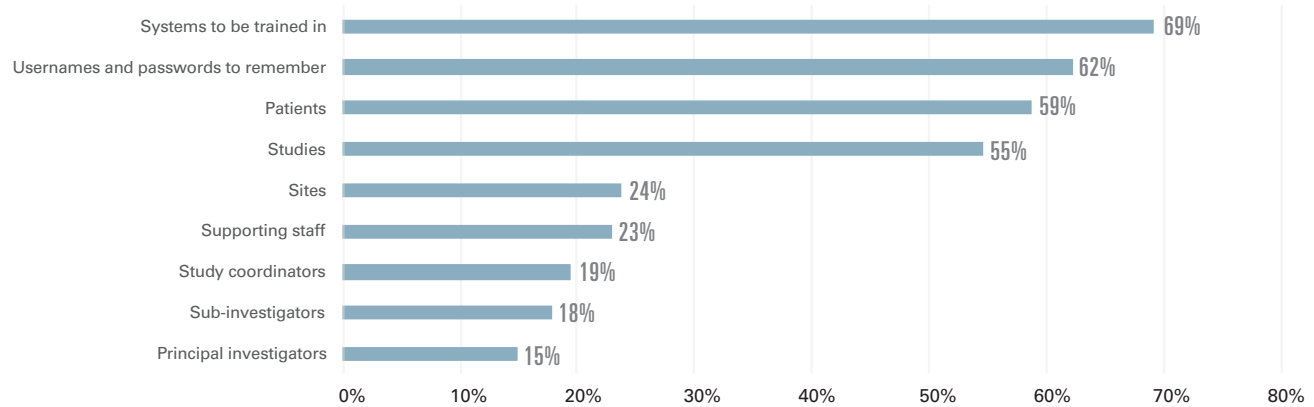
Figure 21

Source: Oracle & SCRS study 2019

Perceived impact of Decentralized Clinical Trials

At a time when sites want to increase the number of studies they are conducting while also addressing current patient recruitment and retention issues, respondents cited the ability to recruit more patients (59%) and qualify to conduct more studies (55%) as the top benefits they envision. However, more work is needed to simplify the use and application of DCT, with respondents reporting more systems to be trained in (69%) and an increased number of login credentials (62%) as their top concerns. Slightly less than half of respondents believe these changes will result in fewer sites (47%) and loss of staff (48%) **Figure 22**.

In your opinion, would decentralized clinical trials (including virtual/site-less studies) result in **more**:



In your opinion, would decentralized clinical trials (including virtual/site-less studies) result in **fewer**:

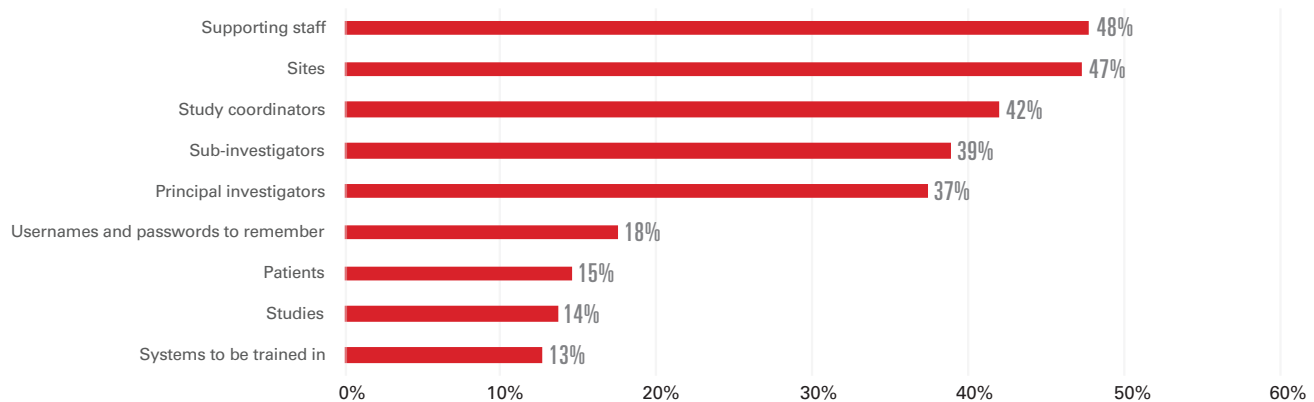


Figure 22

Source: Oracle & SCRS study 2019

CONCLUSION

The survey results highlight the concerns raised by investigative sites in relation to their ability to improve collaboration with sponsors and CROs to create a competitive edge through improved clinical trial performance as they are overwhelmed by the adoption of multiple, silo'ed eClinical technologies and pushed toward patient-centric changes in the industry without being supplied with adequate resources to adapt to these changes.

Site networks, which help reduce the administrative burdens of conducting clinical trials by standardizing procedures, have grown in popularity. This industry initiative is important for both raising site profiles and enabling sites to secure new business. However, technology-based industry initiatives focusing on sites' high-priority pain points with eClinical technologies were found to receive faltering site acceptance, largely due to the low level of support provided when sites adopt new technologies that are required by sponsors/CROs.

Significant opportunities and challenges lay ahead for sites as they transition from participating in mostly traditional studies to participating also in hybrid studies. The impact of new patient-centric technology on sites and future clinical operations is in its infancy and outcomes have yet to be fully realized and quantified. The challenges identified within this research must be addressed before technology and related initiatives will be adopted and have a significant, sustained and positive impact on the global clinical research site community. Sponsors and CROs must work to provide sites with the opportunities and needs laid out within this report to best support the sustainability of their organization and the sites they work with.

For More Information

Oracle Health Sciences' Clinical One cloud environment changes the way clinical research is done – accelerating all stages of the drug development lifecycle by eliminating redundancies, creating process efficiencies and allowing the sharing of information across functions.

References

1. Site Experience with Technology Solutions Designed to Help with Operations Management. 2016 CenterWatch Technology Survey conducted by ACRP and CenterWatch.
2. The Avoca Group. De-mystifying the Qualification of Decentralized Clinical Trials. <http://theavocagroup.com/de-mystifying-the-qualification-of-decentralized-clinical-trials/>



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ABOUT SCRS

Founded in 2012, SCRS is a global organization that unifies the voice of the clinical research site community to create greater site sustainability. Representing over 9,500 sites in 47 countries, SCRS membership provides sites with a community dedicated to advocacy, education, mentorship and connectivity. SCRS is an influential voice for sites and an active partner in industry-wide initiatives and dialogues focused on improving the clinical research enterprise. **Our Voice. Our Community. Your Success.** Join the community