2023 CLINICAL RESEARCH SITE CHALLENGES SURVEY REPORT

Data and Insights Into Current Site Challenges and Recommendations to Help Reduce Site Burden and Improve Clinical Trial Efficiency.

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Introduction

Clinical research is an integral part of improving patient care and advancing medical knowledge, but over the last several years, clinical trials have continued to become increasingly complex. This increase in trial design complexity has added additional burden on clinical research sites, many of which are already facing unprecedented resourcing issues, enrollment challenges, increased technology burden, and more. These challenges, coupled with ever-changing regulations, have led to a robust pipeline of clinical trials waiting to be conducted – especially in the critical areas of oncology and neurology.

More Complex Trials
\+ Inefficient Procceses

= More Challenges at Sites, Research Delays, & Lost Opportunities

As the industry strives to improve patient outcomes and advance medical knowledge, it is important to recognize the main challenges clinical research sites are facing in this stressed clinical landscape so we can implement more effective strategies and run more efficient trials in the future.

To better understand the current site landscape and the challenges sites are facing, WCG presents our 2023 Clinical Research Site Challenges survey report, in addition to recommendations for sites, sponsors, and CROs to better address study needs and the needs of the sites conducting those studies.

Survey Background & Demographics

In February-March 2023, WCG surveyed over 500 US-based clinical research sites. We asked about their perspectives on the major challenges they are facing, solutions they have implemented to overcome their obstacles, and more.

Our objective was to gain and share insights that would empower the clinical research community – sites, sponsors, CROs, and service providers – to address industry challenges and ultimately help sites deliver trials more effectively.

Survey Background & Demographics - Continued

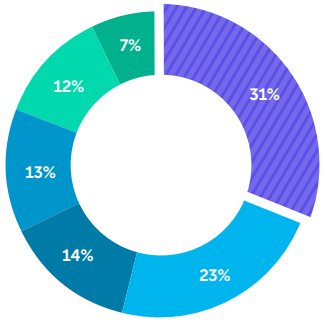
> *"As we know, site success leads to study success, which contributes to the development of new therapies and treatments."*

Most survey respondents (39%) represent academic medical centers (AMCs). The remaining 61% of respondents represent non-academic research centers (non-AMCs) including community hospitals, health systems, physician practices, independent research sites, and others. This blend provides a helpful cross-section of site perspectives.

Most respondents (31%) hold positions as research administration staff, followed by CRC/CRNs, IRB/ regulatory representatives, site leadership/owners, physicians/PIs, and others. This range of participants offers important cross-functional insights.

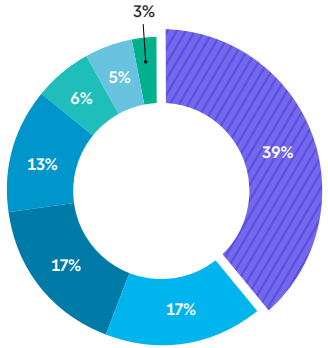
What is your role at your research site?

ANSWER CHOICES	RESPONSES
Research Administration Staff	31%
CRC/CRN	23%
IRB/Regulatory	14%
Site Leadership/ Site Owner	13%
Physician/PI	12%
Other	7%



What type of research site do you represent?

ANSWER CHOICES	RESPONSES
Academic Medical Center	39%
Physician Practice	17%
Independent Research Site	17%
Community Hospital	13%
Integrated Health Care Delivery System	6%
Site Network	5%
Other	3%



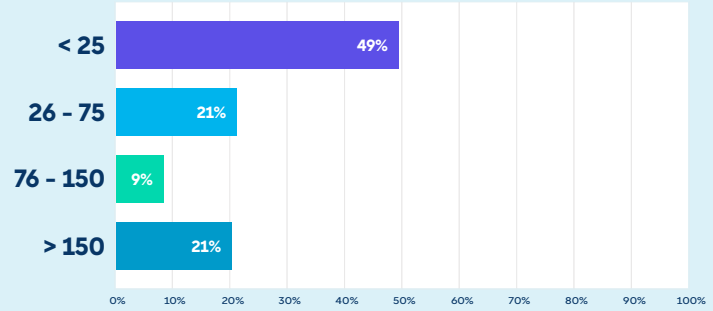
Survey Background & Demographics - Continued

Aggregate responses show that almost half (49%) of the sites surveyed have current research portfolios of fewer than 25 trials, followed by current volumes of 26-75 trials, and then more than 150 trials.

We can gain further insights into sites' current trial volumes when we break out responses for AMCs vs. non-AMCs. The graphs below show that AMCs are handling larger study volumes while non-AMCs have fewer opening and enrolling trials.

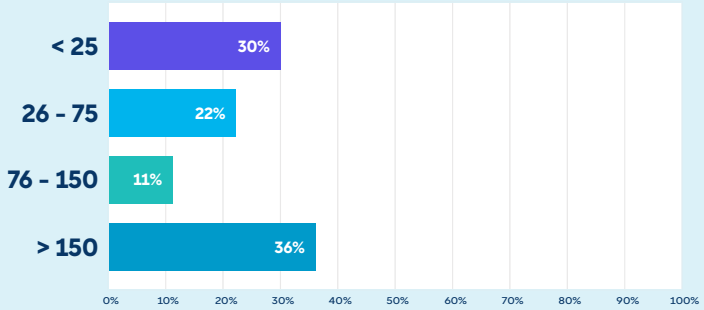
All Data

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



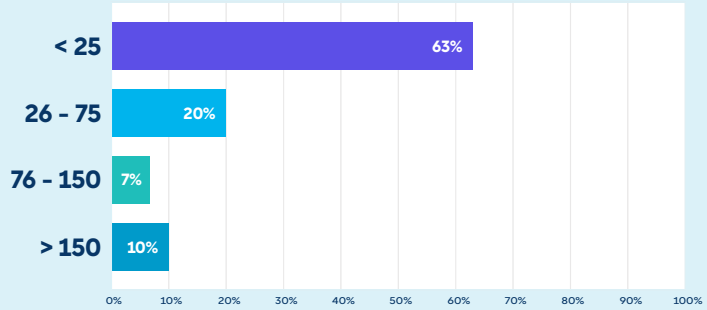
AMCs

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



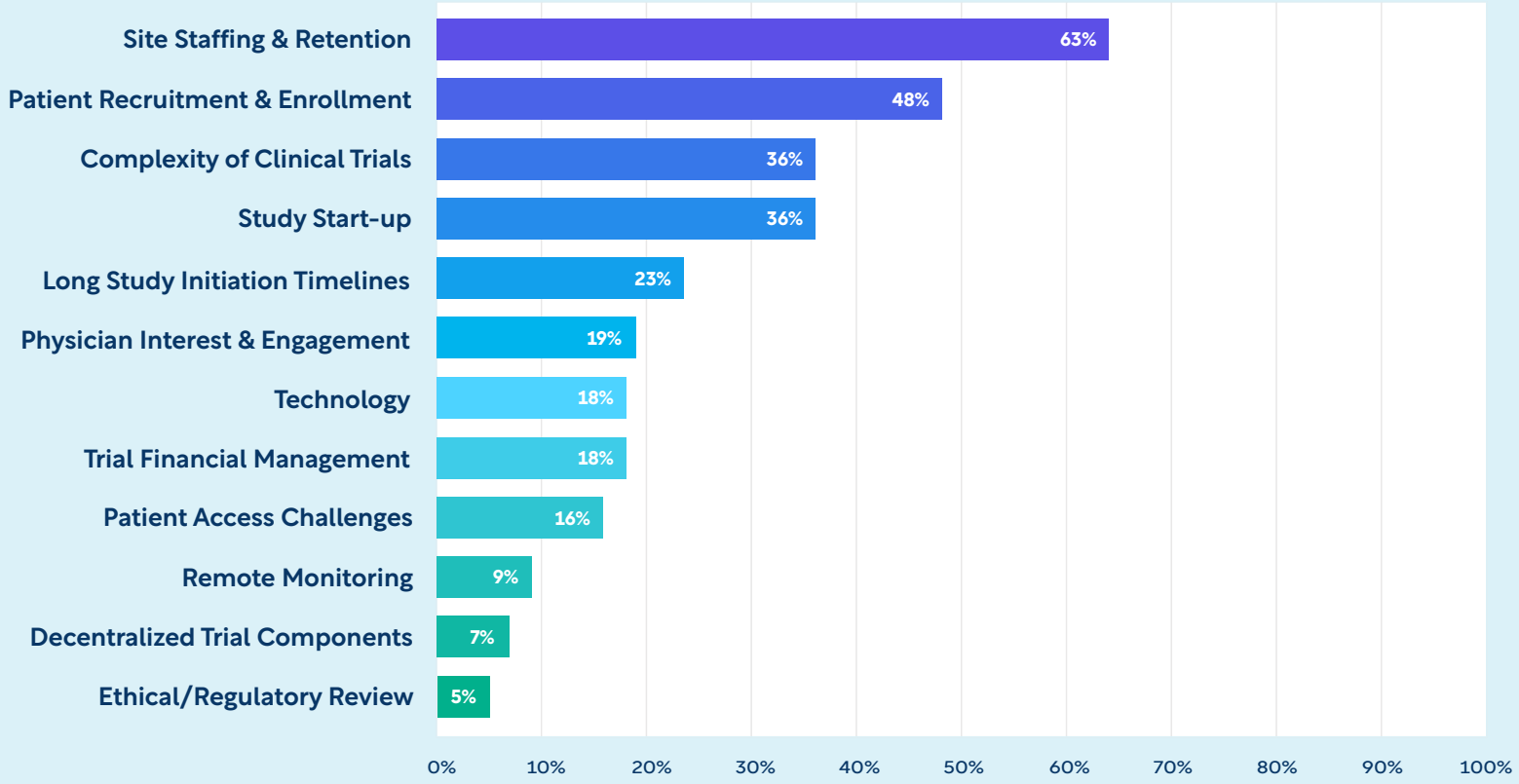
Non-AMCs

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



Top Site Challenges in 2023

What are the top issues impacting your site today?

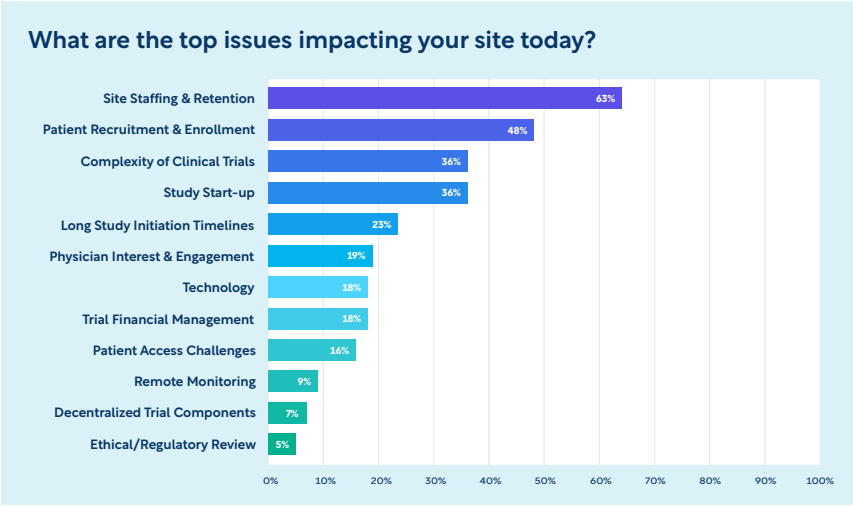


Top Site Challenges in 2023 - Continued

What are the top challenges impacting sites today, per the survey data? Staffing/retention (63%) and recruitment/enrollment (48%) remain the top concerns at research sites in 2023. While the impact of The Great Resignation has lessened, a site's decision to complete feasibility surveys for new trial considerations is largely dependent on having the resources to efficiently conduct those clinical trials. Additionally, enrollment in existing and new clinical trials remains closely tied to site resourcing levels.

In addition to the challenges listed above, trial complexity is frequently mentioned as a major burden to sites, ranking third in this survey (36%). The complexity of trial designs is being closely reviewed at research sites and cited as a reason to forego opening specific clinical trials with multiple arms or complex trial designs (e.g., adaptive, basket, umbrella trials), favoring studies with simpler protocol designs.

Study start-up also ranks in the top issues of sites, at 36%, tied with trial complexity. The scarcity of research professionals extends beyond the clinical research coordinator role to other areas of expertise including research administrative functions essential to trial start-up, specifically those involved in coverage analysis, budgets, contracts, and regulatory submissions. Gaps in immediate access to these essential study start-up functions continue to contribute to longer activation timelines at sites, causing additional trial delays. Moreover, sites acknowledge that trial start-up is impacted by additional study review processes put in place to determine which trials will even be considered for activation.



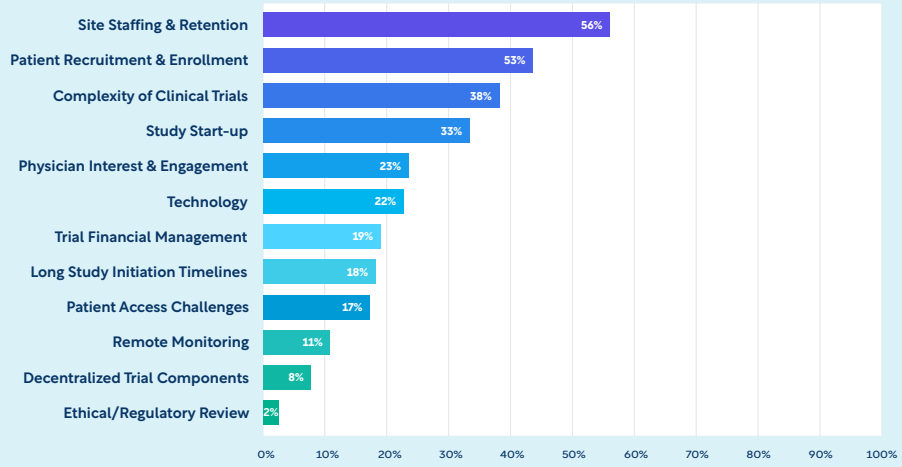
Top Site Challenges in 2023 - AMCs vs Non-AMCs

What factors are significant as we compare AMC data to non-AMC data? In this survey, non-AMCs report staffing to be a more significant issue (74%) than AMCs (56%). AMCs and research offices with larger research teams may be able to expand the duties and functions of existing staff to maintain trial activity during periods of staff turnover. On the other hand, smaller research organizations are more severely impacted by the loss of staff, which reflects a higher percentage of their overall team.

Recruitment/enrollment is identified as the top concern at both AMCs (32%) and non-AMCs (42%). Trial start-up is the third-highest concern at non-AMCs (41%), while trial complexity is identified as the third-highest concern at AMCs (38%). Typically, more complicated trial designs are placed at AMCs; their trial complexity concerns may highlight additional pre-trial deliberations before trial feasibility.

AMCs

What are the top issues impacting your site today?



Non-AMCs

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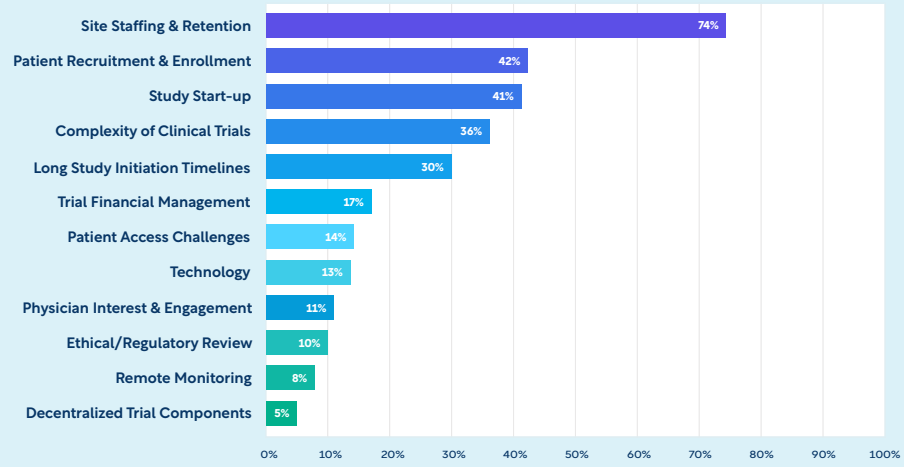
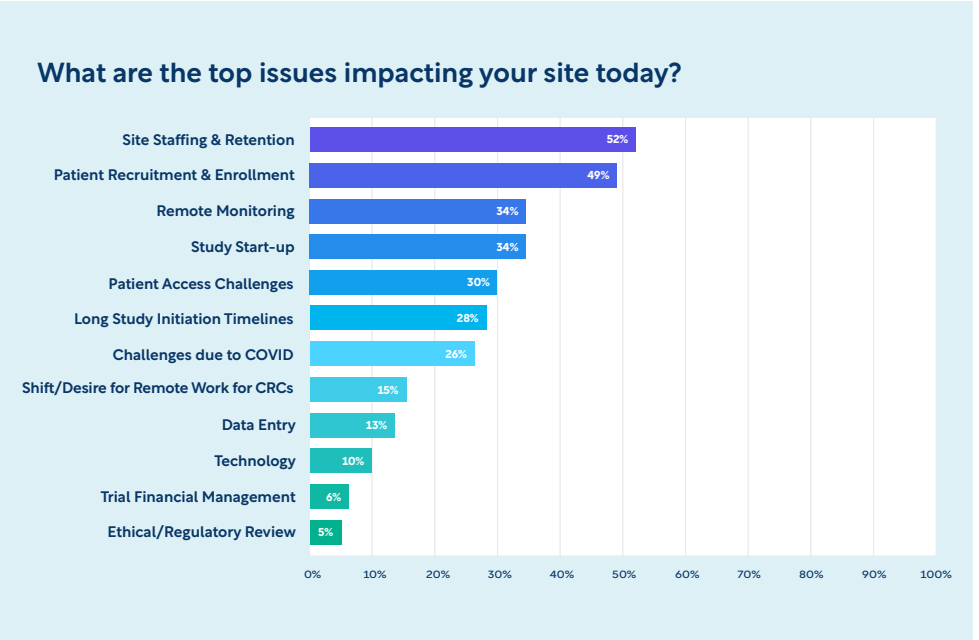


Technology is tied at 22% with physician engagement/interest at AMCs (ranked 4th), while technology ranks 7th at non-AMCs (13%). In addition to staff training and additional overall time required to navigate multiple systems and technologies, cybersecurity is a threat to healthcare organizations and may contribute to these rankings. Of note is the low ranking for decentralized trials at both organization types (8% at AMCs and 5% at non-AMCs). While there has been considerable discussion on DCTs, they remain a small portion of a site's trial portfolio. Moreover, specific functions or components within trials may be decentralized leading to a hybrid model.



Top Site Challenges - 2022 vs 2023 Changes

How have site issues changed in the past year?
Consistent with 2022 data, staffing, trial enrollment, as well as research budgets and contracts (study start-up) remain among the top three site issues. Comparing this year's survey data to 2022, the perceived additional burden of remote monitoring has significantly decreased from 34% in 2022 to 9% in 2023. This decrease may be attributed to more sites re-opening to on-site monitoring as well as sites designing processes to better enable remote monitoring technology.

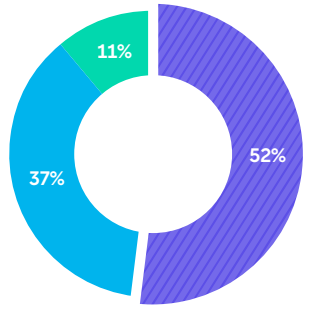
While process and workflow improvement remain ongoing areas of focus at sites, changes to clinical trial workflows due to COVID and remote work for CRCs have largely been addressed from the 2022 survey. Technology ranks higher in 2023 (18%) vs. 2022 (10%).

Impact on Site Capacity

How are these top site challenges affecting their ability to participate in new studies?
Over half (52%) of sites identify these issues as impacting their ability to open new clinical trials, which is cause for concern. If more clinical research sites are finding they are unable to participate in new trials it will have significant implications for the entire industry, including delays in drug developement, reduced patient access to clinical trials, increased costs, and more.

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

ANSWER CHOICES	RESPONSES
Yes	52%
No	37%
Unknown	11%



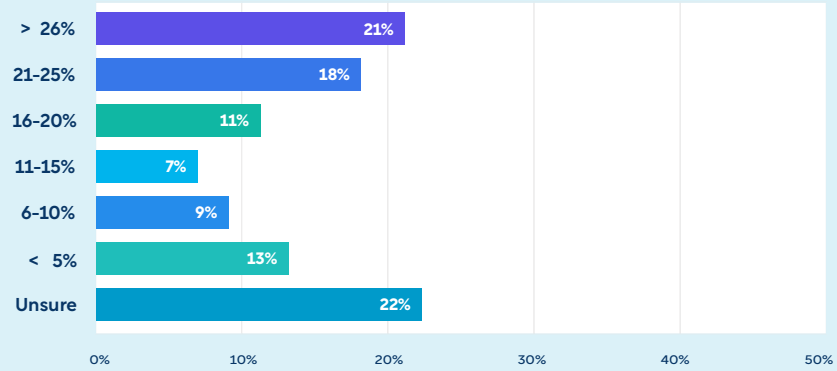
> *"Understanding the current state of site capacity is critical to site planning, study execution, sponsor/CRO placement of clinical trials – and determining the support needed."*

Site Staff Turnover

What are sites experiencing in terms of site staff turnover? As noted in the survey, the biggest challenge currently for sites is site staffing and retention. Experienced and knowledgeable staff at research institutions and sites are vital to delivering impactful research results, yet staff retention continues to be a huge hurdle. When comparing AMCs and non-AMCs, AMCs had a higher percentage of turnover, with 21% saying they experienced a turnover percentage of more than

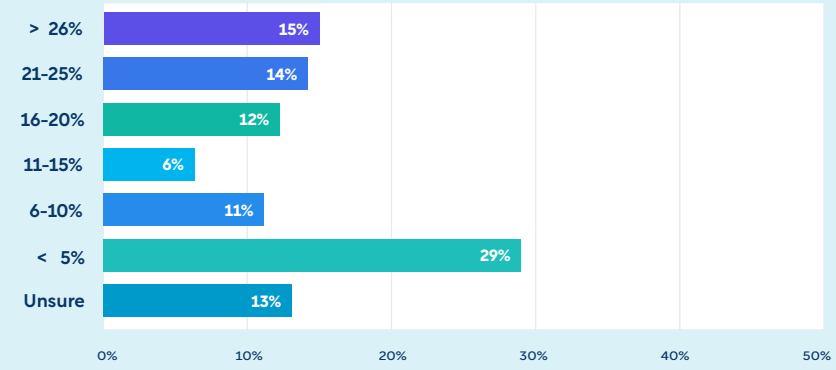
AMCs

Approximately what was the percentage of staff turnover at your organization in the last year?



Non-AMCs

Approximately what was the percentage of staff turnover at your organization in the last year?



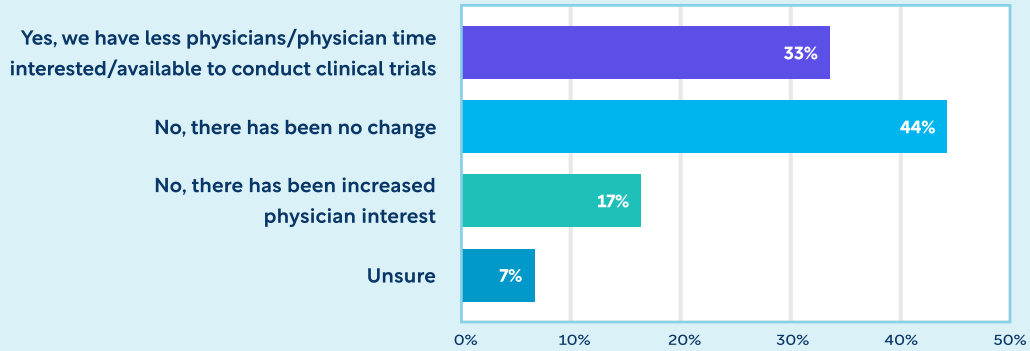
Physician Interest

What are the trends around physician interest and participation? Physician interest and participation in clinical research are critical to study success. Trends in the declining number of US investigators prompted the inclusion of physician engagement in our 2023 survey.

Physician engagement and interest are cited as a concern by 22% of respondents from AMCs, ranking as the 4th highest issue, vs. 11% from non-AMCs, ranking 9th. As sites address ongoing capacity levels, particularly at AMCs, physician engagement must be evaluated.

Anecdotally, many physicians and sites have reported their clinical demands have increased. In addition, many investigators have stated their duties related to clinical trials have increased as a result of the research team staffing shortages. To that end, 45% of physicians only participate in one clinical trial – the "one and done" phenomenon. The key to success for physician engagement and interest is to create an environment where investigator time is dedicated to those functions requiring the physician and to design research teams with well-defined roles. In addition, providing mentoring for new physicians as sub-investigators and subsequently principal investigators can help to address

Has your site experienced a change in physician interest/availability to conduct clinical trials?



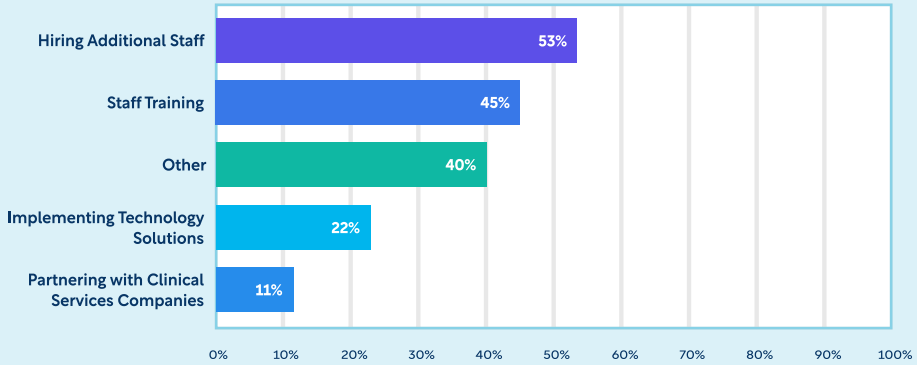
Solutions Sites are Implementing

What solutions are sites implementing to combat the challenges they face? For many years, sites have relied on the same traditional solutions to address staffing and other operational issues. In our 2023 survey, 57% of non-AMCs report hiring additional staff (39% at AMCs) and 45% of non-AMCs identify training as a solution (41% of AMCs) – particularly with hiring new staff. Technology is identified as a solution by 29% of AMCs and 21% of non-AMCs, leveraging it for efficiency in research workflows. Some sites have determined that an effective model for efficiency is partnering with research services organizations – reported as an effective solution at 20% of AMCs and 11% of non-AMCs.

Similar to the reliance on centralized ethical review services, partnering with research services organizations can help with staff support for trial conduct, including recruitment and retention activities, as well as a variety of research administration services (e.g., coverage analysis, budgets, and contracts) required for effective and efficient trial activation.

AMCs

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



Non-AMCs

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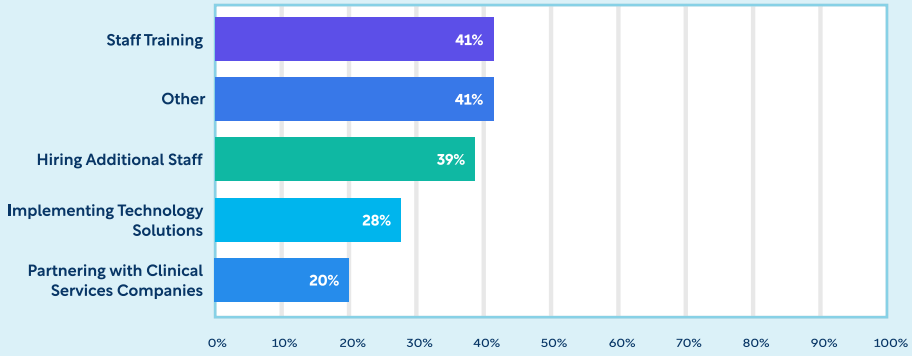

How to Address These Site Challenges & Run More Efficient Trials - Recommendations For Sites

> *"In this era of doing more with less, sites, sponsors, and CROs are seeking innovative solutions that will supporting efficient trial execution while lessening site burden."*

What can research institutions and sites do to address their key challenges? Clinical research, at its core, is an industry that promotes change by advancing science. To flourish, research sites must continue to adapt, but more importantly, intentionally innovate. Research teams need more people highly skilled in specialized research functions along with predictable study activation timelines and enhanced physician engagement.

Ten ways clinical research sites can address their key challenges:

1. Focus on the participant experience throughout the recruitment, enrollment, and retention process.

2. Utilize and invest in technology systems that can improve existing workflows and streamline research operations.

3. Leverage data and technology to optimize participant recruitment, enrollment, and retention.

4. Implement DE&I strategies into your participant recruitment, enrollment, and retention processes.

5. Document, simplify, and standardize workflows and processes that are conducted regularly.

6. Identify where the gaps exist in your research workflows; determine what must be done on-site vs. what can be outsourced.

7. Establish clear communication at your site and ensure that site staff members are aware of their specific roles and responsibilities for each trial.

8. Invest in ongoing training, education, and networking opportunities for site staff.

9. Build strong relationships with sponsors and CROs to enhance communication and transparency.

10. Adopt a quality management system and identify best practices to ensure regulatory requirements are met.

How to Address These Site Challenges & Run More Efficient Trials - Recommendations For Sponsors & CROS

How can sponsors and CROs better help address these site challenges? Sponsors and CROs today understand that the success of their studies is dependent upon the success of their sites. However, sponsors also need to recognize that increasingly complex trial designs and unrealistic trial timelines are placing an undue burden on sites. To combat this, sponsors should consider obtaining input from sites and participants regarding protocol design, which can help reduce site and participant burden, as well as the number of protocol amendments that may be needed later in the trial. By focusing on site and participant needs and addressing their main obstacles to success, we as an industry can better advance clinical research and improve the quality of human health – for our generation and those to come.

Ten ways sponsors and CROs can help address key site challenges

1. Develop protocols with the patient and site experience in mind to address trial complexity concerns and obtain site input on protocol designs before the trial begins.

2. Release the final protocol in a complete state to minimize the site having to address amendments during trial activation or shortly after trial initiation.

3. Set realistic study start-up timelines for the sites conducting your trials.

4. Work to simplify and streamline the feasibility process, budgets, contracts, site training, and safety reporting.

5. Create robust diversity action plans for the sites conducting your trials.

6. Identify site-specific needs and provide personalized support for each site, whether that be through people, process, or technology.

7. Evaluate the technology needs for your trials and provide training for the platforms that sites will be frequently using.

8. Support new and less experienced sites and investigators to improve diversity.

9. Collaborate with sites to evaluate how existing site technology can be leveraged to identify, enroll, and consent potential study participants more effectively.

10. Facilitate open lines of communication and collaboration throughout the trial.

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 solutions designed to optimize and support their research site throughout the clinical trial lifecycle and beyond. Our expert-driven processes and cutting-edge technology help sites start their trials faster, enroll patients sooner, improve financial results, and support more trials. These solutions include:

1. Study Start-up Solutions – Coverage Analysis, Budgets, and Contracts

2. Financial Management Solutions – Accounts Receivable and Claims Review/Adjudication

3. Site Operations Solutions & Data Entry Support

4. Patient Recruitment, Enrollment, and Retention Solutions

5. WCG Velos eResearch CTMS

6. Diversity, Equity, and Inclusion Solutions

7. Study Identification

8. IRB & IBC Solutions

9. Study Advertising and Recruitment

10. 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 protocol design, study start-up, study management, recruitment, enrollment, training, and more. These solutions include:

1. Study Planning & Start-up Solutions

2. Patient Identification, Recruitment, Enrollment, and Retention Solutions

3. Clinical Trial Training

4. Safety Reporting

5. Protocol Assessment Solutions

6. Avoca Quality Consortium

7. Diversity, Equity, and Inclusion Solutions

8. Benchmarking & Analytics

9. IRB & IBC Solutions

10. Central Labs & Imaging Solutions

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