Incremental Insights into Clinical Trial Site Networks

Key Takeaways from the SCRS Global Site Solutions Summit

The Bourne Partners team attended the *Society of Clinical Research Sites (SCRS) 2024 Global Site Solutions Summit* in Florida this week to get incremental visibility into the trends impacting the clinical trial site space. We continue to expect ongoing consolidation of clinical trial sites into larger site networks (or site management organizations) in the coming years. In our view, the rise of site networks is bringing much needed economies of scale to an otherwise fragmented universe of standalone clinical trial sites.

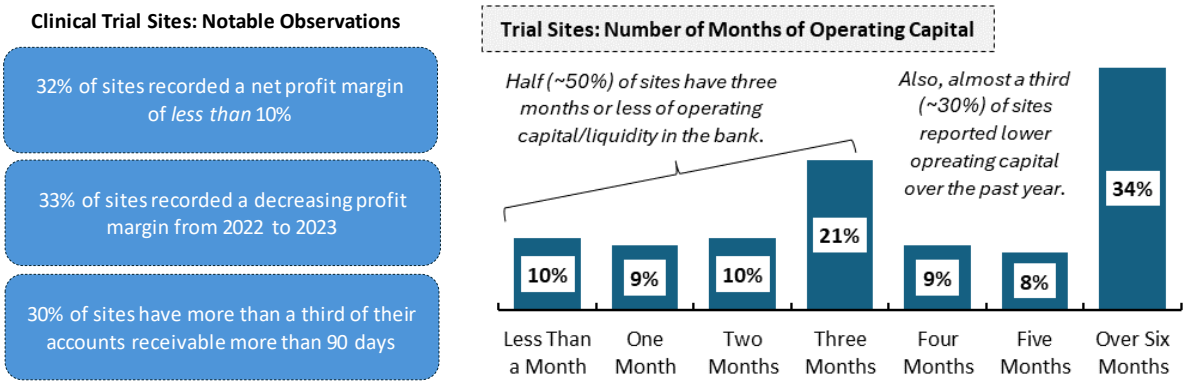
For more discussion, see our recent research report: Clinical Trial Site Networks: Market Research Update *(September 2024).*

Take Away 1:

A Challenging Environment for Standalone Clinical Trial Sites

We see the clinical trial site landscape as overly fragmented, mostly consisting of single standalone sites that lack the economies of scale to absorb rising labor costs, the increasing burdens of information technology adoption, and the administrative challenges of supporting more complex clinical trials. Our thesis was reinforced by our attendance at the Summit this year. Data from the *SCRS Annual Site Landscape Survey* (released at the Summit) confirmed that standalone sites are indeed struggling financially. A third of the sites in the survey reported lower year-over-year profit margins and cash reserves. And, half (~50%) of clinical trial sites in the survey reported having less than three months of operating capital (cash on hand) in the bank. Refer to Figure 1.

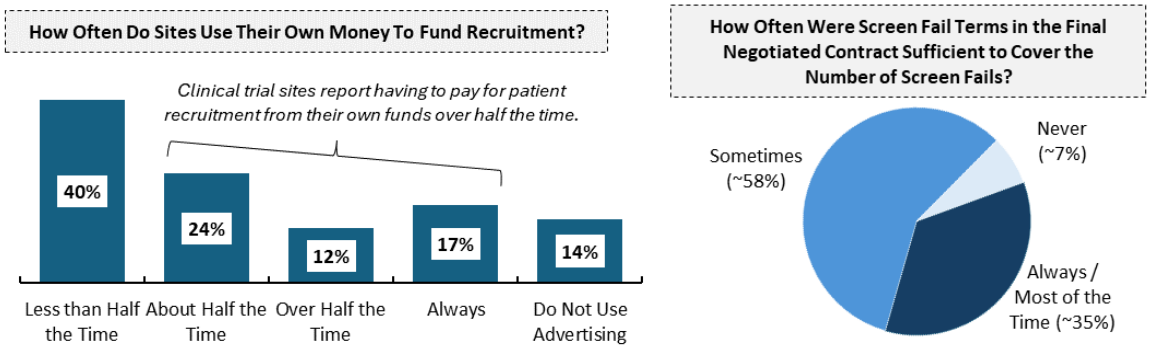
Figure 1: Many Standalone Clinical Trial Sites Are Operating on "Shoe-String" Budgets



Source: The Society for Clinical Research Sites (SCRS) Annual Site Landscape Survey (September 2024) and Bourne Partners

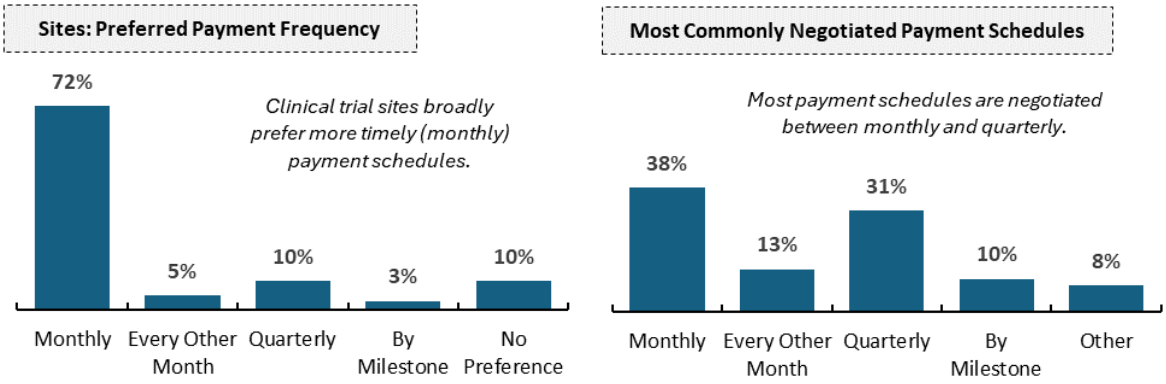
More specifically, **we heard three common challenges at the panel discussions at the Summit that seem to be exacerbating the financial struggles of standalone sites.** First, more often than not, sites are not getting fully funded by sponsors for their patient recruitment costs. This has resulted in many sites having to dip into their own cash reserves. We think site networks are better able to pool advertising and marketing resources and extend outreach campaigns across broader geographies. So, we suspect this has been more of a problem for standalone sites. A second area of financial pressure is time-consuming and costly screen fails, e.g., situations when a site goes through the entire screening process for a patient only to find an exclusionary data point that disqualifies the patient. A simple fix here would be to negotiate payments on a "per procedure" basis. Finally, payment schedules continue to be suboptimal. A solid majority of clinical trial sites (72%) prefer monthly payment schedules, but only ~38% are able to negotiate them. Adding to this, withholding rates remain high, which is resulting in sites not getting paid for a portion of their work for several years (often after the study is closed). Refer to Figures 2 and 3.

Figure 2: Sites Struggling with Costs Related to Patient Recruitment and Screen Fails



Source: The Society for Clinical Research Sites (SCRS) Annual Site Landscape Survey (September 2024) and Bourne Partners

Figure 3: Sites Struggling to Negotiate Favorable Payment Schedules



Source: The Society for Clinical Research Sites (SCRS) Annual Site Landscape Survey (September 2024) and Bourne Partners

Take Away 2:

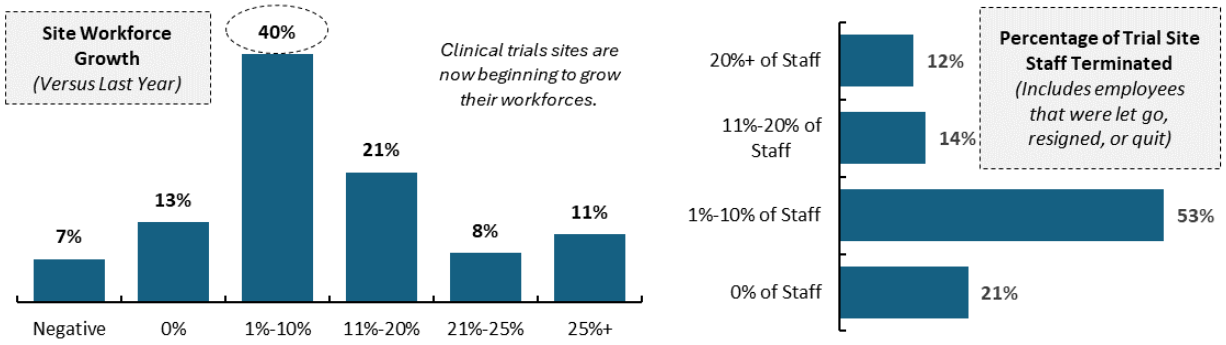
The Labor Environment Appears to Have Stabilized

One piece of good news is that the labor environment for clinical trial sites is finally showing signs of stabilizing (or at least not getting worse), in our view. We heard this from a number of site networks that we spoke with at the Summit, and this was further backed by fresh data from the SCRS survey itself. This would bode well for the operating margins of smaller independent sites that were disproportionately negatively impacted by industrywide labor shortages over the past few years. Specifically, ~38% of survey respondents reported that clinical trial site staff turnover has improved over the past two years (vs 28% who said it has worsened and ~24% who said it has remained the same). Also, most sites have been able to grow their workforces over the past year with only ~7% of sites reporting a declining workforce. Finally, the survey suggested an average clinical trial site employee turnover rate in the single digits (including staff who were let go, resigned, and/or quit). This would compare very well to the general healthcare labor turnover rate, which we believe has been running in the high teens over the past three years. Refer to Figure 4.

Also, **we think clinical trial sites are getting better at engaging with and retaining employees** without resorting to significant wage increases and/or bidding wars over key personnel. There were a number of panel discussions at the Summit focused on how sites can better manage and maintain their staff, while growing in a labor constrained environment. Key strategies included offering employees with flexible hours and schedules, remote working arrangements, and training and professional development opportunities. We see larger site networks as having a distinct advantage here (vs single independent sites) with the larger site networks being able to use their size to better scale staff and to offer junior employees greater flexibility with career development.

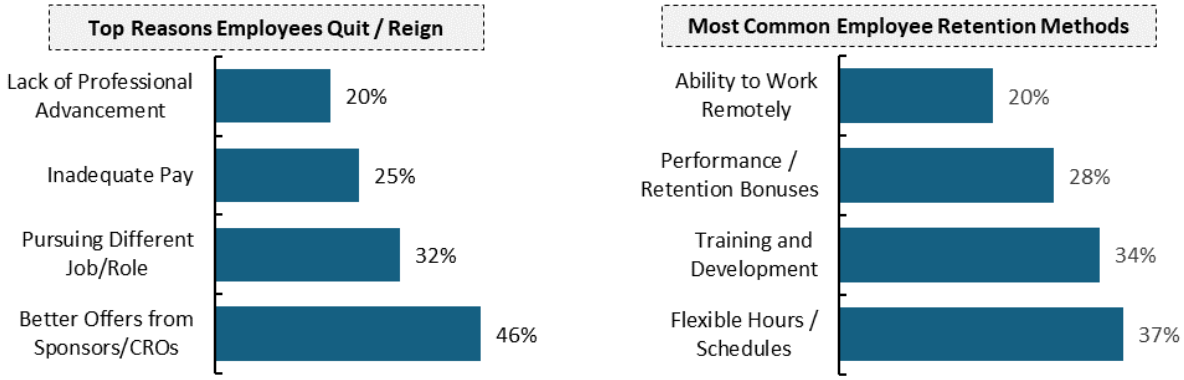
The most common reasons for site staff turnover included (among others): more attractive offers from sponsors and CROs, individuals pursuing different lines of work, inadequate pay, and lack of professional development opportunities. Refer to Figure 5.

Figure 4: Signs of a Stabilizing Labor Environment for Clinical Trial Sites



Source: The Society for Clinical Research Sites (SCRS) Annual Site Landscape Survey (September 2024) and Bourne Partners

Figure 5: Drivers of Labor Turnover and Common Employee Retention Methods



Source: The Society for Clinical Research Sites (SCRS) Annual Site Landscape Survey (September 2024) and Bourne Partners

Take Away 3:

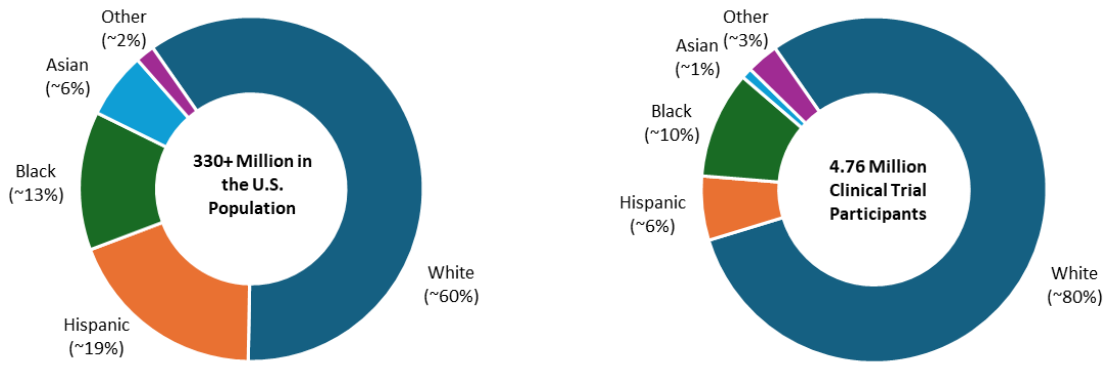
A Long Road Ahead Towards Clinical Trial Diversity

In our view, **there was cautious optimism at the Summit on the recently proposed guidance from the U.S. Food and Drug Administration (FDA) on clinical trial patient diversity.** In June 2024, the FDA issued long-awaited draft guidance that would require participants in Phase III (and other pivotal) clinical trials to be more representative of the patients who will be ultimately using the treatments being evaluated. Sponsors, CROs, and sites all seemed to comment that this proposed regulation is elevating the discussion around the need for greater clinical trial diversity. However, there was also a level of cynicism around the likely regulatory follow-through. The ultimate test will be the enforcement of these regulations. Will the FDA actually reject a life-saving compound based on the perceived degree of diversity of the clinical trial? Refer to Figure 6.

Another challenge that came out of the panel discussions at the Summit will be costs. The pursuit of patient diversity will be expensive, and many sites are already struggling financially and are not in the position to bear additional financial burdens. Improving diversity will involve incremental costs because sites in underserved communities are often in need of updated equipment and facilities. Also, these communities may need extra engagement and education given a currently low level of trust of the pharma industry in many minority communities. Moreover, many patients in these communities may require incremental training with respect to the use of technology, and others may not have reliable WiFi access. Finally, for much of the population in an underserved area, there might not be easy access to EHR data, and many individuals may simply not have a primary care provider. It is possible for

the site to set up a health check-up for a clinical trial participant; however, the costs associated with the check-up would need to be covered by the sponsor. Altogether, clinical trial diversity will necessitate backup data collection strategies and elevated feasibility planning prior to the start of a clinical trial.

Figure 6: Discrepancies Between Clinical Trial Participation and Broader Demographics



Source: Avalere Health, "Reducing Disparities in Medicine: Advancing Equity in Clinical Trials" (September 2022) and Bourne Partners

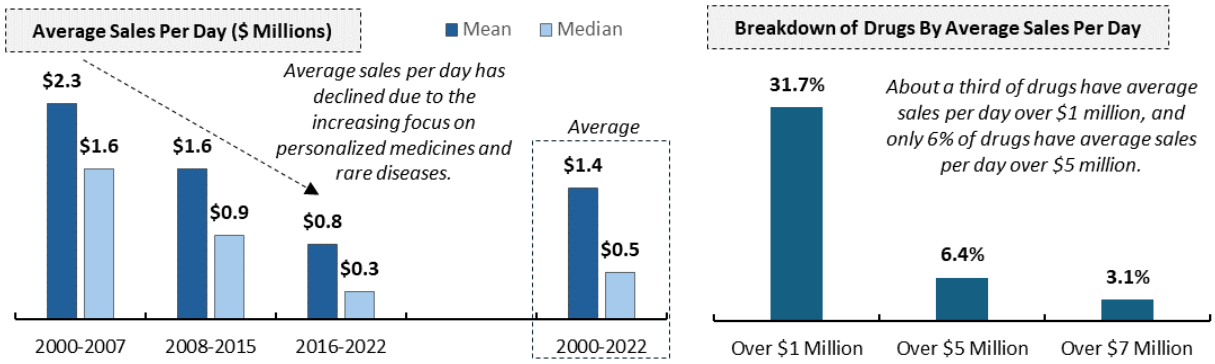
Regardless of one's outlook on new diversity regulations, **we think that market forces are already driving greater clinical trial diversity** since sponsors are realizing that, to be competitive, they need clinical data that is aligned with the demographics of the patients who will ultimately be consuming their products. Over time, sponsors can build trust with minority populations by choosing to consistently work with local sites in these communities. In our view, this will likely put a significant premium on clinical trial sites located in areas with diverse populations (i.e., a high proportion of Hispanic and/or black people).

Take Away 4:

Opportunities for Improved Execution Through Site Networks

The greatest single cost for a drug developer, *by far*, is a day delayed in a clinical trial. Perhaps *the* top driver of clinical trial delays is slower than expected patient recruitment. Herein lies the value proposition of an effective clinical trial site. Specifically, **each day that a clinical trial is delayed represents, on average, lost sales revenue of $1.4M per day (mean) or $0.5M per day (median) for the sponsor**, according to just released analysis from the *Tufts Center for the Study of Drug Development*. For drugs with more significant end markets (~6.4% of drugs), a day delayed can represent lost sales revenue of upwards of $5M per day. This highlights the value of timely patient engagement for the sponsor. The average total clinical trial budget is $24.8M (mean) or $9.4M (median). So, a few weeks delay of a clinical trial can easily result in a greater economic cost for the sponsor than the entire budget for the clinical trial itself. Refer to Figure 7.

Figure 7: New Data Suggests a Day Delayed Costs $0.5M in Lost Sales Revenues (Median)



Source: Smith, Z, DeMasi, J, Getz, K. New Estimates on the Cost of a Delay Day in Drug Development. Ther Innov Regul Sci. 2024; 58(5):855-862

Recognizing this, **clinical trial sites conceptually should command a significant value proposition.** However, in our view, many standalone clinical trial sites lack the negotiating power and in-house sophistication to realize their full value. Many providers appear to operate clinical trials as "side businesses" (or even as a "hobby" according to one site we spoke with). We see larger site networks being able to bring greater focus and sophistication to contracting and budgeting. Site networks give sponsors and CROs a chance to standardize and consolidate their contracting and we expect to see an increasing use of strategic partnerships (preferred provider arrangements) -- similar to those that we have seen develop between sponsors and CROs over the past decades.

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