Unlock Clinical Research Site Potential by Addressing Resource Challenges and Trial Complexity

Staffing and trial enrolment remain the most pressing issues research sites face, according to the 2023 WCG Clinical Research Site Challenges survey. As trial complexity increases and sites continue to struggle with resourcing, sites are having to do more with less. Despite these challenges, sites are finding innovative ways to move forward with help from sponsors, clinical research organisations (CROs), and other partners. All of this has the potential to reshape the future of clinical research.

About the Survey and the Results

In February-March 2023, WCG surveyed more than 500 US-based clinical research sites. The survey asked site leadership/owners, research administration staff, clinical research coordinators/clinical research nurses, institutional review board/regulatory representatives, physicians/principal investigators, and others about their perspectives on the major challenges they are facing, solutions they have implemented to overcome those obstacles, and more. Thirty nine percent of survey respondents represented academic medical centres (AMCs), and the remaining 61% represented non-academic research centres (non-AMCs) including community hospitals, health systems, physician practices, and independent research sites.

A Threat to Opening New Trials

According to the survey results, 63% of sites identified staffing and retention as their most significant concern, recruitment and enrolment was second at 48%, and trial complexity and study start-up tied for third at 36%.

To explore the implications of the survey findings, WCG convened representatives from a sponsor, an AMC, and a non-AMC for a discussion on its podcast, WCG Talks Trials. The episode featured:

- Lisa Richman Ballance – Associate Vice President for Research Strategy and Regulatory Affairs at Virginia Commonwealth University (VCU)
- John Musser – Senior Director, Clinical Research Administration at Florida Cancer Specialists & Research Institute
- Dan Otap – Principal, Alliance and Partnerships Lead at Genentech
- Sandy Smith, RN, MSN, AOCN – Senior Vice President, Clinical Solutions and Strategic Partnerships at WCG

Smith pointed out that 52% of the respondents indicated that challenges they identified in the survey have had a direct impact on their site's ability to open trials. WCG's proprietary data supports this finding: in 2022, more than 3,300 US sites opened only one clinical trial, and fewer than 50 sites opened 50 or more trials.

"What surprised me most about that is that even running one trial…requires a lot of infrastructure," Ballance said, expressing concern that this trend could lead to a decline in smaller sites.

Staffing and Start-up Are Inexorably Linked

Many clinical research sites continue to struggle with staffing and retention, which is affecting the number of trials they can handle. Staffing is a more significant issue for non-AMCs (74%) than for AMCs (56%).

Study start-up challenges relate directly to the shortage of research professionals – not just the clinical research coordinator role but positions in other areas, including coverage analysis, budgets, contracts, and regulatory submissions. This can often lead to longer activation timelines at sites and costly trial delays.

AMCs

Non-AMCs

Meanwhile, the number of US investigators continues to decline. This prompted the inclusion of a question in the survey on physician engagement. Nearly a fifth (19%) of respondents cited physician engagement and interest as a concern. It was a much bigger concern for AMCs (22%), ranking fourth. It came in ninth for non-AMCs, with 11% citing it.

"We are at an inflection point in this industry where we have to have new investigators developed, we have to have staff developed or we're going to have a dearth of opportunity," Otap said.

Ballance agreed: "Let me just say that I have often seen some ebbs and flows over time, but this has actually gotten to a point where if we don't have more physician researchers, we will be in crisis." To that end, VCU has been investing in pipeline programs to bring more people to the table as clinical and translational scientists, including PhD nurses.

Trial Complexity: The Burden Keeps Growing

Over the past several years, clinical trials have become increasingly complex, putting additional burdens on clinical research sites. When the survey inquired about trial complexity, 36% of respondents named it as a top concern. Research sites frequently cite trial and protocol complexity as a reason to avoid clinical trials with multiple arms or complex trial designs.

It was the third-highest concern for AMCs (38%) and the fourth for non-AMCs (36%).

"We have seen more data points, and we have seen lengthier trials with more procedures—and this has impacted our start-up times," Ballance reported. "Part of the issue is we do a lot of trials that are standard of care, plus procedures that are research only. Even just adding complexity to the coverage analysis process can create delays."

Trial complexity and acuity have been top of mind for Otap, and they relate to everything from resource management to feasibility reviews. He points to the Tufts Center for the Study of Drug Development (CSDD) data showing that complexity continues to climb. Phase II and III trials have an average of 20 endpoints or more per study, and phase III trials collect an average of 3.6 million data points.[1] "That's mind boggling to me," he said. "This clearly has downstream effects on a site's ability to both conduct their ongoing studies, as well as open any newer studies."

As Technology Advances, Challenges Increase

Technology continues to be a concern for sites, with 18% of all sites saying it is a top concern, and a significant split between AMCs and non-AMCs. Technology is tied at 22% with physician engagement/interest at AMCs (ranked 4th), while technology ranks 7th at non-AMCs (13%).

From a community practice perspective, John Musser emphasizes the importance of integrating technology solutions, particularly considering the diverse and sometimes conflicting solutions provided by sponsors and CROs.

Otap attributed the fact that technology advancements are sometimes a burden to "innovation outpacing the end user informed experience and feedback from users." He pointed to the "low-hanging fruit" of single sign-on methodologies. Tech's biggest selling point is end-user ease, he explained. "We need to keep that top of mind."

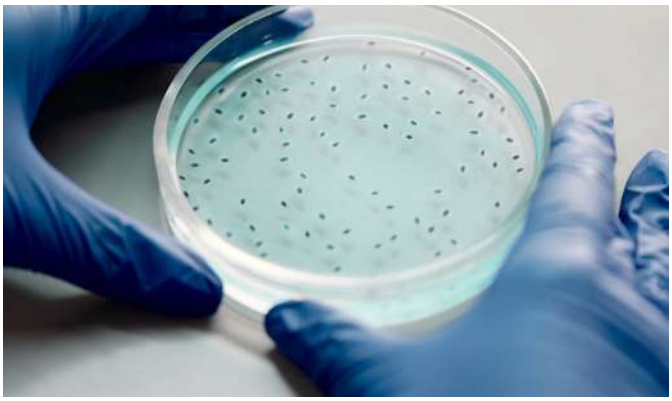
"The take home here, in my eyes, is that as sponsors we have a responsibility to take site staff and participant experience and operationality into consideration when vetting new vendors and deploying new tech software solutions. We need to be intentional about both the upstream planning, as well as the downstream process review so that we can continue to improve in this space."

Focusing on Solutions

Although technology may be a challenge for some sites, it can also be a solution if used efficiently. Both AMCs (29%) and non-AMCs (21%) are leveraging it for workflow efficiency.

Sites are putting solutions in place to solve the challenges they face, especially related to staffing. For example, 57% of non-AMCs report hiring additional staff (39% at AMCs) and 45% of non-AMCs identify training as a solution (41% of AMCs) – particularly with hiring new staff.

"Many sites are filling vacant positions with earlier-career professionals," Smith reported. "So training may be taking a little bit longer." Some sites are designing novel training programs to increase the number of available research professionals.



That's what's happening at Florida Cancer Specialists. "We're having to revamp our entire training regimen to make sure we can find really good candidates and then keep them here and train them," Musser said. "You also have to make sure people feel that they want to stay at that location, especially in community practice settings."

"Creating that person-to-person relationship will go a long way," he added. "And for those scenarios where you're unable to find those people, partner with the right research service to augment [your current staff]." When you can find or train the right people for a role – data management, financial management, budget, contract negotiations, etc. – he recommends working with a partner.

Ballance agreed, stressing the importance of sites prioritizing their investments and focusing on what they do best. "One of the things that we have found incredibly beneficial is to turn to outside expert partners like WCG, especially when it comes to staffing for peak times." VCU has turned to WCG for coverage analysis, contract negotiation, and budget development. The survey finds that 20% of AMCs and 11% of non-AMCs have taken the same approach.

"Sites must speak up about what they need when they need it," Musser said. "Don't wait for a monitor visit. You should be able to pick up the phone and have that conversation with them right then, because if you're having that issue, more than likely another site's having that issue." During all this, research participants need to be the primary focus.

VCU has redoubled its focus on participant engagement. "We should be asking our participants, 'Where are the pain points that really limit the progress of clinical trials?" Ballance said. "It would be a shame to fix technology issues and to find out that parking was the main problem."

Otap agreed: "As simplistic as it sounds to me, the best solution is consistently putting the other person in that scenario face forward and trying to think on their behalf what works best for them."

WCG's survey report concluded with recommendations for both sponsors/CROs and sites.

10 ways research sites can address their key challenges:

1. Focus on the trial participant experience throughout the recruitment, enrollment, and retention process.
2. Use and invest in technology systems that can improve existing workflows and streamline research operations.
3. Leverage data and technology to optimize participant recruitment, enrollment, and retention.
4. Implement diversity, equity, and inclusion strategies in your participant recruitment, enrollment, and retention processes.
5. Document, simplify, and standardize workflows and processes that are conducted regularly.
6. Identify where the gaps exist in your research workflows; determine what must be done on site versus what can be outsourced.
7. Establish clear communication at your site and ensure that site staff members are aware of their specific roles and responsibilities for each trial.
8. Invest in ongoing training, education, and networking opportunities for site staff.
9. Build strong relationships with sponsors and CROs to enhance communication and transparency.
10. Adopt a quality management system and identify best practices to ensure regulatory requirements are met.

10 ways sponsors and CROs can help address key site challenges:

1. Develop protocols with the participant and site experience in mind to address trial complexity concerns and obtain site input on protocol designs before the trial begins.
2. Release the final protocol in a complete state to minimize the site having to address amendments during trial activation or shortly after trial initiation.
3. Set realistic study start-up timelines for the sites conducting your trials.
4. Work to simplify and streamline the feasibility process, budgets, contracts, site training, and safety reporting.
5. Create robust diversity action plans for the sites conducting your trials.
6. Identify site-specific needs and provide personalized support for each site, whether that be through people, process, or technology.
7. Evaluate the technology needs for your trials and provide training for the platforms that sites will be frequently using.
8. Support new and less experienced sites and investigators to improve diversity.
9. Collaborate with sites to evaluate how existing site technology can be leveraged to identify, enroll, and consent potential study participants more effectively.
10. Facilitate open lines of communication and collaboration throughout the trial.

REFERENCES

1. Tufts CSDD Impact Report Volume 23 Number 1 January/February 2021
2. 2023 WCG Clinical Research Site Challenges Report www.wcgclinical.com/insights/2023-clinical-research-site-challenges-survey-report

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