2026

WCG Clinical Research Site Challenges Report

THE COST OF COMPLEXITY

CONTENTS

Overview

About This Report 3

Methodology 4

Executive Summary: The Cost of Complexity 6

Detailed Findings

The Site Landscape 11

Site Pressures and Performance 17

Funding, Budgets, and Complexity 22

Study Start-Up and Amendments 29

AI and Automation 34



About This Report

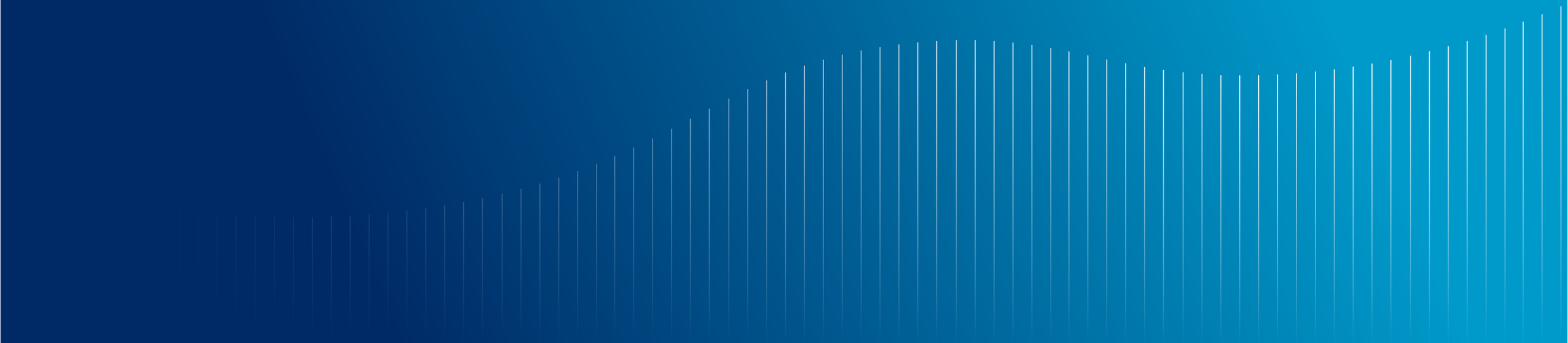
Clinical research is growing faster than the infrastructure built to support it. Protocols are denser, trial volumes are higher, and the administrative work surrounding each study keeps expanding, while the teams responsible for delivering that work have stayed largely the same size.

Since 2021, WCG has surveyed clinical research sites to understand the issues they face and the changes that measurably reduce staff burden, accelerate study start-up, and move research forward. This year, 413 respondents across roles, site types, and geographies shared where the pressure is building and what is helping.

One throughline runs through every question: **complexity has a cost, and sites are absorbing it**. More trials and denser protocols arrive without matching staff or budget, and the shortfall is paid in amendments, delayed start-up, unreimbursed administrative effort, and stretched teams.

The executive summary that follows traces that cost from source to impact, and the detailed findings behind it. While this report reflects site feedback, the takeaways apply to every role and organization in clinical research, because sites may be absorbing the cost, but the opportunity to reduce it is shared.

Methodology

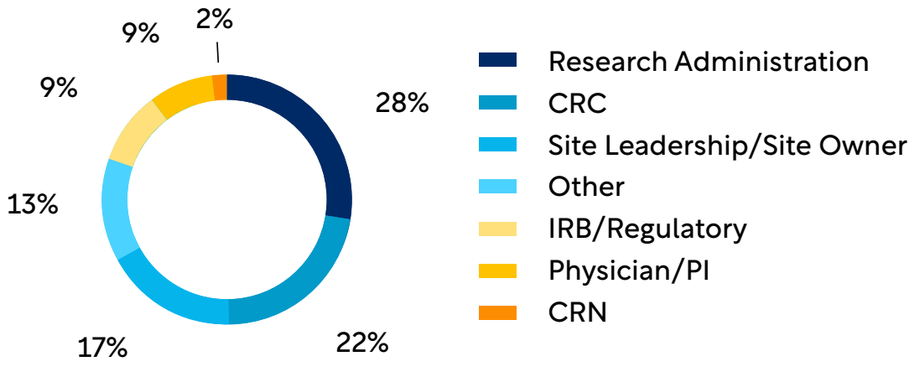


Between May and August 2026, 413 clinical research professionals responded to this global survey, identifying the challenges affecting their sites, the steps they are taking to address them, and the changes delivering measurable improvement. Respondents represent a range of roles, site types, and geographies, providing a comprehensive view of the pressures sites face today.

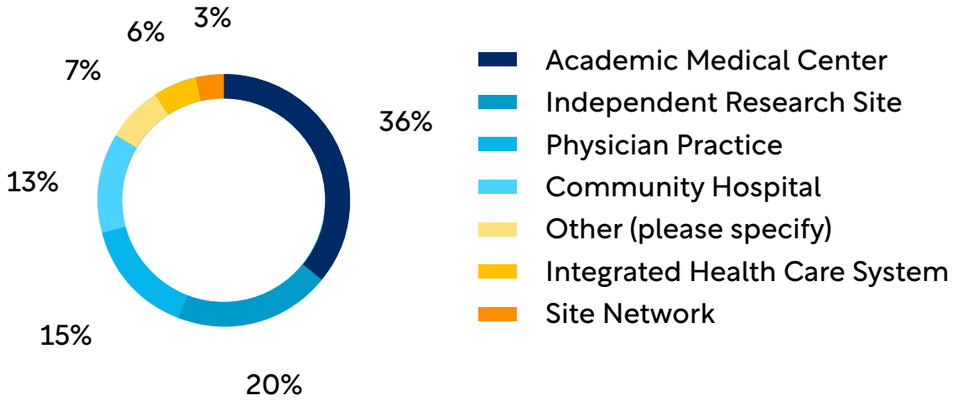
Glossary:

PI – Private Investigator
CRC – Clinical Research Coordinator
CRN – Clinical Research Nurse
IRB – Institutional Review Board

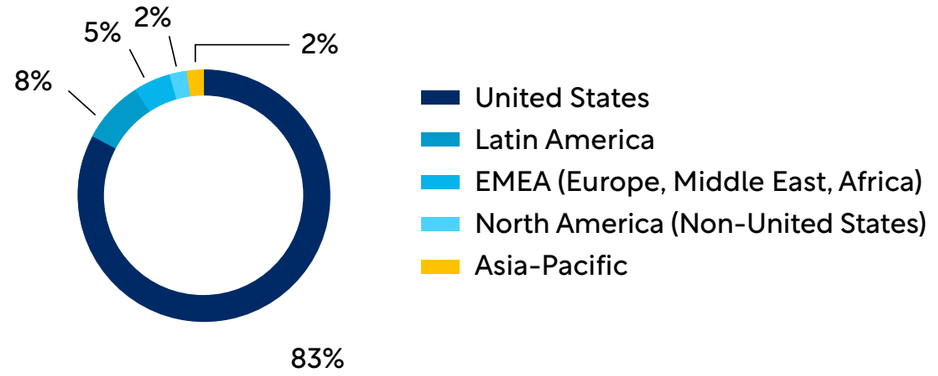
Roles of Respondents



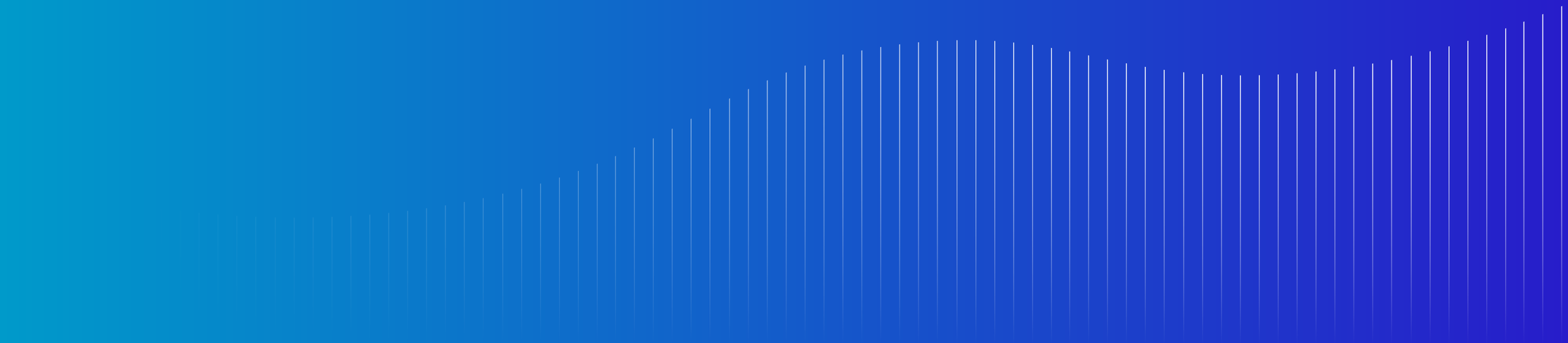
Type of Research Sites



Site Location



The Cost of Complexity



Capacity Hasn't Kept Pace with Demand

The volume of research at sites is climbing. Most sites now manage a high volume of active trials, and the trial opportunities offered to them have increased over the past year. Even sites reporting no significant change describe the same resource strain, because the trials themselves have become more demanding. Tufts Center for the Study of Drug Development (CSDD) has reported a nearly 300% increase in data requirements on Phase III trials compared to 10 years ago, further constraining sites with limited hiring capabilities.

That said, capacity has not increased at the same rate. A shift in federal funding, Medicaid coverage, 3408 pricing, and similar issues, have all impacted the hiring of additional staff at sites. Staffing levels stayed mostly flat, and the gap between accepted work and available people is now visible in the data.

The result is a workforce describing itself as overburdened. The combination of denser protocols, growing study volume, and limited staffing support is increasing the risk of burnout, attrition, and operational errors, with potential downstream effects on the participant experience.



of sites took on moderately more trials this year



increased staffing to match the added work



rate protocol complexity moderately high or very high

2–4 months
the most common study start-up timeline

Budget Negotiation
the most common study start-up timeline

~50%
of start-up time goes to amendments alone

Complexity Shows Up in Budgets, Timelines, and Rework

Complexity converts into cost at three predictable points.

Budget: Sites attribute financial strain primarily to underfunded budgets and unrecoverable administrative effort — work that is performed but never reimbursed.

Timeline: Study start-up most commonly runs two to four months, with budget development and negotiation the single largest contributor, followed by sponsor and CRO communication.

Rework: Protocol design changes are by far the most common trigger of amendments and contract modifications.

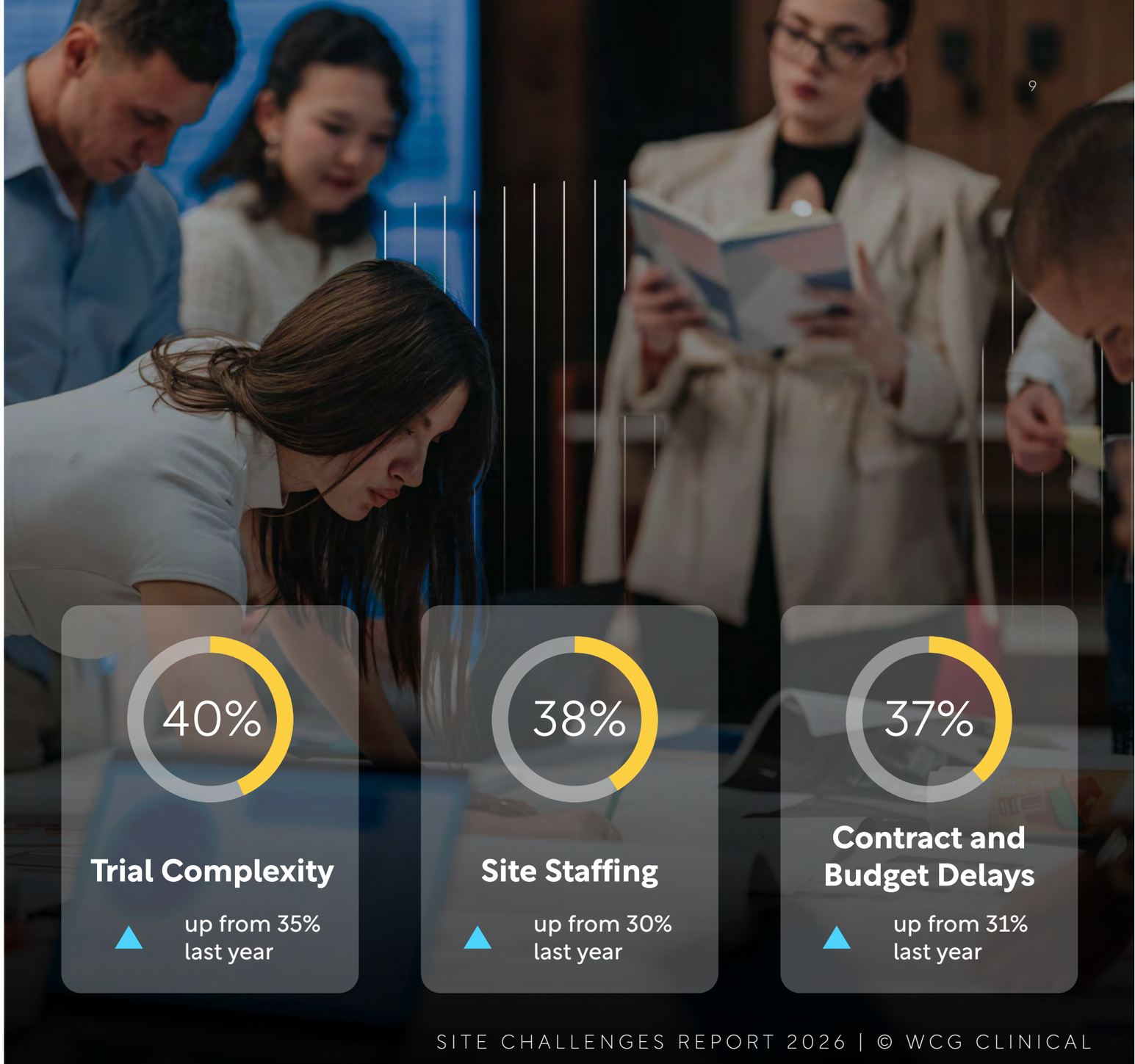
Funding uncertainty compounds all three: sites are pursuing more sponsored trials, and those affected by NIH reductions have held hiring freezes and trimmed travel budgets, pushing still more work onto existing staff.

Sites Are Still Waiting for Relief From Leading Challenges

Sites have pointed to the same top challenges time and time again, and this year, all of them grew. **Trial complexity, site staffing, and contract and budget delays remain the barriers sites contend with most.**

Though the order shifts by site size – large sites feel staffing most acutely (44%), while smaller sites point to complexity (47%) – the challenges themselves hold steady across every site type and region.

Challenges this persistent rarely begin at the site. They take shape earlier, in feasibility, protocol design, benchmarking, and the way sponsors, CROs, and sites work together day to day. That is where the opportunity to provide relief is greatest.



20%
of CTAs now carry AI restriction or permission clauses

38%
are actively exploring AI

~50%
are not yet using AI or automation

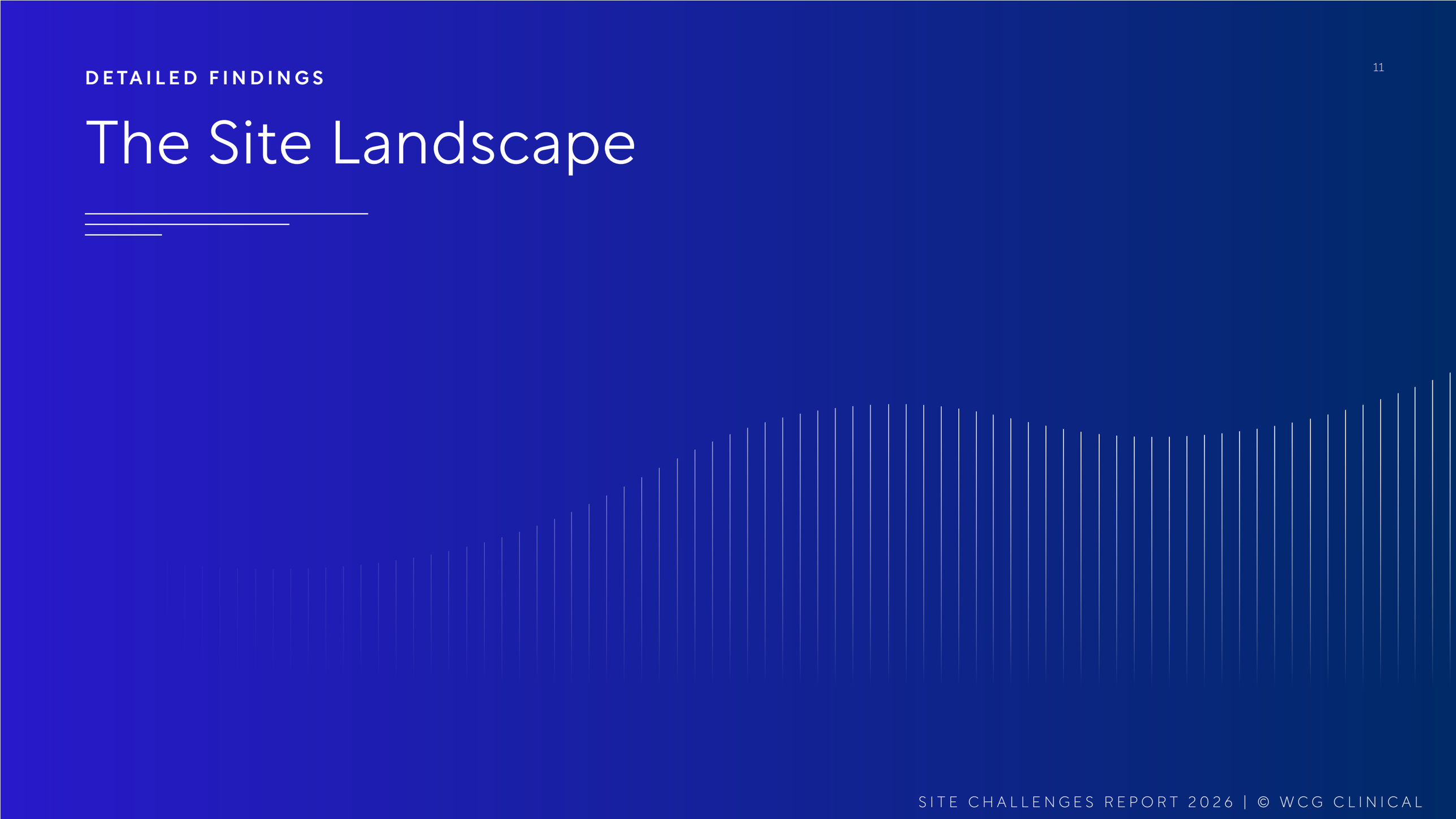
Sites Are Turning to Technology Where the Burden Is Heaviest

AI-enabled technology is the newest lever available to sites, and they are approaching it carefully. Adoption is still early, but interest is real, and the sites that are moving aim it squarely at their heaviest work: finding and matching patients, and ending duplicate data entry. Trial agreements are adapting in step, with AI terms now written into a growing share of contracts.

Used this way, technology does not remove complexity so much as absorb its cost. Every hour returned from manual data entry or a faster path to an eligible patient is time given back to the work only people can do. That is the practical test for any tool a site adopts, and the reason measured adoption is the right pace.

Complexity is not going away; it reflects the ambition of the science. What it costs, however, can be changed.

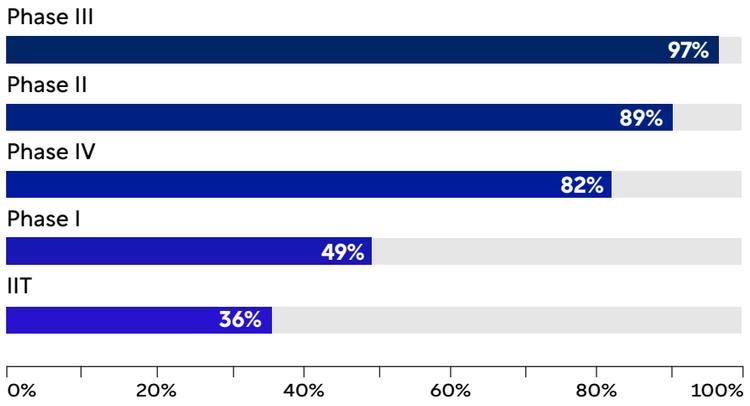
The Site Landscape



Phase III Work Anchors Most Site Portfolios

Phase III leads site portfolios and continues to expand in scope. Over the past decade, Phase III studies have seen 60% more procedures and sites per pivotal trial, with data volume nearly tripling.[1] This broadens the demands on study teams, from coordinating more study activity to managing far more data.

Q4: What study phases does your site support? (Please check all that apply.)



1. Tufts University's Center for Strategic Decision Support in Drug Development (CSDD)





150+ Trials Is Now the Most Common Site Workload

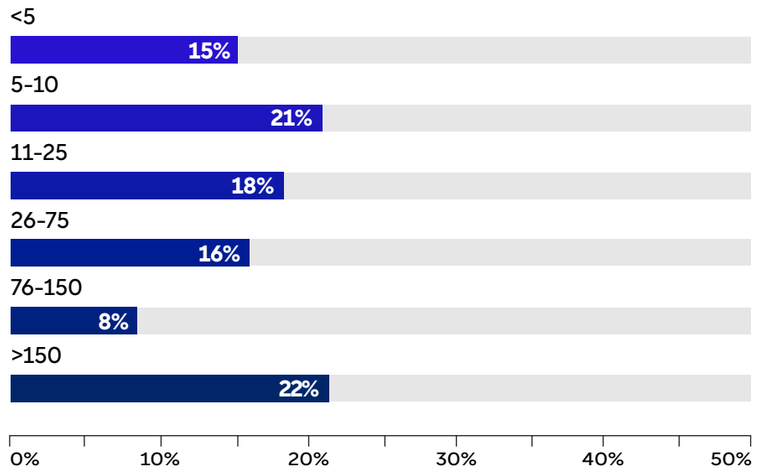
More than one in five sites now carry 150 or more active trials, the largest single group in this year's survey. At that volume, every added protocol requirement multiplies across the portfolio.

YEAR OVER YEAR

▲ +6 pts

Sites running 150 or more trials jumped from fifth place in 2025 to the largest group this year.

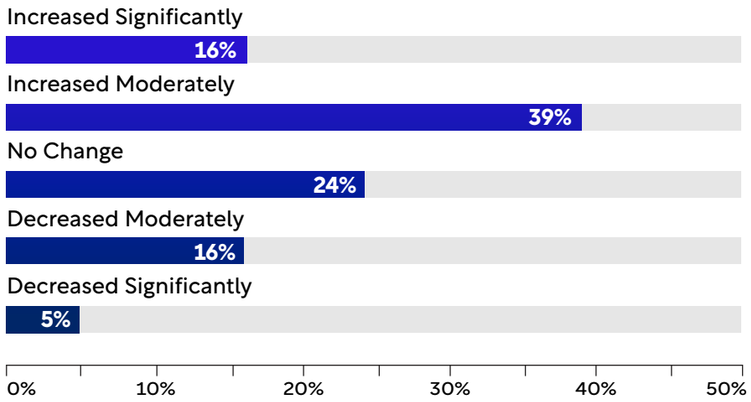
Q5: Please select the current number of open and enrolling trials at your site:



More Than Half of Sites Were Offered More Trials This Year

More than one in five sites now carry 150 or more active trials, the largest single group in this year's survey. At that volume, every added protocol requirement multiplies across the portfolio.

Q6: During the last year, how has the number of clinical trial opportunities offered to your site changed?



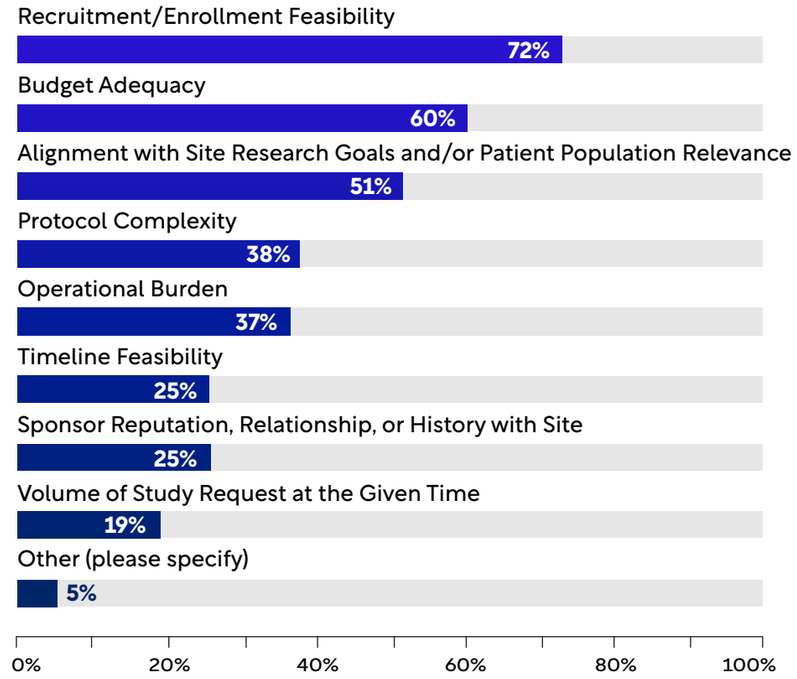


Sites Take On the Trials They Believe They Can Enroll and Financially Sustain

Three considerations drive most acceptance decisions: whether the site can realistically enroll the study (72%), whether the budget covers the work (60%), and whether the research fits the site's goals and participant population (51%).

Protocol complexity and operational burden follow close behind, a sign that sites are weighing the true cost of running a study before they commit.

Q7: What factors most influence whether your site accepts a new trial? (Select your top three responses.)



Sites Signal an Increased Focus on Cardiovascular Studies

Oncology remains the most common therapeutic area of survey respondents at 48%, but cardiovascular now sits just behind it at 46%. This follows broader trends that have seen cardiovascular trial starts surge by 68% since 2015.[2]

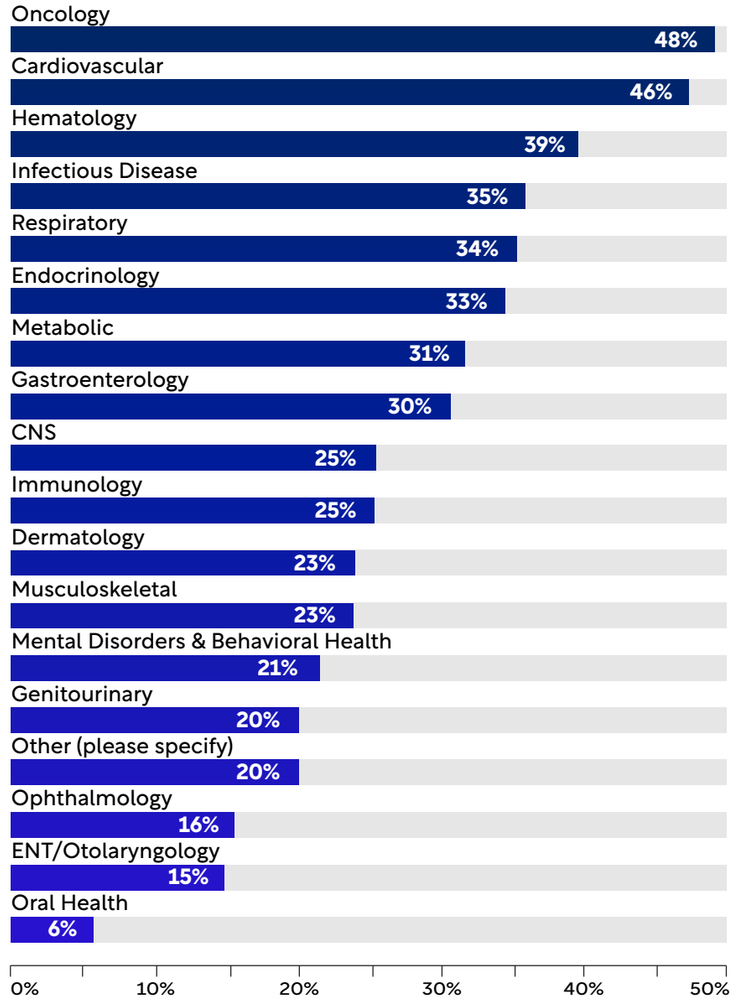
Beyond the top two, sites report a wide spread of work, with hematology, respiratory, metabolic and infectious disease each running at roughly a third of respondents.

YEAR OVER YEAR

▼ -5 pts

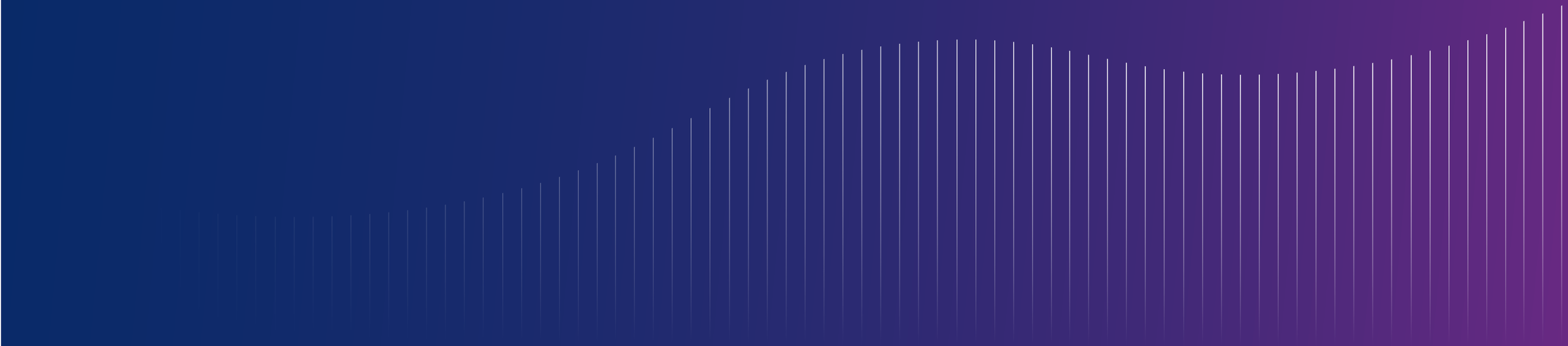
Oncology's lead over cardiovascular narrowed from seven points in our 2025 survey to under two this year, as oncology eased from 52% and cardiovascular climbed to 46%.

Q8: What therapeutic areas did your site conduct trials in over the last year? (Select all that apply.)



2. Clinical Trials Arena
https://www.clinicaltrialsarena.com/sponsored/why-researchers-are-bringing-cardiovascular-trials-to-the-heart-of-the-community/

Site Pressures and Performance



Sites Are Absorbing Several Compounding Pressures at Once

Trial complexity (+6 pts YoY), site staffing (+9 pts YoY), and contract and budget delays (+6 pts YoY) lead again this year. The challenges sites name most have not changed, but the share of sites naming them keeps climbing. Persistence at this scale signals that current approaches are not reaching the root of the problem.

Large sites (academic medical centers, community hospitals, integrated health systems, and site networks) name staffing as their first challenge, at 44%.

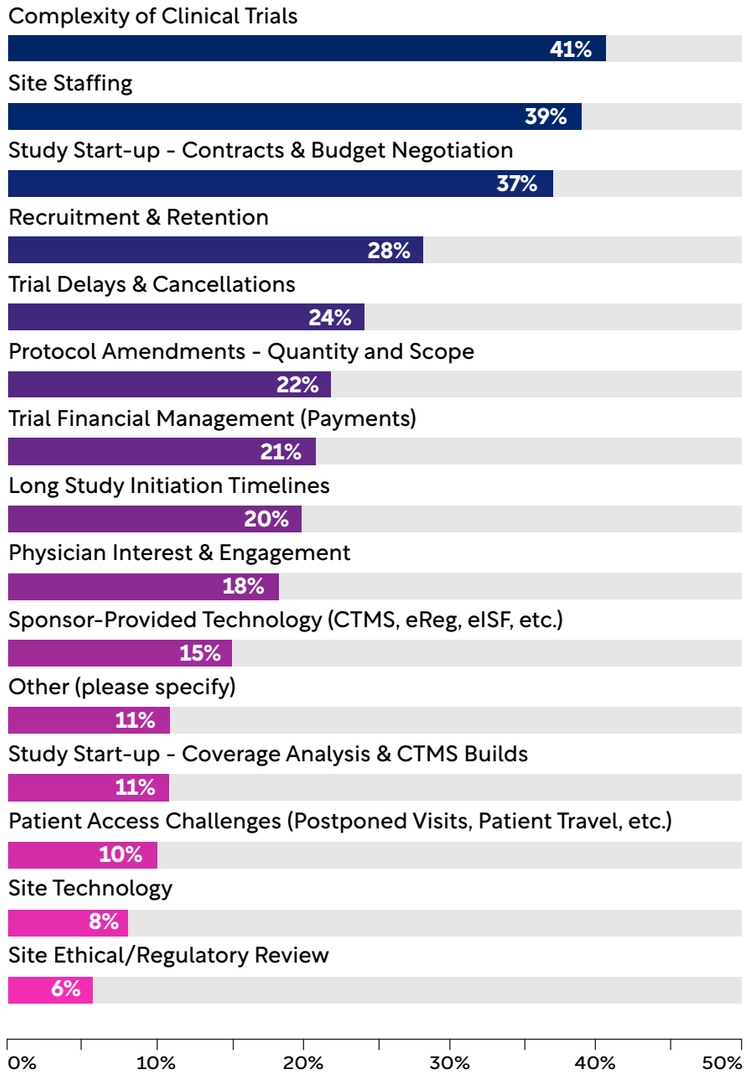
Smaller sites (independent research sites and physician practices) name trial complexity as their first challenge, at 47%.

YEAR OVER YEAR

▲ +6 pts

Sites running 150 or more trials jumped from fifth place in 2025 to the largest group this year.

Q9: What are the top issues impacting your research site today? (Select your top three responses.)



Sites Are Investing in People First to Manage the Pressure

Sites are adding staff and strengthening the training behind them, while taking a fresh look at how their own study operations run. Training is where that investment pays off, giving new team members a fast, confident path to full contribution.

The opportunity ahead is training that is affordable, current, and accessible to everyone, whether virtual, hybrid, or in-person.



Q10: What actions has your site taken in the past 12 months to manage these challenges? (Select all that apply.)

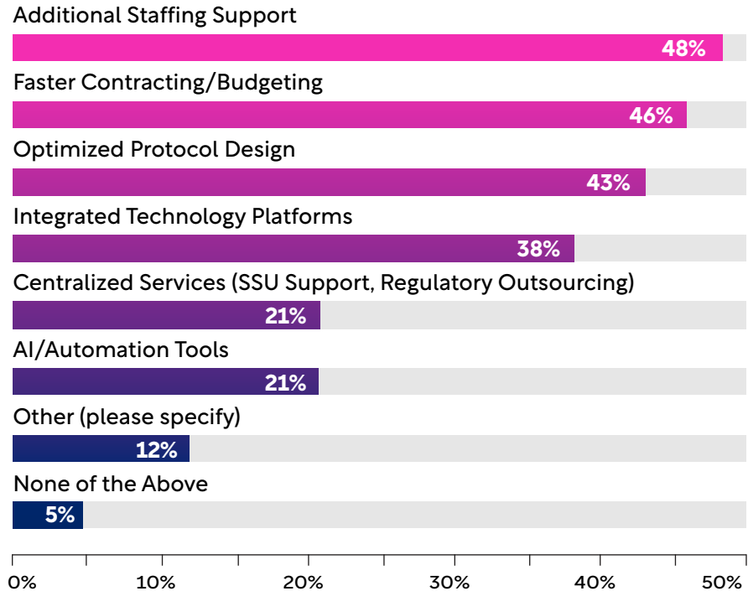


Sites Want Relief at the Source, Not Workarounds

Asked which solutions would have the greatest impact, sites pointed to staffing support (48%), faster contracting and budgeting (46%), and optimized protocol design (43%) – the same pressures they name as their leading challenges. Technology ranks lower, suggesting the remedies sites want sit upstream.



Q11: Which solutions would have the greatest impact on improving your site's performance? (Select your top three responses.)

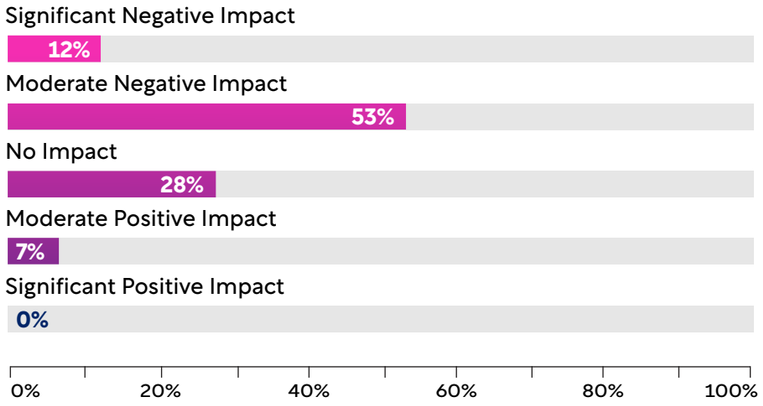




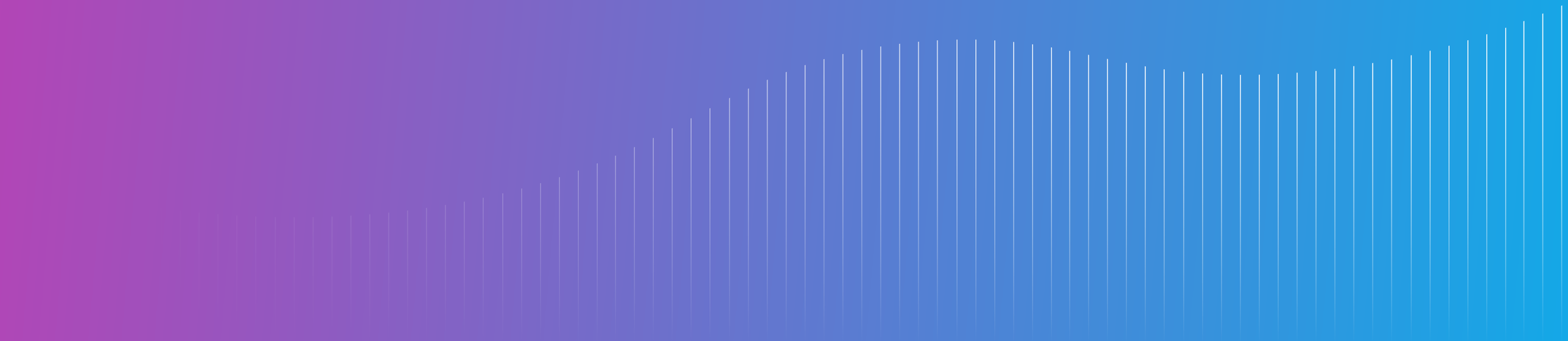
Current Challenges Are Hitting Site Finances, Not Just Workloads

Nearly two-thirds of sites report that current challenges have hurt their financial performance, including 12% who describe the damage as significant. Almost no site reports a benefit, with 7% citing a moderate gain and none a significant one, a reminder that operational burden carries a direct cost.

Q12: How have current challenges impacted your site's financial performance?



Funding, Budgets, and Complexity

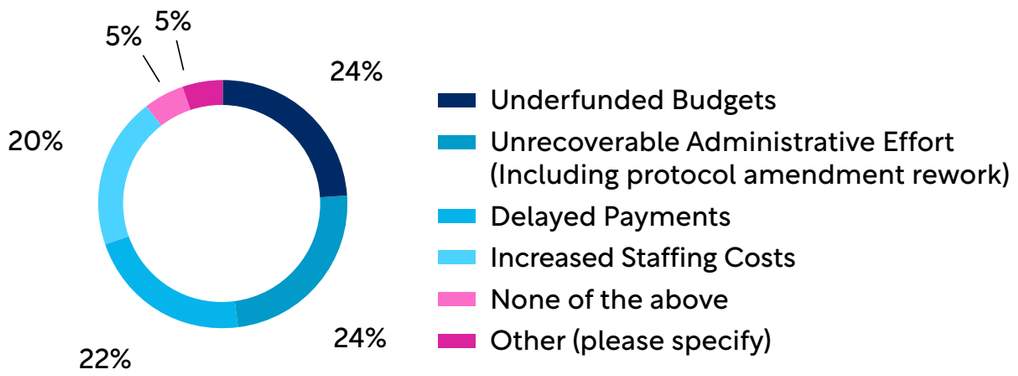


Sites Are Absorbing Costs Their Budgets Were Never Built to Cover

The highest costs are administrative, and protocol amendments are the clearest example: work that is unbudgeted, unrecoverable, and largely avoidable.

Some amendments can be largely prevented before a study opens, through rigorous feasibility and protocols built around the participants who will enroll. Sponsors, CROs, and sites that maintain consistent and transparent communication catch potential issues early. Each of those choices spares the site work it would otherwise do for free.

Q13: Which areas contribute most to your site's financial performance? (Select all that apply.)



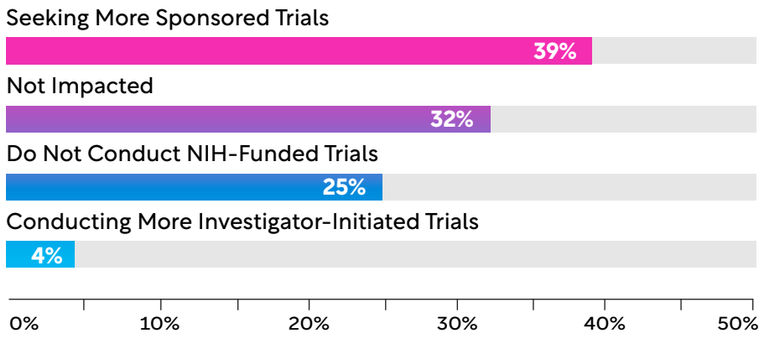




Sites Are Seeking More Sponsored Trials to Combat Uncertainty Around Future NIH Funding

With the uncertainty of NIH funding, budget considerations are at an all-time high. With many sites seeking more sponsored trials, there is a greater need to stay on time and reduce costly timeline extensions in the form of protocol amendments. Additionally, sponsors will be working with more sites and more studies, making the need for consistent, effective communication even more imperative.

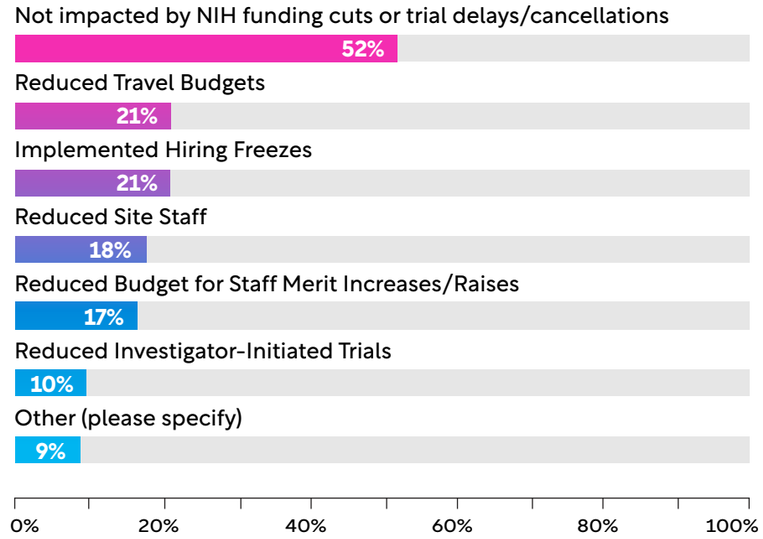
Q14: Over the last year, how has your site strategy shifted based on the uncertainty of future NIH funding?



Sites Hit by NIH Cuts Are Paying for Them in Changes to Staffing

Half of the sites surveyed were not affected by NIH funding cuts, delays, and cancellations. For the rest, the offsets have fallen on staff: hiring freezes first, and in some cases outright reductions. That leaves fewer people to carry a growing volume of trials and the administrative work attached to them, deepening the strain on teams that were already stretched.

Q15: If your site was impacted by NIH funding reductions in 2025-26, what measures remain in place to offset the impact? (Select all that apply.)



Complexity Starts With the Protocol, and It Is Getting Heavier

Sites rank protocol complexity above operational logistics and every other factor as the driver of overall trial complexity.

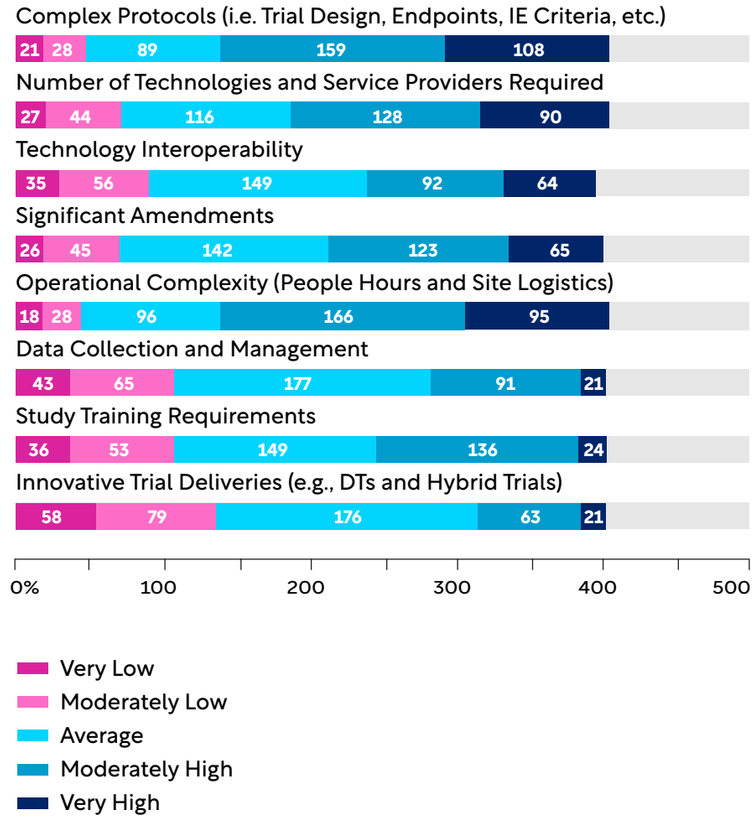
Design decisions made long before a study opens set the workload sites carry for its duration, and that burden is growing rather than easing.

YEAR OVER YEAR

▲ +7 pts

Sites rating protocol complexity a high source of complexity rose from 59% in 2025 to 66% this year.

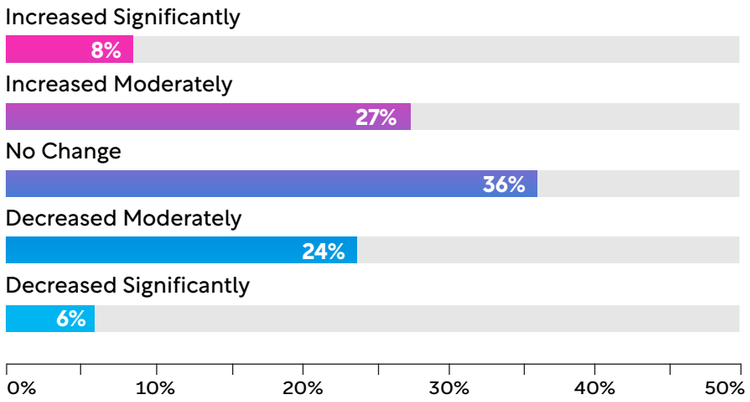
Q16: What factors most influence whether your site accepts a new trial? (Select your top three responses.)

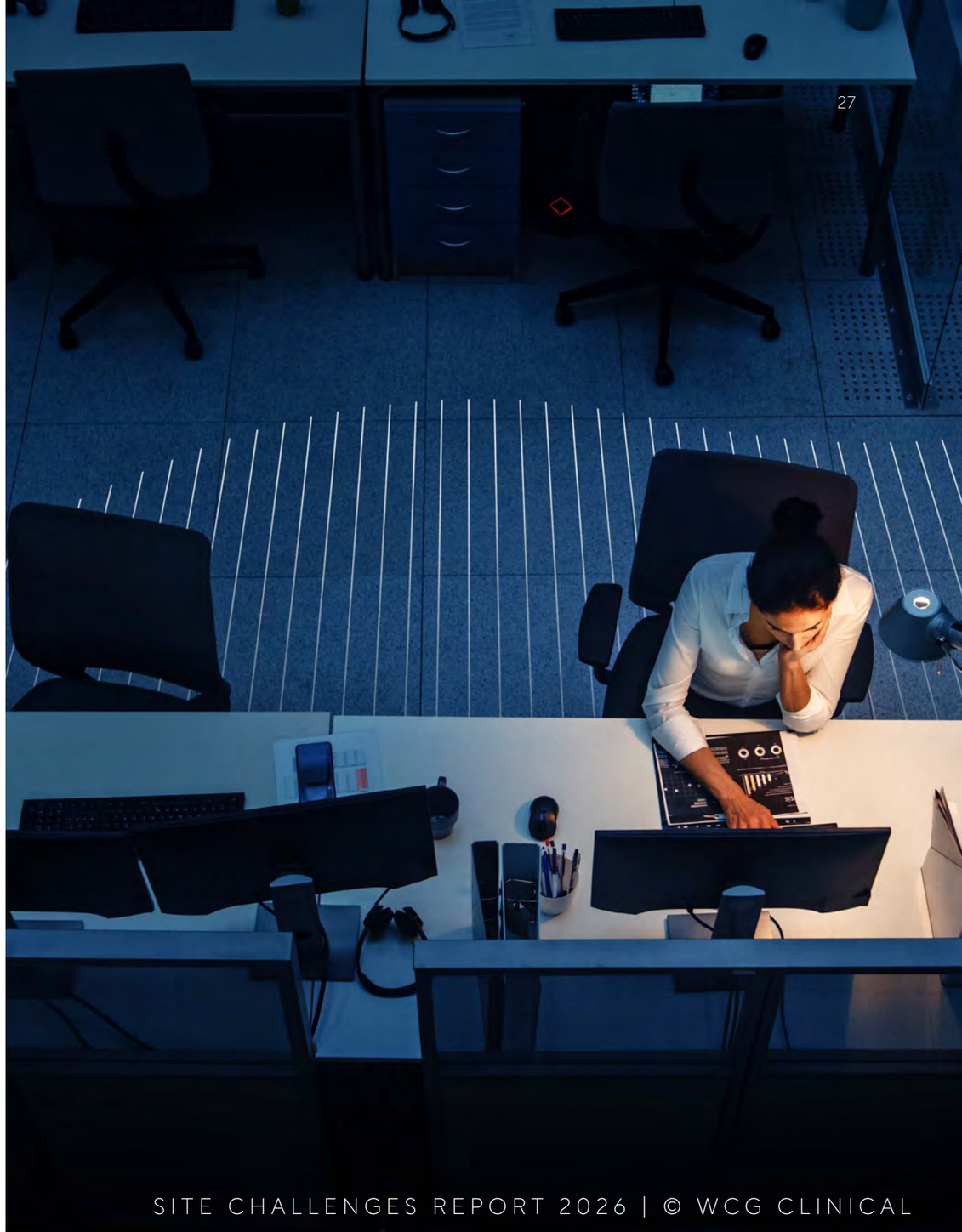


Trial Opportunity Is Outpacing Staffing Growth

Site staffing is split: about a third grew, a third held flat, and just under a third shrank. By contrast, roughly 40% of sites were offered more trials this year, meaning opportunity is expanding faster than the teams available to run them.

Q17: How have your site's staffing levels changed over the last year?



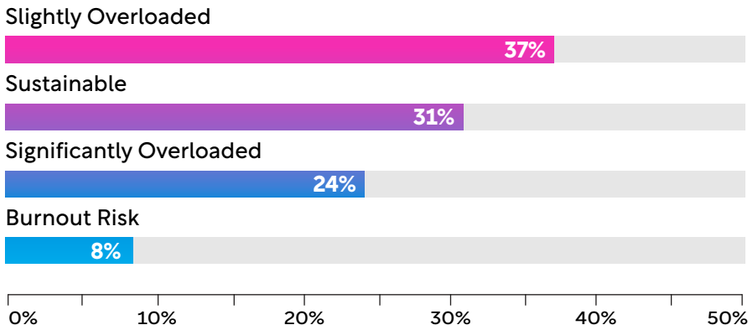


Overload Has Become the Default Setting for Sites

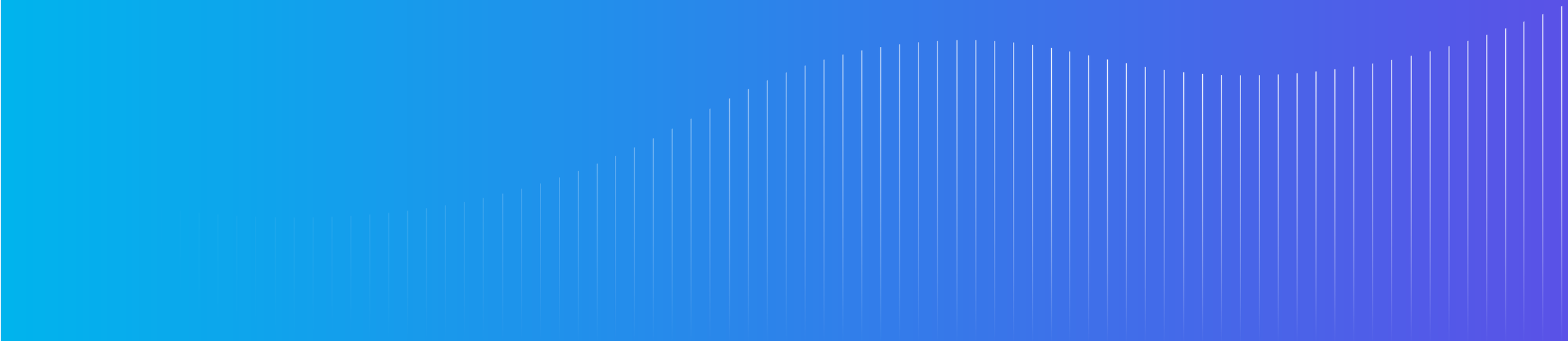
Fewer than a third of sites describe their current workload as sustainable, while two-thirds report being overloaded or at risk of burnout. It is a striking result, though a logical one given the pressures sites are facing: rising protocol complexity, more trials offered, and staffing that has largely held steady. Those forces compound, leaving the same teams to absorb more demanding work without proportionate capacity. Left unaddressed, that sustained pressure is the kind that tests staff retention and stretches the bandwidth sites have for participant-facing time.



Q18: How would you describe current staff workload?



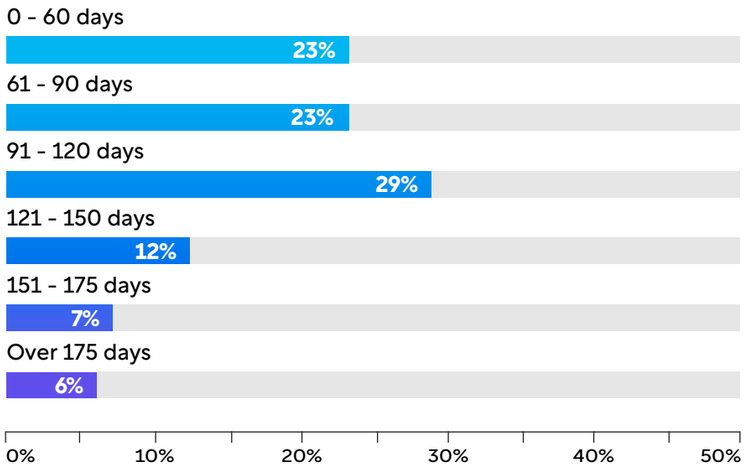
Study Start-Up and Amendments



Over Half of Sites Take Three Months or More to Reach Start-Up

More than half of sites need 91 days or longer to complete start-up, and 13% run longer than five months. That extended timeline represents months lost before the first participant is seen, and it is where the clearest opportunity to compress timelines sits.

Q19: On average, how long did your site's study start-up process take last year?



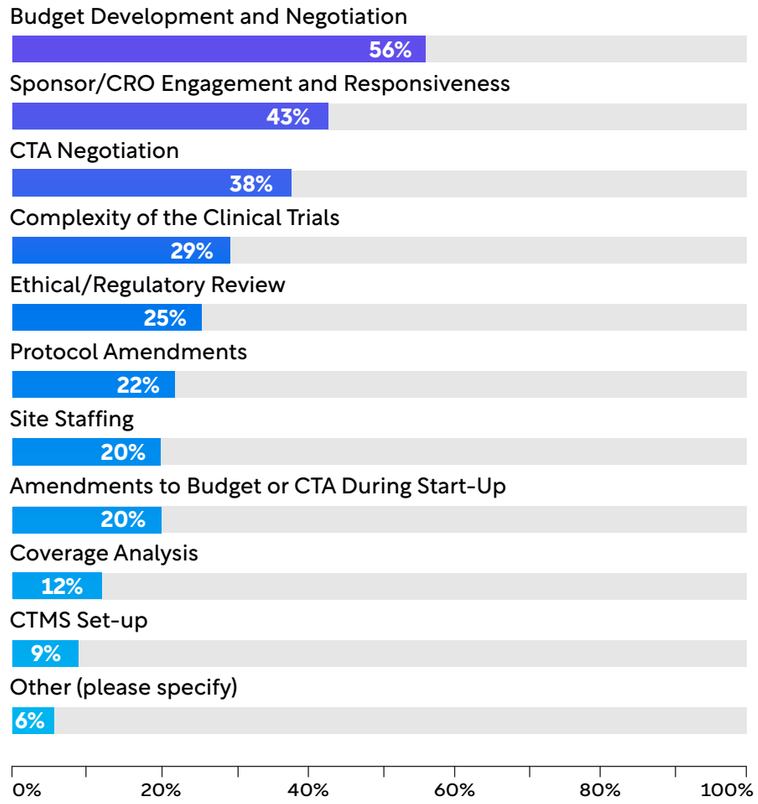


The Biggest Time Savings Are Found in the Work Sponsors and Sites Do Together

The three largest contributors are budget development and negotiation (56%), sponsor/CRO engagement and responsiveness (43%), and CTA negotiation (38%). Each of these is shared work between sponsors, CROs, and sites rather than something either side controls alone.

Factors sites manage on their own rank far lower, with staffing at 20% and CTMS set-up at 9%, pointing to benchmarked budgets, standardized contract terms and tighter joint communication as the most promising levers for shortening start-up.

Q20: What was the largest contributor to your study start-up timelines last year? (Select your top three responses.)



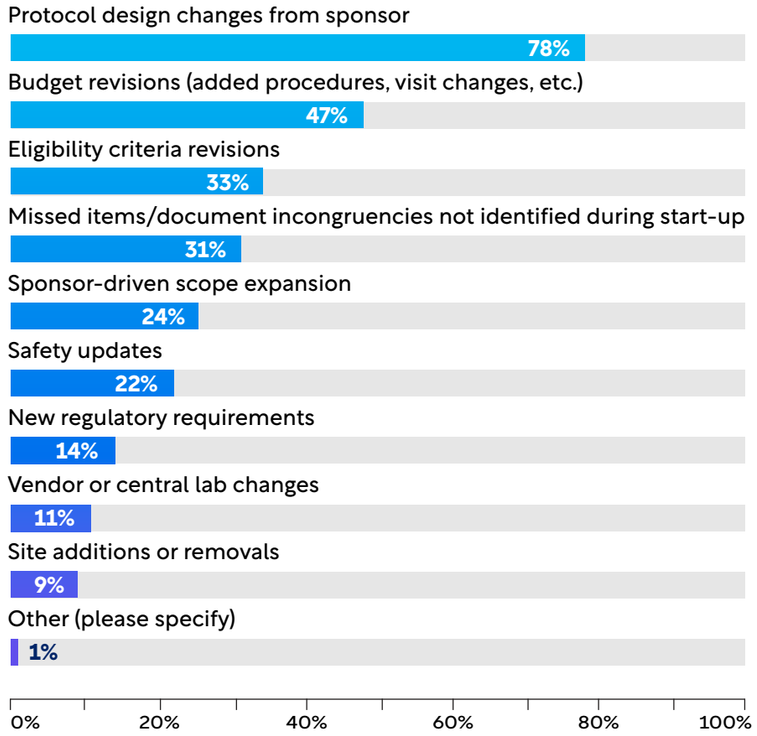
Most Amendments Trace Back to Design Decisions Made Before the Study Opened

Protocol design changes from sponsors drive amendments at 78% of sites, more than twice that of the next trigger.

Budget revisions follow at 47%, with eligibility criteria revisions at 33% and items missed during start-up negotiations at 31%.

These are largely upfront planning questions surfacing after activation, which suggests the same remedies apply across all four: earlier dialogue, feasibility tested against real-world data, and budgets benchmarked before signature.

Q21: What are the most frequent triggers for protocol amendments and contract modifications at your site? (Select your top three responses.)



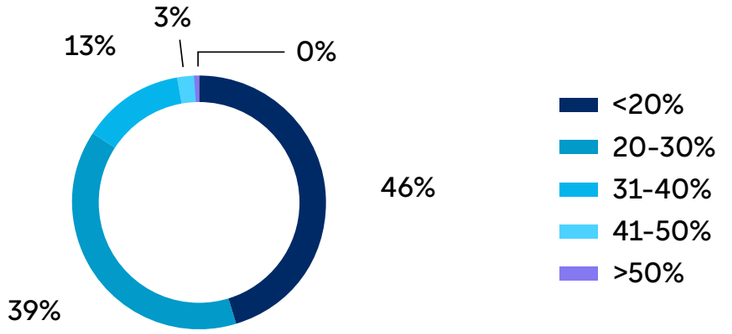
For Most Sites, Amendments Quietly Consume Significant Effort and Time

Amendments rarely dominate a site's start-up, but they are far from marginal: 55% of sites spend 20% or more of start-up time on them, and 16% spend over 30%. That is weeks of effort per study devoted to reworking decisions already made.

The leading triggers are design and budget questions. These can be tested upfront, which is recoverable time.

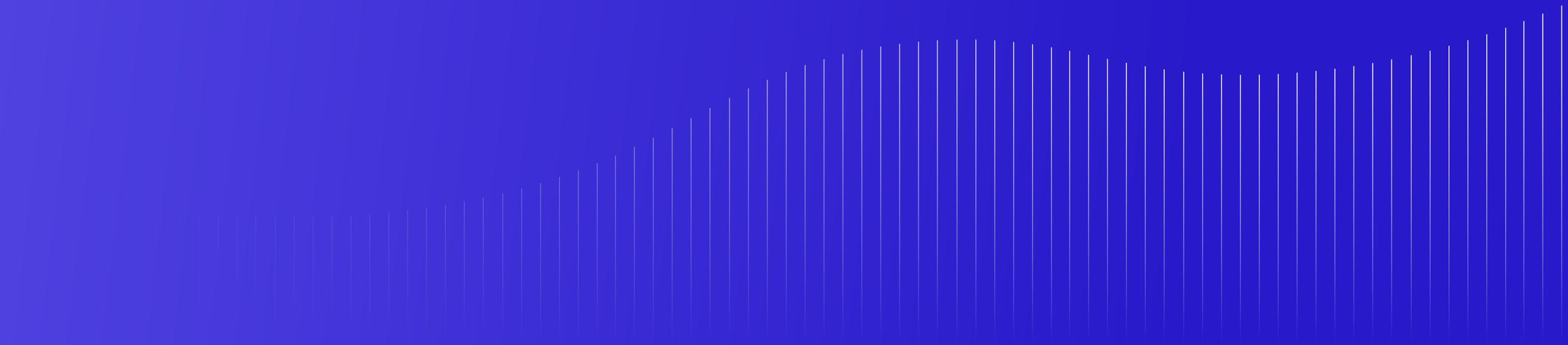
Protocol complexity also ranks among the top five factors in whether a site accepts a trial (38%), making amendment reduction a shared priority for sites and sponsors.

Q22: What percentage of your study start-up time is spent on protocol amendments?





AI and Automation



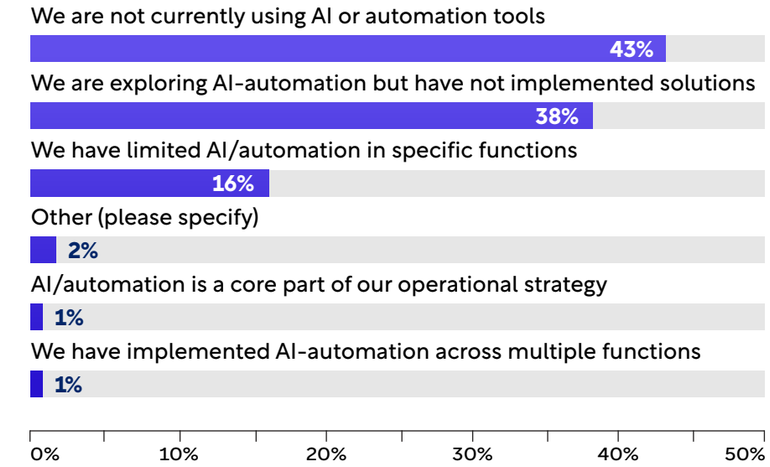
Most Sites Aren't Using AI, and Early Adopters Start With Admin Work

AI adoption at sites is still mostly aspirational: 43% use nothing today, and another 38% are exploring without an implementation, so most sites need a starting point rather than a platform story.

The 16% already implementing AI are focused on specific, administrative tasks: document processing, operational data aggregation, and automated communications.

That is also the clearest path to impact, because the challenges sites name most often — staffing strain and contract and budget delays — are exactly the pressures that ease when repetitive administrative work is automated and those hours go back to the team.

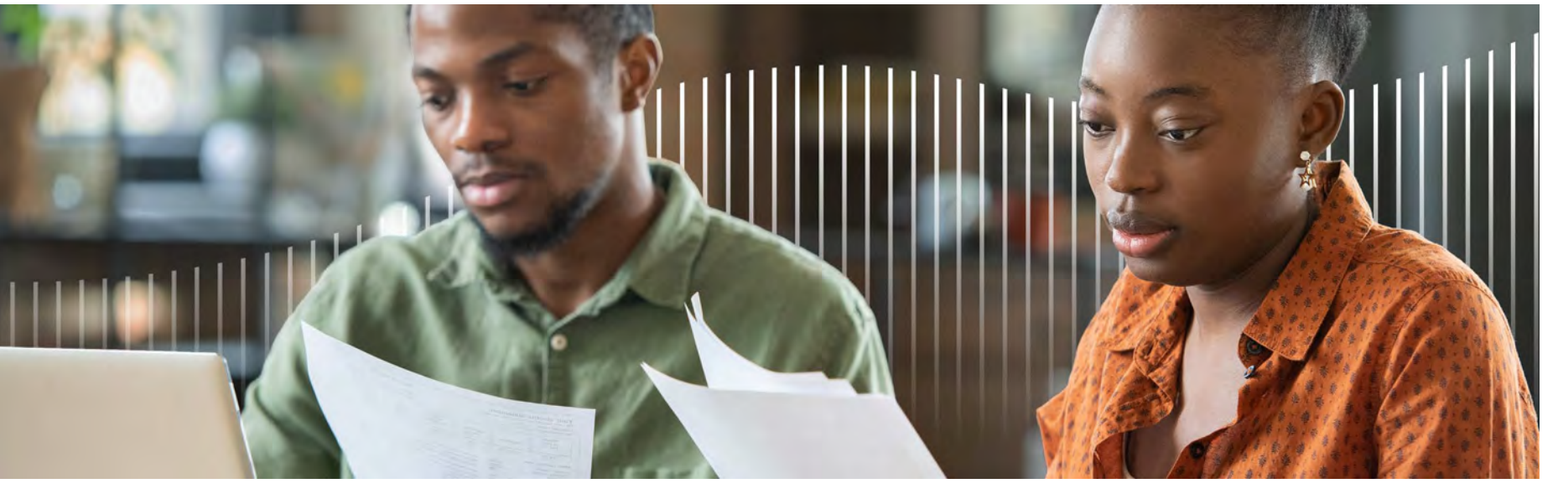
Q23: What best describes your site's current use of AI or automation in clinical trial operations?



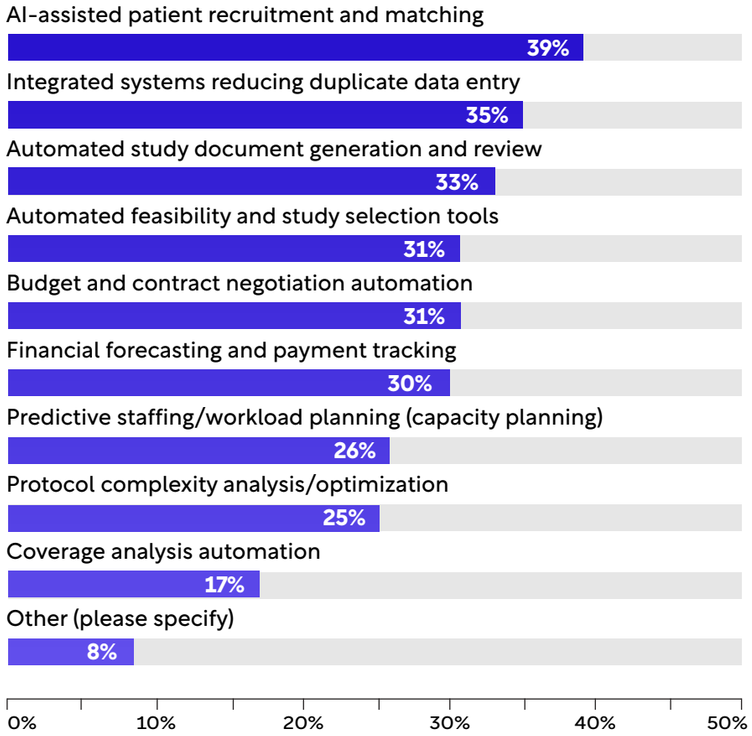
Sites Are Broadly Open to AI to Relieve Pressure on Study Teams

Sites point first to AI-assisted participant recruitment and matching (36%), then to integrated systems that end duplicate data entry (35%).

The tight spread across the rest is the real signal: sites are broadly open to AI anywhere it could relieve the pressures their teams are carrying, from manual documentation and feasibility work to contracting and capacity planning.



Q24: Which AI or automation capabilities would have the greatest impact on your site's performance? (Select up to three responses.)

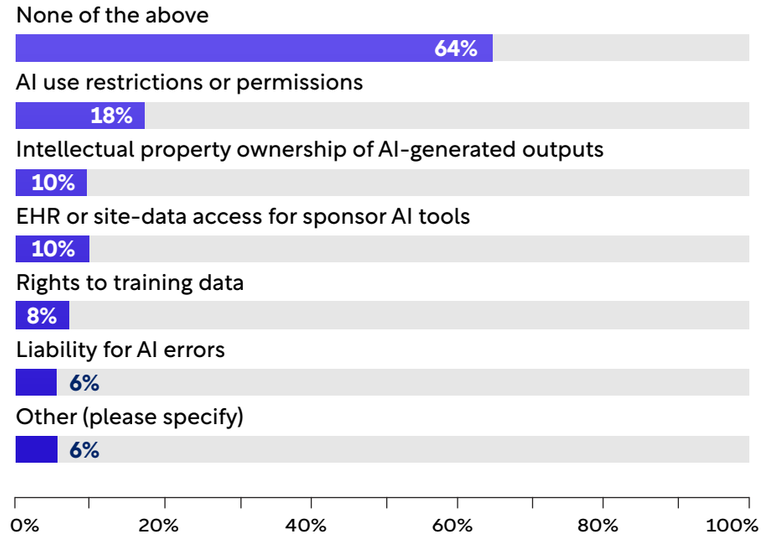


AI Is Entering Contracts Faster Than It Is Entering Workflows

Combined, roughly 44% of sites are already fielding AI-related stipulations in their contracts, from outright restrictions on AI use to liability for AI errors. That's well ahead of AI adoption, where only 16% of site respondents have implemented any AI workflows to date.

Standard, pre-agreed AI language would keep this from becoming another source of delay.

Q25: In the past year, have any sponsor CTAs your site received included clauses addressing any of the following? (Select all that apply.)



Sites have named the problems. Together, we can solve them.

Most of what sites described is addressable upstream, before it becomes an amendment, a renegotiation, or a delay.

WCG's study start-up solutions and study acceleration solutions work on both ends of that — clearing what stalls research before it begins, and keeping studies moving once they do.

Stop paying downstream for complexity you can resolve upfront.

See how at wcgclinical.com.