Overcoming Enrollment Challenges in an Overcrowded Clinical Research Landscape

Sandy Smith, RN, MSN, AOCN
Sr. VP of Clinical Solutions and Strategic Partnerships, WCG

Jamie Harper, MHA
Director of Site Engagement and Relations, WCG ThreeWire

It’s No Secret.

The way that we conduct clinical research has been changing since the onset of the COVID-19 pandemic. What factors are contributing to study enrollment challenges for sites and sponsors? What solutions can we as an industry leverage to overcome those obstacles? As an industry, we are at an inflection point. We can’t keep doing things the way we’ve always done them; we must do better.

Quantifying Challenges

If sites seem busy, know that there are indeed *more trials* this year than last year. Trial starts for the first three quarters of 2021 are up 25% over 2020. Many sites also face a backlog of studies delayed last year due to the pandemic, so prioritizing trials adds to the challenge.

Staffing takes the #1 spot in surveys regarding study challenges *(fig 1.)*, with a predominant 16-30% turnover rate. Personnel difficulties are followed by budgetary and contractual issues plus pandemic effects on workflow. A lack of resources at sites leads to trickle-down challenges in every aspect of clinical trial enrollment.

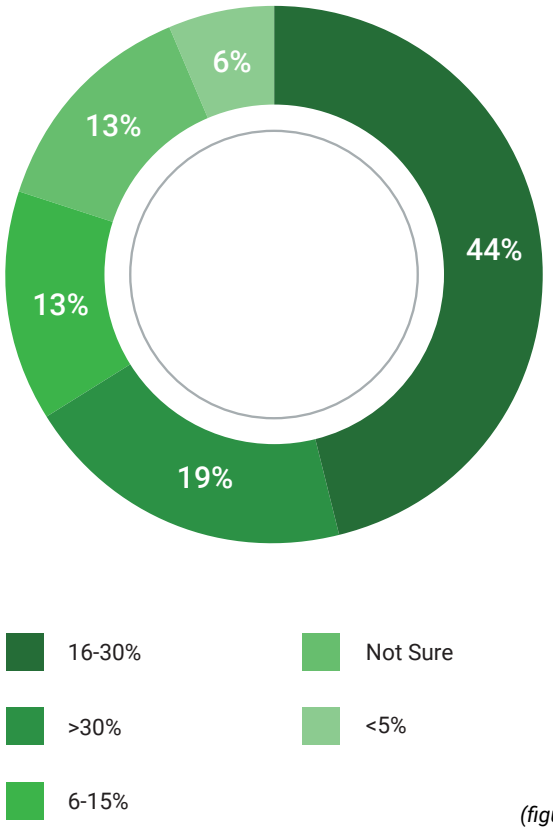
US Clinical Research Site Challenges

(figure 1.)

High turnover (fig 2.) has been a major concern across sites. During the pandemic, we have seen a sizable number of experienced site personnel retire, leading to knowledge gaps and many open positions. At the same time, sites tell us that the number of applicants for open positions has decreased. Often, they are having to hire more junior, less experienced individuals. This situation translates into a longer ramp-up for team competence and confidence.

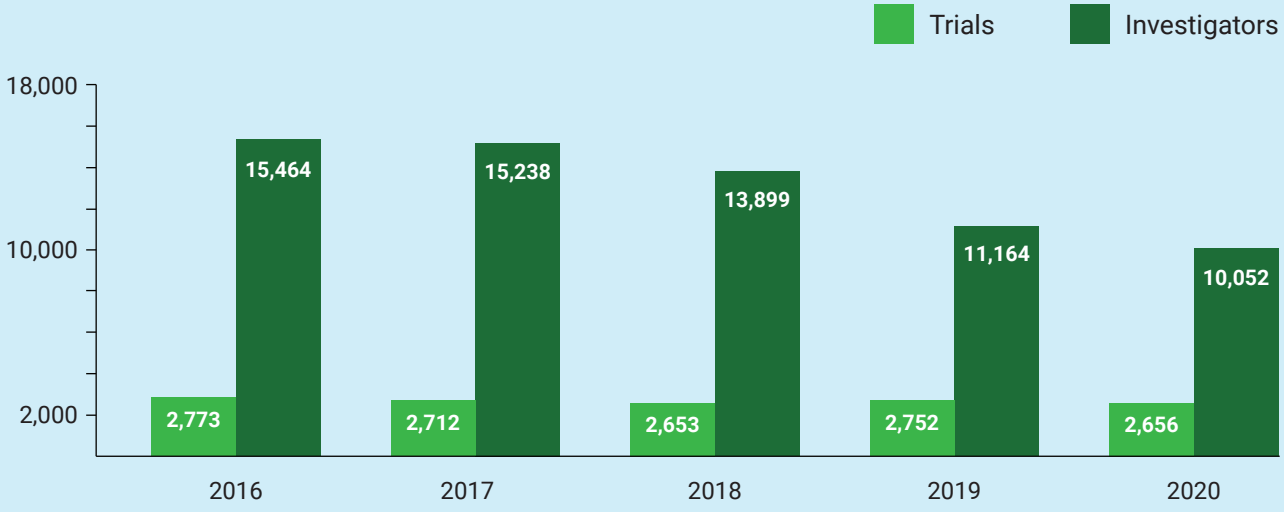
Physician capacity is also a concern for sites. We see fewer investigators available and interested in performing clinical trials, with about 40% of investigators involved in only one clinical trial. Physician burnout factors into the site burden as a challenge to physician engagement. These physicians have to balance seeing patients with addressing protocols that are becoming more complex and taking more time.

US Clinical Research Sites: Staff Turnover



(figure 2.)

Number of Trial Starts & US Investigators



(figure 3.)

The highest percentage of *study start-up timelines* (fig 4.) are currently reported at 61-90 days, followed by 91-120 days. Timelines exceeding 90 days are a red flag likely requiring a review of workflows and efficiencies.

Trial complexity is a challenge for sites already facing staffing shortages. Sites are reporting a 70% increase in Phase III trial procedures over the past decade, along with a 27% increase in endpoints and a staggering 300% increase in data collection points. This escalation of complexity is straining sites that are already running lean.

What do sites need from sponsors and CROs in these challenging times? Having professional, knowledgeable, well-trained monitors and CRAs; being organized and prepared; providing good overall protocol design and having drugs immediately available are all factors that increase a site's ability to enroll studies quickly.

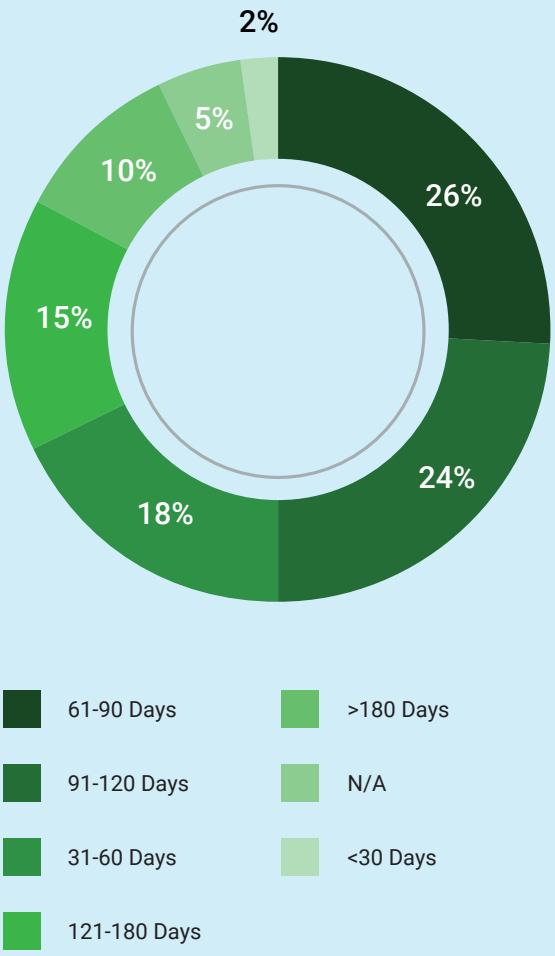
Strategizing Solutions

Trials are becoming very complicated, and there are more trials than ever, plus fewer investigators. There are also fewer patients due to protocol complexity, as it is harder to find patients who meet the qualifications to enroll. This situation requires us to think differently. Despite the challenges, we still have the drive to provide exemplary patient care and move science forward. Let's explore some solutions.

We can identify additional, alternative staffing resources for the sites to continue patient-centric, inclusive medical advancement. For example, sites and sponsors report that augmenting staff using **WCG ThreeWire** clinical research professionals boosts study enrollment across therapeutic areas.

Next, as an industry, we must balance writing protocols that meet regulatory requirements with the need to serve patients – a distinct challenge. Sponsors can work with sites and patient groups to develop less burdensome protocols while meeting the intents of the trials.

What's Your Study Start-Up Timeline?



(figure 4.)

The pandemic had provided an opportunity for us to adapt and look at trial conduct differently. Decentralized trial designs are becoming more available, allowing patients to participate remotely. Telemedicine was necessary for trial continuity during the pandemic; incorporating that feature into future designs may provide access to more patients. Finally, the increasing use of digital devices such as wearables decreases the burden of collecting specific patient data.

Leveraging technology will be increasingly important to position sites for efficiency and effectiveness. We must assess technology and not assume that all technology is "good technology" and will provide site efficiencies. Portals can be helpful, but if sites are juggling multiple portals, each with a unique sign-on, this can create an obstacle for sites. It is important to assess each technology solution relative to potential operational gains.

How *can we engage physicians in our communities?* We can ask them to talk to patient groups about the benefits of study participation for their diseases. Physician involvement attracts patients and may help reduce barriers to enrollment. Peer-to-peer letters to physicians are another tactic to increase knowledge of clinical trials among other physicians in the community. As COVID testing sites draw large numbers of individuals, a presence at these sites with information on relevant trials could also enhance pre-screening activities.

Communication is key to addressing obstacles. Sites must provide feedback to sponsors regarding enrollment issues and study protocols. We need honest communication among sponsors, sites and patients because we all have the same goal: Achieving study success to help patients in need.

For more insights, view our **recent webinar**. If you're ready to help your sites reach their full potential and boost your clinical research capabilities, **contact WCG here.**

"With tight timelines, WCG ThreeWire offers very good support. Getting their CRCs on board and in the delegation log, putting boots on the ground and sending them to different places gave us more engagement to meet enrollment goals. I'm a huge advocate."

Eduardo Mendez
Recruitment Manager
Clinical Site Partners

"Sponsors are willing to help sites get more resources. We've used WCG ThreeWire for sites that are willing to accept the support, and I would urge more sites to have an open mind to augmenting their staff."

Peter O'Neill
Sr. Director, Clinical Operations
Incyte

WCG is the world's leading provider of solutions that measurably improve the quality and efficiency of clinical research. Comprised of two segments, Ethical Review and Clinical Trials Solutions (CTS), WCG enables biopharmaceutical companies, CROs, and institutions to advance the delivery of new treatments and therapies to patients, while maintaining the highest standards of human participant protection.

WCG Clinical - info@wcgclinical.com - 609.945.0101 - www.wcgclinical.com