Staffing Shortages in Clinical Research Highlight Opportunities for Sponsors to Provide Support

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Identifying ways to increase efficiency in the clinical research workforce.

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Introduction: Clinical Research Sites are Plagued by Inefficiency

Staffing shortages at clinical research sites are having a major impact on clinical trials worldwide. Exacerbated by the COVID-19 pandemic, these workforce constraints have forced research professionals to accomplish more with fewer resources.

CRIO and TPS surveyed members of the Association of Clinical Research Professionals (ACRP) to better understand the overall staffing situation at clinical research sites. ACRP is one of the premiere professional organizations for clinical research professionals in the United States, and has wide cross sectional representation across multiple research institutions.

Specifically, we wanted to know more about the time, personnel, and technologies used by clinical research sites. We also sought to identify opportunities to increase their efficiency. We found that:

- Labor shortages are causing clinical research sites to halt enrollment or decline trials. More than one in three respondents (37%) reported that their site stopped or declined trials due to staffing shortages.
- Much of this is due to the flood of manual clerical work sites face. As one example, sites reported an average of 26 hours per week on electronic data capture (EDC) entry alone — over 50% of one full-time employee's time.
- Sites want sponsors to fund personnel support services to support their operations. 66% of sites not currently receiving sponsor-funded personnel support expressed an interest in receiving such support. The services sites were most interested in receiving support for were patient recruitment (58% of respondents) and data entry (56% of respondents).

While sites are used to working with sponsor-provided systems, many are not fully tech-enabled themselves. Many sites do not fully utilize site-specific technologies that could increase their workflow efficiency—only 61% of sites utilize a CTMS system for financial management, 38% utilize an eSource system, 31% utilize an eISF system, and 23% utilize an eConsent system. Only 20% reported using telehealth, which likely indicates that most sites are seeing patients in person.

In short, our survey revealed an opportunity for sponsors to improve the effectiveness of their sites by offering them staffing support, site-facing technology, or both.

Staffing Shortages in Clinical Research Have Persisted for Years

Labor shortages in the clinical research industry are a longstanding issue. Clinical research positions can be hard to fill due to the high demand for qualified professionals, limited capabilities to identify and recruit the required talent, and a potentially limited talent pool. Research positions require intensive training, certification, and experience, which create a high barrier to entry. For example, the ACRP[1] found in 2015 that there were 10,000 open positions for clinical research associates (CRAs), with many clinical trial sponsors and contract research organizations (CROs) often stuck in a never-ending recruitment and turnover cycle for qualified CRAs.

[1] ACRP. A New Approach to Developing the CRA Workforce. Sept. 2015. https://acrpnet.org/wp-content/uploads/dlm_uploads/2016/09/ACRP-CRA-Workforce.pdf

Clinical research also suffers from employee retention issues at a higher rate than other professional industries. A BDO study[2] found that the average turnover rate for CRAs was 30% in 2018, compared to the general annual turnover rate of 19% for all industries in the U.S. This statistic aligns with the findings of the ACRP study cited above, in which one-third of CRAs surveyed said they were considering a job change because of increased workload. Of those respondents, more than half cited "work-life balance" as a factor.

The COVID-19 Pandemic Aggravated Industry Labor Shortages

The pandemic further exacerbated the turnover rate in clinical research. During the height of the pandemic in 2020, around 80% of non-COVID trials were stopped or interrupted.[3] Overall, COVID paused more than 2,000 clinical trials.[4]

When many of these trials resumed in 2021, clinical research sites found themselves short-staffed, as experienced personnel either did not return to work or found more lucrative positions as contractors.

[2] BDO USA. LLP. 2019/2020 CRO Industry Insights Report. Jan. 2020. https://www.bdo.com/getmedia/67988203-bcde-44ec-a188-c7c1ab676a13/2019_CRO-Insights-Report_FINAL.pdf

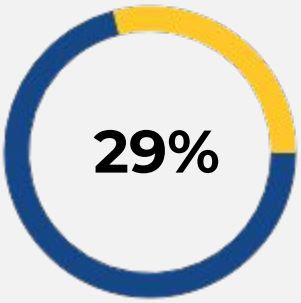
[3] Van Dorn, A. COVID-19 and readjusting clinical trials. The Lancet. Aug. 22, 2020. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31787-6/fulltext

[4] Carlisle, Benjamin Gregory. The Grey Literature. Clinical Trials Stopped by COVID-19. Jan 2021. https://covid19.bgcarlisle.com/

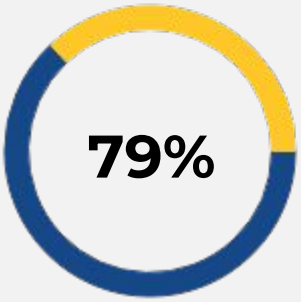
According to an October, 2021 report from Advarra[5], the number of organizations that said they were experiencing staff shortages nearly doubled, rising from 15% pre-pandemic to 29% in 2021. Another study by Applied Clinical Trials[6] found that 79% of clinical research professionals report experienced some form of employee turnover from 2021 to 2022. Meanwhile, 44% of respondents reported looking for a job change.

Trends in the clinical research industry have long paralleled those in the healthcare industry, where 40% of medical practices[7] saw a physician resign or retire early due to post-pandemic burnout. Though clinical research coordinators (CRCs) have reported suffering from burnout for decades,[8] the post-pandemic environment may have made conditions even worse. In a recent study,[9] research coordinators cited their overwhelming workloads as a significant contributing factor to burnout.

In order to ensure continuity and adequate resourcing of clinical trials, CROs and sponsors should prioritize solutions that alleviate workloads placed on staff at their sites.



Sites who said they experienced staff shortages



Clinical Research Professionals who experienced some form over employee turnover from 2021-2022

[5]Advarra Trend Report: The Future of Work in Clinical Research. Oct. 2021. https://info.advarra.com/future-work-clinical-research-report.html

[6] Scorr Marketing and Applied Clinical Trials. 2022 Clinical Research Industry Salary & Employee Satisfaction Survey Report. Feb. 2022. https://www.appliedclinicaltrialsonline.com/view/2022-clinical-research-industry-salary-employee-satisfaction-survey-report

[7]MGMA. Back from Burnout: Confronting the Post-Pandemic Physician Turnover Crisis. Oct. 2022. https://www.mgma.com/practice-resources/human-resources/back-from-burnout-confronting-the-post-pandemic-ph

[8]Gwede, C. K., Johnson, D. J., Roberts, C., & Cantor, A. B. (2005, November). Burnout in clinical research coordinators in the United States. In Oncology Nursing Forum (Vol. 32, No. 6). https://pubmed.ncbi.nlm.nih.gov/16270108/

[9]Mascaro JS, Palmer PK, Ash MJ, Peacock C, Escoffery C, Grant G, Raison CL. Incivility Is Associated with Burnout and Reduced Compassion Satisfaction: A Mixed-Method Study to Identify Causes of Burnout among Oncology Clinical Research Coordinators. International Journal of Environmental Research and Public Health. 2021; 18(22):11855. https://doi.org/10.3390/ijerph182211855.

Survey **Methodology**

CRIO and TPS administered this web-based survey in October 2022 to members of the Association of Clinical Research Professionals (ACRP). To encourage responses, we limited the number of questions to a maximum of 16. We asked respondents for background information on their site, their individual role, their site's practices, and their interest in receiving sponsor-provided operational support. Respondents were offered a gift card from Amazon and a copy of this report in exchange for their participation, and all responses were anonymized to the authors. In total, 128 individual responses were received.

The **Results**

Therapeutic Area

We segmented the sites by therapeutic specialty based on whether the clinical research site is single or multi-specialty, and whether their specialty included or excluded internal medicine or oncology. We focused on Internal Medicine because of its generalist nature, as many Investigators with Internal Medicine certification can run studies across multiple therapeutic areas. We focused on Oncology because of its highly specialized nature.

The majority of sites (65%) report being a single specialty research site, with most of these (38%) being a specialty other than Internal Medicine or Oncology. Of the 35% of sites that reported being a multi specialty research site, most (28%) did not have an Oncology practice. Across all sites, both single and multi specialty, 20% had an oncology capability.

Therapeutic Speciality	#	%
Single Specialty	83	65%
Single Speciality not IM/Oncology	49	38%
Internal Medicine Single Speciality	18	14%
Oncology	16	13%
Multi Specialty	45	35%
Excluding Oncology	36	28%
Including Oncology	9	7%

Size of Sites

To gauge size of site, we asked the respondents how many studies are currently in the Enrollment stage, and how many visits their site conducts per day. Based on this data, we classified 56% of respondents as Small Sites when measured by study volume (1-10 enrolling studies), and 76% as Small Sites when measured by visit volume (1-10 visits per day). We selected these tiers based on experience, as we have found that that these levels of volume typically correlate with fewer than 15 employees.

Size of Site (by # of Trials in Enrollment Stage at Site)	% of All Responses
Small (1-10)	56%
Medium (11-25)	30%
Large (25+)	14%

# of Visits Conducted per Day at Site	% of Total Responses
1-10	76%
11-40	18%
41+	6%

Coordinator Staffing

The majority of respondents (73%) were clinical research coordinators at their sites. Of the 92 survey respondents who were CRCs, 98% had a lead coordinator role, with 64% leading 1-5 studies, 28% leading 6-10 studies, and 5% leading 11-25 studies. Critically, this distribution of responses indicate that the survey respondents had direct knowledge of their site's practices, meaning that these survey findings are likely to be highly reliable.

# of Studies that CRC is Assigned to as Lead Coordinator	% of CRC Respondents
0	2.2%
1-5	64.1%
6-10	28.3%
11-25	5.4%

Effect of Staffing Shortages on Trials

In order to measure the impact of post-pandemic labor shortages on clinical research sites, we asked respondents whether or not they had ever declined a trial or stopped enrollment in a trial due to lack of staff. We selected this question because it most succinctly captures a discrete event that, from a sponsor's perspective, clearly impacts their ability to complete trials.

Overall, we found that 37% of clinical research sites reported declining or stopping trials due to a lack of personnel resources.

Have Declined or Stopped Trials Due to Lack of Personnel	%
Yes	37%
No	63%

The percentage of sites reporting this remained the same across site size, indicating that even larger sites are impacted by labor supply constraints.

Size of Site	%
Small (1-10 visits/day)	34%
Medium (11-40 visits/day)	41%
Large (41+ visits/day)	40%

Personnel Assigned to Data Entry

The majority of sites (67%) designate data entry to lead CRCs. More specifically, the lead CRC is the only staff member responsible for data entry at 67% of sites. Only 27% of sites have internal data entry personnel to offload this to. Only one site (1%) among all respondents outsources data entry to a third-party vendor.

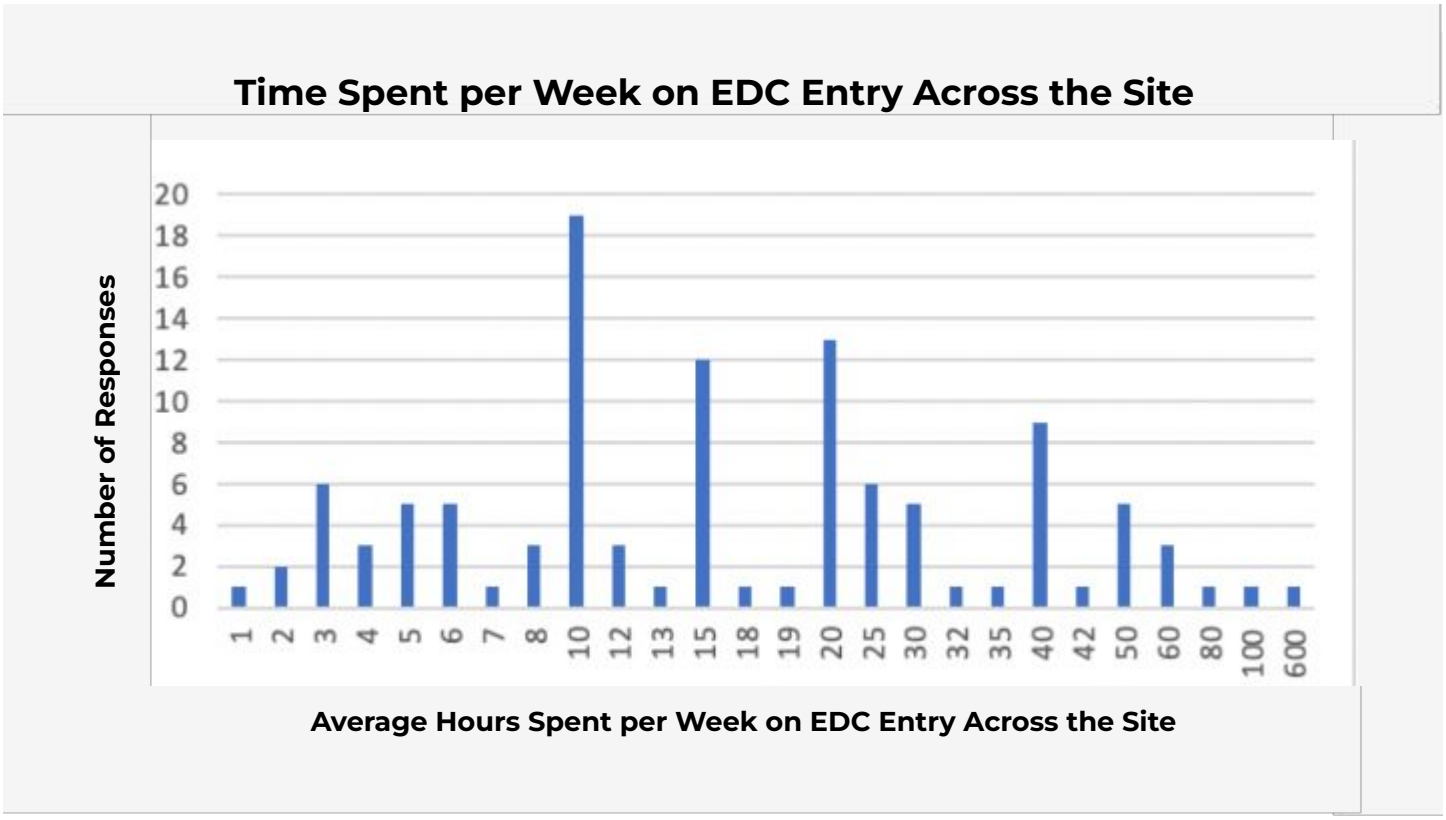
Personnel Responsible for Data Entry at Site	%
Lead CRC	67%
A research assistant or other individual who does that as part of a range of tasks	14%
A data entry person or group for whom that is their primary focus	13%
All CRCs	4%
Outsourced	1%

Time on Data Entry

We asked respondents to specify how much time their site spends entering source data into their sponsor's electronic case report forms (eCRF) housed in the electronic data collection (EDC) system used for the trial. The median total time spent per week on EDC entry across a site was 15 hours, and the average was 26 hours.

The average time spent on EDC data entry increased with site size, as expected. Broken out by the number of visits per week performed, the averages were as follows:

# of Visits Conducted per Day Across the Site	Average # of Hours per Week Spent on EDC Entry Across the Site
1-10	18
11-20	30
21+	79



Given that we asked respondents to estimate instead of providing an exact number, we unsurprisingly found clusters of responses on round numbers such as 10, 20, and 40 hours per week. Accordingly, the time estimates from our survey should be taken as directional only.

As expected, sites with a designated data entry specialist have larger EDC entry workloads: Sites with designated specialists spend an average of 60 hours per week on EDC entry, while sites where the lead CRC performs data entry on their own spend an average of 18 hours per week.

Use of and Demand for Personnel Support Services

22% of sites report receiving sponsor-funded research personnel support services. Of this subset, 64% received recruitment support, 57% received additional CRC staffing, 36% of sites received EDC data entry support and 18% of sites received clinical rater support.

Type of Research Personnel Support Service Requests	%
Patient Recruitment Support	64%
Clinical Research Coordinators	57%
Data Entry Support	36%
Clinical Rater Support	18%

We asked respondents at sites that do not currently receive support to indicate if they would be willing to recommend these services to their sponsors in the future, and if so, in which areas. Of the sites not currently receiving personnel support services from their sponsors, 66% reported they would be willing to recommend that their sponsors provide support services. Of this subset, the most frequently cited areas of support were patient recruitment (58%) and EDC data entry (56%).

Type of Research Personnel Support Service Requested	%
Patient Recruitment Support	58%
Data Entry Support	56%
Clinical Research Coordinators	47%
Clinical Rater Support	16%

Use of Technology

In order to research the efficiency of clinical trial management, we asked survey respondents what tools they currently use at their sites. Given the options of CTMS, EHR, eSource, eISF, eConsent, and telehealth tools, all sites report using at least one of the listed solutions. The most commonly used system is EHR, with 75% of survey respondents reporting using an EHR at their site.

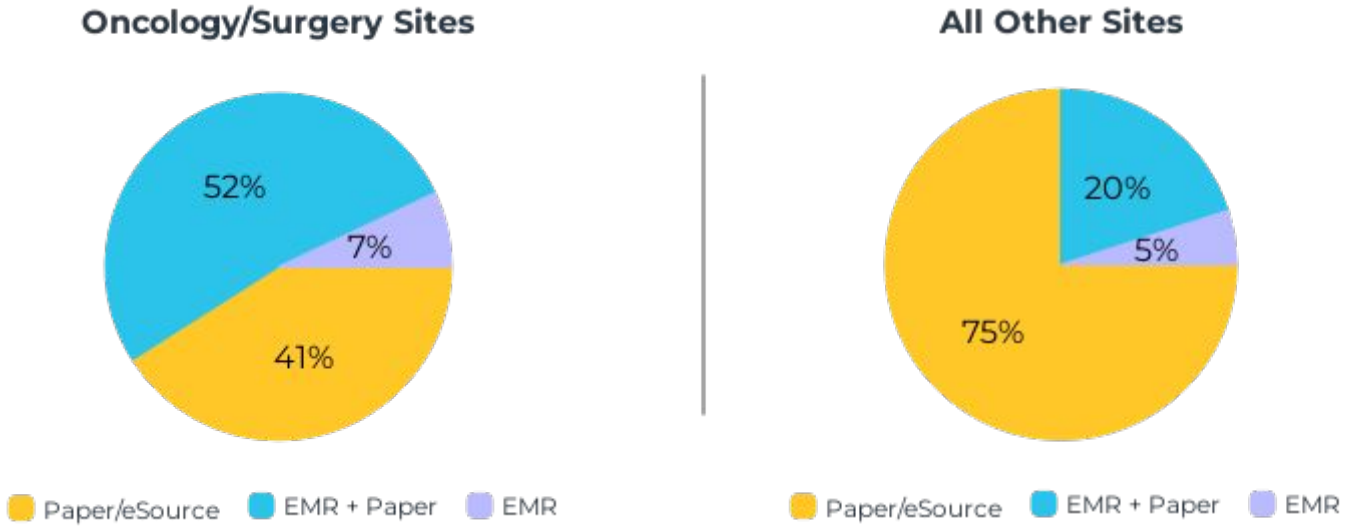
Technology System	%
EHR	75%
CTMS	61%
Electronic Source	38%
Electronic Investigator Site File	31%
Electronic Consent	23%
Telehealth	20%

Of the respondents who use an EHR, the most common uses for an EHR at their site are for patient recruitment, and as an informational source for the subject's medical history, medications, and adverse events.

How EHR is Used in Clinical Trials	%
Identify and/or recruit patients to studies	88%
As an informational source for the subject's medical history, medications, adverse events, etc., but not necessarily as the source of truth for study-specific visits and procedures	88%
Schedule patients for site visits	76%
As the actual source of truth for study-specific visits and procedures (i.e., including visits and procedures conducted solely for the trial, not as part of routine care)	42%
Respond to feasibility questionnaires	37%

Notably, less than half (42%) cited using the EHR as the clinical trial source of truth for study-specific visits and procedures. WIthin this group, 83% supplemented the EHR with the use of paper. Expressed as a percent of all sites, only 6% use the EHR exclusively for source data. This clearly indicates that the sites' existing EHR systems are not optimized for clinical trial data collection.

By therapeutic area, there is a clear divide between oncology and surgery sites on the one hand, and remaining specialties on the other. Among oncology and surgery sites, 52% report using the EHR, and among remaining sites, only 25% report using the EHR as a source tool.



Since most sites who do use the EHR for source data collection also report using paper to complement it, we asked the respondents how and why they were using these paper charts. 90% of respondents indicate that they used paper charts to supplement data capture for the trial with study-specific procedures - most likely, this represents procedures that the EHR does not support. Another 75% indicate that they used paper charts to detail instructions on how the data is to be collected, indicating that their EHR templates were not sufficiently customizable to reflect the protocol-specific requirements on methodology.

Supplemental Methods Used	% of Sites Using EHR as a Source That Supplement EHR With This Method
A supplemental sheet for capturing information that your EHR templates do not cover; examples may include clinical significance, AE of Special Interest status, etc.	90%
An instruction sheet or cheat sheet to describe what data is to be collected and/or what procedures are to be done and how	75%
EHR data is printed out in paper form, then modified or added to, signed and dated; this is then filed as the source	53%
None of the above	13%

Conclusion

Our survey reinforced findings from many other reports on the labor challenges that research sites face. Specifically, the pandemic exacerbated long-standing conditions of burnout and turnover in research, and as a result over 1 in 3 sites have turned away or stopped working on at least one study due to inability to adequately conduct them. Over 2 in 3 sites report that they would welcome more operational support in the areas of recruitment, research coordination and EDC data entry - all critical activities that if not properly resourced, will slow the rate of enrollment, decrease study conduct quality, and further limit the development of new therapeutics. Moreover, many sites have not fully made use of the range of site-facing technologies available, and the vast majority, especially outside oncology, do not utilize the EHR for study-specific data collection, which is at the core of their activities.

CONCLUSION

Without efforts by sponsors to further support clinical trial sites with personnel and technology aimed at reducing the burden of study execution, our survey indicates that sponsors will continue to face study operational challenges that will protract study completion timelines, decrease data quality, and further disadvantage clinical trial sites. This survey suggests that two options for sponsors are providing support services and/or more site-friendly technologies.

FOR MORE INFORMATION, CONTACT:

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