2024 Clinical Research Site Challenges Report

Data-Driven Insights on Current Site Challenges and Strategic Recommendations to Overcome Barriers and Boost Clinical Trial Efficiency

wcg™

Contents

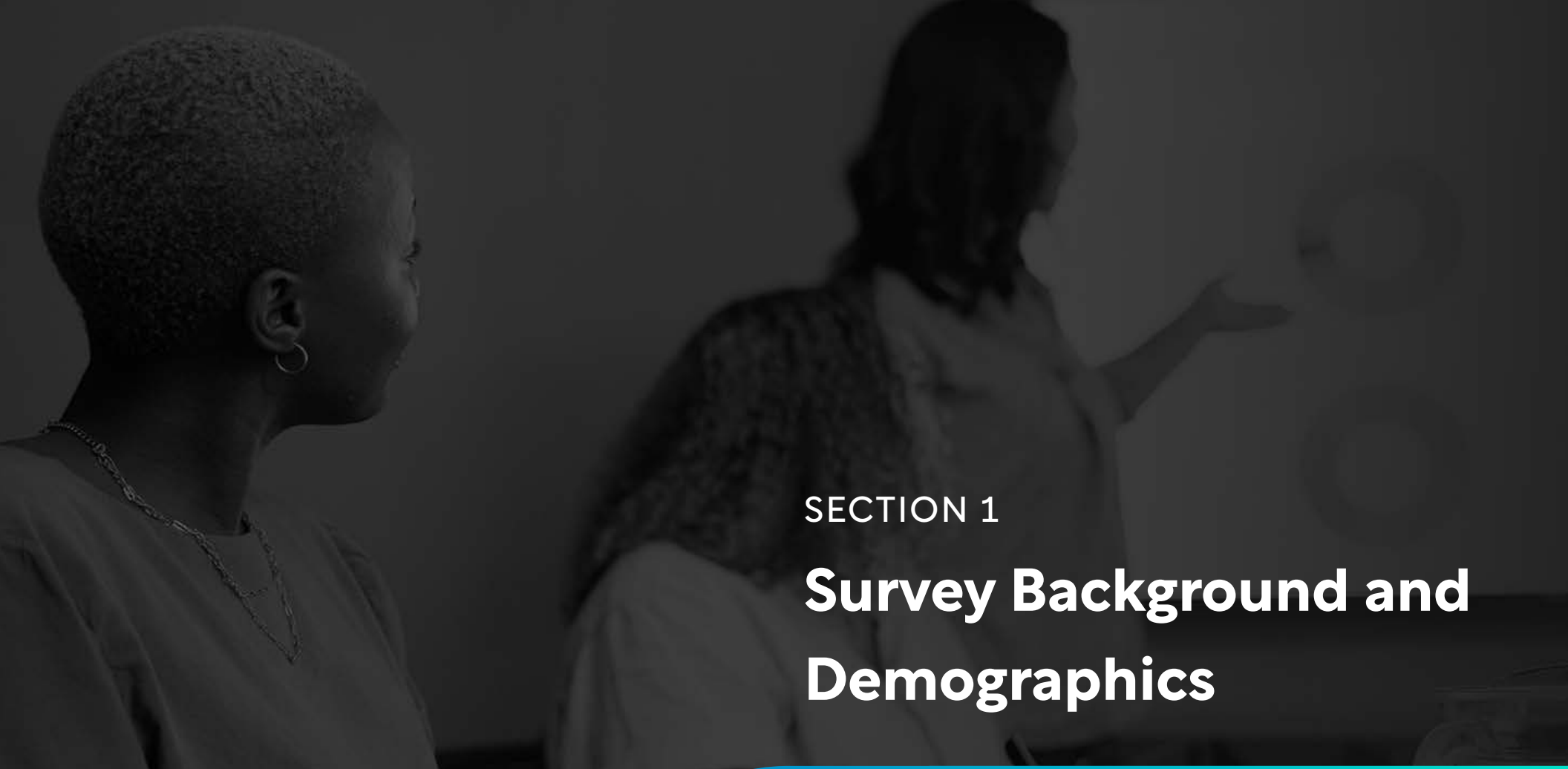
INTRODUCTION

The clinical research industry plays a vital role in advancing medical knowledge and improving healthcare; however, the increasing complexity of clinical trials has created a perfect storm of challenges for clinical research sites, posing significant risks to the efficiency, effectiveness, and sustainability of clinical trials at large. The growing complexity of clinical trials is, in part, a testament to the industry's advancing knowledge and capabilities, but it also necessitates that research sites are provided with more robust site support and study resources to manage these increasingly sophisticated trials successfully.

According to a recent Tufts Center for the Study of Drug Development impact report, a staggering 70% of global investigative site staff reported that trials have become much more difficult to manage in the last five years[2]. This trend of increasing trial complexity has exacerbated ongoing time constraints, resourcing issues (people and the budgets to pay them), and enrollment challenges, while the influx of new technologies has further burdened sites. As a result, many sites are struggling to keep pace with the mounting demands of modern clinical research.

In response to these challenges, WCG conducted a comprehensive survey of hundreds of clinical research sites around the world to better understand the obstacles they face and identify opportunities for improvement. Our 2024 Clinical Research Site Challenges Report presents the findings of this research, providing actionable insights and recommendations for clinical research sites, sponsors, CROs, and service providers to work together more effectively.

Our goal is to shed light on the critical issues impacting clinical research sites today and provide intelligence to inform the entire industry to drive meaningful change. By addressing these key site challenges, we believe we can break down silos, foster greater collaboration, and ultimately improve lives by accelerating research, together.



SECTION 1

Survey Background and Demographics

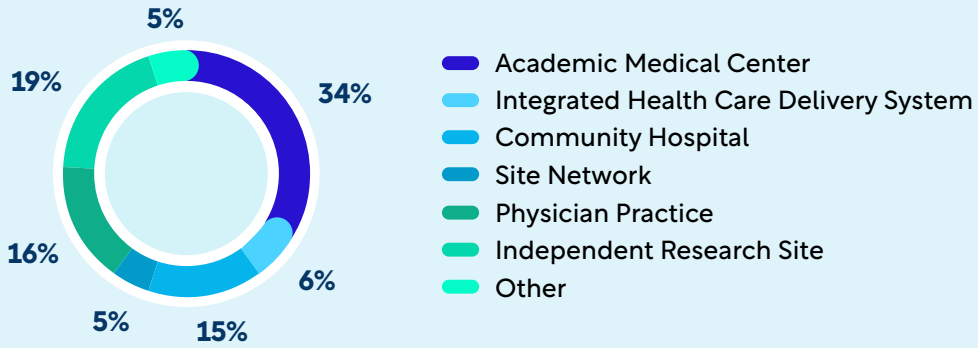
In a survey conducted between April and June 2024, WCG engaged with 852 clinical research sites globally, gathering valuable insights into the top challenges they are facing, the solutions they've implemented, and more.

WCG's 2024 Site Challenges Survey gathered insights from a wide range of clinical research sites. 55% of site respondents were from academic medical centers, health systems, or community hospitals. 40% were from independent sites, physician practices, or site networks, and the remaining 5% of respondents represented other types of research sites.

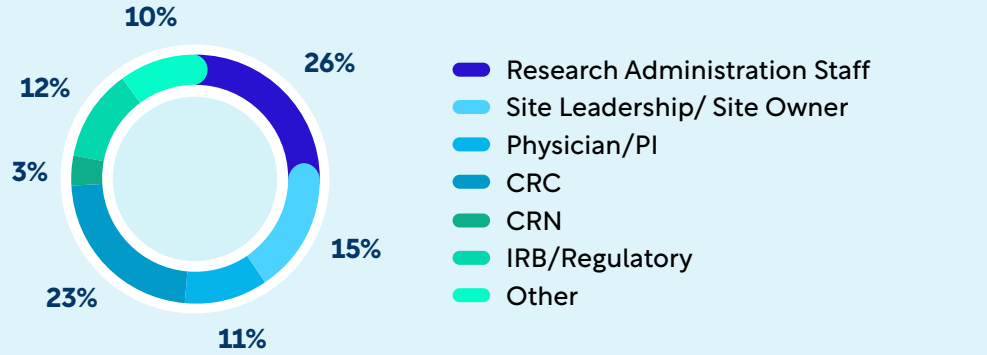
We collected responses from a wide range of professionals working in clinical research sites, representing various roles and levels within their organizations. The respondents were diverse, with 26% working in research administration, 26% Clinical Research Coordinators/Clinical Research Nurses (CRCs/CRNs), and 15% in site leadership positions. Additionally, 12% of respondents handled IRB and regulatory matters, 11% were Principal Investigators (PIs), and the remaining 10% were in other job types.

The survey respondents were also geographically diverse, representing multiple regions around the world. 77% of the survey respondents were in North America, while the other respondents were distributed across major regions, including 12% in Latin America, 8% in Europe, Middle East, and Africa, and 3% in Asia-Pacific.

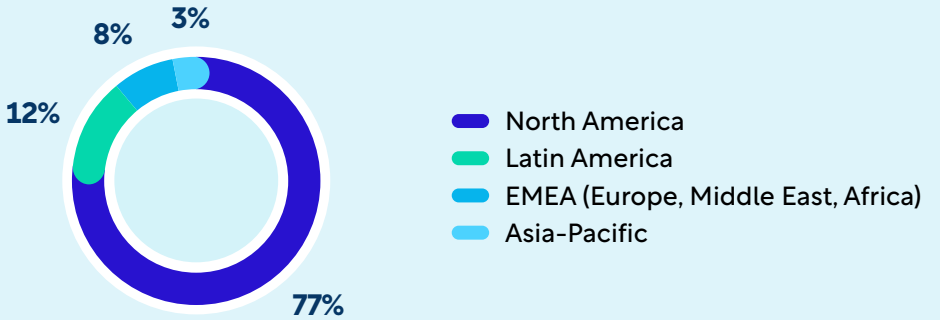
What type of research site do you represent?



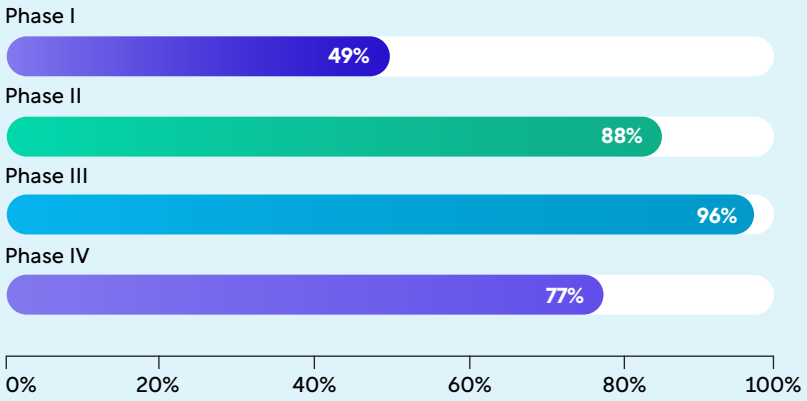
What is your role at your research site?



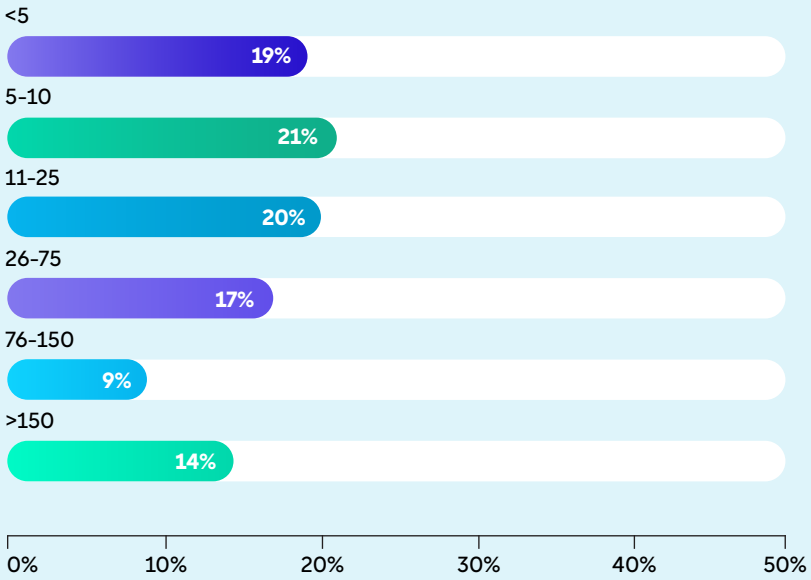
What region is your site based in?



What study phases does your site support?



Please select the number of open and enrolling trials currently at your site:

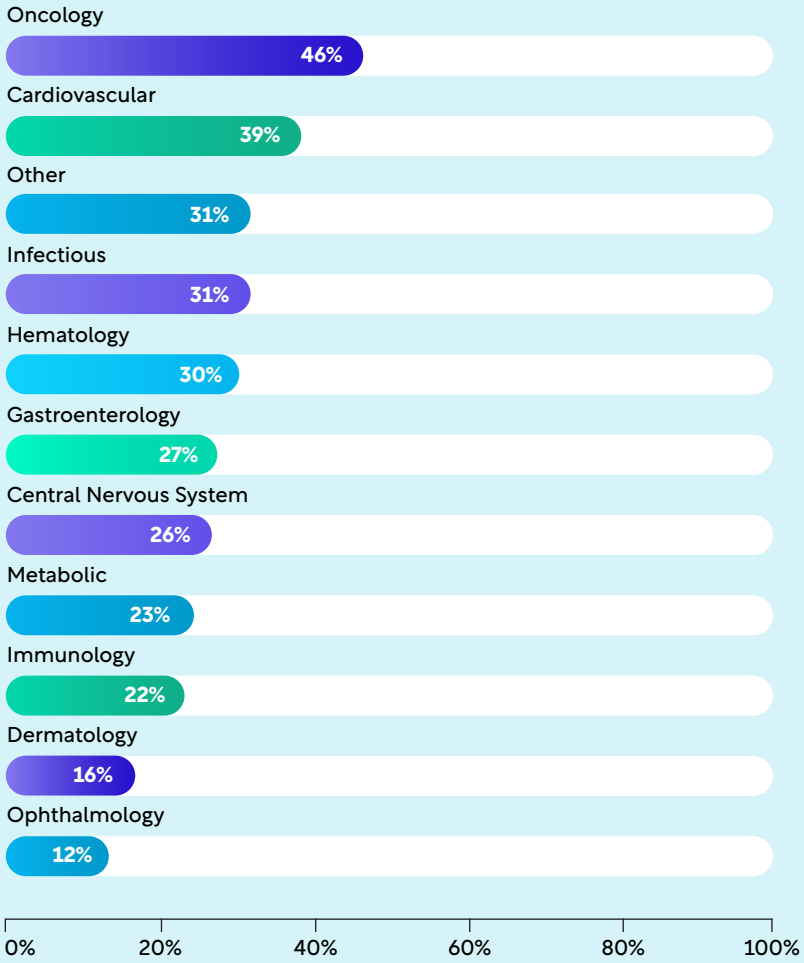


The sites that responded to our 2024 Site Challenges Survey are actively conducting trials across many phases. While nearly half (49%) of sites surveyed support early-stage phase I studies, most sites support phase II and III studies, coming in at 88% and 96% respectively. Furthermore, more than three-quarters (77%) of sites are involved in conducting phase IV studies, indicating a broad range of research activities across the clinical development spectrum.

We gathered data from our respondents on the number of open and enrolling trials their site(s) are currently running. Nineteen percent had fewer than five open and enrolling trials, while 21% had between 5-10 trials. Another 20% of sites were managing a moderate-sized portfolio, with 11-25 trials. Seventeen percent of sites had a larger portfolio of 26-75 trials, and a portion of the sites surveyed had even more, with 9% having 76-150 trials and 14% having more than 150 trials. These sites with a higher number of open and enrolling trials typically represent hospitals, health systems, and academic medical centers, which may have multiple site locations with different therapeutic areas of focus.

In addition, we also collected data on the therapeutic areas in which sites conducted trials last year. The top three therapeutic areas were oncology, cardiovascular, and infectious disease. Other notable top therapeutic areas in which surveyed sites conducted trials included hematology, gastroenterology, and central nervous system.

What therapeutic areas did your site conduct trials in last year?



SECTION 2

The Top Challenges Clinical Research Sites are Facing in 2024

Clinical research sites continue to face a wide range of challenges, with the following four being the most prevalent in 2024 for all site types:

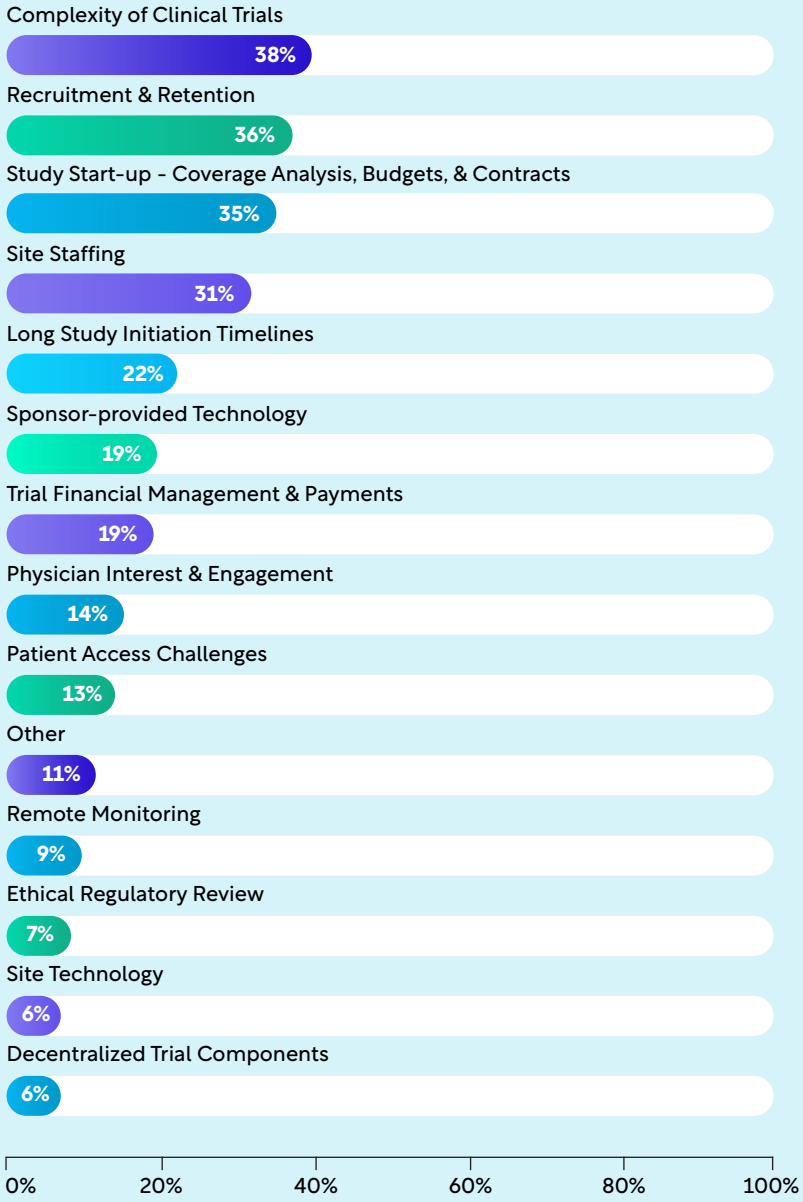
1. Complexity of Clinical Trials (38%): "Complexity of Clinical Trials" has risen to the top spot, surpassing site staffing/retention, which was the leading site challenge in 2022 and 2023. The increasing complexity of clinical trials is likely being driven by the growing demand for innovative study designs and adaptive trials, more complex protocols and data points, and the incorporation of new technologies, but we will explore this point more later.

2. Recruitment and Retention (36%): Recruitment and retention challenges continue to plague the industry, highlighting the need for more effective strategies to attract, enroll, and retain participants. Additionally, precision medicine in oncology and other complex therapeutic areas is leading to narrower inclusion/exclusion criteria, making site selection and recruitment more challenging. Similarly, increased clinical trial complexity can reflect not only the requirements for greater data collection but also the challenge of finding participants who meet inclusion criteria (and do not hit exclusion criteria), without becoming "screen failures."

3. Study Start-up (35%): Study start-up has remained a consistent top challenge for research sites, with 35% of sites citing it as a top issue in 2024, compared to 36% in 2023. Many sites continue to struggle with study start-up processes like coverage analysis, budgets, and contracts, as highly specialized skills are needed to complete these activities. Finding ways to prioritize and streamline these study start-up processes while working to improve communication between sites, sponsors, and CROs is essential to addressing this challenge.

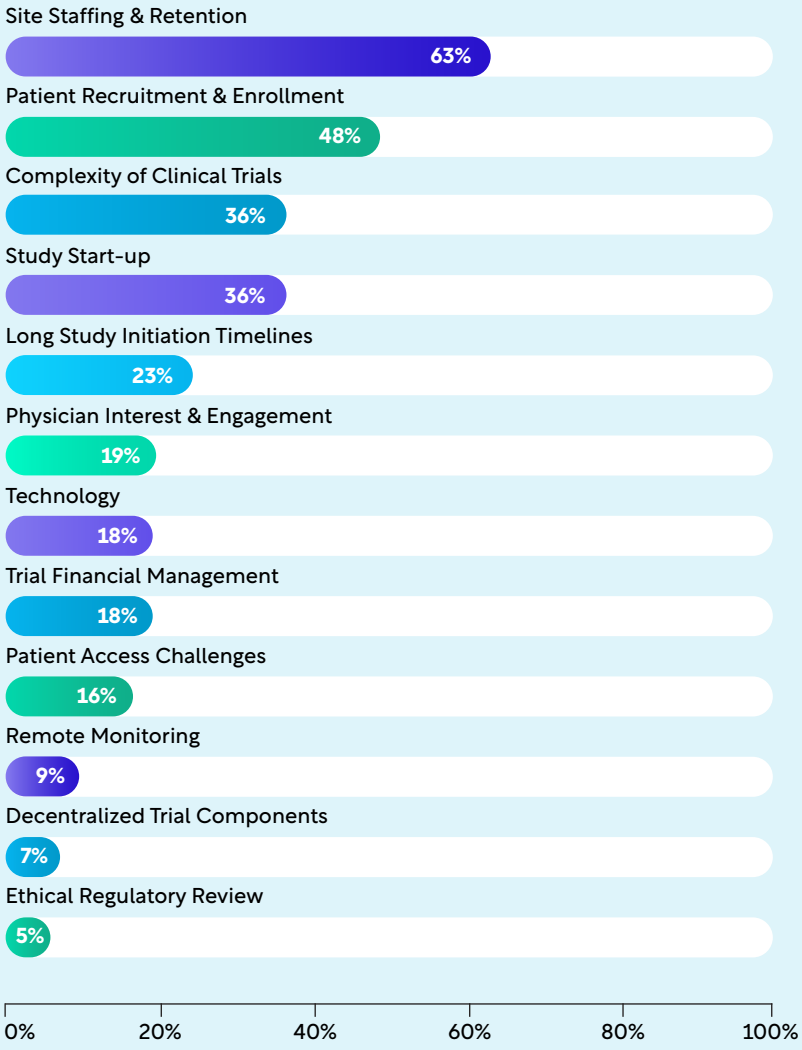
2024 RESULTS - ALL SITES

What are the top issues impacting your research site today?



2023 RESULTS - ALL SITES

The top site challenges in 2023



4. Site Staffing (31%): Site staffing, while still a major challenge, has decreased significantly from 63% in 2023 to 31% in 2024, suggesting that efforts to address site staffing concerns are yielding progress. However, it remains a significant challenge for many research sites today. This improvement is also evident in the stabilization of the clinical research workforce over the last several years, as more sites invest in extensive training programs to onboard less-experienced staff and implement new talent acquisition strategies, such as offering work-from-home options. To some extent, this challenge may reflect the slow adoption of third-party outsourced solutions for research teams, which can help solve some of these staffing-related challenges.

Top Challenges by Site Type: Larger vs. Smaller Sites

Clinical research sites vary in size, structure, and operational complexity, which can significantly influence the types of challenges they encounter. Survey data revealed distinct differences in the top challenges reported by larger sites (academic medical centers/health systems/community hospitals) compared to smaller sites (independent sites/physician practices/site networks). Recognizing these differences is crucial, as it can enable sponsors and CROs to develop more effective strategies to support sites and tailor their resources to better address the unique needs of each site type, ultimately improving the efficiency and effectiveness of clinical trials.

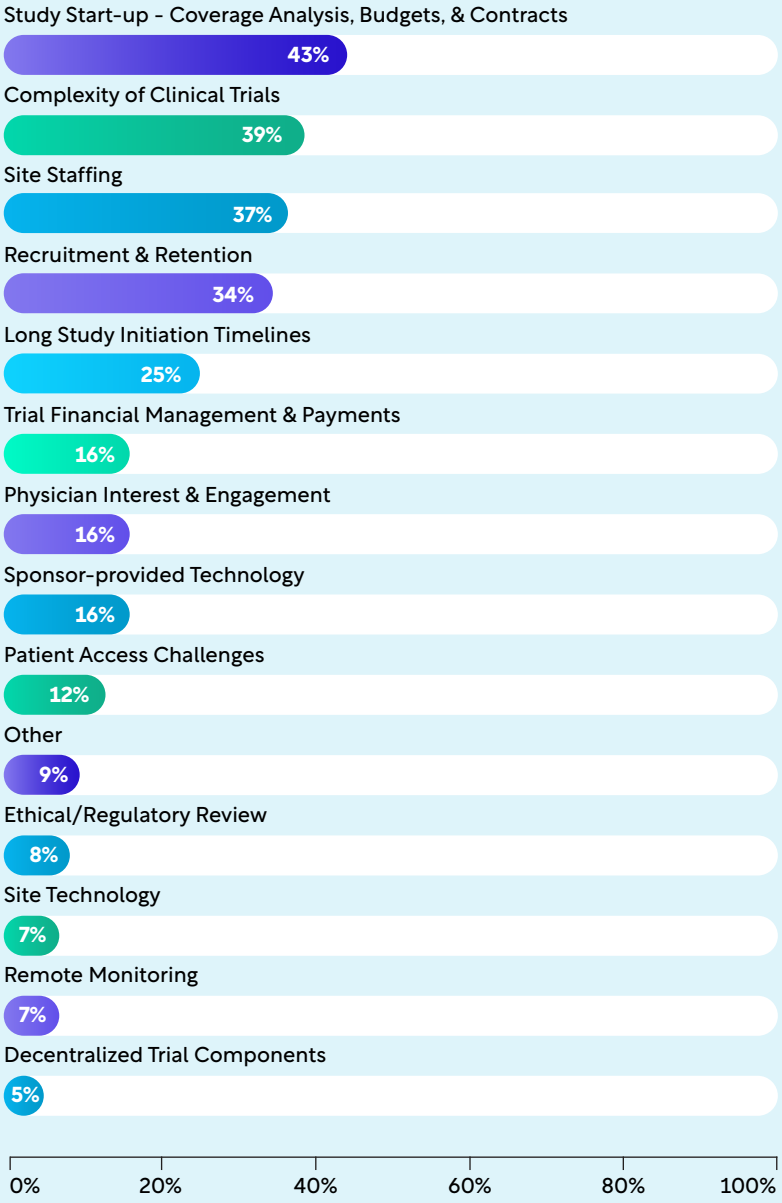
Top Challenges Faced by Academic Medical Centers, Health Systems, and Community Hospitals

Larger sites, including academic medical centers, health systems, and community hospitals, face a distinct set of challenges, with study start-up, complexity of trials, and site staffing as their top three concerns.

Forty-three percent of these sites cite study start-up as a major challenge, compared to 24% of smaller sites, likely due to the complexities of managing multiple stakeholders at multiple sites (i.e. departments), lack of centralization of research administration services, and regulatory requirements. Additionally, 39% of larger sites say that the complexity of clinical trials is a top challenge, likely stemming from their involvement in more complex therapeutic areas like oncology, working across multiple therapeutic areas, and having a higher number of open and enrolling trials. Furthermore, 37% of larger sites report that site staffing is a significant challenge, which may be attributed to managing a larger workforce (with many ongoing trials) within a large and often bureaucratic organization, compared to smaller, more agile sites, leading to higher turnover rates on average. Additionally, larger sites may also struggle with staffing due to the unpredictability of trial pipelines, as the feasibility and funding of potential trials are often uncertain, making it difficult to accurately forecast staffing needs and resulting in periodic under- or over-staffing.

ACADEMIC MEDICAL CENTER, HEALTH SYSTEM, AND COMMUNITY HOSPITAL DATA

What are the top issues impacting your research site today?



Top Challenges Faced by Independent Sites, Physician Practices, and Site Networks

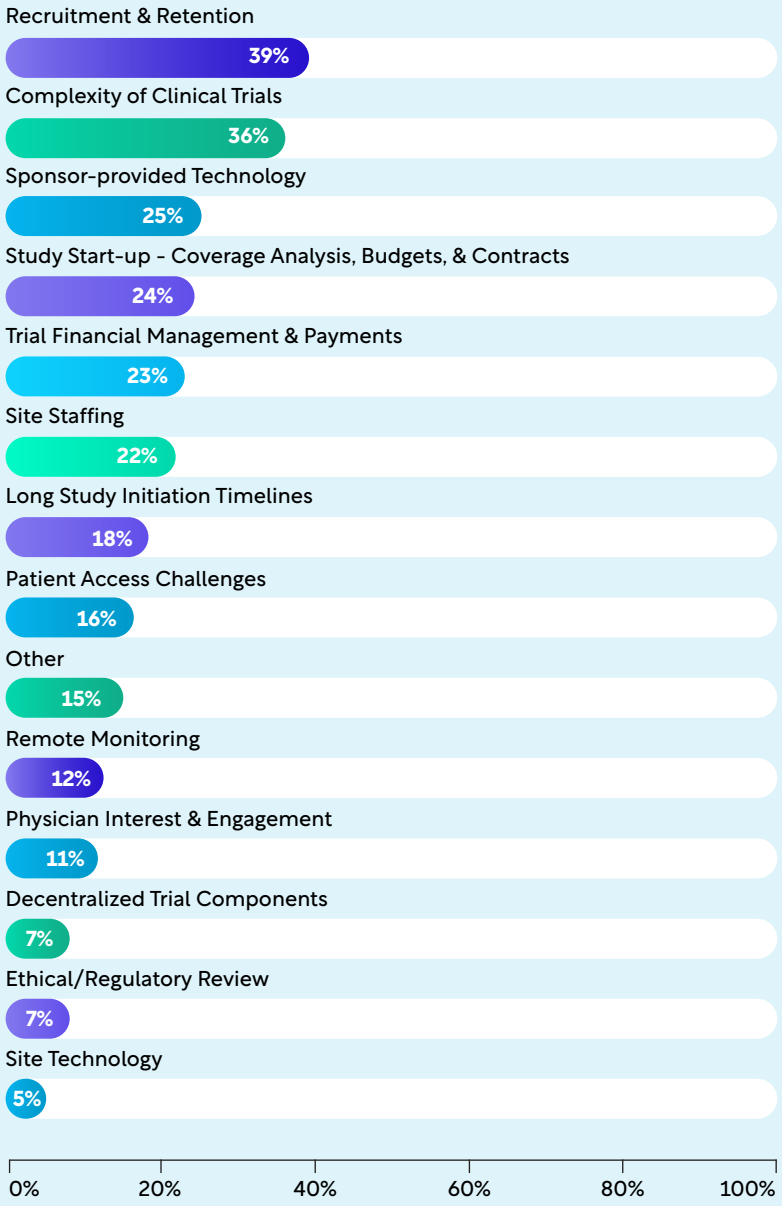
Smaller sites, including independent sites, physician practices, and site networks face a unique set of challenges in comparison to their larger counterparts. Participant recruitment and retention is a top major challenge, cited by 39% of these sites, likely due to more limited resources, a smaller patient pool, fewer staff members, and less access to research-specific technologies like eRegulatory, Clinical Trial Management Systems (CTMS), and tools to search medical records. Additionally, 36% of smaller sites struggle with the increasing complexity of clinical trials, which can be particularly daunting for sites with more limited resources. Furthermore, 25% of smaller sites report difficulties with sponsor-provided technology, which is a higher proportion than the 16% of larger sites that reported this challenge. This disparity suggests that smaller sites may require more support and training from sponsors/CROs to effectively utilize these technologies.

Top Challenges of US-Sites Compared to Ex-US Sites

While there are many similarities between the top challenges faced by clinical research sites in the U.S. and those outside of the U.S., there are some notable differences. U.S.-based sites reported the complexity of clinical trials (40%) and study start-up (39%) as their top two challenges. In contrast, ex-U.S. sites ranked recruitment and retention (36%) as their top challenge, followed by the complexity of clinical trials (32%). Notably, study start-up was cited by significantly fewer ex-U.S. sites (23%) as a top challenge.

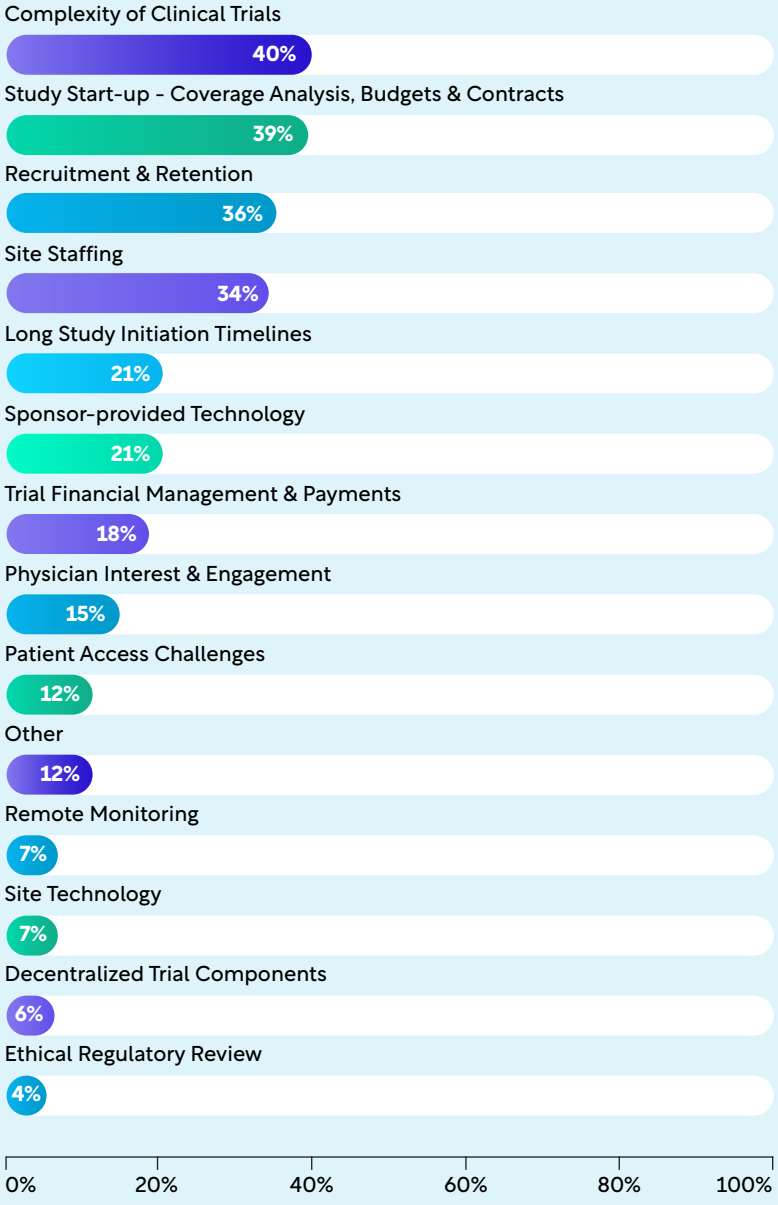
INDEPENDENT SITE, PHYSICIAN PRACTICE, AND SITE NETWORK DATA

What are the top issues impacting your research site today?

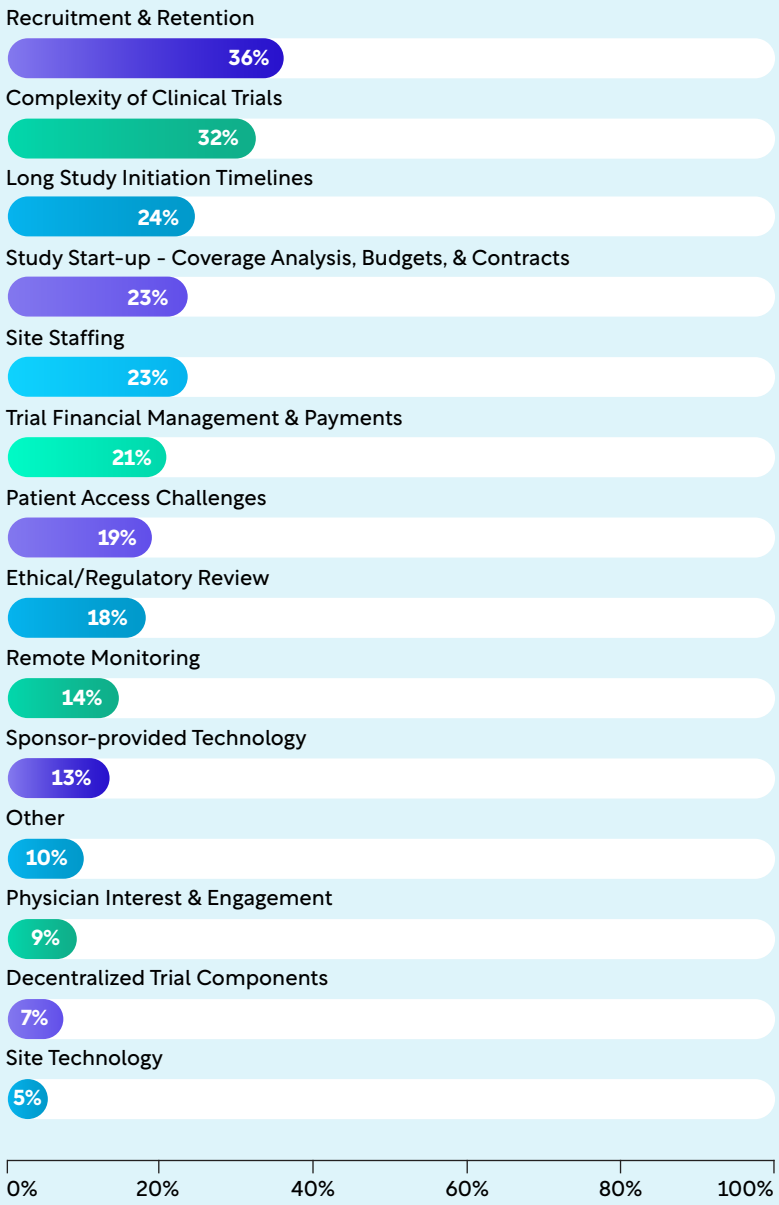


What are the top issues impacting your research site today?

US-SITES



EX-US SITES



SECTION 3

Examining the Increasing Complexity of Clinical Trials and Why Sites are Feeling the Burden

By prioritizing site support and empowering sites to manage complex trials successfully, we can ultimately accelerate the advancement of medical science and bring new treatments and therapies to patients who need them.

The complexity of clinical trials continues to escalate, placing a mounting strain on clinical research sites of all sizes. As industry trends indicate, this complexity is not only persistent but also intensifying, with far-reaching repercussions for sites, sponsors, CROs, and the overall productivity of clinical trials if this increase in complexity is not managed and supported properly. But what's behind this rise in complexity? Many factors contribute to this challenge, including more intricate study protocols, a steady rise in amendments and endpoints, increased requests for more data points, and the growing technological landscape. To gain a deeper understanding of the burden faced by sites, it is essential to examine key industry data points and identify the factors contributing to the growing complexity of clinical trials and how they are impacting sites.

As the industry has evolved over the past few years, sites have shouldered more responsibilities due to the increase in trial complexity. While they have shown remarkable adaptability in responding to shifting demands, additional support is necessary to ensure their continued success. To enable sites to meet expectations while maintaining the highest standards of quality and safety, a high degree of collaboration will be needed between sites, sponsors, and CROs, matched with more investments in support and resources for sites, training, and infrastructure.

By prioritizing site support and empowering them to manage complex trials successfully, we can ultimately accelerate the advancement of medical science and bring new treatments and therapies to patients who need them.

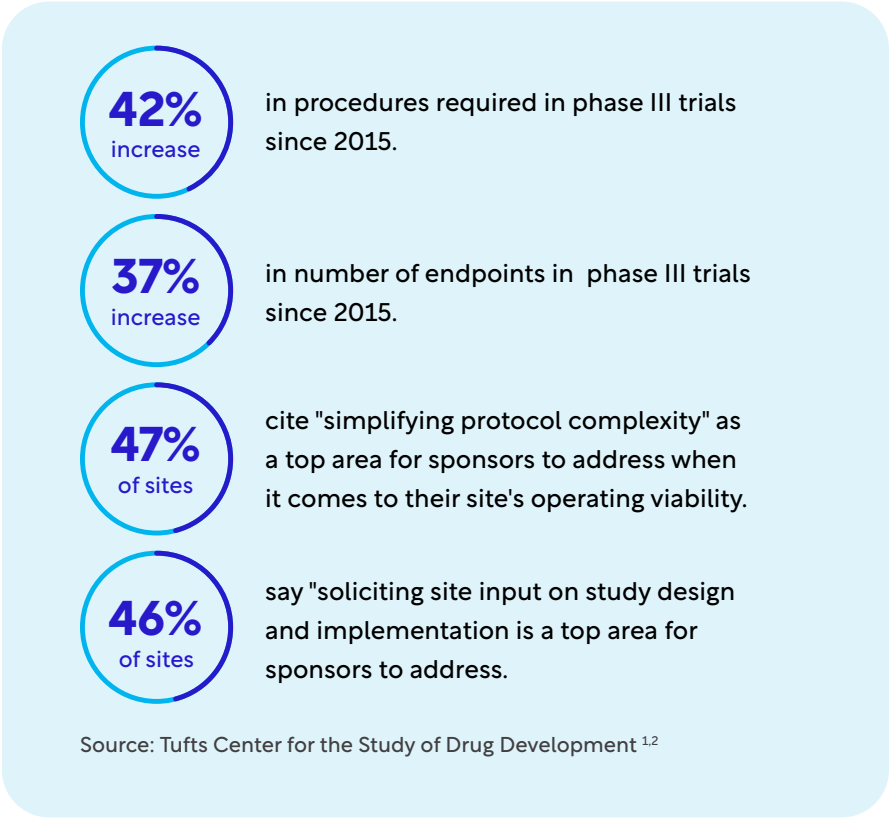
Endpoints, Amendments, and Protocol Complexity are on the Rise

According to the Tufts Center for the Study of Drug Development in their May/June 2023 Impact Report, the mean number of protocol deviations and substantial amendments has increased across all clinical trial phases since 2015[1]. This trend is particularly pronounced in Phase III trials, which have seen a 42% increase in required procedures, a 37% increase in average planned study visits per participant, and a 37% increase in the number of endpoints since 2015[1].

Clinical research sites conducting oncology trials are shouldering an even greater burden when it comes to the complexity of clinical trials, with Phase II protocols having twice as many substantial protocol amendments compared to non-oncology protocols, and Phase III trials facing a nearly 40% increase in substantial amendments compared to non-oncology protocols[3]. Furthermore, the increasing specificity of oncology indications, often driven by biomarker components, adds an additional layer of complexity, requiring sites to conduct more extensive evaluations before agreeing to participate in a trial to ensure they can adequately enroll and conduct the study. In addition to increased protocol complexity and feasibility evaluations, sites conducting oncology trials often face significantly longer trial timelines, with oncology trials taking 30-40% longer, on average than non-oncology trials[10].

This surge in complexity is taking a toll on sites, which are struggling to manage the added burdens of more intricate trials. In fact, 47% of sites surveyed in the Tufts Center for the Study of Drug Development January/February 2023 Impact Report cited “simplifying protocol complexity” as a top area for sponsors to address when it comes to their site’s operating viability[2]. Additionally, 46% of sites surveyed said they want sponsors to solicit site input on study design and implementation[2].

It is also important to highlight how the recent FDA draft guidance, 'Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies’, impacts trial complexity for research sites. The guidance underscores the critical need for clinical trials to reflect the diversity of the populations that will ultimately benefit from the treatments being tested. However,



Source: Tufts Center for the Study of Drug Development [1,2]

clinical research sites can sometimes be left to bear the brunt of implementing these changes alone, facing the challenge of developing and executing DE&I strategies with limited guidance and resources from sponsors and CROs. As the industry strives to improve diversity in clinical trials, it is essential that sponsors, CROs, and research sites collaborate to share best practices and ensure that the work needed to achieve diversity in clinical trials is distributed equitably.

42% of sites stress the need for sponsor acceptance of their technology in study participation, according to Florence's 2024 State of Technology Enabled Clinical Trials report.

43% of sponsors view their software's adoption as a key selection criterion according to Florence's 2024 State of Technology Enabled Clinical Trials report.

38% of sites find sponsor-provided technology inadequate, according to Florence's 2024 State of Technology Enabled Clinical Trials report.

60% of research sites are using more than 20 systems daily, according to a 2022 poll conducted by SCRS.

Source: Florence Healthcare & Society for Clinical Research Sites [4,5]

25% **of independent sites, site networks, and physician practices** ranked sponsor-provided technologies as a top challenge.

16% **of AMCs, community hospitals, and health systems** ranked sponsor-provided technologies as a top challenge.

The Mounting Technology Burden: A Growing Concern

The proliferation of technology in clinical trials has created a new set of challenges for sites. According to the WCG 2024 Site Challenges Survey, sponsor-provided technologies, such as training tools, screening and tracking tools, enrollment technology, and electronic data capture (EDC) systems, are often cited as a top challenge for sites. In fact, 19% of all sites reported that sponsor-provided technologies were a top challenge, with independent sites, physician practices, and site networks being disproportionately affected (25%). In addition to these challenges, according to a 2022 poll conducted by the Society for Clinical Research Sites (SCRS), 60% of the sites they surveyed were using more than 20 technology systems per day.

These challenges highlighted above reinforce the need for better alignment between sponsors/CROs and sites when it comes to technology. According to Florence's 2024 State of Technology Enabled Clinical Trials report, 42% of sites stress the need for sponsor acceptance of their technology in study participation. However, 43% of sponsors view their software's adoption as a key selection criterion,

suggesting a mismatch between sponsor expectations and site needs. Furthermore, 38% of sites find sponsor-provided technology inadequate.

To alleviate the technology burden on clinical trial sites, the industry must take steps to improve sponsor-CRO-site alignment, standardize and simplify technology solutions, and consider site-preferred options. Sponsors and CROs must work closely with sites to understand their needs and provide adequate support and training on technology solutions required for their trials. Technology providers should prioritize developing user-friendly, integrated, and interoperable systems, with a focus on integrations for systems commonly used by sites to reduce data entry and administrative burden currently affecting sites.

Sites may also want to identify a site IT professional who can fully engage in all research-related technology, gain an understanding of research technology regulatory requirements, and serve as the conduit to harmonize all site, sponsor, CRO, vendor, and site technologies. By fostering collaboration, gathering feedback, and involving sites in the development process, the industry can create more site-friendly technology solutions that reduce burden, improve the overall efficiency of clinical trials, and ultimately speed the development of new treatments and therapies.

SECTION 4

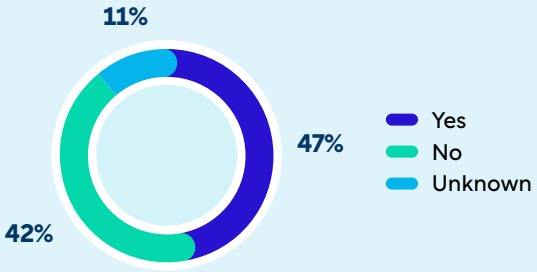
Impact on Study Participation: How Top Challenges are Limiting Site Capacity

The top challenges faced by clinical research sites are having a significant impact on their ability to participate in new studies. Our research reveals that nearly half (46%) of sites reported that these challenges are restricting their capacity to agree to participate in new studies. Furthermore, 47% of sites stated that they agreed to fewer studies over the past year due to these top challenges. This trend is particularly pronounced in the U.S., where 50% of sites reported a reduction in the number of studies they agreed to participate in during the last year, compared to 37% of ex-U.S. sites.

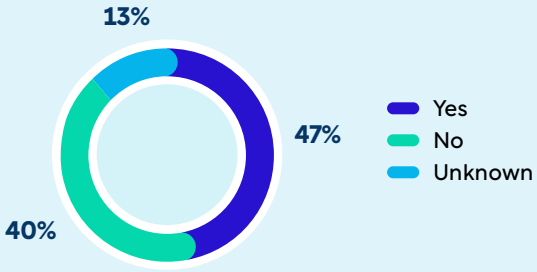
The effects of these challenges on site participation (and the development of new sites) have significant implications for the entire industry. As more sites struggle to participate in new trials, we can expect delays in drug development, reduced patient access to clinical trials, increased costs, and other far-reaching consequences. Understanding the current state of site capacity is critical for effective site and study planning, study execution, and determining the support needed to mitigate these top site challenges.

ALL SITE DATA

Are these challenges impacting your site's ability to participate in new studies?

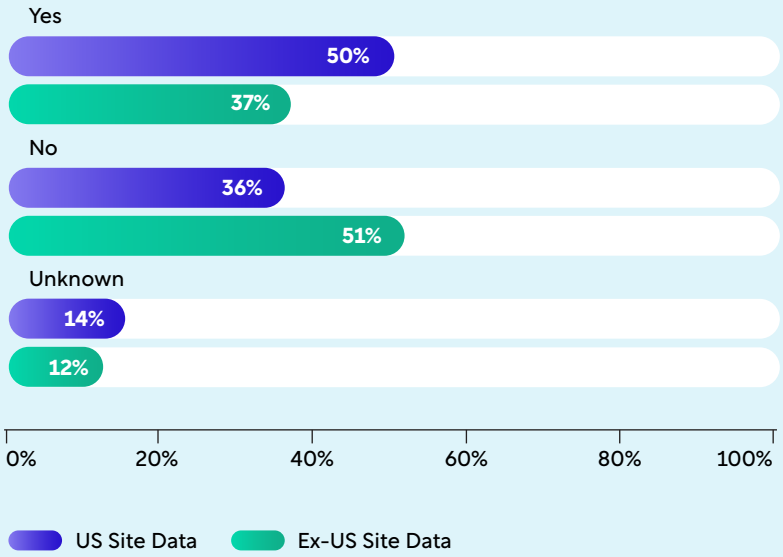


Did these challenges reduce the number of studies your site agreed to participate in during the last year?



US vs. EX-US SITES

Did these challenges reduce the number of studies your site agreed to participate in during the last year?



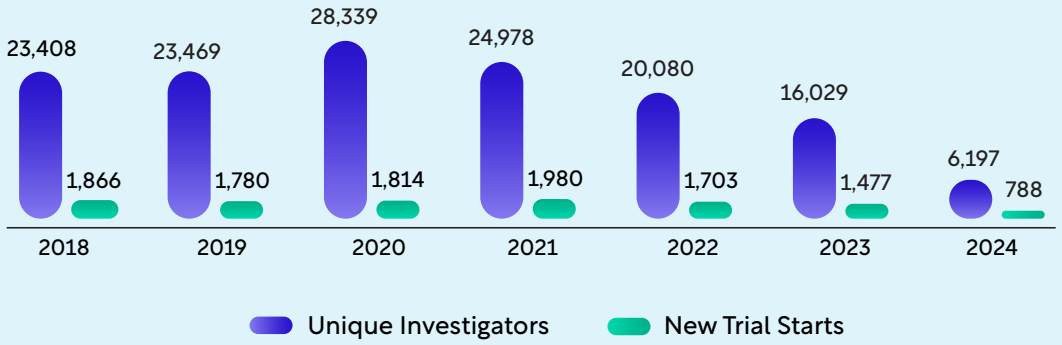
SECTION 5

A Deep Dive into Physician Interest and Availability to Conduct Trials

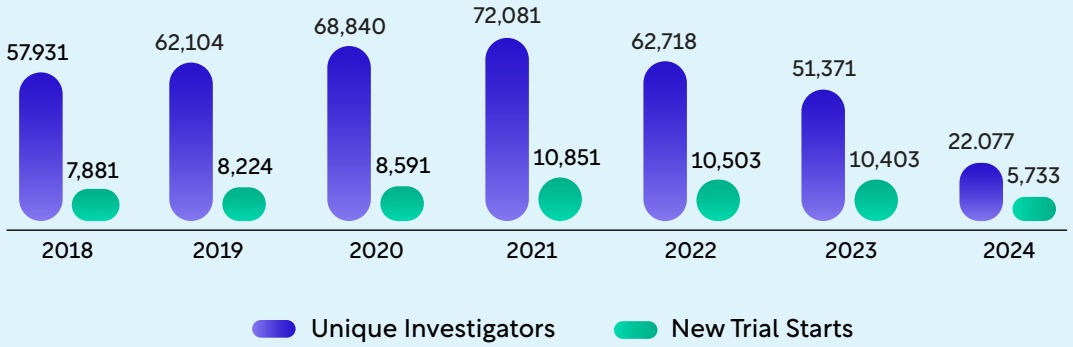
The landscape of physician interest and availability to participate in clinical research is multifaceted. While some sites have reported an uptick in physician availability/interest, others continue to struggle.

The number of investigators participating in clinical trials and the number of trial starts have both significantly declined in the U.S. and globally over the last several years. In the U.S., the number of unique investigators has decreased by more than 78% from 2020 to 2024, while trial starts in the U.S. have decreased by 57% over the same period[8]. Globally, the trend is also concerning, with a 68% decline in unique investigators and a 33% decrease in trial starts from 2020 to 2024[8]. Some of this decline can be attributed to the post-pandemic plateau of COVID-19 trials, but when comparing 2024 numbers to pre-pandemic data there is still a significant decline in investigators and trial starts, which is cause for concern for everyone in the industry. This trend should alarm not only those directly involved in clinical research, but also the broader healthcare community, as a dwindling pool of principal investigators can lead to additional delays in the development of new treatments and ultimately hinder the advancement of medical science.

U.S. Investigators Participating in Clinical Trials Compared to New Trial Starts Since 2018



Global Investigators Participating in Clinical Trials Compared to New Trial Starts Since 2018

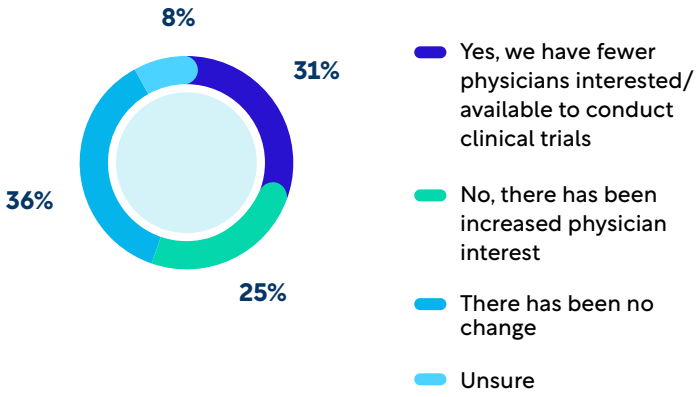


Source: WCG ClinSphere*2024 data is preliminary
Filters: Represents Industry Sponsored, Interventional, Ph I – Ph IV, Trial Starts & Investigators in the U.S. Since 1/1/2018

According to our survey, 25% of sites reported an increase in physician availability/interest in conducting clinical trials in 2024, up from 17% in 2023. However, the percentage of sites struggling with physician availability and interest remains a concern. In 2024, 31% of survey respondents reported having fewer physicians available and interested in conducting trials, which has remained relatively stagnant from 33% in 2023. This lack of availability and interest is particularly pronounced among larger sites like AMCs, health systems, and community hospitals, with 37% reporting fewer physicians available or interested in serving as principal investigators.

ALL SITE DATA

Have you experienced a change in physician availability or interest to serve as PIs that has negatively impacted your site's ability to open new trials?



INDEPENDENT SITE, PHYSICIAN PRACTICE, AND SITE NETWORK DATA

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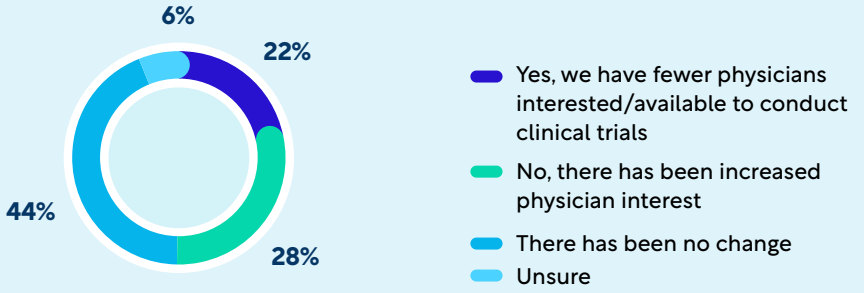
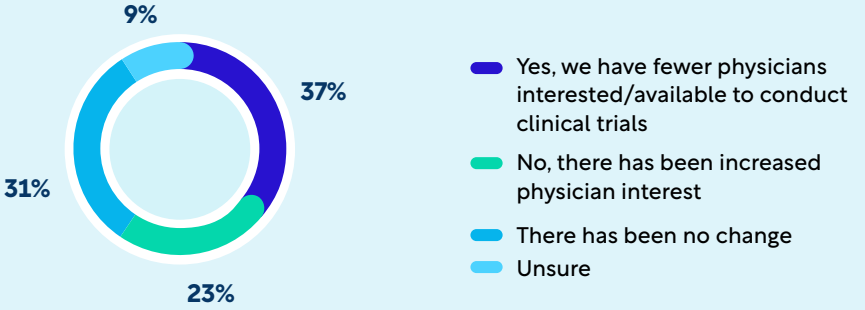


ACADEMIC MEDICAL CENTER, HEALTH SYSTEM, AND COMMUNITY HOSPITAL DATA

Have you experienced a change in physician availability or interest to serve as PIs that has negatively impacted your site's ability to open new trials?



Additional anecdotal evidence suggests that increasing clinical demands and research team staffing shortages are contributing to these challenges. Many physicians report being stretched with their clinical duties, leaving limited time for research activities. In fact, 66% of physicians who practice clinical research only participate in a single clinical trial[6], a phenomenon known as the "one and done" phenomenon.

To address these challenges, it is essential to create an environment that supports physician engagement and interest in clinical research. This can be achieved by designing research teams with well-defined roles, allowing investigator time to be spent on high-value tasks, and providing mentoring opportunities for new physicians to develop their research skills. It is also important to acknowledge the financial barriers that may influence a physician's decision to conduct clinical research. Some physicians may be deterred from participating in clinical research due to economic realities related to the time investment required as an investigator versus time dedicated to providing routine clinical care. To address this issue, increasing funding opportunities and providing protected time for research participation could encourage more physicians to engage in clinical research.

It is essential to create an environment that supports physician engagement and interest in clinical research.

SECTION 6

Staff Turnover Trends at Clinical Research Sites

Our survey data suggests a favorable shift in staff turnover rates at clinical research sites in 2024. Overall, sites reported lower staff turnover rates compared to 2023, indicating a potential improvement in site staff retention.

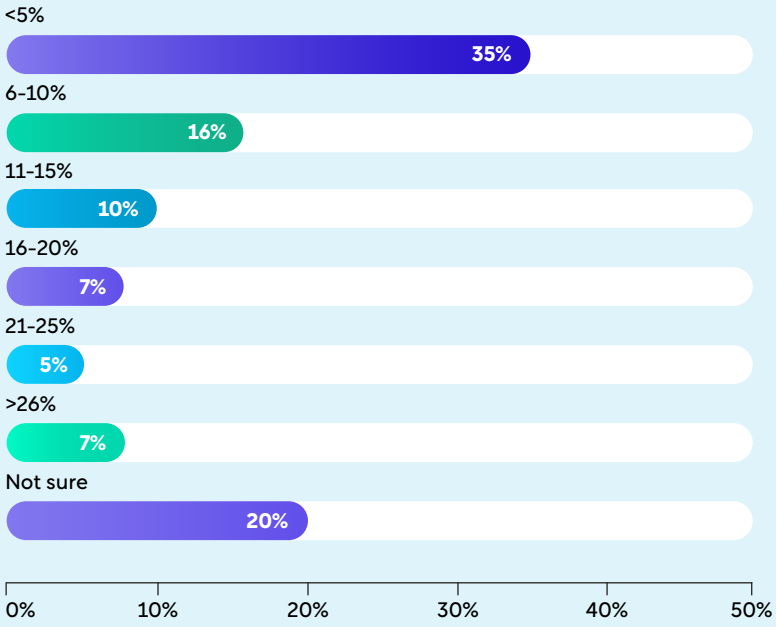
In 2024, 51% of sites reported a yearly staff turnover rate of less than 10%, while 35% of sites reported a rate of less than 5%. This represents a notable change from 2023 when only 22% of sites reported turnover rates below 5%.

We also see a significant difference in turnover rates between smaller and larger sites. Smaller sites tend to have lower turnover rates, with 48% reporting a rate below 5%, compared to just 25% of larger sites.

Many sites will continue to be challenged in finding research professionals with sufficient experience to facilitate good and accurate trial results, and staff training will remain a priority. In addition, competencies are changing to include more technical skills to navigate the current clinical trial landscape. With demand for research professionals still outweighing supply, site leaders may need to focus more on retention and other approaches to maintain optimal staffing levels.

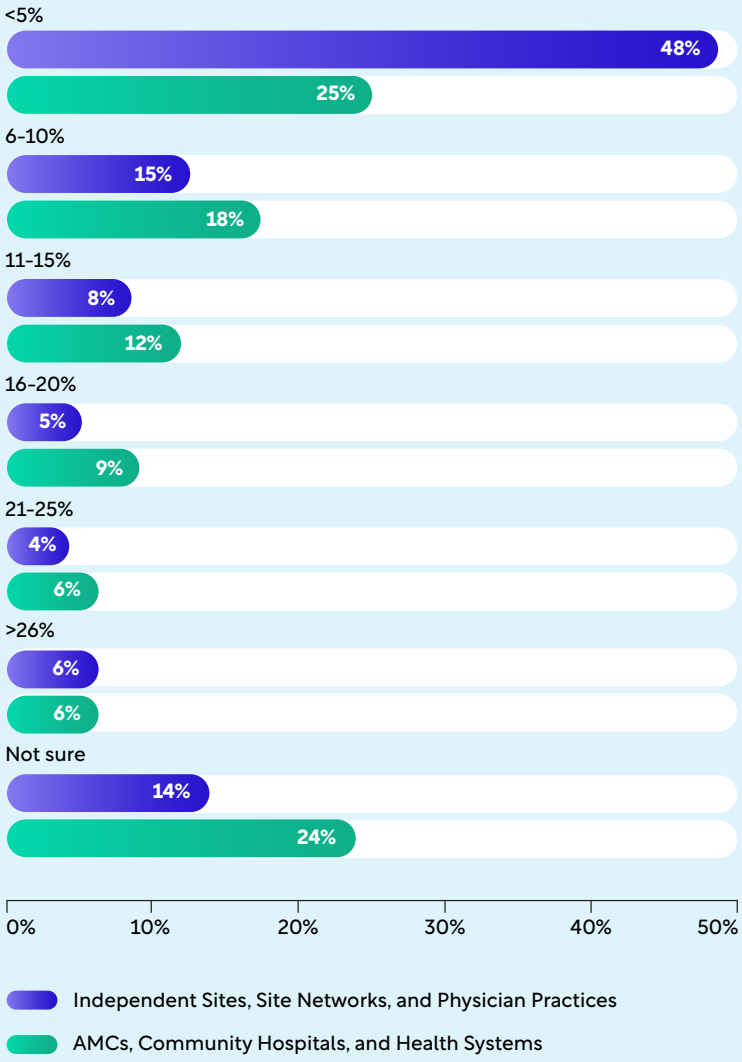
ALL SITE DATA

Approximately what is the yearly percentage of staff turnover at your organization?



ACADEMIC MEDICAL CENTERS, HEALTH SYSTEMS, AND COMMUNITY HOSPITALS VS INDEPENDENT SITES, PHYSICIAN PRACTICES, AND SITE NETWORKS

Approximately what is the yearly percentage of staff turnover at your organization?



SECTION 7

Study Start-Up: A Persistent Challenge for Clinical Research Sites

The study start-up (SSU) process continues to be a significant challenge in the clinical trial initiation process, with study start-up timelines (from protocol approval to first participant, first visit) steadily increasing by a substantial 30-45% since 2015[1]. Despite advances in technology and process innovations, study start-up remains a critical bottleneck for all site types, underscoring the need for improved efficiency and streamlined processes.

It is also important to highlight the need for study budgets to better reflect the true work efforts of clinical research sites. 19% of our survey respondents identified trial financial management and payments as a top challenge, indicating the need for significant improvement and support in this area. According to a recent Tufts Center for the Study of Drug Development impact report, two-thirds of sites overall, and nearly 90% of administrative site staff, rate study budgets that reflect true work effort as the top factor ensuring operating viability[2]. Study budgets often fail to account for all the requirements mandated by the FDA or sponsor, which places an undue financial burden on the site. Furthermore, it is equally essential for sponsors and CROs to prioritize making timely and accurate payments to sites for the work they conduct on their trials, as delayed or incorrect payments can exacerbate the financial strain on research sites and undermine their ability to operate sustainably.

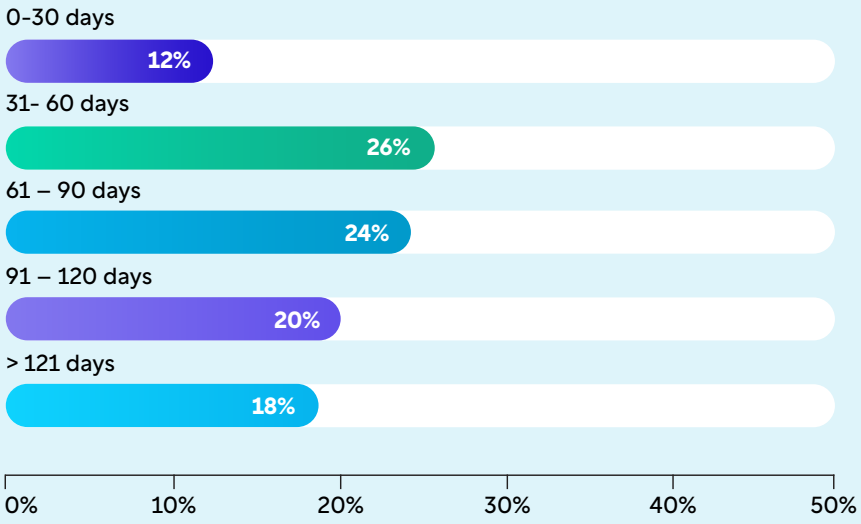
Study Start-up Timelines: A Comparison Across Site Types

The length of reported study start-up timelines varies significantly across different types of clinical research sites. Notably, independent sites and physician practices tend to have more streamlined SSU processes, with 60% reporting that they can initiate studies in under 60 days. In contrast, academic medical centers, community hospitals, and health systems face longer timelines, with 77% saying their study start-up timelines exceed 60 days. Geographic location also plays a role – with 48% of ex-U.S. sites reporting their SSU processes taking less than 60 days, compared to 65% of U.S. sites reporting timelines exceeding 60 days.

Additionally, for sites conducting NCI-sponsored cancer studies, nearly 60% of cancer centers reported activating NCI-sponsored studies within 90 days but only 9% reported meeting a 90-day activation timeline for industry-sponsored studies[7], suggesting there is significant opportunity for these types of sites to drive additional efficiency during the study start-up process.

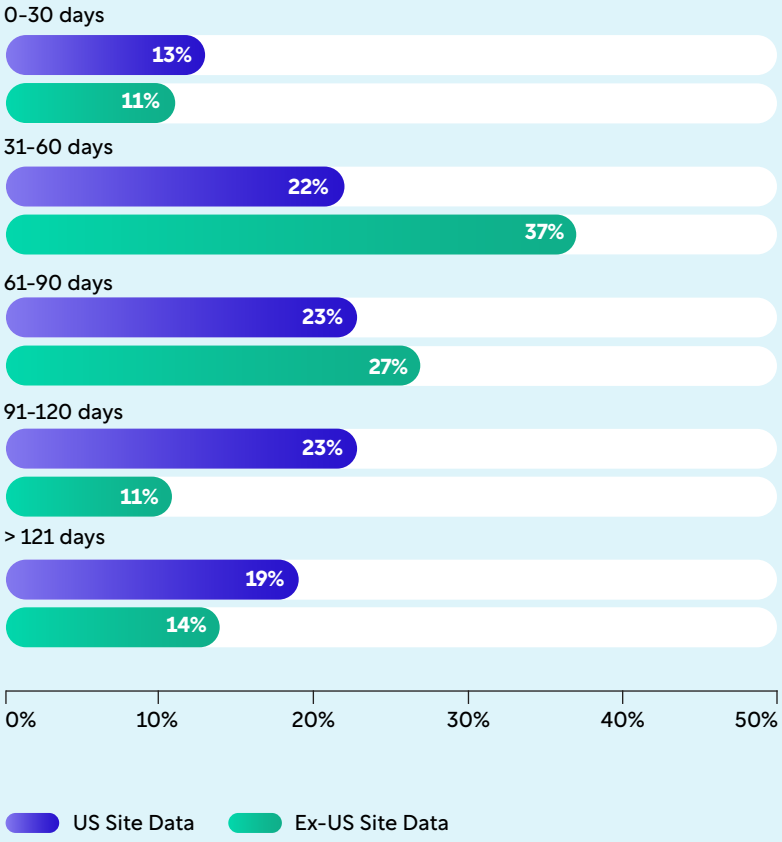
ALL SITE DATA

How long did your site's average study start-up process take last year?



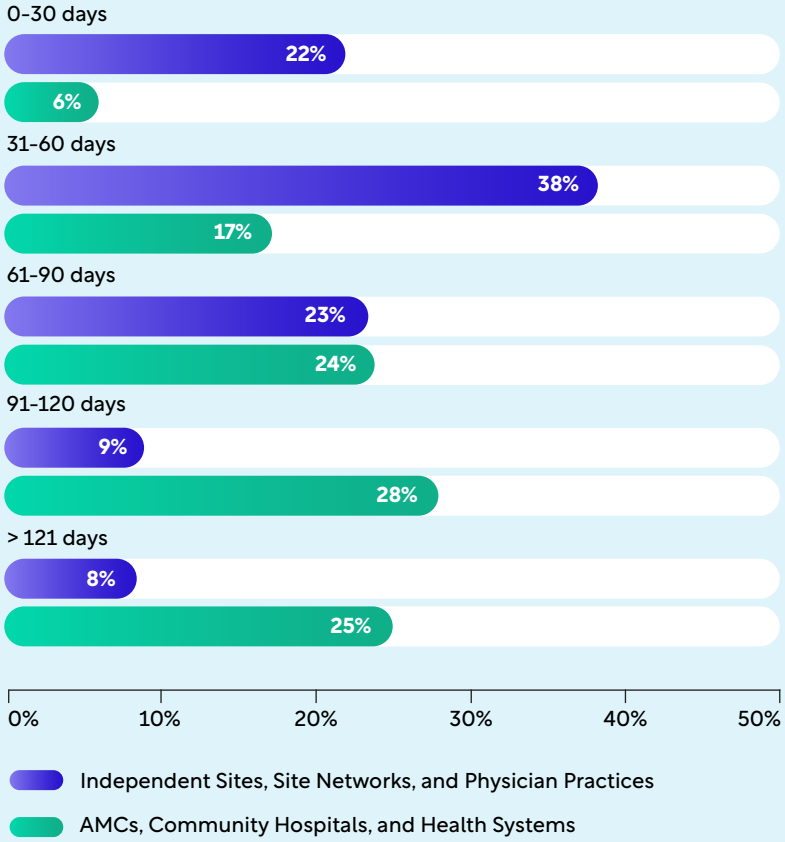
US VS EX-US SITES

How long did your site's average study start-up process take last year?



ACADEMIC MEDICAL CENTERS, HEALTH SYSTEMS, AND COMMUNITY HOSPITALS VS INDEPENDENT SITES, PHYSICIAN PRACTICES, AND SITE NETWORKS

How long did your site's average study start-up process take last year?



Examining the Largest Contributors to Study Start-Up Timelines

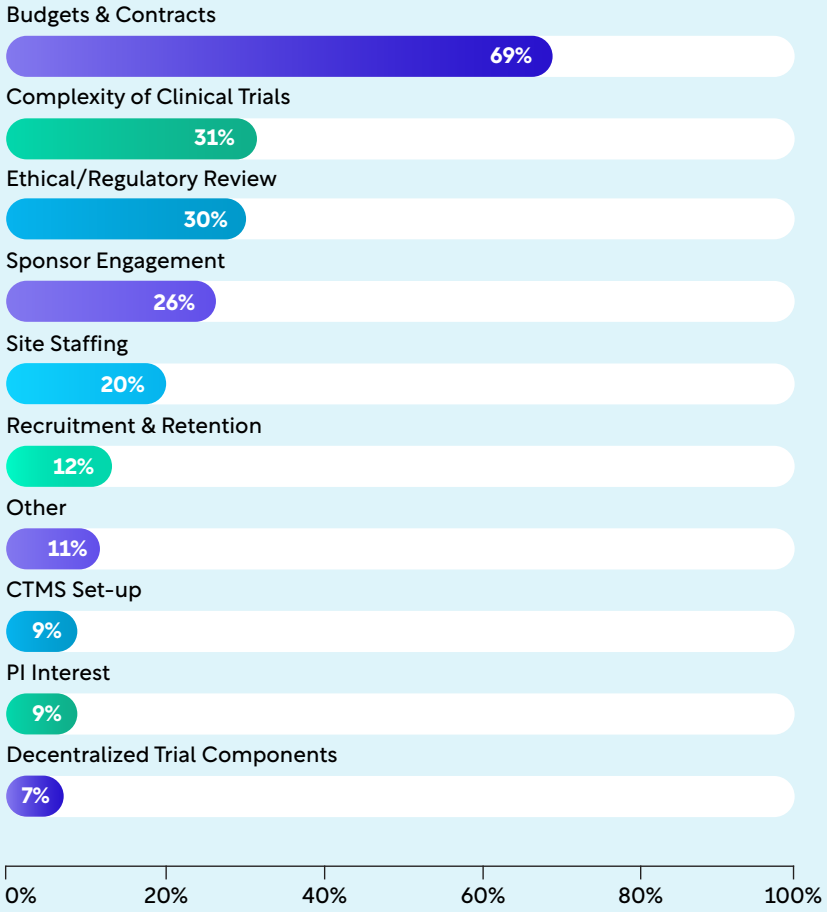
Across all types of clinical research sites, budgets and contracts were the main offenders contributing to delayed study start-up timelines, affecting 69% of respondents. The complexity of trials and regulatory hurdles were also significant contributors, at 31% and 30%, respectively. Notably, there was a geographic divide in the responses, with 58% of ex-U.S. sites listing ethical/regulatory review as their top challenge, while 77% of U.S. sites pointed to budgets and contracts as the primary obstacle during start-up.

Despite advances in technology and process innovations, study start-up remains a critical bottleneck for all site types, underscoring the need for improved efficiency and streamlined processes.

Overall, these findings highlight the need for improved efficiency and effective communication across all stakeholders involved in the clinical trial start-up process, with a focus on addressing the persistent challenges of budgeting and contracting. Specialized skills in research revenue cycle are required for creating and negotiating compliant research budgets and contracts, and the absence of these skill sets at sites may not only delay trial initiation but could place sites at risk for potential compliance and financial implications.

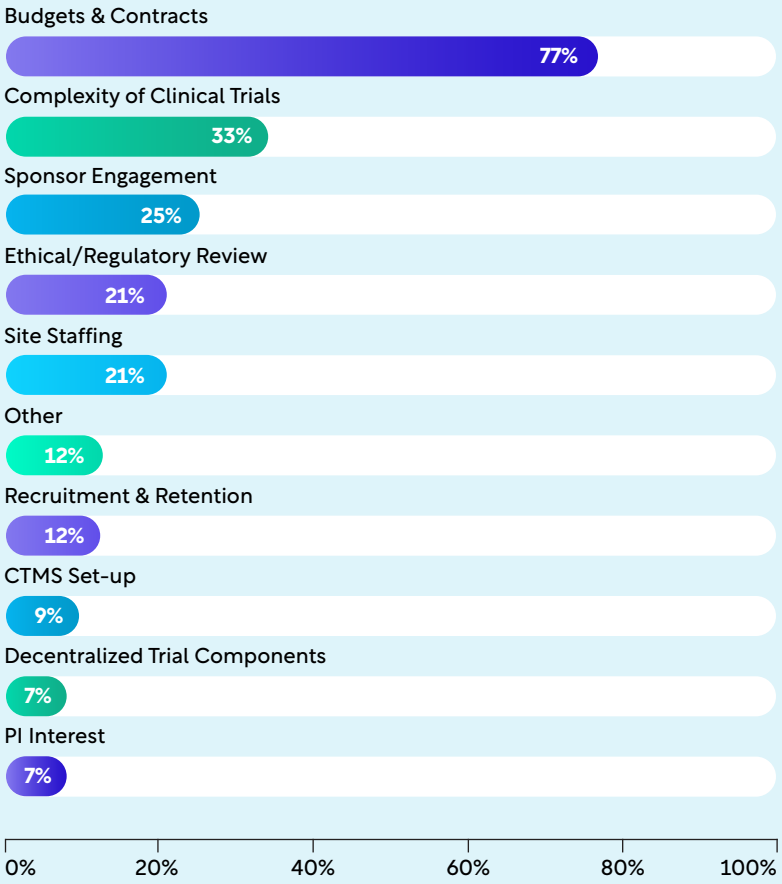
ALL SITE DATA

What were the largest contributors to your study start-up timelines last year?



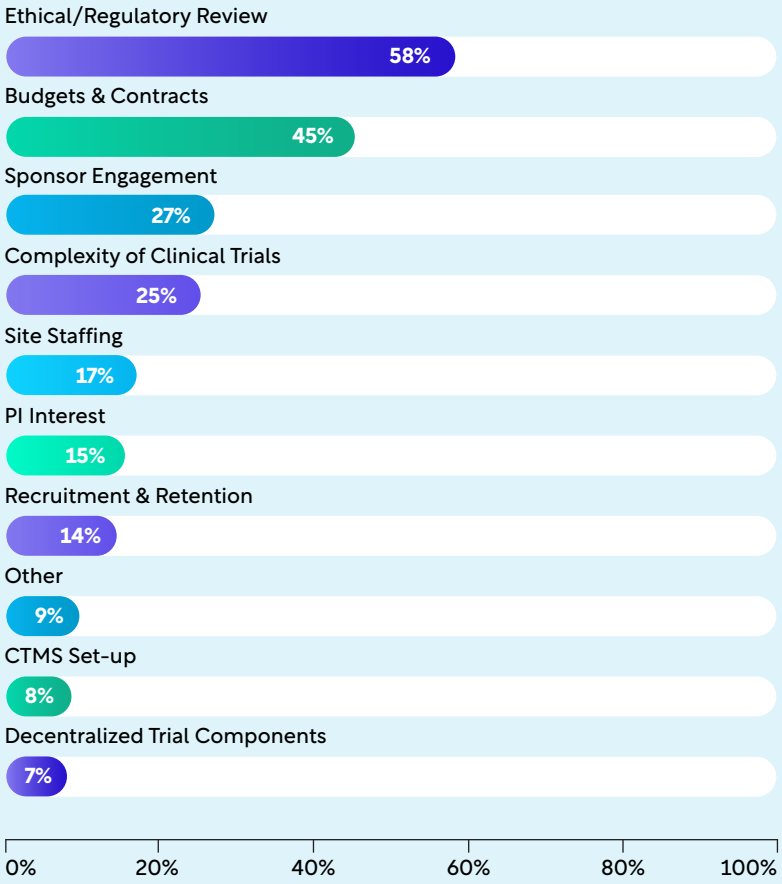
US SITES

What were the largest contributors to your study start-up timelines last year?



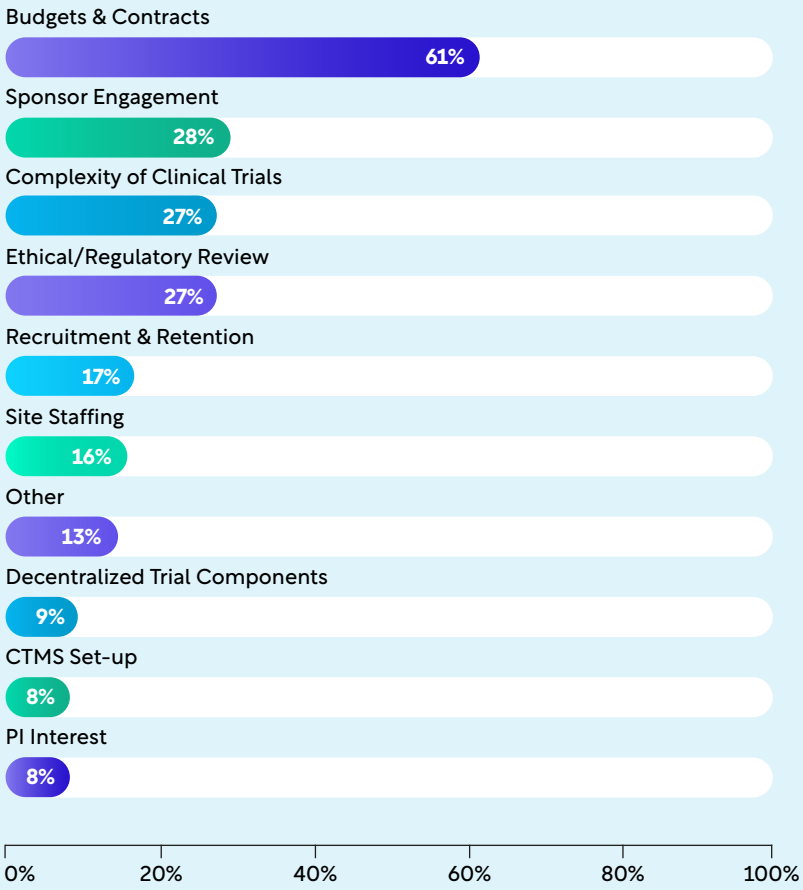
EX-US SITES

What were the largest contributors to your study start-up timelines last year?



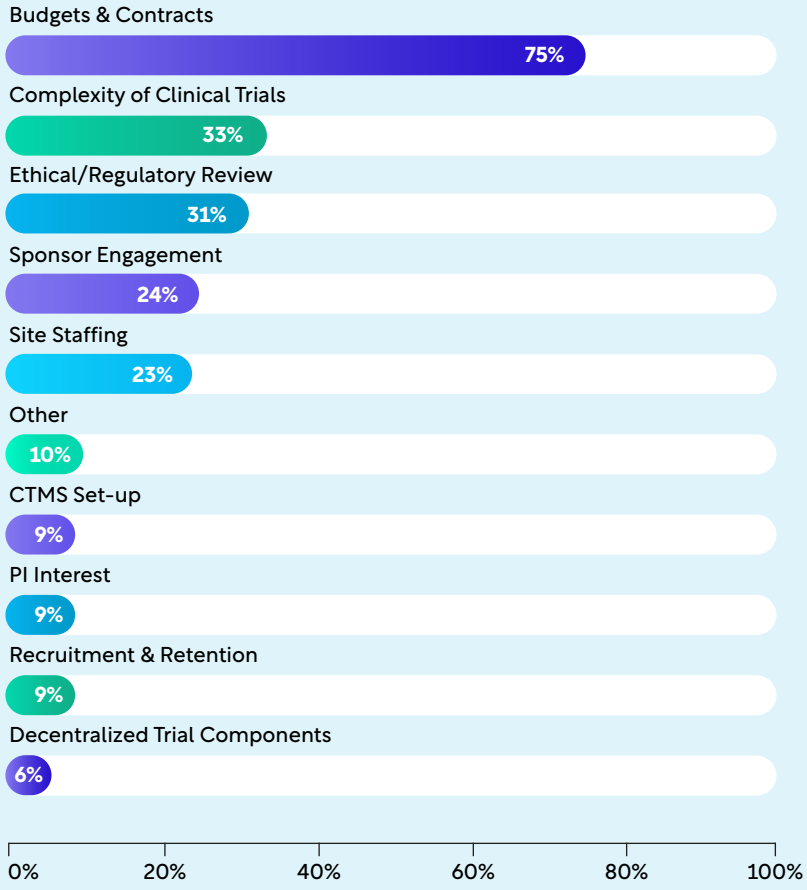
INDEPENDENT SITE, PHYSICIAN PRACTICE, AND SITE NETWORK DATA

What were the largest contributors to your study start-up timelines last year?



ACADEMIC MEDICAL CENTER, HEALTH SYSTEM, AND COMMUNITY HOSPITAL DATA

What were the largest contributors to your study start-up timelines last year?



SECTION 8

Solutions Sites are Implementing to Combat Their Top Challenges

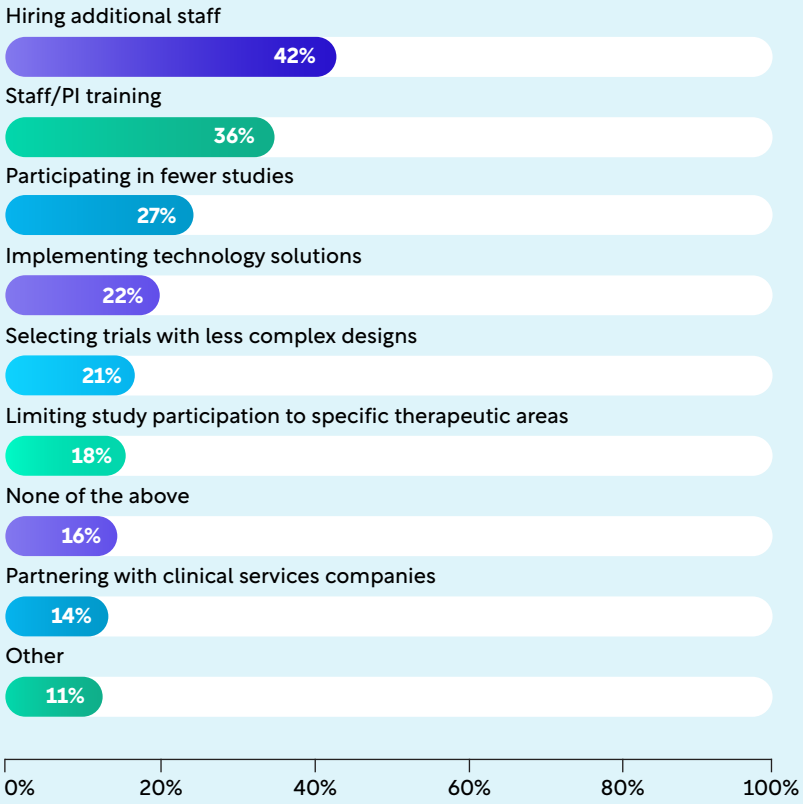
Despite the ongoing nature of the top challenges faced by clinical research sites, many sites are taking proactive steps to mitigate their impact. According to our survey, the most common solutions implemented by sites are hiring additional staff and prioritizing staff training. In fact, 42% of sites reported hiring additional staff as their top solution, a strategy that remained relatively consistent with last year's findings (44% in 2023). Staff training follows closely as the second most common solution, with 36% of sites prioritizing it, albeit with a slight decrease from last year's 43%.

Beyond these top two solutions, sites are also adopting other strategies to combat their challenges. Some sites are scaling back their study participation, with 27% of sites choosing to participate in fewer studies, while others are being more selective in the types of studies they participate in, with 21% opting for studies with less complex protocols. Additionally, 18% of sites are limiting their study participation to certain therapeutic areas, further indicating a trend toward strategic study selection, while 14% of sites are partnering with clinical services companies to help address their key challenges.

As clinical research sites continue to face numerous challenges in the ever-evolving landscape of clinical trials, many are turning to innovative strategies to stay ahead. To address talent acquisition and retention, some sites and organizations like ACRP are implementing new approaches to highlight a career in clinical research as a viable and rewarding option. Additionally, some sites are revolutionizing their training programs by offering more CRC training options and working to upskill physicians to become new investigators. Some sites are adopting adaptive staffing models that tailor resourcing to protocol complexity and becoming more discerning in protocol selection.

ALL SITE DATA

What solutions has your site implemented to successfully combat these challenges?



Furthermore, many sites are leveraging the expertise of technology professionals to develop efficient processes enabled by cutting-edge technology, enhancing overall site productivity and performance.

In addition to some of the innovative approaches mentioned above, partnering with clinical services companies and outsourcing certain functions can be a strategic move for sites looking to optimize efficiency, reduce costs, and maintain high-quality data. Partnering with specialized clinical research service providers can bring numerous benefits, including access to expert personnel, cutting-edge technology, and best-in-class processes. By outsourcing non-core administrative functions like budgets, contracts, CTMS study builds, and more, sites can free up internal resources to focus on high-value activities, such as patient care and research coordination, while minimizing administrative burdens on their existing site staff. Furthermore, external providers can offer scalability and flexibility, allowing sites to quickly adapt to changing study demands, unexpected setbacks, or sudden increases in workload.

SECTION 9

Looking Ahead to the Future – Industry Changes on the Horizon

The industry is expected to face significant changes in the coming years, including the implementation of the U.S. Food and Drug Administration's (FDA's) single Institutional Review Board (sIRB) changes and ICH E6 updates. Sites, sponsors, and CROs must be prepared to adapt to these changes and prioritize site support and training to ensure the continued success of clinical trials.

Single IRB Mandate

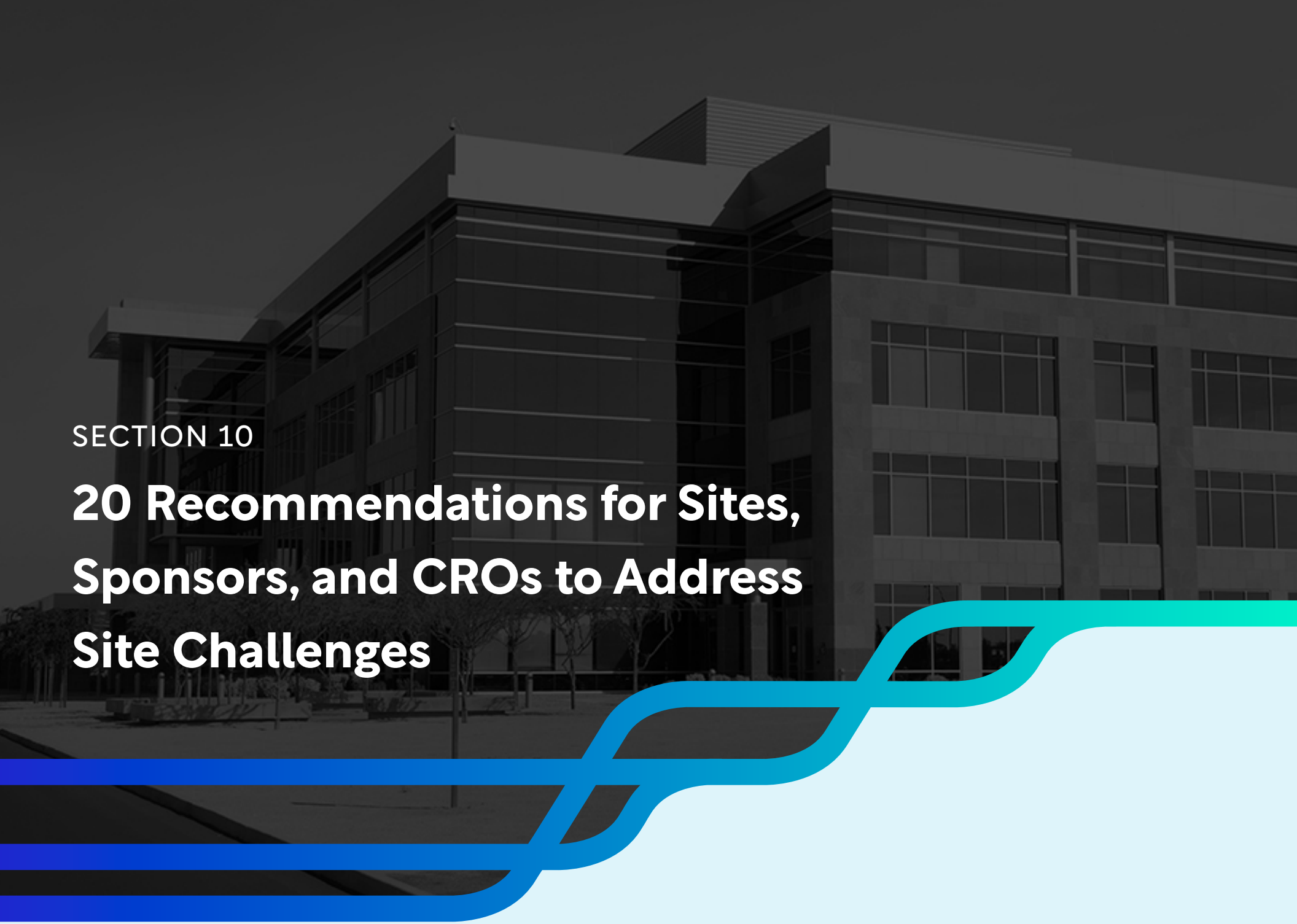
In 2022, the FDA issued two Notices of Proposed Rulemaking (NPRMs). One NPRM was on the "Cooperative Research," i.e., the single Institutional Review Board (sIRB) requirement, and the second NRPM was on the "Protection of Human Subjects and Institutional Review Boards." These NPRMs are intended to harmonize the FDA regulations with the "Common Rule" to the extent possible. The Common Rule is the informed consent and IRB regulations that have been adopted by 16 agencies, including the Health and Human Services (HHS), the Department of Defense, and others. In 2018, the Common Rule was revised to improve the consent process and reduce the regulatory burden on minimal-risk research.

Under the sIRB mandate, any institution located in the United States (US) participating in FDA-regulated, multi-site research will need to rely on review and approval by a single IRB for that portion of the research conducted in the US, with a few exceptions. The goal of this is "to streamline the review process and decrease regulatory burden without compromising human subject protections[9]." In other words, if you are a sponsor or CRO, you will be required to use a single IRB unless an exception applies; and if you are an institution or investigator, you will be required to use the single IRB chosen by the sponsor or CRO or decide not to participate in the research. It is important for sponsors, CROs, and sites to proactively update their processes and policies to ensure a seamless adaptation to the upcoming sIRB mandate. By partnering together, we can accelerate a smooth transition and propel research forward with increased efficiency.

Sites, sponsors, and CROs must be prepared to adapt to these changes and prioritize site support and training to ensure the continued success of clinical trials.

ICH E6 (R3) Updates

ICH Good Clinical Practice E6 (R3) Annex 1 is anticipated to be finalized before the end of this year with Annex 2 (decentralized elements / real-world data sources) driving toward finalization in 2025. ICH E6 (R3) encourages thoughtful study design focused on activities critical to achieving the trial objectives while highlighting risk-proportionate approaches across all aspects of clinical trial conduct. There are enhanced oversight expectations for Investigators and the new data governance/computerized systems section will require careful consideration. Collaboration, starting at the beginning of the study, across all stakeholders in the clinical trial ecosystem will support successful implementation. Learn more about the impact of ICH E6 (R3) on sponsors, providers, and sites in the 2024 Avoca Industry Report to elevate your preparedness.



SECTION 10

20 Recommendations for Sites, Sponsors, and CROs to Address Site Challenges

RECOMMENDATIONS FOR SITES

To overcome their primary obstacles, research sites must embrace a culture of innovation and adaptability. As a driving force behind scientific progress, clinical research sites thrive when they proactively evolve to meet the changing landscape. Key to this evolution is the continued development of specialized research talent and PIs, streamlined study activation timelines, and strengthened partnerships with sponsors, CROs, and service providers. By addressing these essential elements, research sites can better position themselves for success and continue to advance clinical research.

1. **Elevate the Participant Experience:** Focus on the participant experience, implement DE&I strategies, and leverage data and technology to optimize recruitment, enrollment, and retention.
2. **Invest in Staff Development:** Invest in staff training and prioritize approaches to staff retention, including ongoing educational development and networking opportunities.
3. **Optimize Operational Efficiency:** Document, simplify, and standardize your regularly conducted workflows, and track key metrics against industry benchmarks to identify areas of improvement.
4. **Communicate and Collaborate with Purpose:** Foster open and proactive communication with sponsors and CROs throughout the study start-up and conduct phases, ensuring seamless collaboration and timely response to your site's needs.
5. **Harness Technology for Success:** Leverage and invest in technology systems that optimize your workflows and streamline research operations, and designate an IT liaison to oversee research-related technology systems at your site.
6. **Streamline by Strategically Outsourcing:** Analyze your site's workflows to pinpoint areas where gaps exist and explore opportunities to outsource non-core functions like study start-up, study identification, and data entry to clinical services companies.
7. **Clearly Define Roles and Responsibilities:** Clearly define and communicate the roles and responsibilities for each trial to your site staff, ensuring everyone is well-informed and equipped to work together effectively.
8. **Ensure Quality and Compliance:** Adopt a quality management system and identify best practices to ensure regulatory requirements are met and quality metrics are evaluated.
9. **Cultivate Strategic Partnerships:** Participate in forums and conversations with sponsors, CROs, and service providers to build stronger relationships and enhance transparency about operational needs, technology solutions, and best practices.
10. **Think Innovatively:** Innovate for the future, not from the past. Launch pilot projects to test new ideas, experiment, and discover better solutions for tomorrow.

RECOMMENDATIONS FOR SPONSORS & CROS

To better support sites and drive the success of clinical trials, sponsors, and CROs must shift their focus toward addressing the unique challenges sites face. The success of a study hinges on the success of its sites, and yet, the growing complexity of trials, shrinking budgets, and unrealistic timelines are placing an unsustainable burden on site staff. By prioritizing site and participant needs and working to overcome the obstacles that hinder their success, sponsors and CROs can help pave the way for more efficient and effective clinical research. By doing so, we can collectively advance the clinical research industry and bring new treatments to market faster.

1. **Support Site Development:** Support site development and innovation to increase diversity and expand the pool of potential investigators, research professionals, and clinical trial participants, with a focus on supporting new and less experienced sites and investigators.

2. **Design Patient-Centric Protocols:** Create protocols that prioritize patient and site experience by assessing burden early on, incorporating participant and site input, and releasing the final protocol in a complete state to minimize the site having to address amendments during or shortly after trial initiation.

3. **Set Realistic Timelines and Budgets:** Set realistic study start-up timelines, ensure study budgets reflect the true work efforts of the sites, and consider pay-for-performance options to facilitate rapid activation.

4. **Streamline Study Operations:** Optimize study planning, start-up, and study execution by streamlining critical processes such as feasibility assessments, budgeting, contracting, site training, recruitment, and safety reporting.

5. **Ensure Timely and Accurate Site Payments:** Prioritize timely and precise payments to research sites to help support their financial stability and foster more productive partnerships.

6. **Deliver Personalized Site Support:** Provide flexible and adaptable solutions to support the sites conducting your trials by identifying site-specific needs and providing personalized support for each site, whether that be through people, processes, or technology.

7. **Increase Recruitment and Retention Support:** Boost site success by offering enhanced recruitment and retention support - a crucial need for 41% of sites, which cite 'increased patient recruitment and retention support services' as a top priority for sponsors to address in order to ensure site operational viability[2] .

8. **Advance Diversity, Equity, and Inclusion:** Develop comprehensive diversity action plans for your sites to foster more inclusive environments and promote equitable participation from diverse populations in your trials.

9. **Reduce Technology Burden:** Evaluate and address technology needs for your trials, collaborate with sites to leverage existing infrastructure and evaluate new platforms, and provide training on frequently used technology to optimize operations and reduce tech burden.

10. **Foster Site Engagement and Collaboration:** Promote site engagement and collaboration by establishing open communication channels, soliciting site feedback, and fostering a culture of continuous improvement and innovation.

SECTION 11

How WCG Can Help

How does WCG help clinical research sites run their trials more efficiently?

WCG partners with research sites to provide comprehensive, integrated Site Enablement solutions designed to optimize and support them throughout the clinical trial lifecycle and beyond. Our expert-driven processes and innovative technology enable sites to accelerate trial start-up, boost patient enrollment, enhance financial performance, and expand their capacity to support more trials. These solutions include:

- IRB Review
- IBC Review
- Study Identification
- Study Start-up
- Coverage Analysis and Billing Compliance
- Budget Development and Negotiation
- Contract Review and Negotiation
- WCG eResearch CTMS
- Site Resource Augmentation
- Financial Management
- Total Feasibility Platform
- Avoca Quality Consortium

How does WCG help sponsors and CROs reduce the burden on their sites to help them run their trials more efficiently?

WCG partners with sponsors and CROs to accelerate their trials by providing solutions that improve study planning, site ID and feasibility, study management, recruitment and retention, site training, and more. These solutions include:

- Study Planning, Site Identification and Site Feasibility
- Recruitment and Retention Solutions
- Clinical Trial Training
- Safety Reporting
- eCOA and ePRO
- Protocol Assessment Solutions
- Avoca Quality Consortium
- Diversity, Equity, and Inclusion Solutions
- Benchmarking, Analytics, and Consulting
- IRB & IBC Solutions
- Central Labs & Imaging Solutions
- WCG Clinical Trial Listing Service

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WCG is a global leader of solutions that measurably improve and accelerate clinical research. Biopharmaceutical and medical device companies, contract research organizations (CROs), research institutions, and sites partner with us for our unmatched expertise, data intelligence, and purpose-built technology to make informed decisions and optimize study outcomes, while maintaining the highest standards of human participant protection. WCG raises the bar by pioneering new concepts, reimagining processes, fostering compliance and safety, and empowering those who perform clinical trials to accelerate the delivery of medical therapies and devices that improve lives. For more information, please visit wcgclinical.com or follow us on Twitter @WCGClinical or LinkedIn.

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