



Australia-New Zealand Site Landscape Benchmark Your Site

ANZ Site Solutions SummitTM

SPEAKERS



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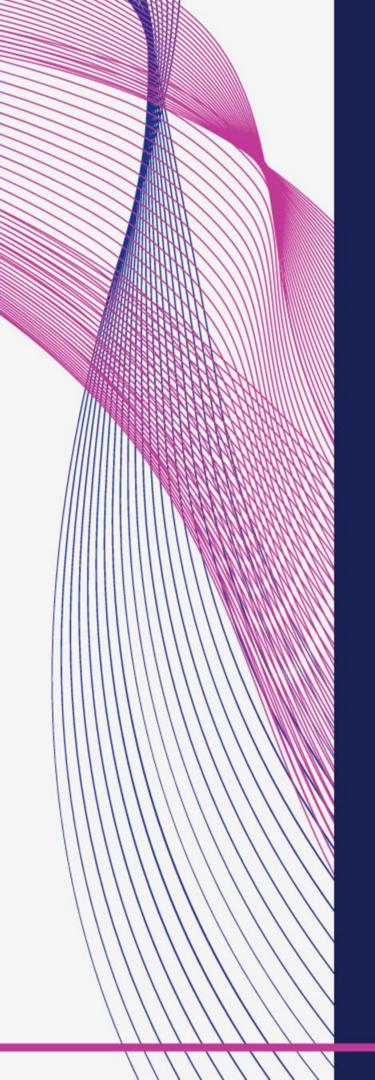
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FACULTY DISCLOSURE

In compliance with ACCME Guidelines, I hereby declare:

I do not have financial or other relationships with the manufacturer(s) of any commercial services(s) discussed in this educational activity.

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Criteria for AWARDING CONTACT HOURS

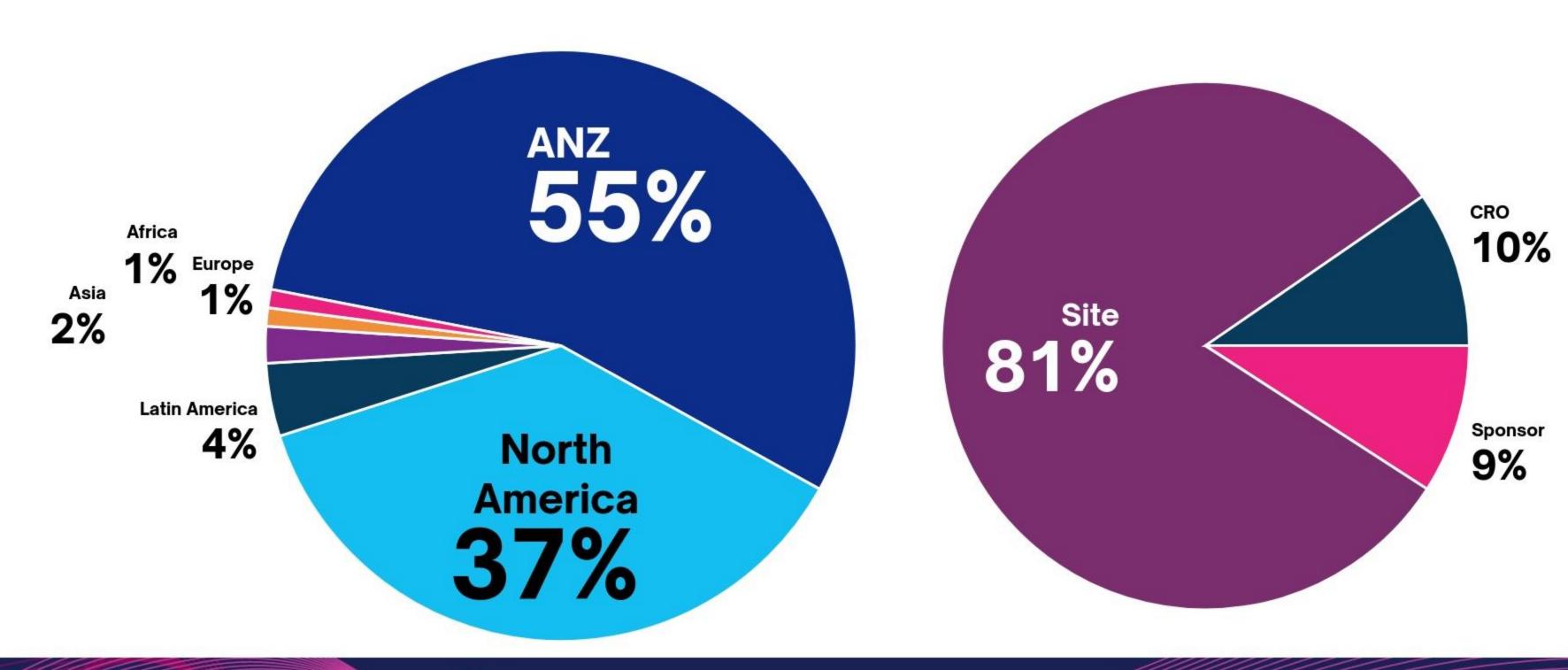
Applicants must be present during the "live" event, contact hours are not issued for recordings

Applicants must attend the activity the whole time, missing no more than ten minutes of the activity

Applicants must complete the post-meeting survey with a score of at least 70% Applicants must complete the post meeting survey evaluation questions

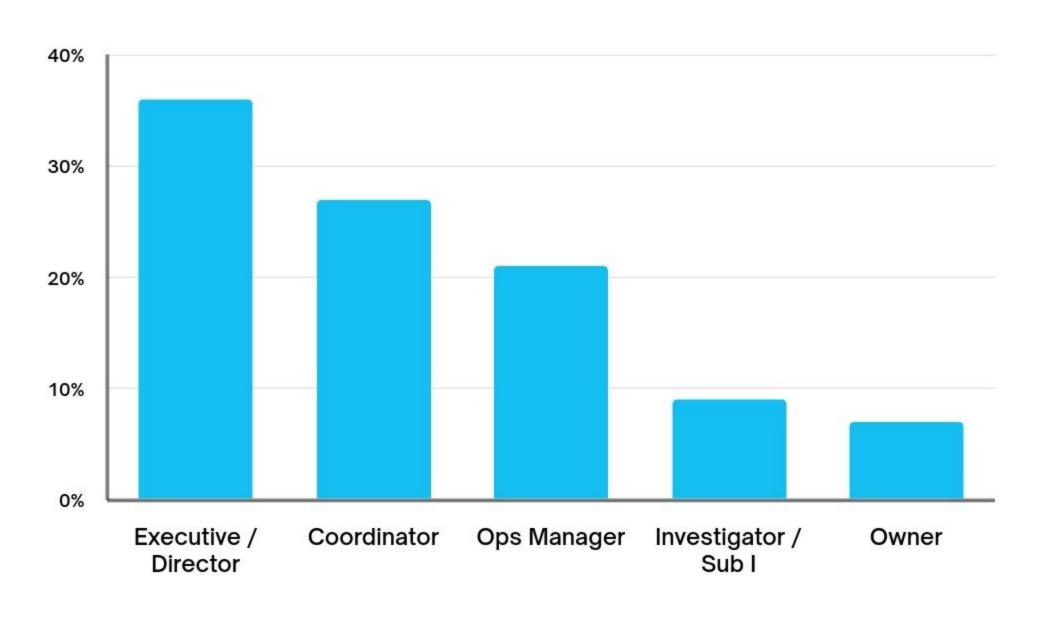
Society for Clinical Research Sites, Inc. is accredited as a provider of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation

Respondent Profile

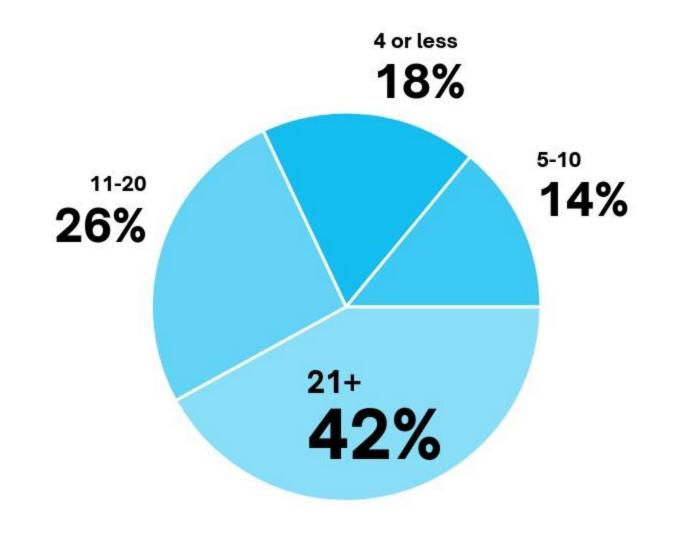


Role Demographics

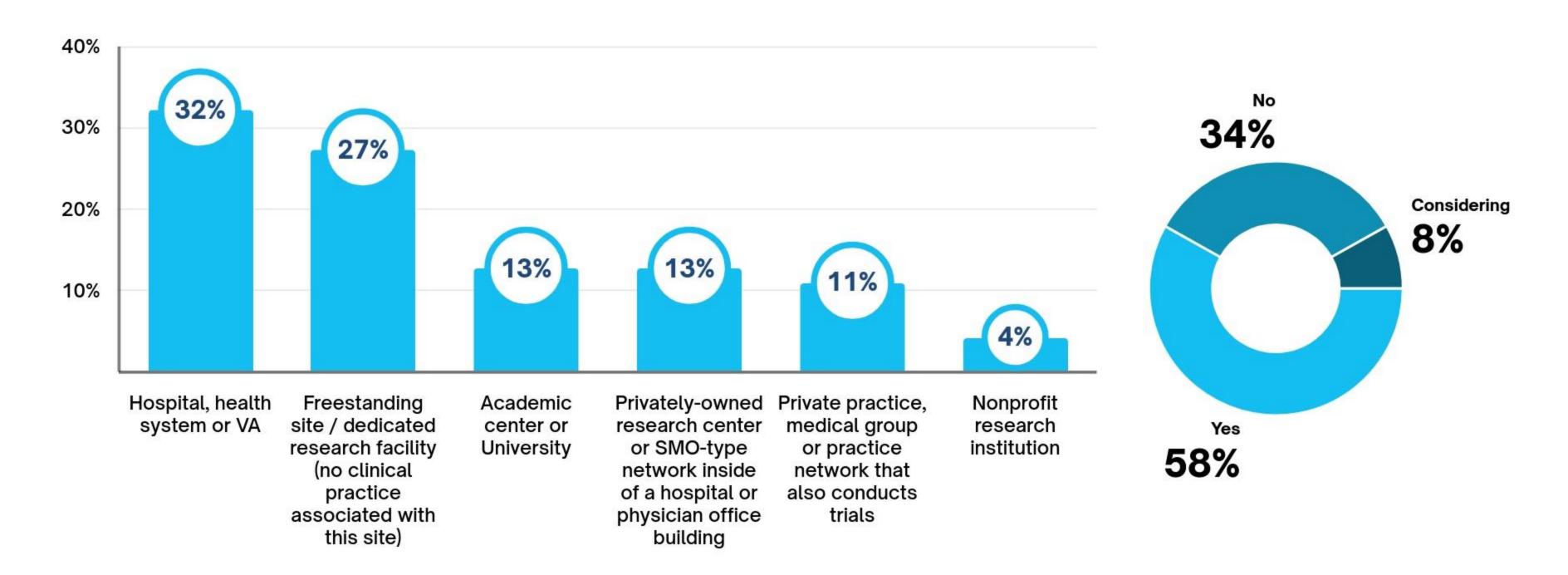
Current Role



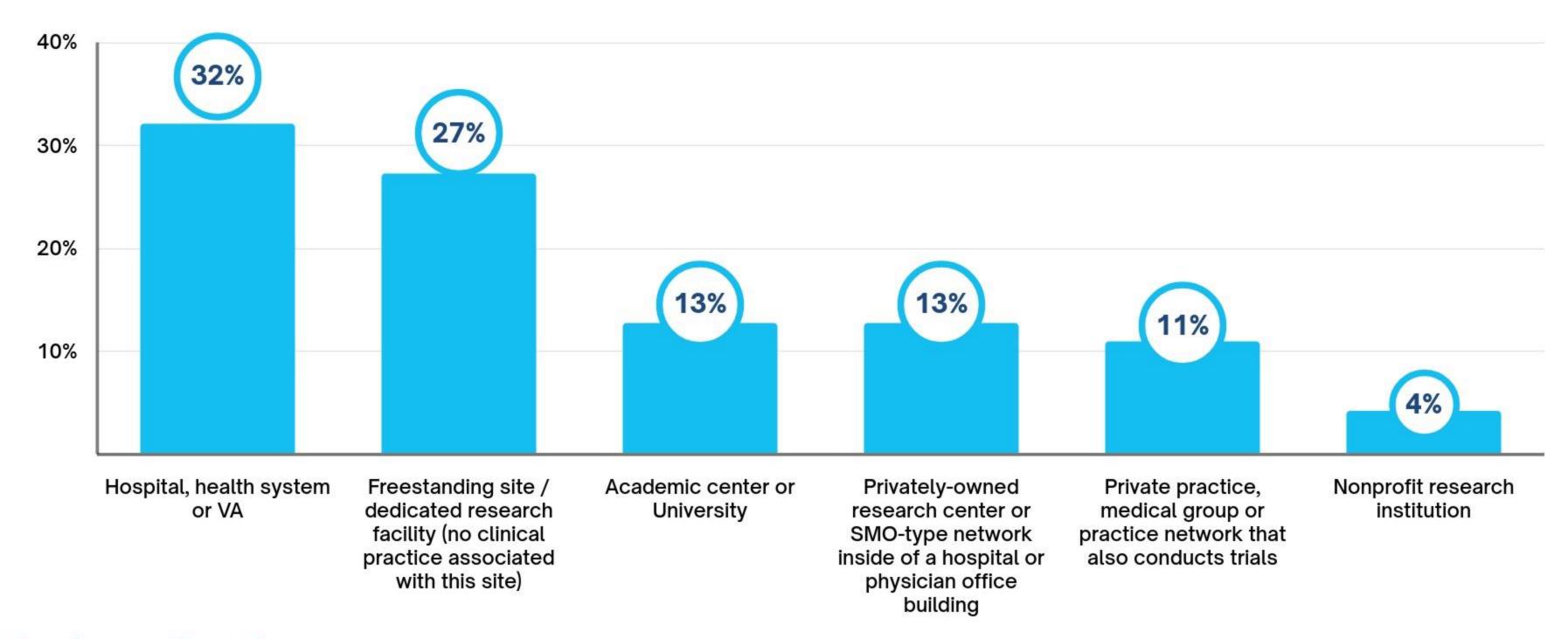
Years Site Has Been Involved in Clinical Research



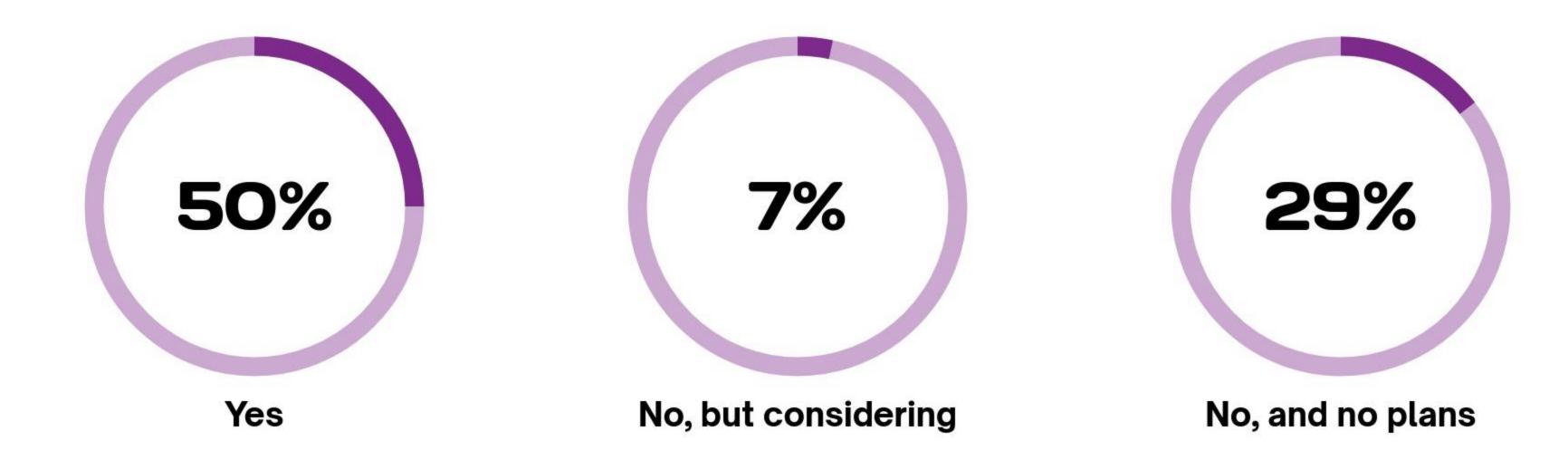
Site Organization Type



Site Organization Type



Site Network

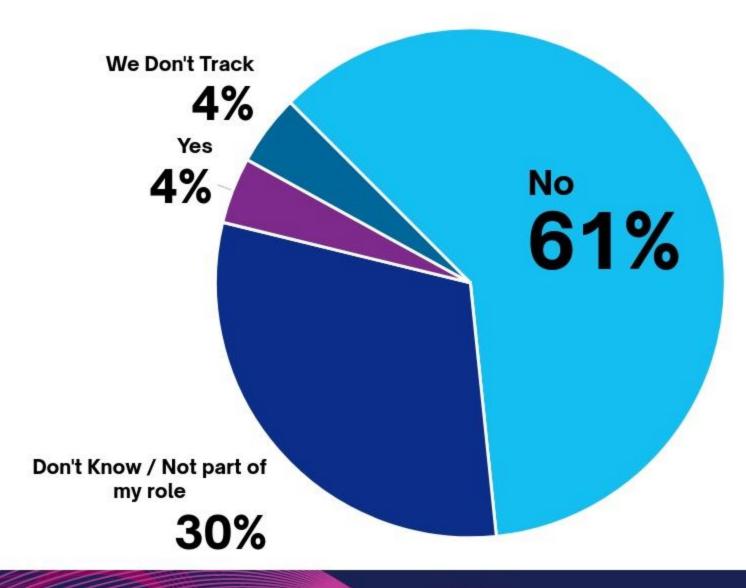


Section 1

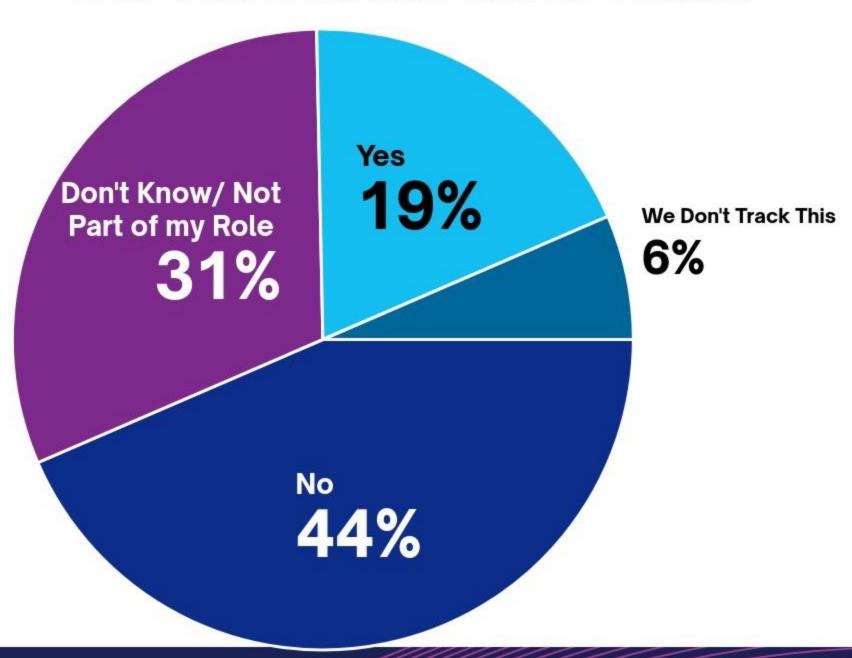
Study Volume, Delays & Cancellations

Study Opportunity Decline

Experienced a Decline in Study Opportunities?



Did You Decline More Trials?



Reasons for Declining Clinical Trials



Site does not have protocol-required patient population (48%)

2 Staffing challenges at the site (28%)

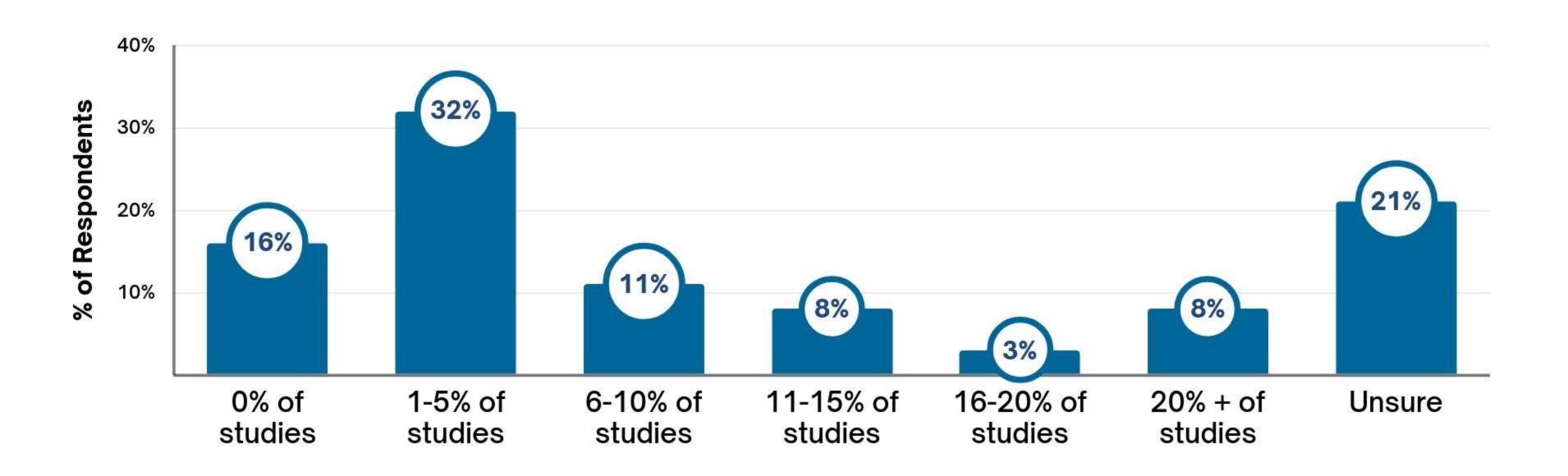
Could not agree on budget (24%)

Site had competing study / studies (24%)

Other reasons

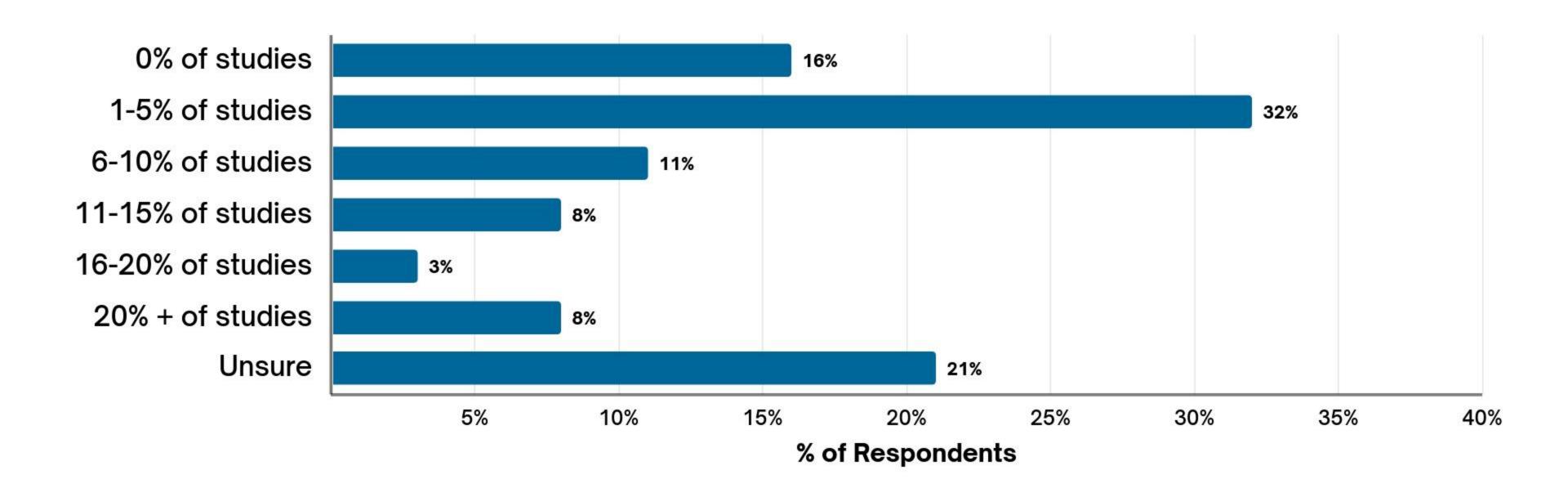
Of those that declined, Select up to 2

Study Opportunities Cancelled Before Enrollment (By Sponsor or CRO)



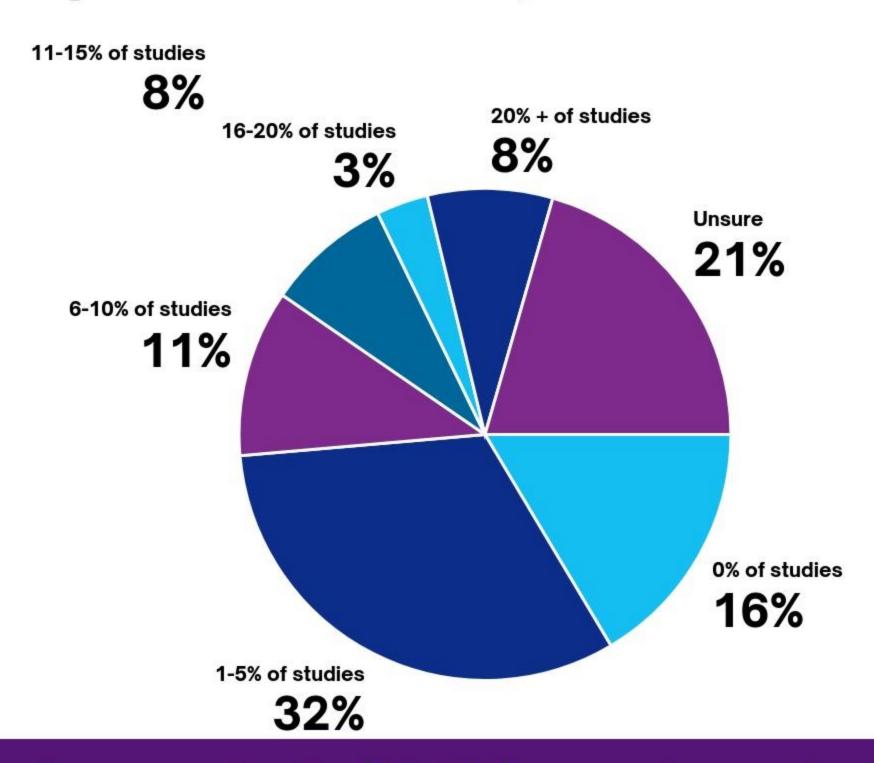
The majority of respondents (32.2%) experienced cancellation of 1-5% of study opportunities at their site in the past 12 months.

Study Opportunities Cancelled Before Enrollment (By Sponsor or CRO)



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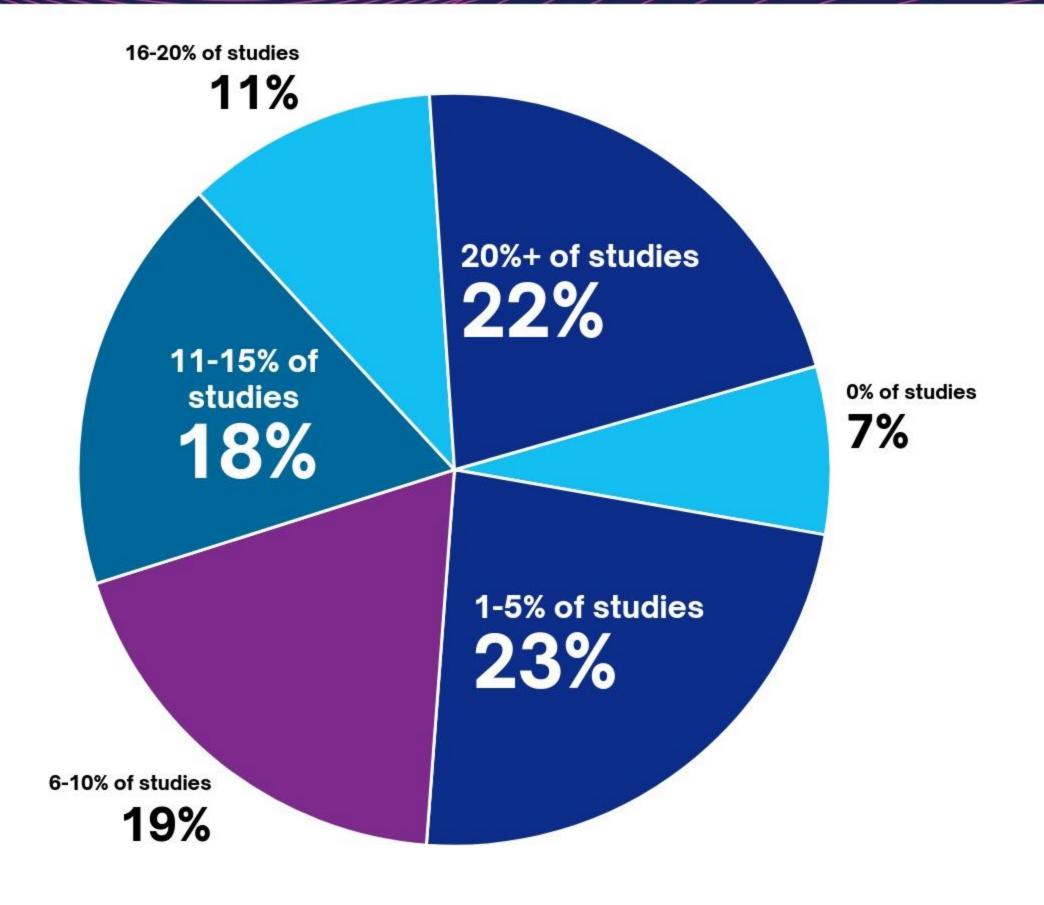
Study Opportunities Cancelled Before Enrollment (By Sponsor or CRO)



The majority of respondents (32.2%) experienced cancellation of 1-5% of study opportunities at their site in the past 12 months.

Study Opportunity Delays Greater Than 30 Days

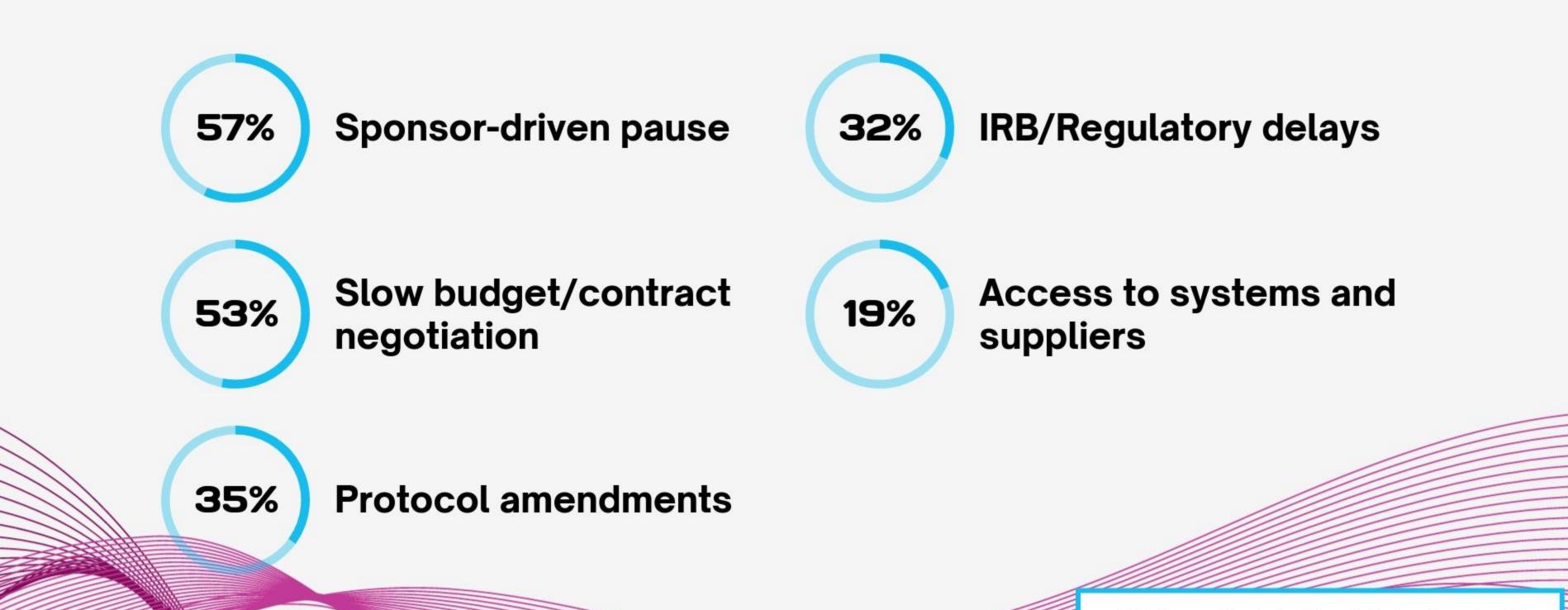
(By Sponsor or CRO)



Reasons for Delayed Trials



Of those that declined, Select up to 3



Reasons for Cancelled Trials

specify





Of those that declined, Select up to 3

Strategies to Reduce Clinical Trial Delays and Cancellations



Stronger communication channels with Sponsor/CRO

40% said improved coordination and transparency with study sponsors and contract research organizations to address issues more efficiently.



Increasing staffing capacity

25% hired additional personnel to handle increased workload and support trial operations more effectively.



Quicker and stronger budget or contract negotiations

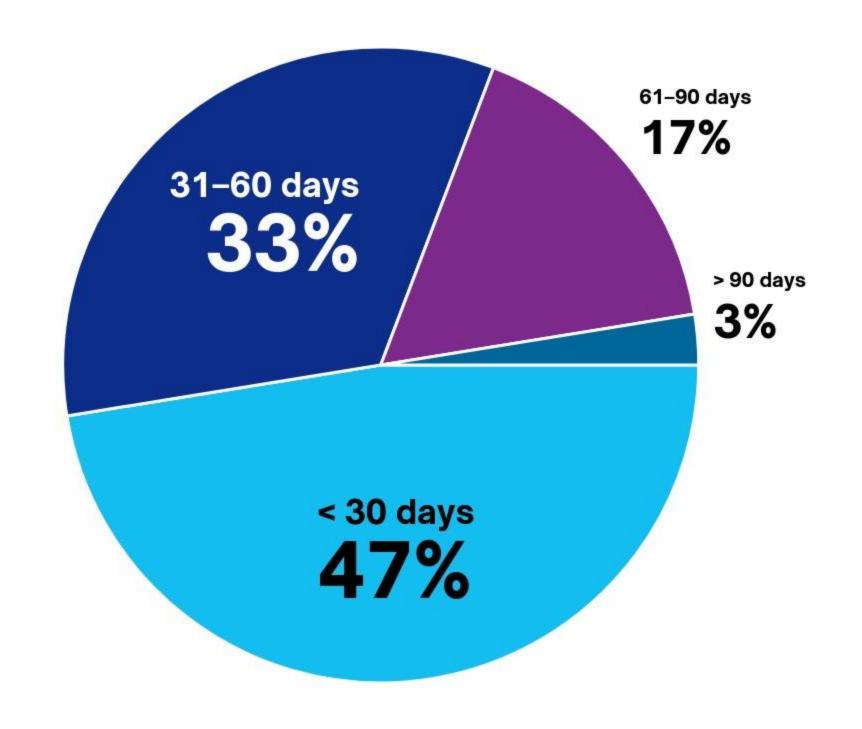
24% said streamlined the financial and contractual processes to reduce delays in trial initiation and execution.

35% also feel they have no influence over the cancellation or delay of trials.

Section 2

Contracts, Budgets & Payments

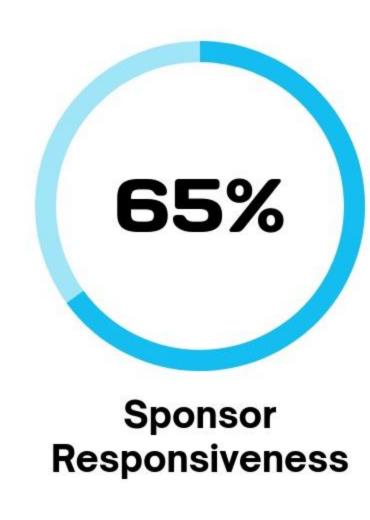
Average Clinical Trial Agreement Finalization Timeline

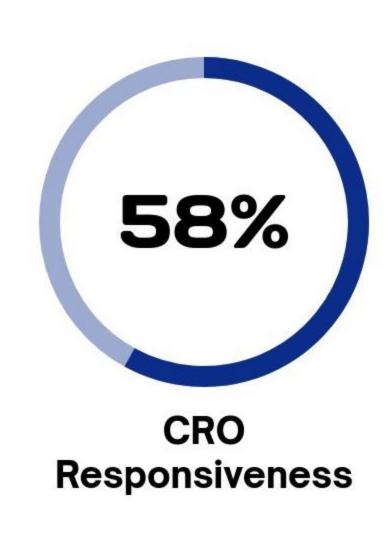


The majority of clinical trial agreements/contracts are finalized within 60 days. Nearly half (47.4%) are completed in 30 days or less.

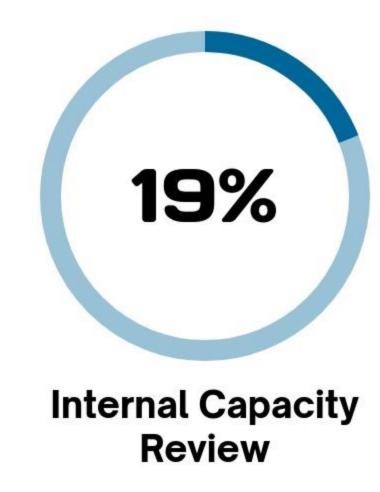
Factors Delaying Contract Finalization

Select up to 2









Improving Contract Finalization Time



Templated language - 21%

Develop standardized contract templates with pre-approved language, reducing the time spent on legal review and revisions.

33% for ANZ Audience (#1)



Dedicated staff for contract negotiation - 43%

Assign a team of experts to handle contract negotiations, leveraging their specialized knowledge and experience to streamline the process.

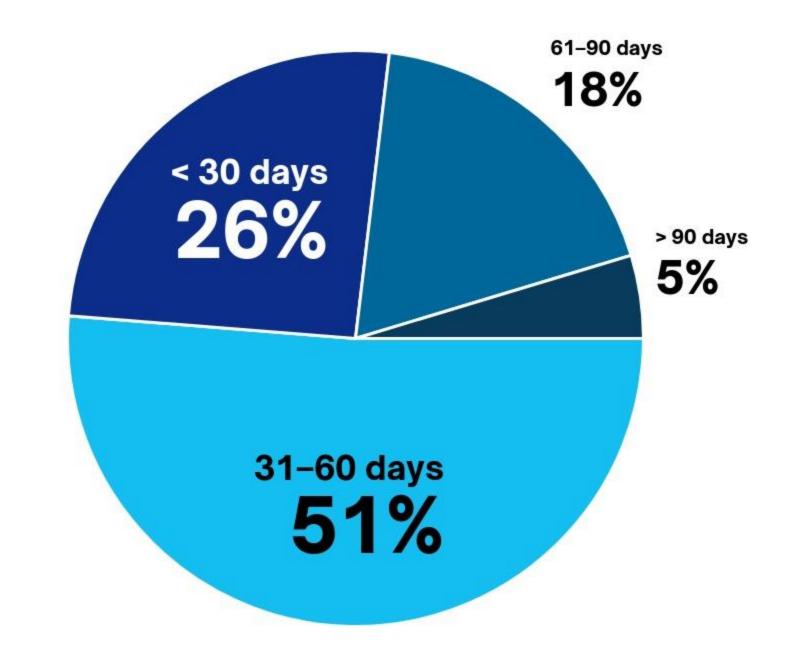
29% for ANZ



We have not been able to improve contract turnaround time - 20%

Despite efforts, the organization has struggled to find effective solutions to reduce contract finalization time.

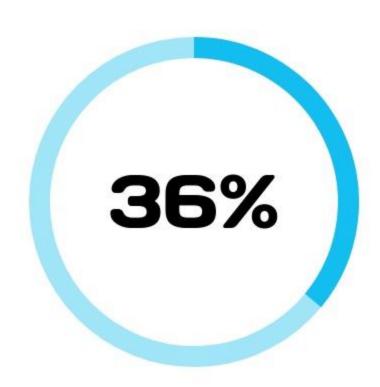
Budget Finalization Timeline



Compared to Global data, ANZ lags behind. Globally, 40% of budgets are finalized within 30 days compared to only 26% in ANZ.

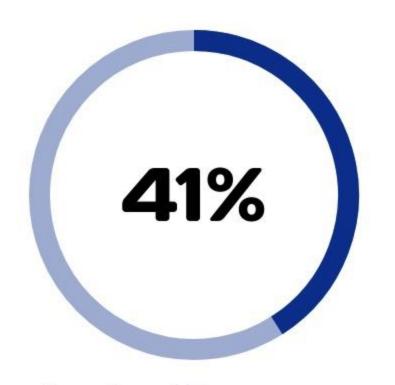
Factors Delaying Budget Finalization

Select up to 2



Large budgetary misalignment

#1 Answer in ANZ at 38%



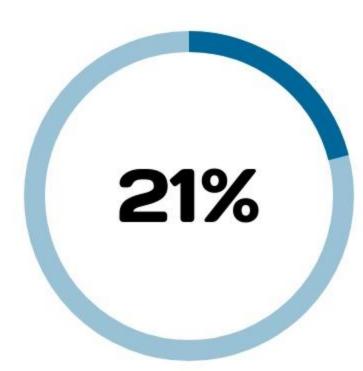
Lack of Sponsor responsiveness

#2 in ANZ at 32%



Lack of CRO responsiveness

#5 in ANZ at 18%



Lack of internal capacity or resources (ANZ)

#6 answer globally

Partner for Progress
INNOVATE FOR IMPACT

Improving Budget Finalization Time



Dedicated staff for contract negotiation - 29%

Assign a team of experts to handle contract negotiations, leveraging their specialized knowledge and experience to streamline the process.



Budgetary Start point - 21%

Develop a effective and realistic starting point, laying an effective foundation for budgetary negotiations

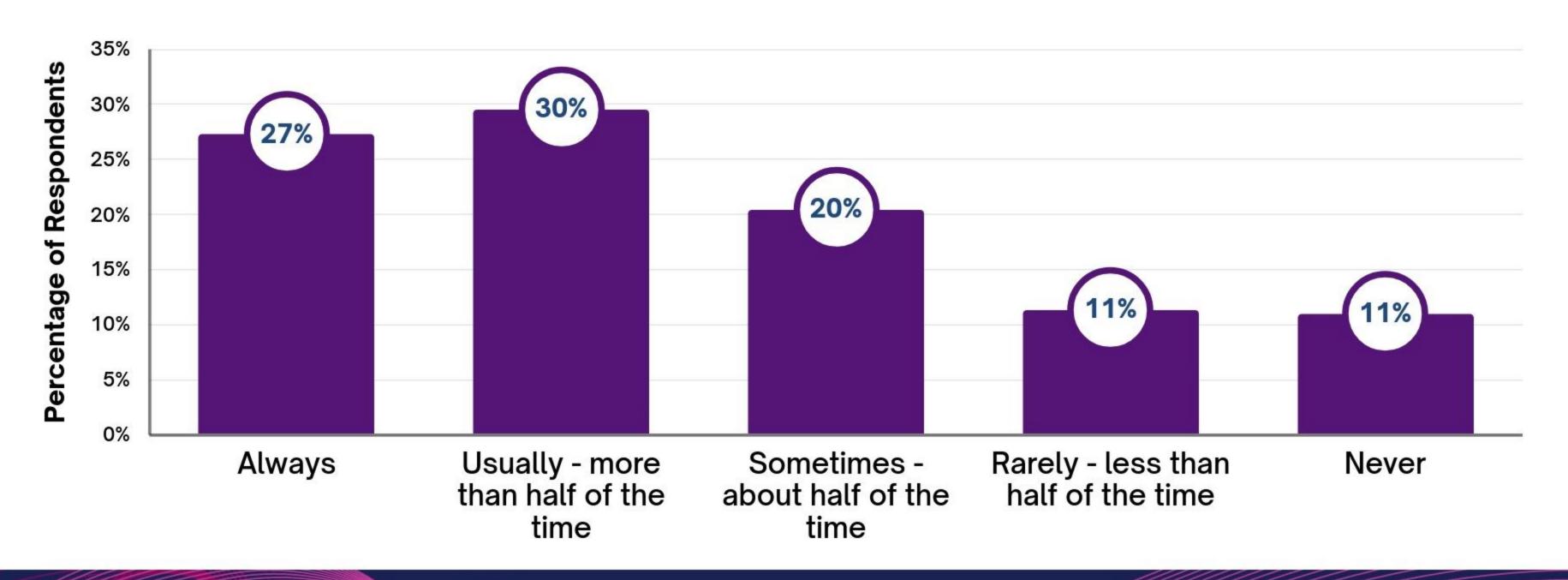
#3 answer globally



Detailed Justifications - 18%

Building and establishing effective and detailed justifications for budgetary items is essential

Frequency of Initial Budgets Received with 0% Withholding



Commonly Underfunded Budget Items



Startup Costs

Startup costs account for the largest share at <u>58%</u>, making them highly vulnerable to underfunding.



Screen Failure Reimbursement

With 50% of the budget allocated to screen failure reimbursement, this category is significantly affected by underfunding.



Training

Recruitment, at 41%, is the third-largest category impacted by underfunding.

Recruitment is number 3 globally at 42%

Effective Negotiation Strategies for Securing Budgets

Select up to 2



Better knowledge of our costs (61%)

Thoroughly understanding our own costs and expenses helps us build a more realistic budget proposal.



Improving our justification language (43%)

Using clear, persuasive language to justify our budget requests makes them more compelling.



Phone calls or meetings instead of emailing (37%)

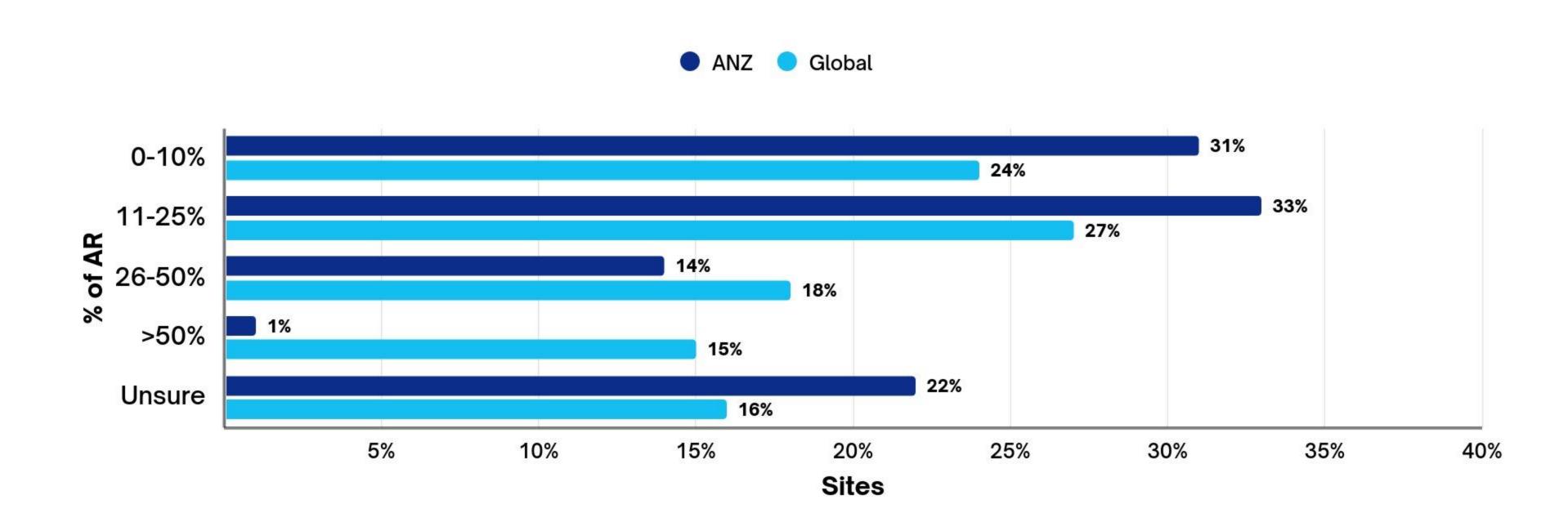
Face-to-face
communication allows for
more nuanced
negotiations and can lead
to better outcomes.



Being willing to walk away (25%)

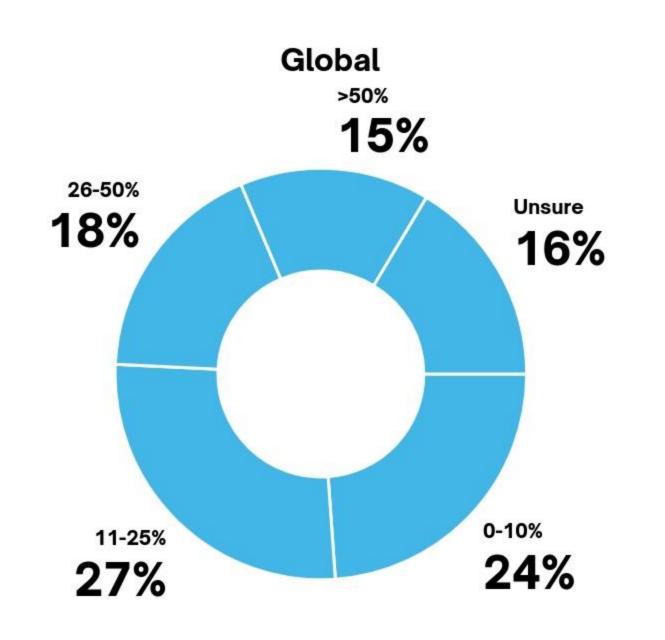
Maintaining leverage by being prepared to decline an unacceptable budget shows our commitment to fair negotiations.

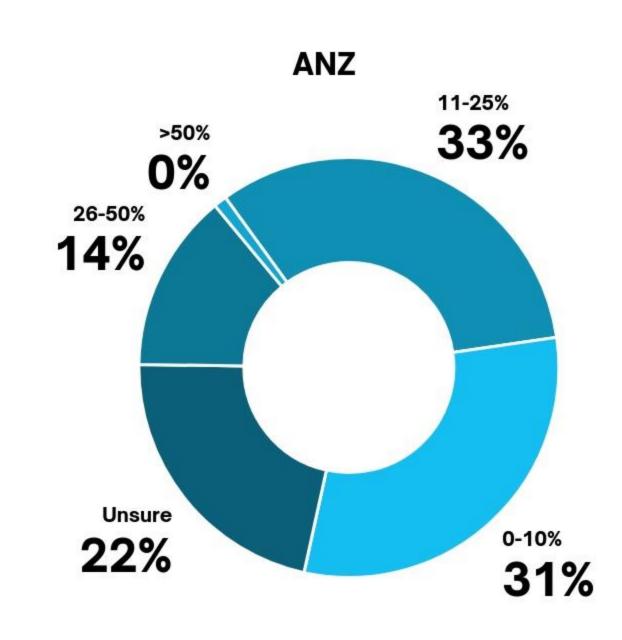
Average % of A/R 90+ Days Old



Finance and Accounting (A/R) Finalization Timeline

Average percentage of A/R over 90 days



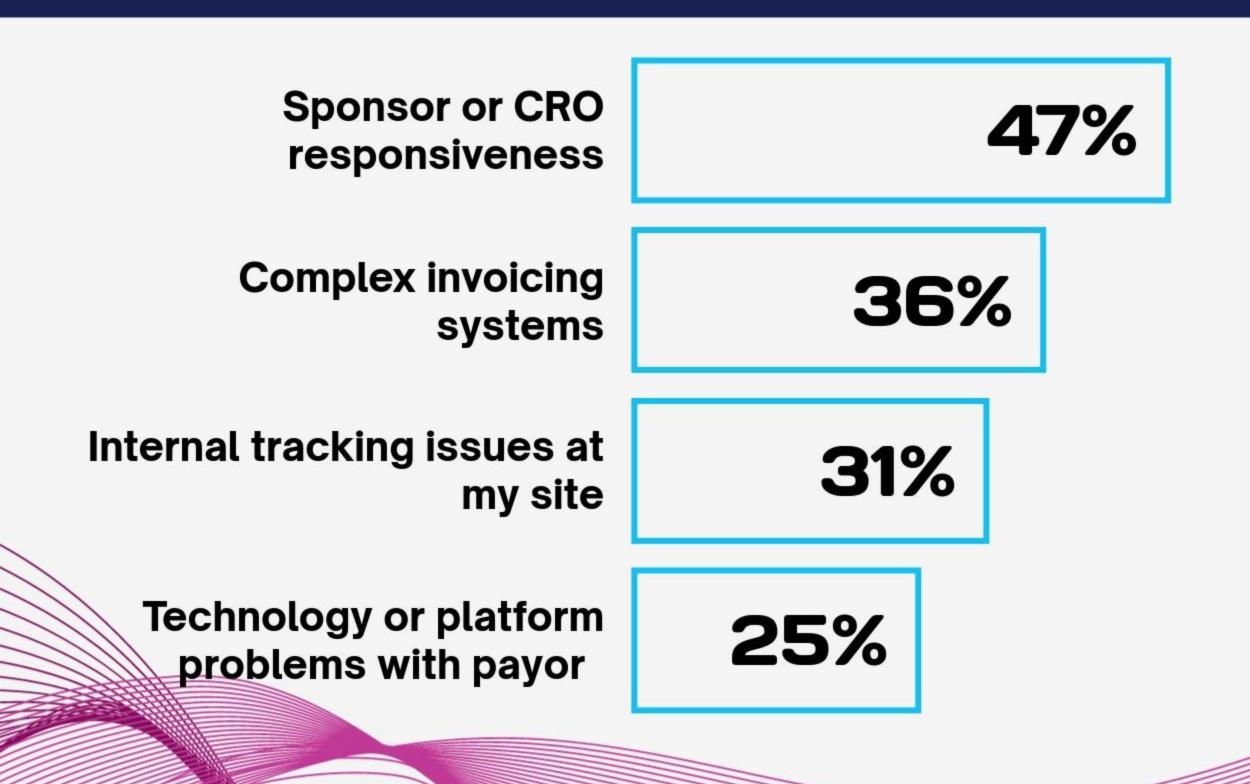


Over a third of sites report that at least 25% of their AR is greater than 90 days old globally, while a vast majority (63%) of ANZ sites report less than 25%

Primary Reasons for Delayed Payments



Select up to 2



Similar to Global Data

Improving Payment Timeliness and Tracking

Select all that apply



Dedicated staff/resources to accounts receivables (A/R) and payment management (67%)

Same Globally



Better internal tracking mechanisms (52%)

Developing robust systems to monitor payment status and follow-up



CTMS implementation and usage (33%)

Leveraging CTMS to streamline payment tracking and management



Clear communication of policy to Sponsors and CROs of escalation actions (14%)

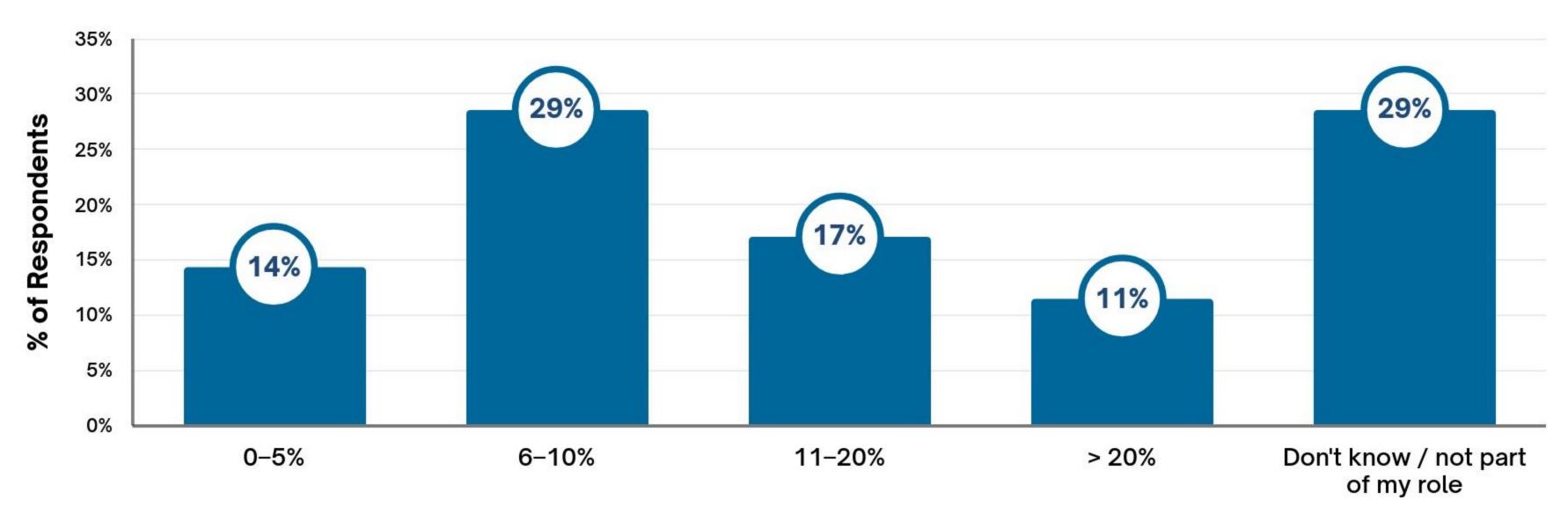
Proactively informing partners about payment policies and enforcement

By implementing a combination of technology, dedicated resources, and clear communication, sites can significantly improve payment timeliness and tracking.

Section 3

Site Operations

Operating Cost Increase in 2024



Operating Cost Increase

The majority of respondents experienced an operating cost increase between 6-10% in 2024.

Costs That Have Increased the Most

1 Salaries
ANZ - 80%

2 Regulatory Fees

ANZ - 24%

Global - 15% (#4)

3 Technology ANZ - 21%

Global - 26% (#2)

Costs That Have Increased the Most

Global - 26% (#2)

Salaries

80%

Regulatory Fees

24%

Technology

21%

Global - 15% (#4)

Changes That Helped Mitigate Rising Costs

We HAVEN'T been able to mitigate rising costs

Staff Restructuring

Lowering % pay increases

Using AI and technology to create efficiencies

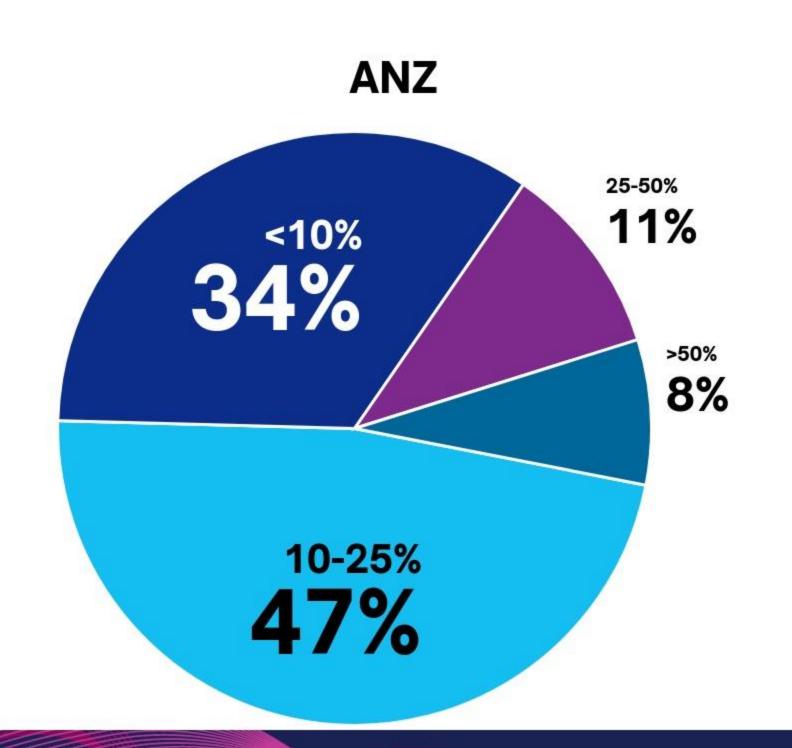
How Did Your Workforce Change In 2024?

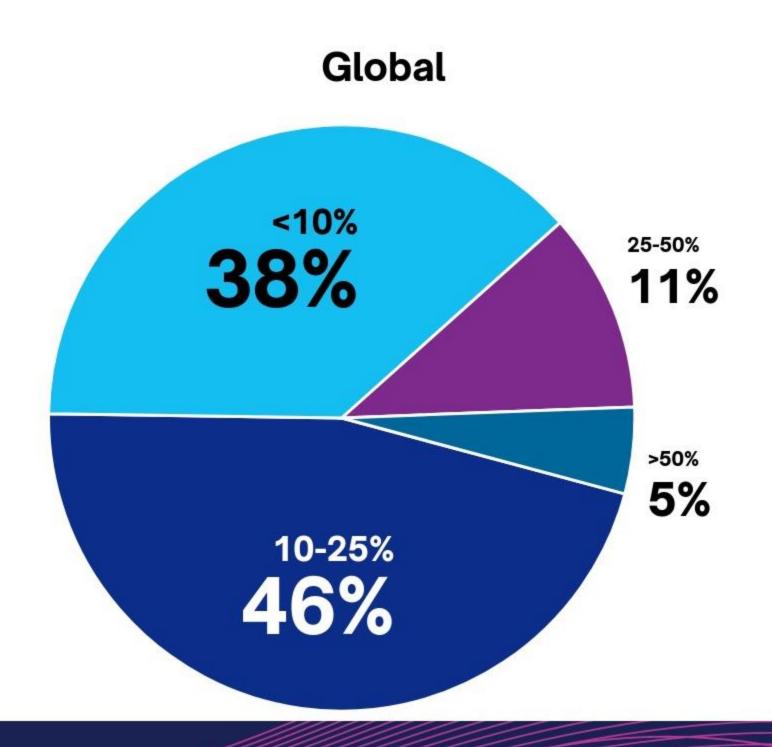


The majority of sites experienced an increase in staff numbers in 2024.

Workforce Growth

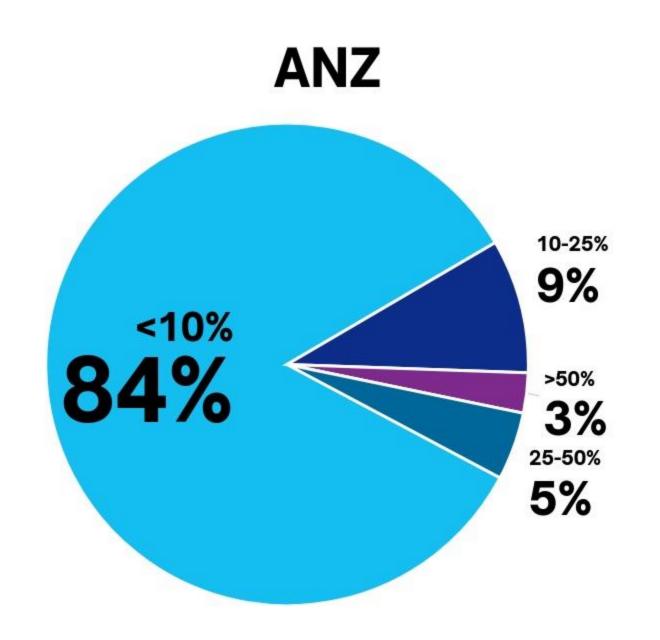
Changes in 2024 Staff Numbers

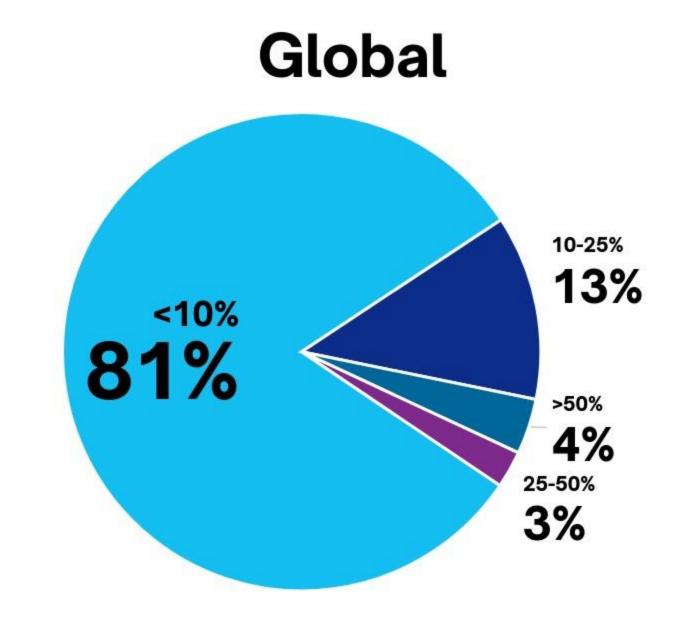




Workforce Decrease

Changes in 2024 Staff Numbers





Challenges with Staff Retention

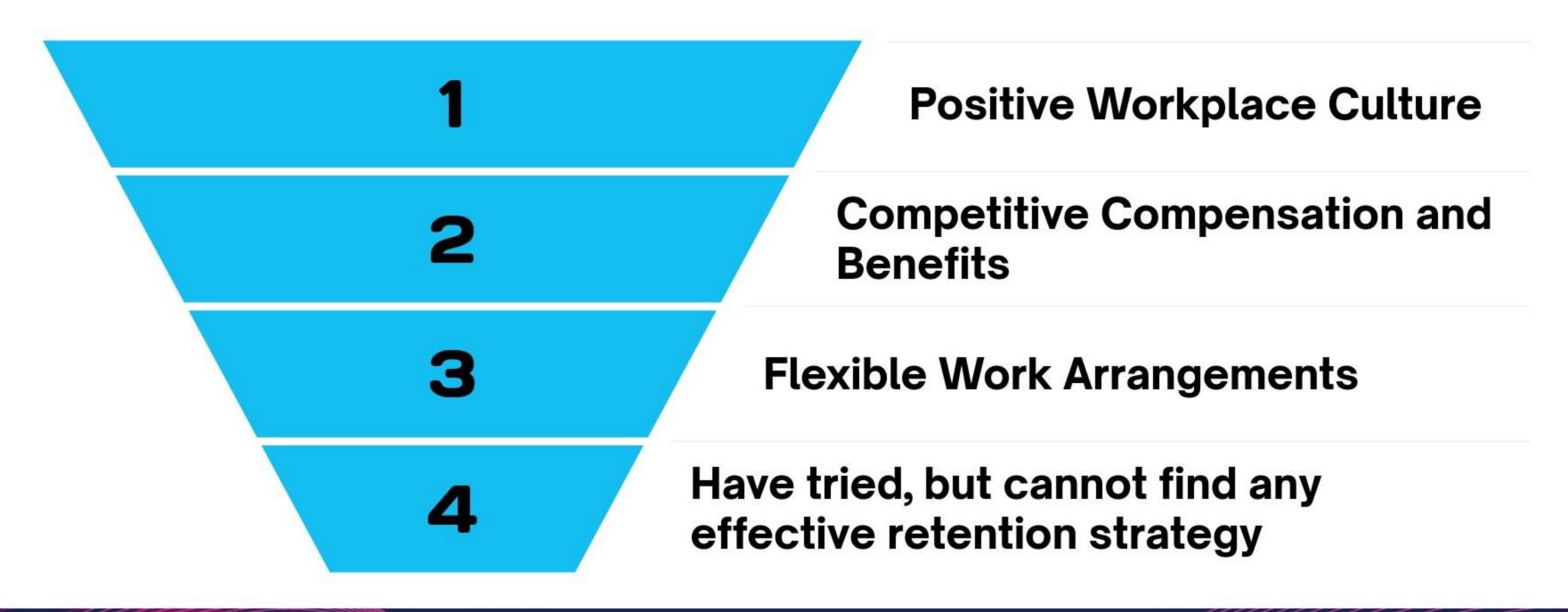
Choose up to 2

- Career Progression ~ 40%
- Salary Competition ~ 35%
- No Problems 22% ANZ
 15% Globally

- Burnout 19%
- Training needs ~7%
- Remote Work Limitations
 - 4% ANZ

12% Globally

Staff Retention Strategy with Greatest Impact



Section 4

Industry Priorities & Collaboration

2025 Site Priorities for Improvement



- 1 Staff Training and Capacity Building 55%
- 2 Faster Study Start-up 41%
- 3 Patient Recruitment and Retention 33%

4 Financial Management - 30%



BUSINESS DEVELOPMENT GCTMS ADOPTION

Actions from Sponsors & CROs to Positively Impact Site Operations

Select up to 3

Reduce or eliminate redundant site training

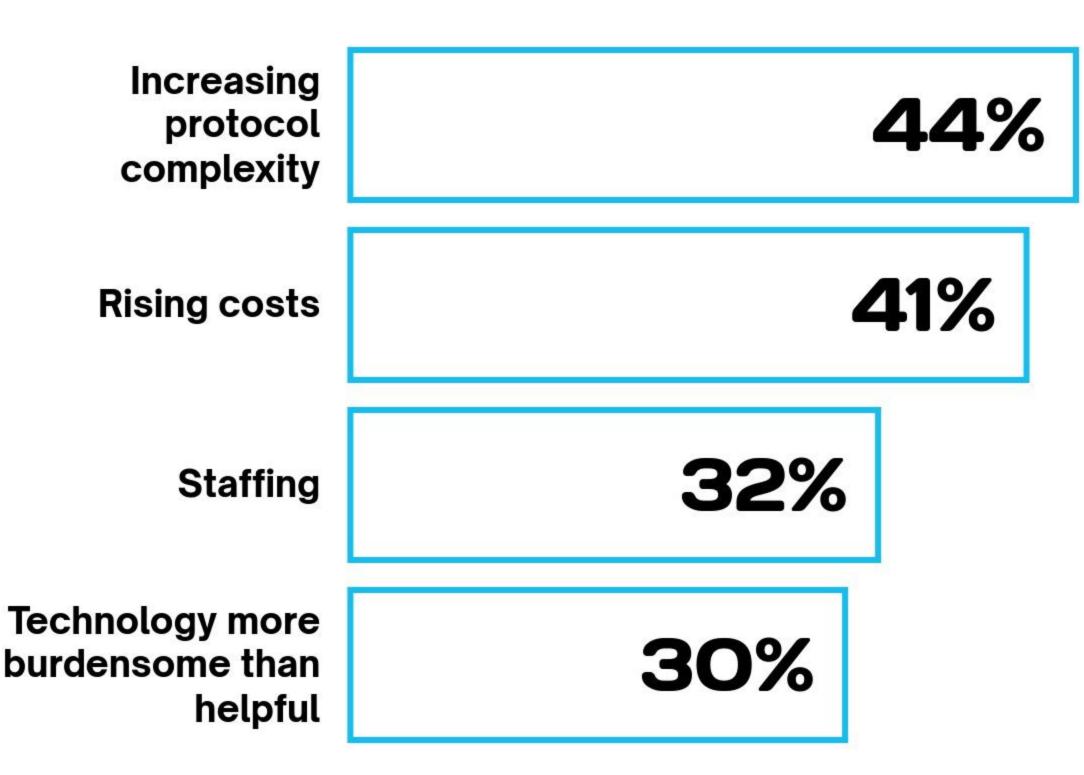
Cut 25 in 2025 anyone?

- 2 Having a single point of contact for the site
- Increase recruitment budgets

- 4 Simplify Protocols
- Increase recruitment budgets
- Improve the technology they required the site to use

Most Pressing Issues for the Industry in 2025

Select up to 3



Pressing Industry Issues: Anecdotal

ANZ-Specific

RGO Process Delays: Research Governance Office timelines are "embarrassingly slow, inconsistent and unreliable" - taking >8 weeks and no longer running parallel to ethics review HREC Capacity Issues: Human Research Ethics Committees are fully booked for months, adding significant delays to start-up and activation plans

Australia's Competitive Position: Rising costs exceed global fair market value benchmarks, making Australia less attractive for study placement

ANZ Increased Demand: With FDA uncertainty, more sponsors are looking to Australia/New Zealand, creating pressure on already stretched site capacity

Pressing Industry Issues: Anecdotal

Global Responses

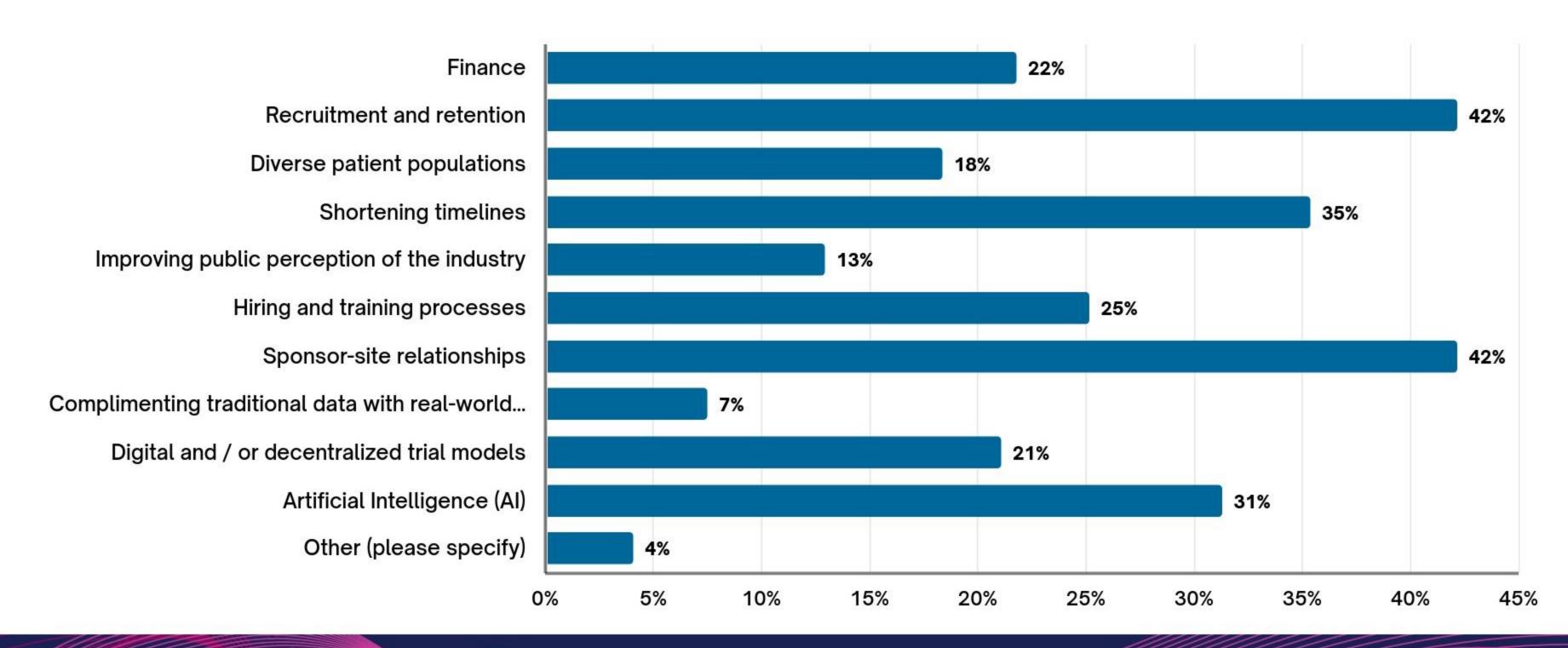
Protocol Complexity: 20+ page assessment schedules, require additional resources, have too many endpoints, and increasingly restrictive Inc/Exc

Workforce: High turnover rates, underpaid and undervalued, lack of professional recognition, risk aversion to the public health sector

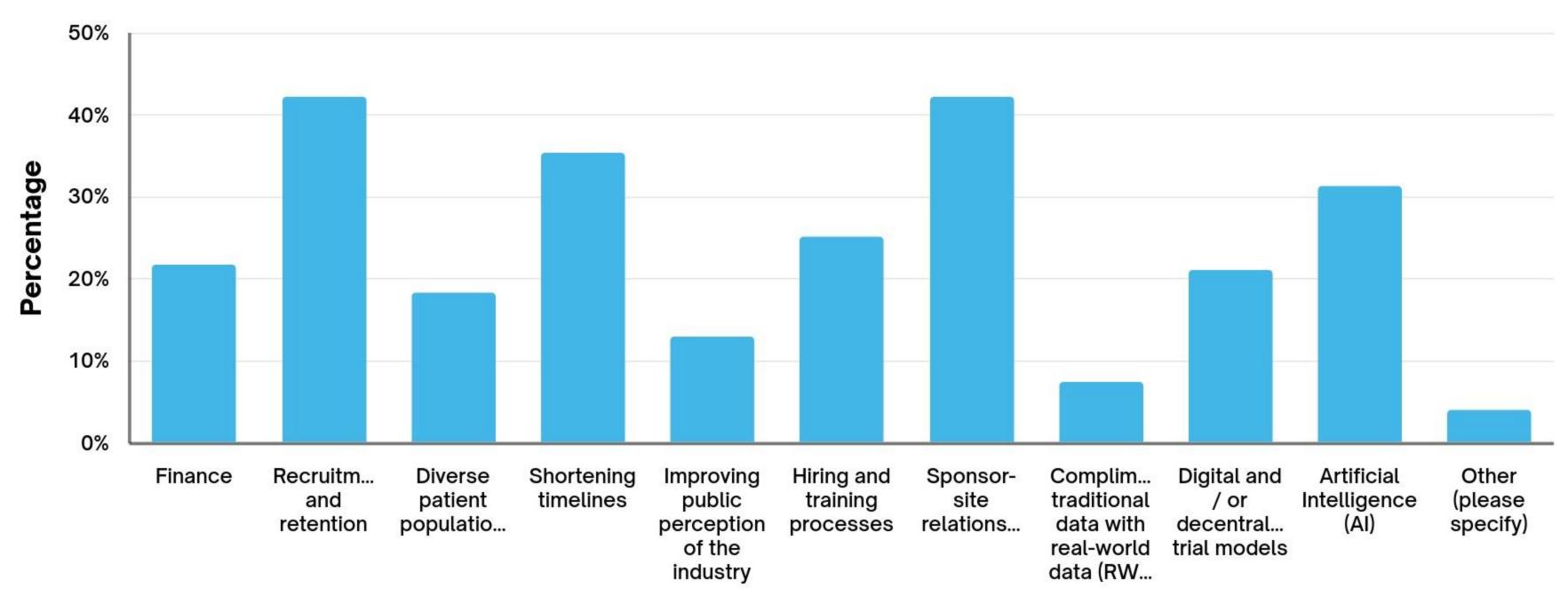
Recruitment and Retention: Public trust erosion, increasing participant burden, advertising budgets continue to constrict

Global Market Uncertainty: pipeline disruption, significant delays and cancellations, biotech funding reluctance, geopolitical pressures

Areas of Innovation Exploration



Areas of Innovation Exploration

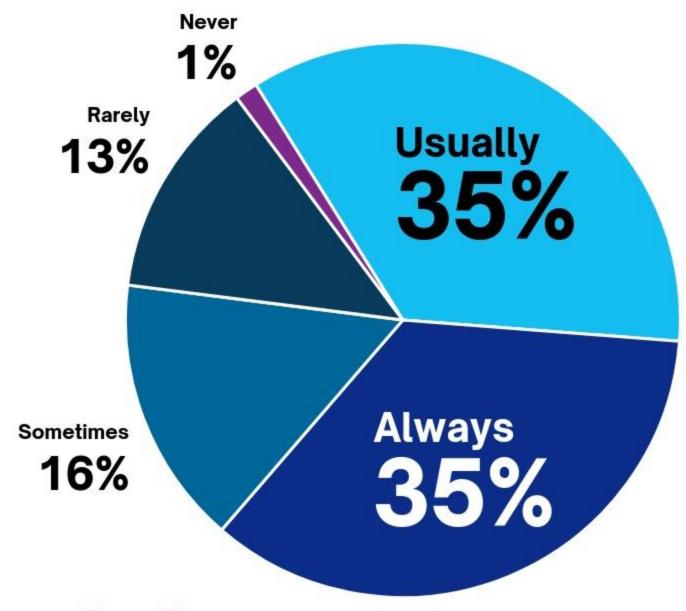


Areas of Innovation

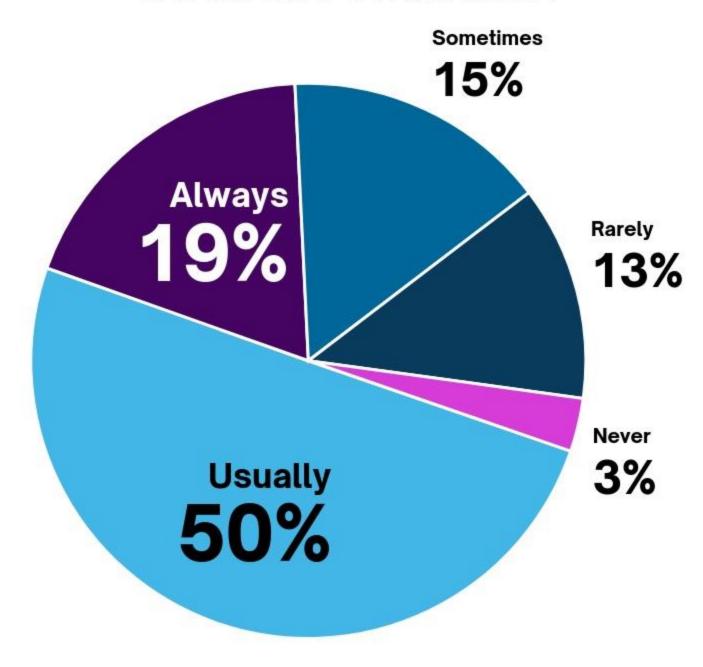
Site Communication

Answered by Sponsors and CROs

Single Point of Contact?



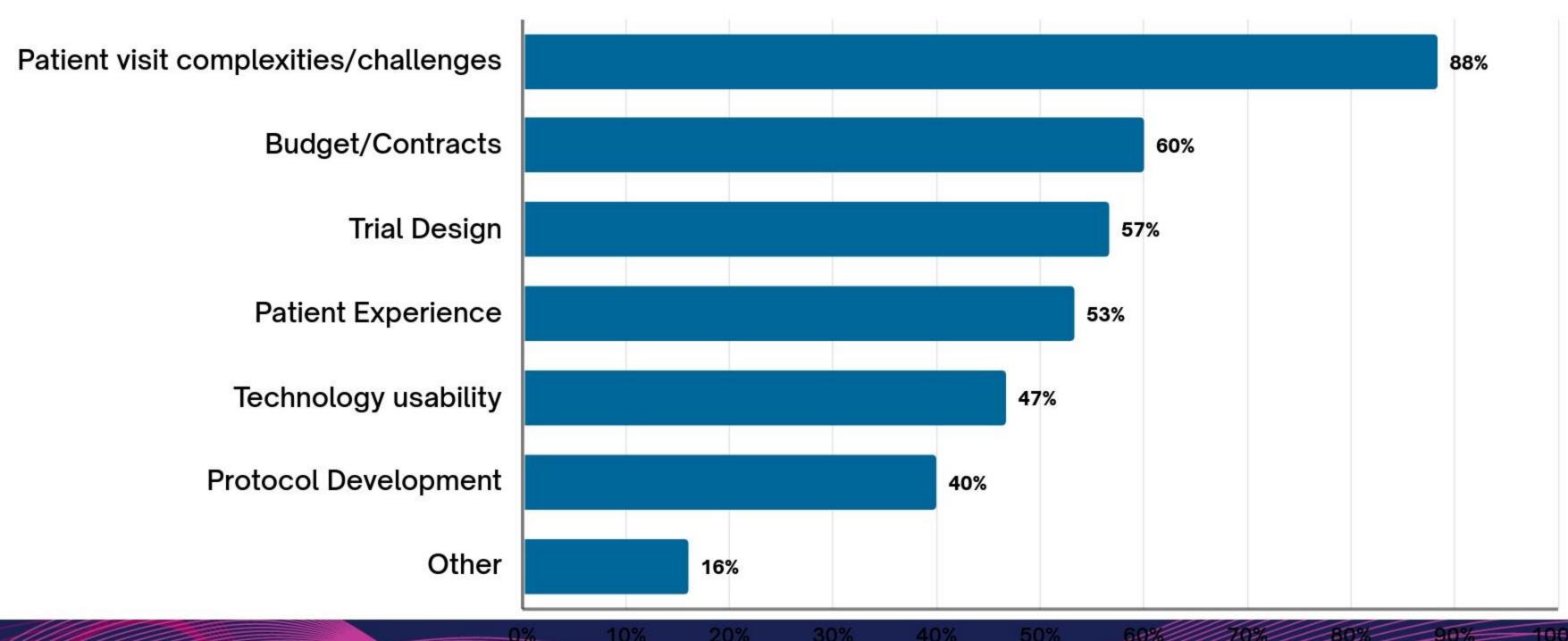
Collect Feedback?



Partner for Progress
INNOVATE FOR IMPACT

Areas for Site Feedback Requested

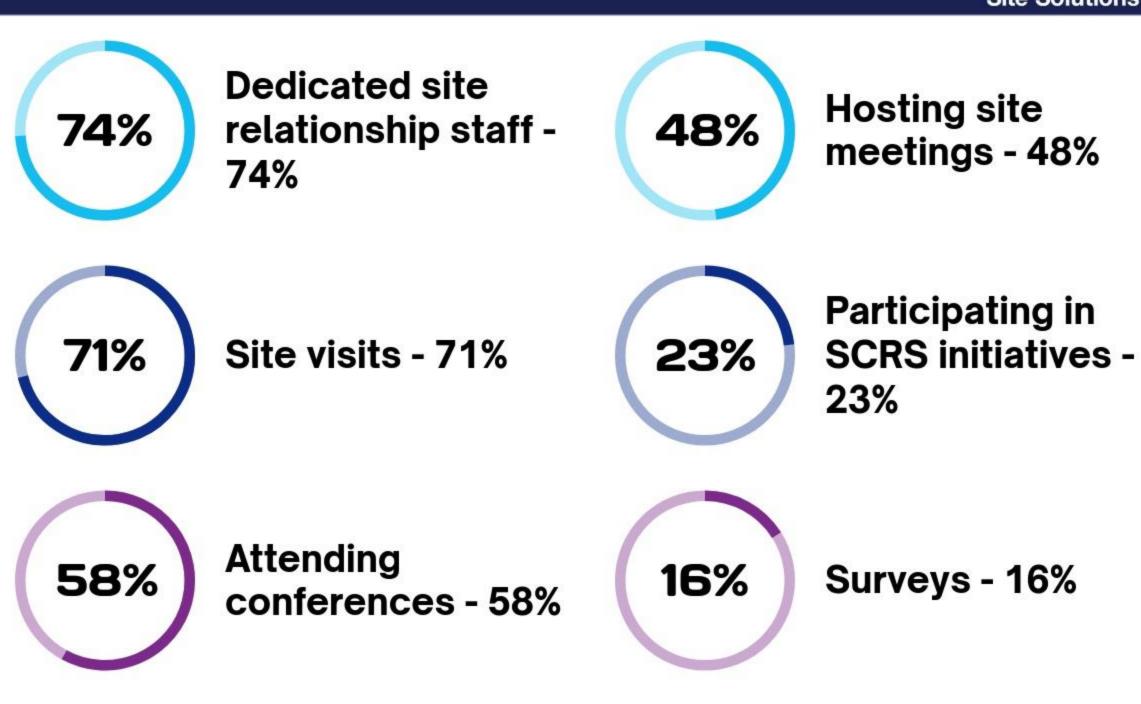
Select all that apply







Select all that apply







Improving Site Collaboration Tools

Select all that apply

 Dedicated site relationship staff - 74%

Assign staff to build and nurture relationships with individual sites

Site visits - 71%

Onsite visits to better understand site operations and identify areas for improvement

Attending conferences -58%

Connect with sites in-person to foster collaboration and share best practices

 Open communication channels - 58%

Enable easy, transparent communication between your team and sites

Hosting site meetings -48%

Bring sites together to discuss challenges and solutions collaboratively

Participating in SCRS initiatives - 23%

Engage with the Site Consortium for Research Sites to align on industrywide improvements

Surveys - 16%

Gather direct feedback from sites to understand their needs and pain points

