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WHITE PAPER

What keeps site leaders up at night?

Challenges we all face and best practices to overcome them

March 2025

In this white paper, we discuss strategies for site leaders around:

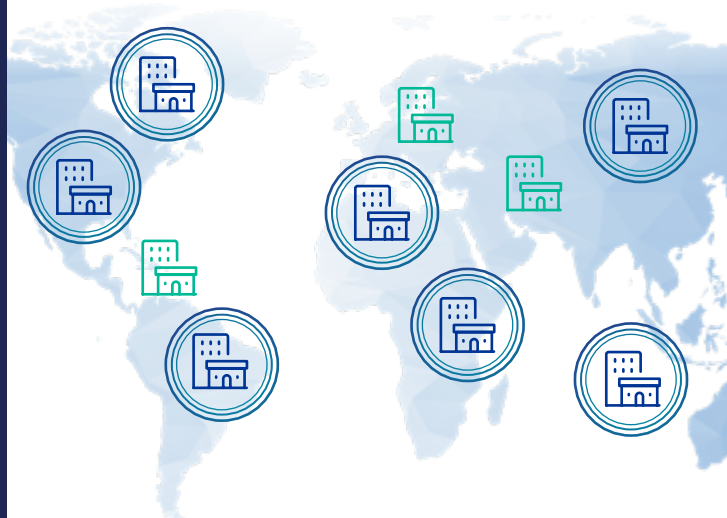
- Business development
- Staffing and resourcing within the sites
- Hidden costs and budget negotiations
- Managing fiscal health

Introduction

Do you often feel alone in your daily concerns—if so, don't be. Uncertainties around clinical trials that are beyond sites' control, such as business development, trial start-up, supply access, canceled trials, on-time payments, and early study closures, have long kept site leaders up at night, and the burden on clinical research sites continues to increase as clinical trials grow more complex.

70%

of global investigative site staff report that trial management has become more complex over the last 5 years.[1]



New and innovative drug classes, the increasing use of diagnostic and treatment biomarkers, evolving regulatory requirements, and the persistent desire to shorten drug development timelines have contributed to trial complexity. Other factors include regulatory mandates to include representative populations in clinical research, which can require additional safety assessments, dose modifications, and adaptive trial designs.

In phase III trials over the last 10 years:[2]

42%
increase in the number of procedures

37%
increase in the number of endpoints

In fact, trial complexity was the number one challenge cited by sites in 2024,[3] followed by study start-up (e.g., coverage analysis, budgets, and contracts), and site staffing. This set of the top site concerns is not surprising given that trial complexity contributes to challenges across the spectrum of site activities, including time constraints, appropriate staffing of experienced personnel, training to upskill staff, and being paid for the work performed.

Business development

In the highly competitive clinical research environment, standing out from other sites can be a daunting task that requires a strategic approach to communication and marketing your capabilities, participant population, and staff. This is especially true for individual sites trying to remain competitive among the trend of site consolidation into site networks. Working with a site network can be preferred by sponsors due to benefits such as a single point of contact and centralized functions (e.g., budgets, contracts, IT), standardized workflows and processes, SOPs that reflect best practices, less variability and more consistent data collection across sites, and geographic and therapeutic diversification.

Therefore, business development (BD) activities are key to being consistently awarded the most lucrative studies and maintaining a robust research portfolio.

These activities include:

- Building strong relationships
- Timely contact around funding activities for both large, mid and small sized sponsors
- Evaluating the feasibility of studies for the site
- Maintaining and sharing a comprehensive site profile

Relationships with sponsors and CROs form the foundation of a BD strategy because oftentimes the site's BD representative is their first point of contact. Building strong relationships rely on regular, clear communication; reporting on deliverables and any impacts to the study timeline and budget; and knowing how to navigate sponsor or CRO turnover. At the end of the day, sponsors and CROs want to know that they have a site partnership that will deliver high-quality, regulatory-grade data on time and on budget.

Making sure that your site conducts studies that are suitable for your site's capabilities, participant population, and therapeutic expertise sets the site up for success. Being involved in studies that are not a good fit could compromise the site's and principal investigator's reputations and the sponsor's or CRO's willingness to award future studies. For example, a lack of community contacts or participants with the condition of interest can result in poor recruitment and enrollment rates, while limited experience in the therapeutic area could produce low-quality data.

Therefore, BD teams have an important role in identifying suitable studies and assessing their feasibility before contracting to conduct them. Maintaining close contact with sponsors and CROs can assist with this because they are already familiar with the site's capabilities and the site's BD representative knows the types of studies typically conducted by the sponsor or CRO.

Additional strategies to identify and assess studies include monitoring clinical trial databases, attending industry conferences, and networking with others in the industry. When attending conferences and networking, having a comprehensive site profile ready to share streamlines the conversation. The site profile should highlight the staff's research and therapeutic area expertise, the site's facilities and equipment, participant population, community partnerships, recruitment and enrollment metrics, typical study start-up times, and other metrics that highlight the quality of research conducted by the site

Staffing and resourcing within the sites

Maintaining an appropriately sized and trained clinical trial workforce has been a challenge for over a decade.[4] High turnover is a true threat, and site staff often move for more competitive salaries or better work-life balance at CROs, sponsors, or sites in other locations. With a growing emphasis on conducting trials in underserved geographic areas and greater representation within study staff, this becomes an even larger issue.

35-61%
turnover rate for participant-facing clinical research professionals[5]

In addition to not being able to efficiently operate, staff reductions imperil the quality of research, study timelines, participant enrollment, compliance with good clinical practice, and data integrity. Furthermore, they affect relationships with sponsors and CROs as well as the participant experience. Having a consistent site contact(s) is important to instilling trust for all stakeholders in the trial conduct as well as upholding safety. Moreover, turnover places a greater burden on remaining staff who need to take on extra responsibilities and train new team members.

We've found that the following strategies assist with staff retention:

- Having a positive, inclusive workplace culture
- Providing professional development and training opportunities
- Outlining career advancement and enrichment pathways
- Maintaining open communication between site leadership and the rest of the team
- Incorporating staff feedback into processes and procedures
- Recognizing and celebrating achievements
- Understanding and discussing market comps and being creative around incentive plans

Hidden costs and budget negotiations

Sponsor and CRO budgets often use "fair market value" and therefore do not always accurately reflect each site's expenses for conducting a clinical trial. With average estimated costs of $41,413 per participant in a clinical trial,[6] underestimated expenses in a proposed budget can have a significant effect on a site's financial health when they are compounded over multiple participants. Therefore, establishing an initial robust internal budget and continuing to negotiate expenses with the sponsor or CRO help ensure that sites receive appropriate compensation for trial activities. In addition, renegotiating as costs change is just as important as the original negotiation activities.

To determine the estimated costs associated with a clinical trial, thoroughly review the protocol, sponsor/CRO budget, and any accompanying documentation. In addition, consider any expenses that the sponsor or CRO has not included in the budget but are fundamental to trial conduct such as the time and effort from research staff (e.g., investigator, study coordinator, and data manager).

Potential protocol amendments also occur for 82% of phase III studies,[3] and protocol-specific training can take 5-15 hours per month and is overlooked in the budget by 40% of sites.[7] Participant recruitment costs can also account for substantially higher costs than amendments and training and are typically not covered by the sites.

$3,685
median cost for each site visit[6]

Establishing and using a budget grid template can expedite this process and make sure that nothing is overlooked with each new study. This analysis helps calculate the direct per-participant costs within the internal budget and the coverage analysis, which identifies a payer (e.g., insurance, sponsor/CRO) for each item. In addition, consider which items are non-negotiable and which have some flexibility before entering budget negotiations. Document the reasoning for all costs. For this, justification letters are useful, especially when supported by other resources such as regulations, journal articles, and internal processes and procedures when available. Having these on hand prior to any budgeting takes some time up front but speeds up the process for each study.

Finally, establishing and maintaining good rapport with the sponsor or CRO contact is essential to a good working relationship during this process, and starting the negotiations early helps ensure no stakeholder feels rushed or pressured.

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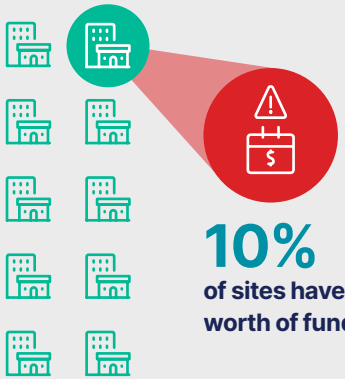
Managing fiscal health

Having internal budgeting processes in place, paired with keen negotiating skills, contribute to strong fiscal health for sites. Also key is the ability to effectively manage accounts receivable, which continues to be a challenge for sites, especially around how to effectively speed up the process to maintain healthy cash flow. Compromised cash flow, such as by long collection periods after study completion, constrains a site's cash reserves. This could potentially result in an inability to cover operating expenses and effectively conduct studies.



10%

of sites have <1 month's worth of funds[7]

34%

of sites experienced a decline in operating capital over the last year[7]

While negotiating the budget with the sponsor or CRO, consider discussing payment terms as well, including shorter net terms, minimizing or eliminating holdbacks, and shortening lead times between SIV and first payment. Although monthly payment agreements have become more common, approximately 50% of sites still operate under quarterly payment schedules.[7]

However, even with better payment terms, sites might need to work with sponsor and CRO partners to streamline and expedite payment processes. For example, one-quarter of sites have a significant proportion of invoices that have been overdue for >90 days.[7]

Finally, an agreed-upon financial escalation plan can help collect payments when they become overdue. As with budget negotiations, open communication and maintaining good relationships with the sponsor or CRO benefit a site's financial health.

Develop your business, staff, and budget with confidence

As with every aspect of clinical trials, early planning and preparation can minimize the stress associated with day-to-day site operations and sponsor/CRO communications. Strategies for staff retention should be built into site operations and communicated clearly to all team members, helping minimize turnover and the subsequent disruption to other team members and ongoing studies. Clear policies and procedures for budgeting, financial negotiations, and communication as well as having a toolbox of supporting documentation streamline activities that are required for each study and can improve site financial health.

Although there will always be uncontrollable factors in clinical trials, their disruptive effects can be mediated by systematic approaches to site operations, which can also help site leaders sleep better at night.

References

1. Global sites optimistic about the future of clinical trials despite ongoing challenges. Impact report: analysis and insight into critical drug development issues. Tufts Center for the Study of Drug Development. January/February 2023;25(1).

2. Protocol design scope and execution burden continue to rise, most notably in Phase III. Impact report: analysis and insight into critical drug development issues. Tufts Center for the Study of Drug Development. May/June 2023;25(3).

3. 2024 Clinical Research Site Challenges Report. WCG. October 2024. Available at: https://www.wcgclinical.com/wp-content/uploads/2024/10/WCG_2024_Clinical_Research_Site_Challenges_Report.pdf

4. Freel SA, Snyder DC, Bastarache K, Jones CT, Marchant MB, Rowley LA, Sonstein SA, Lipworth KM, Landis SP. Now is the time to fix the clinical research workforce crisis. Clin Trials. 2023;20(5):457-462. doi: 10.1177/17407745231177885

5. Open Letter to Sponsor and CRO Colleagues Regarding the Workforce Retention and Inflationary Pressures Affecting Clinical Trial Sites. Society for Clinical Research Sites (SCRS). Available at: https://myscrs.org/workforce-challenges-letter/

6. Moore TJ, Heyward J, Anderson G, Alexander GC. Variation in the estimated costs of pivotal clinical benefit trials supporting the US approval of new therapeutic agents, 2015-2017: a cross-sectional study. BMJ Open 2020;10(6):e038863. doi: 10.1136/bmjopen-2020-038863

7. Bechtel J. The Results Are In — Survey Reveals Barriers & Opportunities In Site Sustainability. Clinical Leader. March 27, 2024. Available at: https://www.clinicalleader.com/doc/the-results-are-in-survey-reveals-barriers-opportunities-in-site-sustainability-0001

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Headlands Research is a multinational integrated clinical trial site organization with a mission to improve lives by advancing innovative medical therapies. Its network of sites focuses on large-volume recruitment and retention of diverse, inclusive populations through its extensive site databases and physician partnerships. With key opinion leaders, experienced principal investigators and site staff, and a broad range of therapeutic area expertise, the sites deliver meaningful participant experiences, operational excellence, and the highest quality data. To date, Headlands Research has successfully supported more than 5,000 clinical trials. Additional information about the company is available at www.headlandsresearch.com.

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