The 2022 Site Landscape Survey

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Introduction

For the 10th consecutive year, the Society for Clinical Research Sites (SCRS) has conducted an annual survey of members to gather data about the current state of operational health at clinical research sites. The survey responses help us understand factors that are impacting the sites' success and longevity, and provide helpful insights that can be conveyed to the life sciences industry at-large to optimize clinical research productivity. The 2022 Site Landscape Survey includes data from about 500 respondents, most of whom represent executive-level leaders with more than a decade of experience in clinical research. In addition, non-site participants – including sponsors, industry partners, and clinical research organizations (CROs) – were invited to participate in the survey and respond to six questions. Their perspectives will help supplement and diversify the data points to glean richer insights and viewpoints.

Survey respondents represent a broad array of research facilities including freestanding, dedicated research facilities (37%), private practice medical groups (23%), hospitals or health systems (15%), privately owned research centers (12%), academic centers (8%), and non-profit research institutions (4%). They also represent regions of the world most active in clinical development including North America, South America, Europe, and Asia.

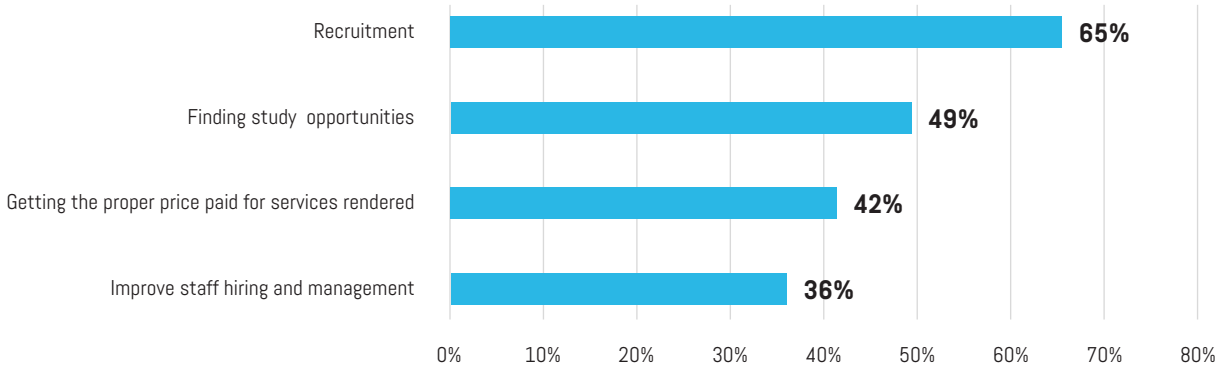
The results of these survey data offer useful insights into the evolution of clinical research from the perspective of one of the most pivotal stakeholders in the process, as well as a better understanding of factors that impact site operations and sustainability such as finances, workforce considerations, and larger trends such as decentralization and digitalization. Altogether, this will help clinical research sponsors and organizations optimize their approaches to trial design and conduct in a way that empowers sites with the necessary processes and tools to conduct productive, effective, efficient, and accurate studies.

In reviewing the survey data, several macro trends emerge as useful lenses through which to examine the current state of clinical research sites' sustainability: site operational and financial health, workforce considerations (a new focus for 2022), the impact of trends in clinical trial design including decentralization and digitalization, and finally, sites' perspectives and experiences with diversity and inclusion initiatives. By assessing the state of clinical research through these perspectives, all industry stakeholders can deduce how their policies and strategies impact their site partners and subsequently make informed decisions to promote site productivity and longevity in the face of rapidly changing conditions.

Site Operations & Sustainability

The survey opened as it has in past years by asking sites to identify the top three factors that affect productivity and performance. Echoing the results from this same question last year, sites and non-site respondents agreed that "finding trial opportunities" and "recruitment" are the top two factors that are crucial for success and sustainability. Lisa Bjornestad, Vice President of Operations and Growth at DM Clinical Research summed it up during the 2022 Global Site Solutions Summit Landscape presentation: "Recruiting patients…is pivotal to our success." Sites also reported that collecting an appropriate fee for services rendered is a top concern and focus area, as well as improving staff hiring and management. The latter ranked highly for both sites and non-sites, possibly a reflection of staffing difficulties encountered throughout the COVID-19 pandemic. Non-site respondents identified additional priorities in their rankings of factors that affect site sustainability, which included recruitment, improvement of sites' operational efficiencies, and staff hiring and management.

Figure 1. Please rank the top 3 factors that are most important for sites to improve to achieve consistent sustainability and success (overall)



Both groups were also asked to identify top areas for improvement. Perhaps not surprisingly, sites indicated that recruitment, budget and contract negotiations, communications with sponsors/CROs, and feasibility are top areas of focus, while non-sites ranked recruitment, budgeting and contracting, and Principal Investigator oversight as high priorities. In this case too, sites and non-sites have considerable overlap in prioritized areas for improvement.

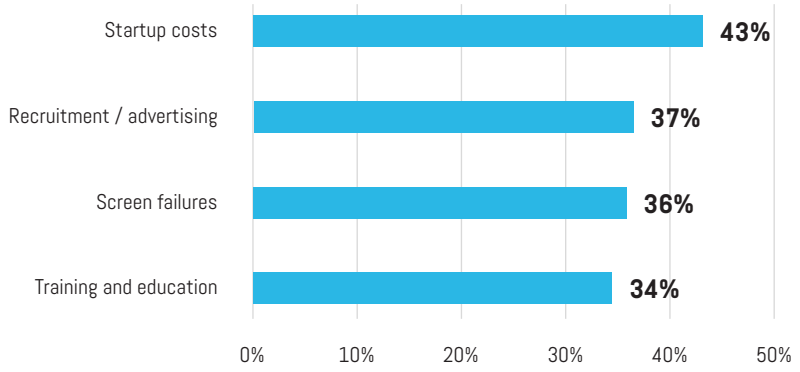
In terms of recruitment, sites indicated that projections are often overstated, and enrollment goals are frequently not met. Both sites and non-sites agree that prolonged budget and contract negotiations that lead to longer execution time are another area for improvement. As noted during the Summit Landscape presentation by Bill Taaffe, Chief Strategy Officer at Affinity Health, sites are not getting paid for changes that occur during studies, so it is crucial that budgeting is something "we have to get right" to maintain site sustainability.

Finally, trial feasibility was another top-ranked area for improvement. Often, sites receive incomplete or inaccurate information, and it can prove difficult "to get enough information up front," according to Ana Marquez, Chief Diversity Officer at Flourish Research, during the Summit.

Financial Health

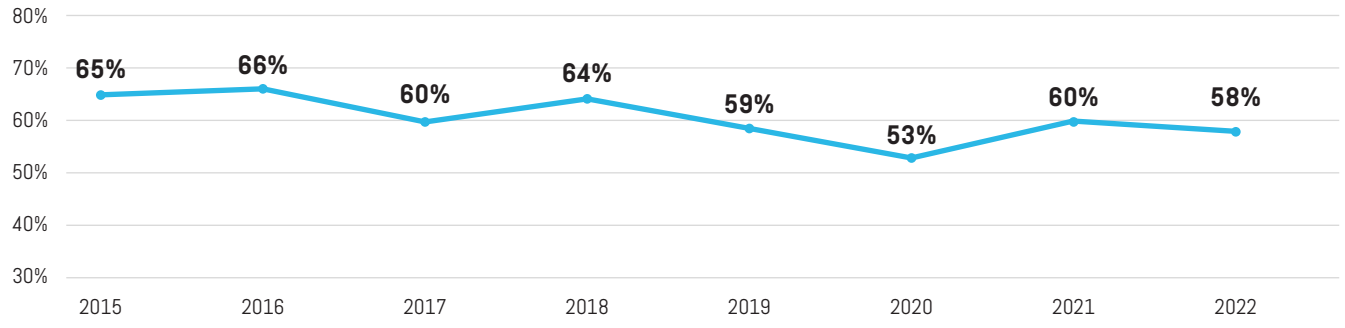
In the context of macroeconomic challenges and aforementioned operational challenges, sites have experienced worsening financial health throughout the past year. Overall, more sites lost money than earned revenue, with a third of respondents reporting a net loss or no more than 5% profit, and two-thirds of respondents reporting a decrease in revenue from the prior year. No sites reported earning more than a 25% profit. Declining financial stability across sites can be attributed in part to increased operating costs related to the adoption of new technologies, additional employee training, or hiring to compensate for high turnover.

Figure 2. Which areas of the clinical trial budget outside of the per-subject budget do you consider to be the top three that are underfunded? (overall)



But other hurdles related to accounts receivable, budgets, and contracting have also contributed to sites' financial struggles. In fact, an increasing number of sites reported they did not even have enough operating capital to last 30-60 days. Only less than 20% of site respondents reported that their accounts receivable balance was mostly settled up, which could explain why more than half reported that they had less than six months of operating capital and less than 5% reported higher operating capital.

Figure 3. Sites with 3 months or less operating cash



If sponsors and CROs want to seek out ways that will impact site sustainability the most, they can focus on the top underfunded areas:

- Startup costs
- Recruitment and advertising fees
- Screen failures
- Training and education

Industry stakeholders may also consider reviewing their approach to budgeting and contracts to be more accommodating to site needs. For example, a significant majority of sites prefer monthly payment terms over quarterly or any other longer-term remuneration structure that puts strain on study cash flow. The data show that sites have been more successful negotiating these favorable terms in 2022 – 56% reported that their final contracts offered monthly payment terms compared to 45% in 2020. Sponsors and CROs might also consider eliminating holdback payments, an outdated and unproductive practice that SCRS continues to advocate against as it is detrimental to site sustainability.

Today's clinical trial agreements should include a budget that is sufficient to cover commonly requested fees related to pharmacy startup and closeout, serious adverse event reporting, long-term document storage, protocol amendments, sponsor audits, and employee and technology training, especially if the sponsor or CRO is interested in conducting a remote trial. Sites invest 10-20 hours on average per month per trial conducting or participating in trainings related to decentralized or remote trial conduct, much of which goes uncompensated.

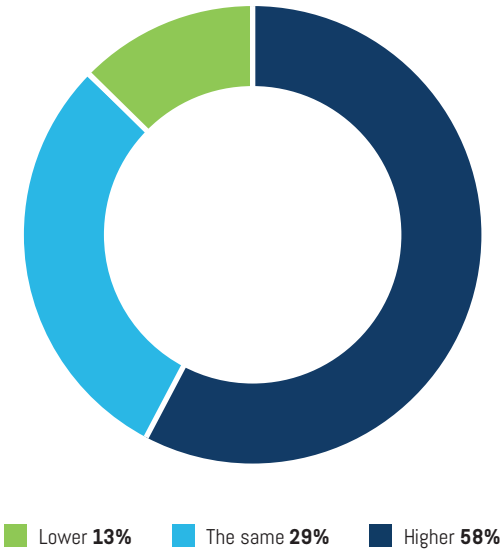
It is also important to note that more than half of respondents declined contracts during negotiations due to insufficient budgets, and this does not account for other respondents who had to negotiate unacceptable terms before agreeing to conduct a trial. If sponsors and CROs want to help ensure study success, especially given the pressures, they should do more to proactively offer a budget that covers all the costs imposed on the site related to running their trial.

Workforce & Personnel

This year's survey revealed that a new factor impacting site sustainability is staff turnover rate and retention. Overall, more than half of survey respondents said that turnover rate has increased over the last two years, now exceeding the 2022 industry average for turnover at hospitals. Many site staff were lured away by more attractive offers and higher salaries with sponsors or CROs. Some, but not all, of sites had employee benefits in place, such as training and development opportunities, regular feedback on performance, a retirement package, a performance bonus, flexible work arrangements, formal onboarding and orientation, or retention bonuses.

However, it is also important to note that most of these benefits are standard offerings by employers and may not be adequate to prevent site staff from leaving for other opportunities. In fact, top reasons for leaving a site included more attractive job offers, the desire to pursue a different role or career, inadequate pay, and the feeling of being overworked with a general lack of support. Therefore, sites must prioritize incentive programs and an inclusive, supportive work environment for all staff with opportunities for career development.

Figure 4. How has the turnover rate at your company been over the last two years?



High turnover rate and a lack of experienced staff can have a detrimental impact on sites and their existing studies. The cost to hire and train new employees is typically not accounted for in trial budgets that have already been negotiated, nor are additional perks and benefits intended to improve talent retention.

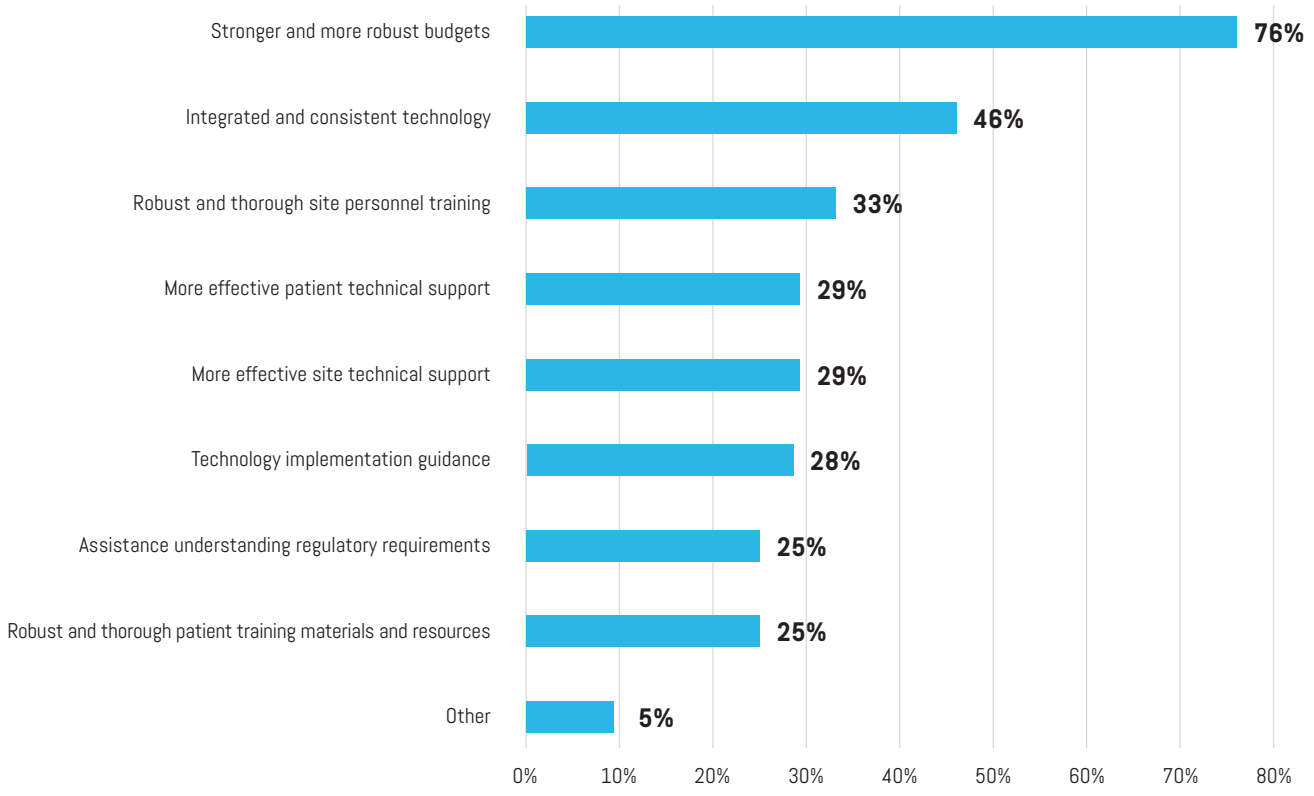
As is essential for resolving other site sustainability challenges, it is crucial to improve the supportive relationship between sites and CROs or sponsors. Whether it comes to negotiating higher trial budgets to account for additional employee training on new processes and technologies or offering trial continuity plans if site staff are recruited away, sponsors and CROs can play a more proactive and generous role in supporting sites through periods of high turnover. Furthermore, the industry needs to collectively invest in more opportunities for professional and workforce development training such as internships, scholarships, and hiring outside of the clinical research industry.

To help sites address such workforce challenges and current inflationary pressures, the SCRS workforce task force developed resources such as a toolkit for sites and an open letter to sponsors and CROs that shares concerning stories from sites and critical calls to action, including encouraging open dialogue between sites and industry, negotiation of existing budgets to sustain recruitment and retention, and sourcing of employees from non-sites.

Decentralization and Technology in Clinical Research

Insufficient budgets also had an impact on sites' adoption of decentralized (DCT) methods since essential training on remote solutions and strategies can be very costly. The COVID-19 pandemic necessitated and accelerated adoption of remote solutions and strategies to keep trials running. However, based on survey responses, it appears that fully remote trials are not yet very common – approximately a quarter of respondents reported that they were approached about conducting a trial where no patient visits would occur on location.

Figure 5. What does your site want or need in the form of support from Sponsors and CROs in regards to participation in decentralized or hybrid decentralized trials?



Over half of those sites agreed to participate because they were eager to try new things and adapt to rising trends and modern DCT practices. However, the top-cited reason sites declined participation because they were hesitant to adopt these methods without a sufficient budget to cover additional training or the integration of new technologies. As Lisa Bjornestad pointed out in the Site Landscape presentation, remote patient visits require sites to conduct coordination and training work to prepare the patient and study team, ensure recording equipment is set up correctly, and adhere to protocol requirements, all of which remains uncompensated. This also helps make clear why patient safety concerns were also cited as a top reason for declining to run a completely remote trial, with some respondents claiming that having participants on site would help clinical trial staff manage their health or adverse events more efficiently.

On the other hand, a majority of survey respondents (64%) were approached to conduct a hybrid trial in which some but not all of the trial activities, such as study visits, were conducted virtually. This indicates significant challenges in fully remote trial designs overall, especially when sites are not consulted about remote strategies, technology, or vendors but are expected to hold all responsibility for required oversight without adequate compensation to do so.

Still, many survey respondents are eager to bring their site into the future of DCT trends – most (82%) of the respondents who were asked to run a hybrid trial agreed. Nearly a quarter of those sites said they agreed because a hybrid model would be beneficial to trial participants by reducing travel burdens associated with on-site visits, especially if they are experiencing disease or treatment symptoms that hinder mobility.

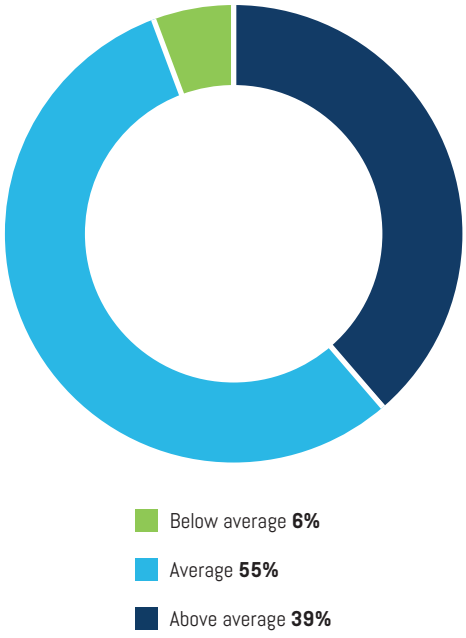
Sites were also more comfortable running hybrid trials because they were not dissimilar from traditional trial designs that have in-person visits supplemented by phone or telehealth assessments and consultations. The sites that did not agree to run a hybrid trial cited the same reasons as sites that did not agree to run fully remote trials – over a quarter of sites approached about conducting hybrid trials turned them down due to low budgets, inexperience with hybrid trials, or the technologies and processes involved, as well as patient safety concerns. Lisa Bjornestad summed up the impact of decentralization at the 2022 Site Solutions Summit: "look at decentralized trials as an opportunity to make patient participation easier, not site participation harder."

Diversity & Inclusion

Most clinical research sites, and more broadly most stakeholders in clinical development, are interested in enrolling diverse patient populations to ensure that the clinical data they collect is reflective of the global population that would use the approved therapeutic product. A majority of survey participants (54%) reported that they have been asked to conduct trials with specific diverse population targets. Nearly three-quarters said they have experience enrolling diverse populations, and of those, they rated their abilities to recruit and enroll diverse populations as average or above average.

Essentially, sites appear aware of the need for inclusive patient populations and know where they stand with enrolling diverse participants into clinical trials, but since most sites are small and may lack the capital to implement operational modifications, more than half agree that they need support with diversity enrollment planning. Fortunately, SCRS offers a Diversity Awareness Program including a Diversity Site Assessment Tool (DSAT) as well as other resources to support sites' diversity initiatives. Since this is a new section in the site sustainability survey, it will be interesting to see how these data evolve in future surveys.

Figure 6. How would you rate your ability to recruit and enroll diverse participants?



Looking Ahead

Figure 7. What role could SCRS play with regards to virtual / decentralized and hybrid trials that would have the greatest impact for your company?

61% Develop best practices for sites pertaining to virtual and hybrid trials

41% Provide education on virtual and hybrid trials to sites

40% Provide education to industry on how to include sites in virtual and hybrid trials

In this era of rapid transformation that continues to characterize the clinical development landscape, clinical research sites, who are under pressure to adapt yet continue to meet challenging performance metrics and compliance goals, continue to find themselves in tenuous revenue and profit cycles year after year.

The site community has made clear in this survey as well as prior years that the paradigm shift that is driving trial activities away from research sites impacts the structural integrity of the clinical research site-sponsor and site-CRO relationship. For example, sites still incur costs associated with supporting trial activities that take place in alternative locations. From recruiting efforts to training, technology, and operational modifications, sites absorb hard and soft costs while carrying extra responsibilities for safety and quality oversight of remote trial activities.

In this way, sponsors may want to consider how to mitigate these costs or to refine their budgeting process to include such considerations. This would also offer the opportunity to revise payment terms and other aspects of contracts with sites to better align with modern realities and operating conditions. Given the tenuous financial and operational conditions revealed in this and past surveys, many sites lack the personnel, tools, and/or compensation mechanisms that may be needed to participate productively in today's evolving clinical trials.

In addition, workforce development programs – an area in need of renewed focus – can help increase staff recruitment and retention. In a competitive labor market, clinical research site staff are valuable candidates for a variety of roles across and outside of industry. Turnover negatively impacts a site's ability to complete essential trial activities including safety and data quality oversight. In these ways, costs incurred for such workforce development programs, which may include additional compensation, retention initiatives, training, and other components, may be a smaller up-front investment than the bigger picture costs of hiring and training new staff.

As an advocate for sites' needs and perspectives, SCRS has played a direct role influencing industry to better support one of its most critical research partners. We have successfully helped to reduce or fully eliminate the practice of payment holdbacks, increased acceptance of monthly payment terms, and developed diversity planning tools, among many other accomplishments. We'll build on this progress by continuing to develop educational resources and tools such as those suggested in figure 7 and conducting this annual survey to monitor indicators of site sustainability. Including industry partners in the Site Landscape Survey will continue to be a practice in future surveys as well – these perspectives offered new and deeper insights that will serve as the basis for continued improvements in site-sponsor and site-CRO relationships. Afterall, advancing public health depends on close cooperation and working towards common goals to achieve the promise of medical research.

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