

The 2023 Site Landscape Survey



Introduction

Since 2006, the Society for Clinical Research Sites (SCRS) has conducted surveys of its members to gather data regarding operational health at clinical research sites. Information from these surveys shows an honest look at what's impacting sites' success from year to year and how those trends lend themselves to the broader life sciences industry to optimize clinical research productivity.

The Site Landscape Survey has been a cornerstone of SCRS's work for many years. The results provide information for the site community to benchmark themselves against their peers and for industry partners to understand what's happening at the site level. SCRS also utilizes this data to drive initiatives and build programs for the clinical research site community.

This year's survey includes data from approximately 550 respondents, most representing sites. SCRS also invited participation from industry sponsors, clinical research organizations (CROs), and industry service providers, most of whom are at the executive level. A majority of the respondents are from freestanding sites (42%), but private practices (20%), hospitals or health systems (16%), privately-owned research centers (15%), academic centers (4%), and non-profit research institutions (2%) also participated.

As many as 49% of responders reported their site has been involved in clinical research for 21+ years. They also represent the world's most active clinical development regions, including North America, South America, Europe, and Asia.

As a result of the current pulse of the industry, this year's survey reflects insights related to technology and innovation, diversity and inclusion, financial health, and record retention. While there were questions related to workforce and staffing considerations included in the survey, SCRS has dedicated a [separate publication](#) to those results.

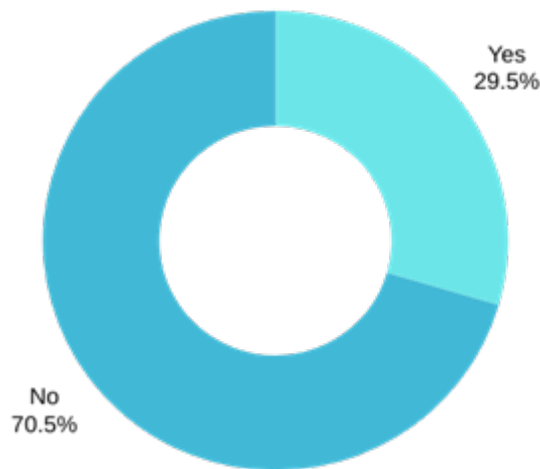
The Landscape Survey originally began collecting data to help sites get a 360-degree view of how other sites handled industry regulations, tackled challenges, and managed contracts. Years later, the survey responses reflect that same intention and can serve as a tool for sites and organizations to optimize their approaches to trial design and conduct to empower sites with the necessary processes and tactics to lead productive, effective, and efficient studies.

Record Retention

The topic of record retention is new to the survey but was a necessary addition, as many sites face frustrating challenges in housing files long after studies have ended. David Vulcano, SCRS Honorary President, explained the importance of these questions during the 2023 Global Site Solutions Summit Landscape presentation: “This is something that we’re going to be focusing on a lot this year, and to be able to focus on it, we needed data.”

While the FDA requires sites to keep records for at least two years, other regulations require records to be kept for at least three years. However, sites often find themselves contractually bound to hold records for 10-25 years after the study has closed, which brings new challenges.

Figure 1. Does your site want to offer long-term record achieving services after your regulatory retention obligations have expired?



If there were no rules or contracts, 38% of site respondents said they would only keep records for two years or less. Of course, sites understand they must meet business requirements and legal regulations and fulfill contracts. Still, a general understanding among sites is that keeping records past these obligations becomes a burden they must be better equipped to carry. Vulcano reiterated this sentiment, saying “If you’re keeping the records for 25 years past the regulatory period, you’re now a record storage vendor for the sponsors and CROs.”

As many as 70% of respondents said they want to refrain from offering long-term document storage. As a surprise to some, the remaining 30% said they’re interested in developing a document storage service offering as a differentiator and a value-add to sponsors and CROs. However, SCRS wants to ensure sites understand what exactly they are signing up for when agreeing to store study records long-term.

More than 60% of respondents said they feel uncomfortable with long-term archiving, so training and additional resources are essential. Long-term electronic record archiving demands include hardware degradation cycles, technology obsolescence, cybersecurity, and long-term password management — many staff members question who will deal with these records 25 years later.

Most sites (68%) feel the current budgets for record retention must adequately support the demand. Currently, these sites are faced with low budgets that don’t cover the cost of record storage and would like to see significant rethinking in this area. In most cases, it’s in the best interest of sponsors and CROs to consider the sites’ capacity for record storage, especially once the study has closed.

Vulcano predicts record retention will be a popular topic in the coming years, and the data collected in this survey will drive the conversations and related work.

Technology and Innovation

The results of these questions were initially presented at the inaugural SCRS West: Clinical Tech & Innovation Summit in June and included data from 2022 and early 2023 technology-based surveys. As many as 73% said a sponsor or CRO approached them to conduct a hybrid-type trial, and of those approached, 93% said they participated in the trial.

The results showed that most sites participated because it would benefit participants and patients in their community. A general sentiment surrounding this was the idea that sites could bring the trial to them.

Another reason for participating in the hybrid trials was to bring the site into the future or for financial gain. Very few sites reported that the technology was why they participated in the trial. If sites didn't participate in the trial, they said it was due to not being selected, a low budget, or being uncomfortable with the type of trial.

Nadege Gunn, Medical Director of the Impact Research Institute, shared her thoughts on the data at the Landscape presentation: "I certainly appreciate the forward-thinking of bringing technology into the research, but I do think we need some optionality. Not every site, not every community, is going to be in tune with technology, and we have to appreciate that."

The survey responses reflected that while decentralized trials may only be for some study participants, having the tools and technology is excellent for providing options. However, more consideration should be given to risks, building trust, and religious inclusion related to using technology.

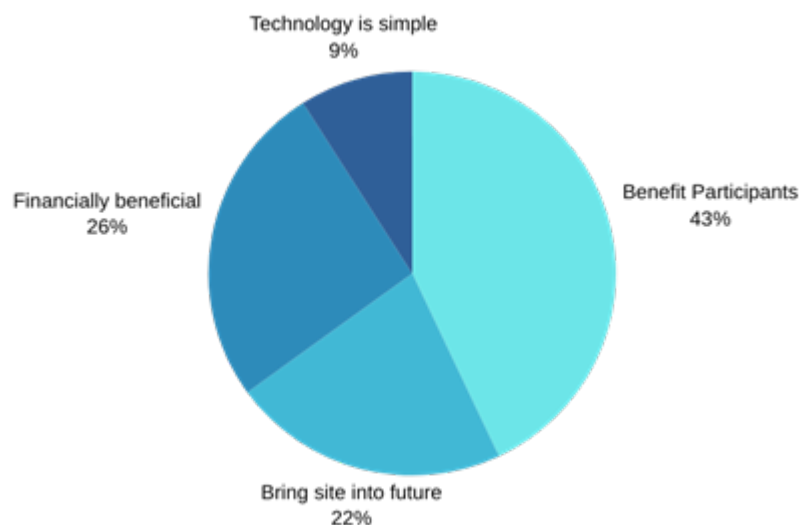
SCRS also asks sites what they expect to be a challenge versus what — in actuality — was a challenge for tech-enabled trials.

Most sites expected data quality, staffing, and support challenges, but the hurdles were financial. Some common themes between expectation and experience include having the staff necessary and supporting numerous technologies and vendors.

74% of survey participants highlighted their top need is for more robust budgets from sponsors and CROs, which aligns with data from the last few years.

Jimmy Bechtel, SCRS Vice President of Site Engagement, explained further during the Survey presentation: "It doesn't just mean we need more money for our clinical trials. We need to be reimbursed as sites for the true and real costs associated with participating in these types of trials." As technology continues to be integrated within trials, sites now have a better understanding of what resources are needed to manage them.

Figure 2. Top reasons cited for participating in hybrid decentralized trials



Other desired support included integrated, consistent technology to minimize duplicative data entry. 60% of sites polled in a May 2022 Sites NOW meeting said they are using 20+ systems on a daily basis. However, that number increases even more when considering other systems that are needed less frequently. The industry needs to move in the direction of integrating these systems and build some consistency around what we are asking sites to use. Bechtel commented, “If I’m working with a sponsor on one trial within that therapeutic area, I hope that when I get that study again, I can rely on them to use the same technology, or at least something that’s extremely similar, so that I don’t have to go through this iteration process on new training, new technology, new systems every single time I do a study.” Sites also appreciate having the option to suggest or select vendors to work with. eSource and eConsent are particular areas of interest for sites to adopt their own technologies. Sponsors could then evaluate sites’ vendors and pre-approve them as trusted partners.

More effective patient technical support is also needed to reduce site burden. Ensuring support is offered in multiple languages and time zones is crucial. Frustrations arise when a diary malfunction or technical issue leads to a screening failure, jeopardizing the progress of the trial. Such situations often result from factors unrelated to the site or the protocol itself. However, with reliable customer service from the vendor, these challenges can be promptly addressed, mitigating potential setbacks and preventing the loss of valuable study participants.

In 2022, sites reported they spent an average of **17.5 hours per study per month training** for trials with remote technology. This year, **40% said they spent 5-15 hours training**, which is a tremendous amount of time that could be spent with patients.

Karri Venn, Chief Operating Officer of Centricity Research, pointed out that much of this training is unpaid, although they are starting to see some sponsors and CROs offering compensation.

Budgets and contracts were the overarching theme regarding technology. Sites must understand costs and provide appropriate justification for non-standard costs, while the industry should give the information sites need sooner and recognize reasonable costs.

Diversity and Inclusion

SCRS collected diversity, equity, and inclusion data at the Diversity Site Solutions Summit in April 2023. The data shows that most sites know their country's diverse clinical trial enrollment regulations. Of those aware of the regulations, 44% said that guidance helps them with diverse enrollment.

"I think we all have a pretty fair understanding of the expectations from legislation and the FDA, but I do not feel that we have the tools to navigate that well," said Dr. Gunn. "It takes work and effort that goes beyond the trial. That's the piece I feel is missing because it's always about how we are going to recruit for this study rather than how do we equip you to reach the populations that aren't being represented and continue that work forward."

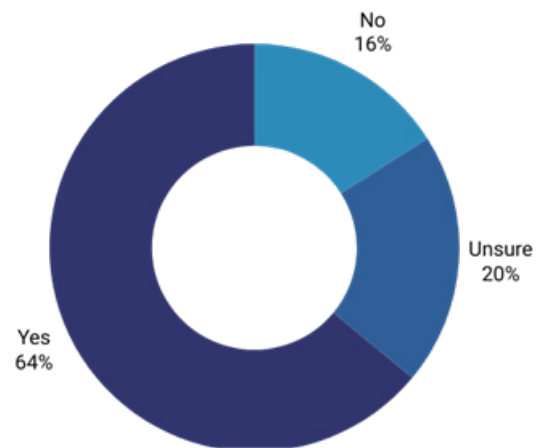
Although 64% said their site successfully represents diverse populations, 60% said they need more support for diverse recruitment. Audrey Escobedo-Escotto, Vice President of Emerson Clinical Research Institute, said help could come from financial aid or staffing. Survey respondents requested support through trial budget items, continuous community engagement, and educational resources.

SCRS also asked service providers to indicate if their solutions are designed with diversity, equity, and inclusion in mind, and 75 percent said yes, their solutions are diversity, equity and inclusion focused. Yet only 18% of sites report that technology has enabled their diverse patient recruitment. Dr. Gunn further commented on this statistic, sharing that diversity is not a bullet point or a check box. "It is intentional work that needs to be supported not just with technology, but with funds and efforts long-term."

Additionally, 65% of respondents said that more than 20 percent of the tools and resources that are associated with their protocols have diverse preclusive language in them. That is a significant number of resources, tools, questionnaires, patient diaries, consents, etc. that have diverse, preclusive language. It's imperative we holistically consider what it means to engage some of those populations and adapt trial technology and protocols accordingly.

Finally, most sites are updating their protocols to meet modern diversity, equity, and inclusion requirements. All of the sponsors, CROs, and partners that participated in the survey agreed that the capability of a site to recruit diverse populations does matter regarding site selection. Therefore, the industry needs to keep working on what it means to enroll diverse and inclusive patient populations and build that into processes and budgets.

Figure 3. Is your site successfully representing diverse populations?



Financial Health

A financial question that's always a part of the survey is regarding operating capital, and the results were consistent with those from previous years. While 26% of sites reported having six months of financial runway, many sites have only a few months (10% have less than one month) of funds, which means they're one late payment from exiting the industry.

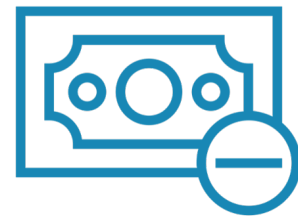
While 33% said they had the same amount of operating capital in the bank as the previous year, 34% reported having less. In 2022, 16% of sites reported a net loss. If sites are underfunded, the studies likely are, too.



55% of sites saw a decrease in profit compared to the previous year



Of those with decreased profit, more than 50% experienced a decrease higher than 20%



22% of sites reported having lower operating capital compared to the previous year

As many as 40% of sites saw a lower profit year-over-year, which can partially be attributed to current inflationary challenges with overhead and workforce costs. A clinical research site is a valued partner in getting new medicine to market and people, so it's time to seek viable solutions for survival and success.

Payment terms trends have come a long way since 2009, when quarterly payments were the norm: today, 51% of sites reported having monthly payment agreements. However, sites report not receiving monthly payments, even if those are the agreed-upon terms. As many as 23% of the sites say they have 31-40% of invoices already more than 90 days late. Cash flow keeps sites and studies healthy. This is not a sustainable way to do business, and sites must be adamant about being paid on time.

Holdback payments are still common, which SCRS has tried to eliminate over the years. Sites reported that the most common withholding amount is 10-14%.

"At the start of the COVID pandemic, SCRS was a big advocate of releasing the holdback money for sites to keep them afloat, and we appreciate all the sponsors and CROs that did that, but we've seen this resurgence after COVID of trying to put that back in, so I don't know why cash flow is different," Vulcano said.

He reiterates that the purpose of the closeout fee is for final tie-ups and there should not be any funds held back. Sites need cash flow during the study, so withholding funds can have a detrimental effect.

Vulcano encourages industry partners to consider holdback payments as part of an unfair game. "If I play Monopoly, I don't get \$180 when I pass Go and only 10 percent of the rent from everybody, and the rest of the money when the game's packed up. I need it during the game. Give us all the tools we need to make your study successful."

In summary, nearly 80% of sites have less than six months of capital in the bank, 40% saw a profit decrease year-over-year, and accounts receivable ageing is a concern considering a large number of accounts receivable are more than 90 days old.

Key Takeaways

This year's survey data shows clear trends moving in the right direction for some aspects of research site operations — diversity and inclusion, for example, and other segments that need adjusting, such as record retention.

While record retention is a new topic for the survey, it's an integral part of what sites must manage. Even outside retention regulations, it has become commonplace for sponsors to request record archiving for 15-25 years beyond the study's closing, which brings many challenges for both sites and sponsors.

Technology and innovation are embraced by sites, and they are adept at identifying solutions that provide options and efficiencies for studies and patients. However, sites report that there needs to be adequate budgets and resources to feel comfortable utilizing all the technology offered.

As for diversity and inclusion, most sites said they represent diverse communities but could use support for diverse recruiting. The majority of sites indicated they are still updating their diversity and inclusion protocols to meet regulations.

The financial portion of the survey had some concerning trends, including 80% of sites with less than six months of capital in the bank, those that saw decreased profit this year, and the large number of sites reporting nearly half or more of their accounts receivable at least 90 days late.

This data is solely used to help industry stakeholders work together and find solutions that best fit the sites and the industry. Many sites reported that they'd like to see:

- Major rethinking for budgets to meet long-term archiving requests
- Improvement in the areas of budget and contract, communication, and feasibility

You can expect more programming and conversations surrounding these topics in the coming year. The Site Landscape Survey began more than a decade ago to help sites see how they were doing compared to other sites. For years, clinical research sites operated without knowing how many coordinators were necessary, the right amount of startup fees, or what other sites were asking for.

While the Landscape Survey drives engagement among the SCRS community, there are additional ways to get involved. Every industry stakeholder has experience and knowledge that is valuable, and you can contribute by attending events, joining an initiative or participating in surveys. SCRS suggests that sites consider joining a Site Advocacy Group (SAG), contributing to the online member forum, or taking a survey (even if it's just answering a single question) to empower these conversations with additional data. Your involvement matters; your voice is part of our community and its success.