Workforce Challenges at Clinical Research Sites

SCRS
Society for Clinical Research Sites

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Introduction

Since the COVID-19 pandemic began, changing macro- and micro-economic factors have continued to impact all industries, and clinical research is no different. With unprecedented workforce challenges and increasing costs, clinical research sites – already experiencing operational pressure as previous surveys have shown – are struggling to recruit and retain qualified staff. The impacts of turnover and other recruitment and attrition issues are far-reaching, and span the lifecycle of pharmaceutical development.

For the first time, The Society for Clinical Research Sites (SCRS) has conducted a global survey to explore the current workforce challenges at clinical research sites and understand the impact they are having on the clinical research industry. Through these insights, SCRS is developing resources and potential actions industry stakeholders can employ to cooperatively improve the situation in the interest of productive, successful clinical development.

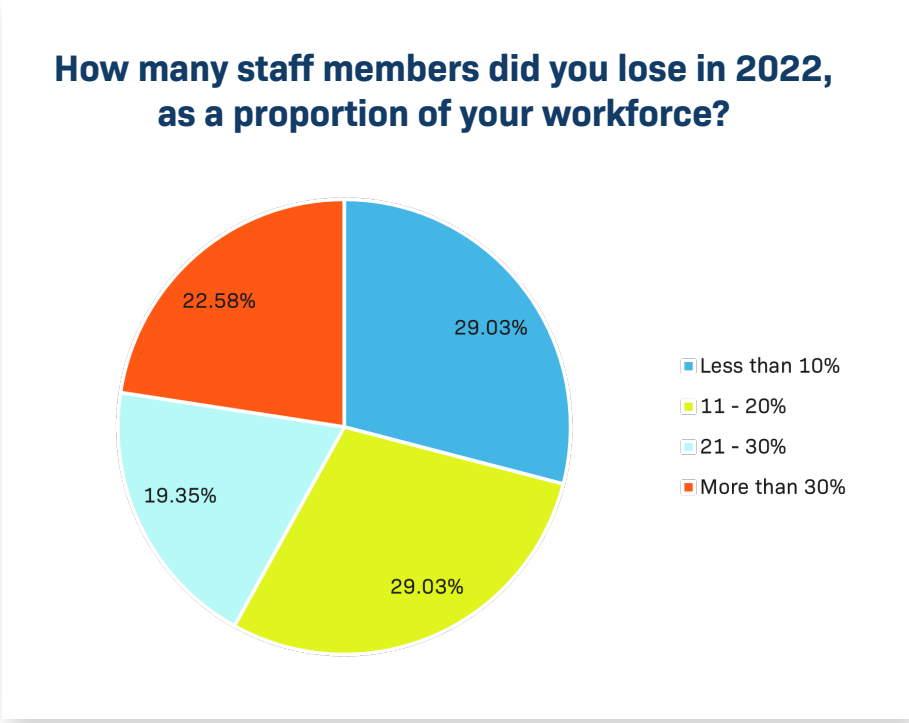
Workforce Challenges for Clinical Research Sites

ATTRITION

In highly specialized industries such as clinical research, with its relatively limited pool of qualified staff, professionals moving from organization to organization is inevitable. However, the collective feedback SCRS has received from sites responding to the survey indicate that the current turnover rate of patient-facing staff is much higher than in previous years: Sites are averaging double the usual turnover rate of patient-facing staff from a range of 10%–37% in a typical year to current rates of 35%–61%.

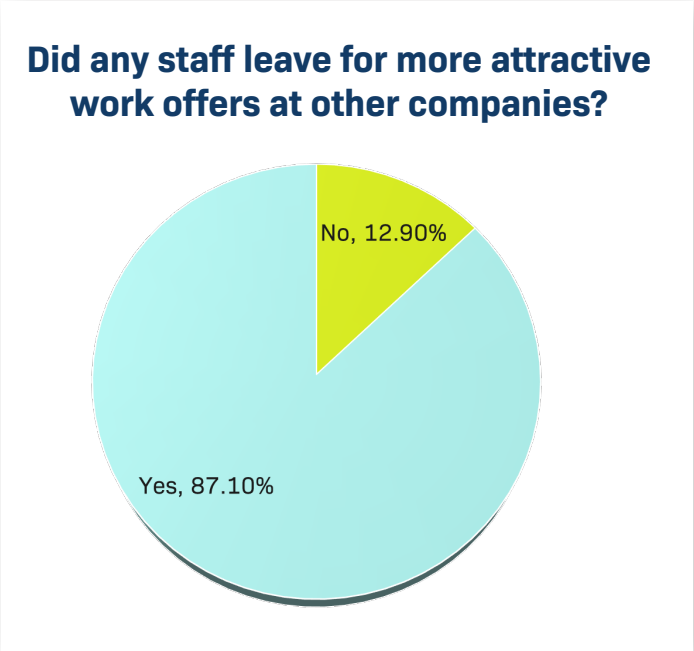
Several factors contribute to this trend including:

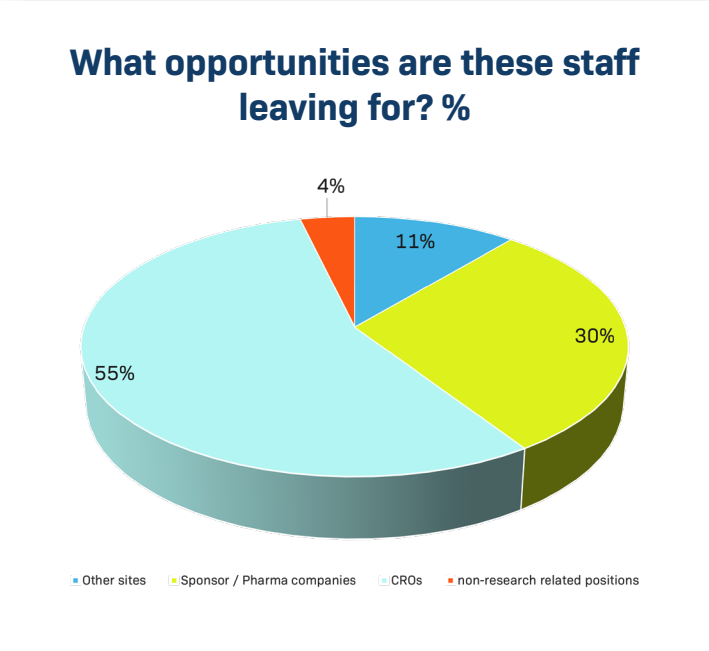
- Changes in workers' expectations of employers
- Competitive offers from other organizations
- Patient recruitment difficulties resulting in burnout and turnover
- Historically high costs of living
- Lack of opportunities for career growth or advancement



One site shared that their staff is not only overloaded for patient recruitment but also all the burden of start-up, such as obsolete paperwork, trainings, multitude of vendors, and fragmented information.

The data show that recruitment of site staff to sponsors and contract research organizations (CROs) offering lucrative sign-on or "start immediately" bonuses, strong compensation and benefits packages, and flexible work options (shorter weeks, hybrid work location) are the primary drivers of this trend. 85% of staff departing clinical research sites went to sponsor and CRO organizations.





RETENTION

While some sites may not be able to match salaries offered by pharmaceutical companies, there are many other ways to help mitigate employee attrition. Many sites have ramped up their benefit offerings to encourage employees to stay. Strong benefit packages, healthy work-life balance, and flexible work schedules were touted as the most valuable strategies for retaining their workforce. These benefits packages may include competitive salaries, bonus programs, generous vacation and PTO policies, matching retirement contributions, health insurance, and tuition reimbursement. Work-life balance is a priority for many employees. Sites can rearrange duties and/or scheduling as best possible to improve work-life fluidity. Flexible working schedules are also often desired, and sites could offer 4-day weeks, half days once per week, or every other Friday off, for example.

Additionally, sites can provide learning and/or growth opportunities for staff. Consider allowing them to become cross-trained in other departments, apprentice in an area where they are interested, or shadow a leader to prepare for promotion. Industry conferences may also be valuable for employees to attend. Conducting more frequent meetings with staff members can help sites understand why their employees work there, what they need, and opportunities for improvement and career advancement.

RECRUITMENT

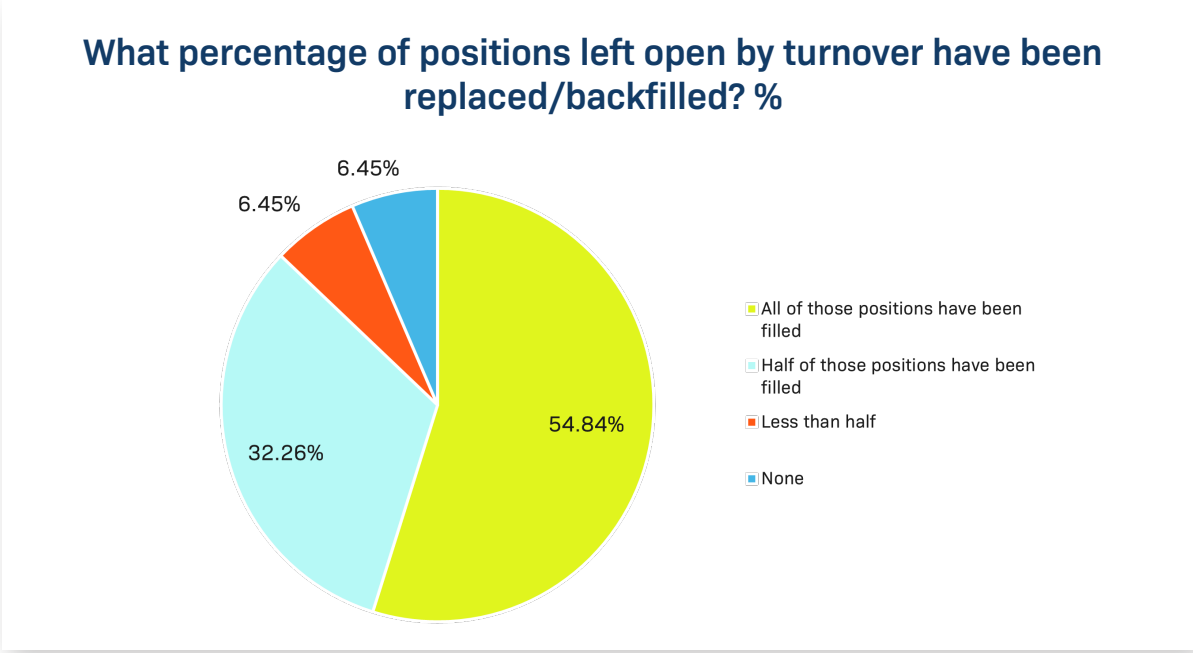
Recruiting qualified clinical research site staff is challenging due to the specific skill set or experience requirements, increasing costs, as well as the impacts of new technologies and protocol designs, among other factors. With the added pressure of increased competition from CROs and sponsors that can offer higher salaries and bonuses, turnover rates have increased two to three times from pre-pandemic levels.

To bridge the gap, organizations are increasing compensation and benefits packages where possible, but they are also investing more in advertising, onboarding, and non-compensation benefits and perks. They also employ creative recruitment solutions such as looking for transferable skills from other industries or backgrounds such as project management, administrative, or technology-related roles.

IMPACT ON CLINICAL TRIAL OPERATIONS

The challenges posed by the current workforce and inflationary pressures have a direct impact on the success of clinical trials. Sponsors and CROs are beginning to experience the negative impacts of staff turnover on study management, which include:

- Lack of continuity in the research process, which can cause delays and inconsistencies in data collection and quality
- Lack of expertise and resources, resulting in schedule delays and/or diminished research operations quality
- Difficulty maintaining accurate records and tracking study progress
- Increased risk of compliance issues, which can lead to costly penalties and ultimately delay the development of new treatments
- Missed enrollment goals
- Longer onboarding process and increasing training and oversight costs
- Loss of revenue to sites due to curtailed patient recruitment and enrollment



In addition, the cost of recruiting and training a new patient-facing staff member is approximately six months' pay. Sites are increasingly having to replace departing research coordinators with individuals without clinical research experience, requiring a longer onboarding process and increasing training and oversight costs. In these ways, it can take 6-12 months for sites to get back on track with a study when a coordinator leaves.

Beyond recruiting and onboarding, site overhead costs are continuing to grow significantly from as recently as one year ago. Factors driving these increases include turnover-related issues like non-monetary investments in employee retention efforts, increases in quality assurance/improvement resources to manage turnover, and post-COVID rises in operational costs.

Moreover, general inflationary pressures have caused prices to rise at a rate of 5 times higher than the last decade's average of 1.7% annually. SCRS estimates that sites' overhead costs in the next 6-18 months will continue increasing at unprecedented rates, driving up the overall cost of developing new treatments and therapies.

Resources & Approaches to Improve Workforce Sustainability

In response to the feedback and data from sites about workforce challenges, SCRS has created a Workforce Task Force to develop resources and recommendations with the intent of reducing staff-related pressures and burdens affecting the conduct of studies. The task force has identified several tools and actions stakeholders can employ to improve the situation:

1. First, there should be an open dialogue with individual sites to learn more about the macroeconomic pressures affecting the conduct of studies. From these conversations, we can identify ways to work together creatively to improve resources and/or take away burdens so that sites can successfully continue current and future studies. The task force's Open Letter to Industry Partners is a first step towards encouraging this dialogue.

2. Second, there should be an investment in renegotiation of existing budgets to sustain prior efforts of recruitment, retention, and quality until the industry reaches a steady, more predictable state of cost increases. Without bringing these kinds of payment terms to more sustainable levels, sites will have to divert additional resources to cash management and finance resources which could otherwise be used for additional recruitment, retention, and quality efforts.

   Additionally, sponsors and CROs can consider offering a study continuity plan to help minimize the impact to the site and study when coordinators are recruited from them. Sites can also leverage SCRS' Site Workforce Toolkit to help improve financial and operational sustainability.

> ***"It is incredibly important for sponsors and CROs to gain a better understanding of workforce trends and staff resourcing issues at our clinical research sites. These survey results provide critical insights into what our sites are facing and how these forecasts will ultimately impact our studies in the near future. With these insights, we can work collaboratively to find solutions that will better serve our patients and alleviate some of the burden facing our site staff across the industry."***
>
> - Lindsey Morales, Associate Director, Clinical Operations – Inflammation with Gilead Sciences and SCRS Membership Committee member

3. Third, sponsors and CROs can consider non-site sources of experienced professionals. Over the past few years, several large sponsors have successfully piloted accepting academic degrees in research management, internships, related experience in other disciplines (e.g., project management in non-life science areas), data analytics/management, and other experience as sufficient for entry-level duties. This could help the industry build a much more expanded applicant pool and reduce focus on a site's clinical research coordinators (CRCs) as the primary source of recruitment.

Conclusion

The current workforce and economic challenges at clinical research sites are having a direct and significant impact on the industry. Stakeholders must take action to identify and implement tools and solutions to continue the successful conduct of clinical trials. This includes open dialogue with individual sites, investment in renegotiation of existing budgets, and exploring and expanding other sources of talent.

SCRS's resources – including its advocacy and education initiatives, task forces, membership committees and advisory boards, and toolkits – can facilitate communication and cooperation, which are the keys to resolving these pressing issues. With collective action, sponsors, CROs, and sites can ensure the durability and sustainability of sites, ensuring they can continue to deliver high-quality, reliable study conduct and patient care.

SCRS' Resources to Address Workforce Challenges

- Workforce Challenges Task Force
- Open Letter to Industry
- Site Advocacy Group
- Career Center
- Site Workforce Toolkit
  available to SCRS memebers
- Membership Advisory Board
- Advocacy & Education
- Membership Committee

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