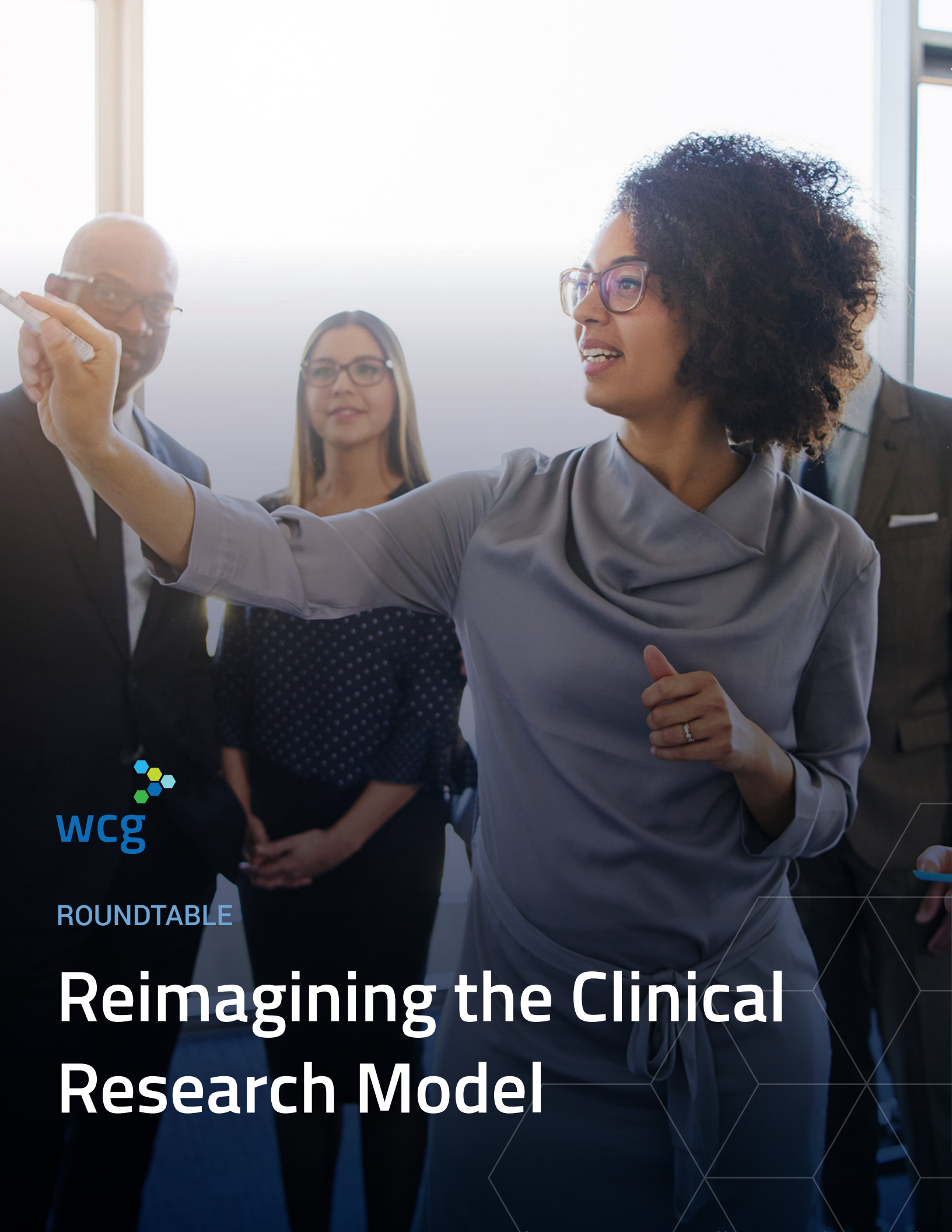

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ROUNDTABLE

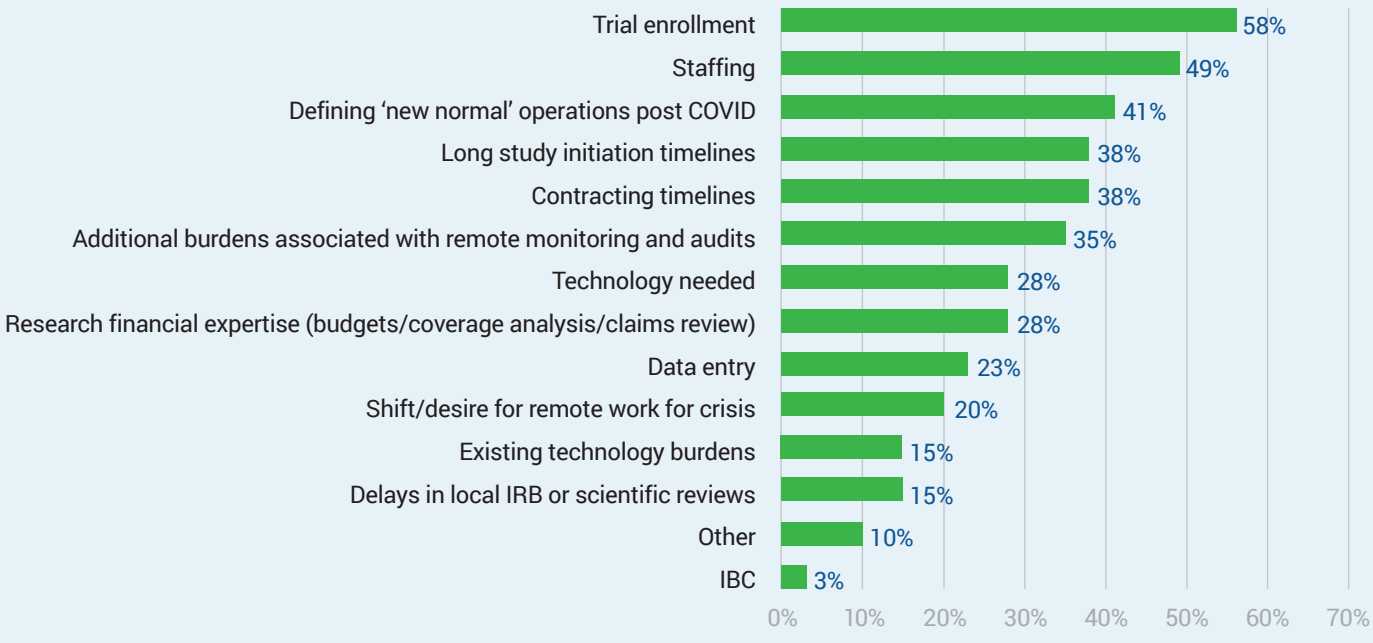
Reimagining the Clinical Research Model

Rising costs. Shifting resources. “New normal” virtual settings. Today’s clinical research challenges provide ample opportunity to re-imagine the business model. We recently hosted a series of roundtables with industry leaders to discuss challenges and solutions around enhancing efficiency while ensuring quality and compliance.

The industry has experienced the perfect storm between pandemic staffing shortages, financial constraints and new study registrations. As a result, many sites are being motivated to re-imagine their research model. What can we learn from the last year or more? How can we leverage “lessons learned” to approach research in a new light?

A recent WCG survey quantified top issues impacting sites (see graphic below). As you can see, trial enrollment topped the list, followed closely by staffing, post-COVID operations, study timelines and remote monitoring challenges. Our roundtable team selected key topics for discussion.

WHAT ARE THE TOP ISSUES IMPACTING YOUR SITE TODAY?



STAFFING AND TRAINING

The industry has seen an increase in staffing fluidity plus associated training challenges. We know that, without proper staffing, trial enrollment doesn't happen. Sites already face significant challenges around enrolling patients (see graphic below). At the onset of the pandemic, hospital sites paused non-COVID activity to free up beds. At the same time, academic institutions and for-profit hospital systems alike faced hiring freezes.

CLINICAL TRIAL ENROLLMENT

11% of active sites fail to enroll a patient

68% of sites fail to meet enrollment tagets and timelines

Many parents in the healthcare workforce were overwhelmed with COVID-related childcare issues. By late 2020 and early 2021, the industry saw lights on the horizon in terms of vaccines and treatments, which led to a huge groundswell of new projects, staffing needs and nursing shortages.

What are the solutions? In the short term, signing bonuses and higher salaries help attract and retain talent. In the mid-term are staff rotations, certificate programs, loan forgiveness and other incentives. Long-term approaches include cultivating clinical nurse residency programs, training and certification, forming a pipeline of career professionals.

Another approach is to pull responsibility components, such as data submission or regulatory submission, off the nursing staff and hire separate team members to cover those aspects. Acknowledging that employees may not occupy roles for long terms anymore, it can be helpful to create "how to" tools for newer staff members to build their capabilities. Throughout the pandemic, we have learned that working from home and rotating schedules allow team members to balance home and work.

REMOTE MONITORING

The monitoring process, critical for ensuring data integrity and compliance, became a significant challenge during the pandemic. Remote monitoring required sites to provide platforms and systems, along with access to electronic health records (EHRs) plus security and new procedures. On top of that challenge were increased trial complexity (see graphic) and special COVID protocols, with more people wanting to engage with the infrastructure. Accommodating this activity has taken exhaustive time on the part of the team.

COVID has offered the opportunity to look at monitoring through a different lens. Hybrid models allow monitors to visit sites but separate them from staff and patients. Most

CLINICAL TRIALS ARE MORE COMPLEX

Increasing trial complexity and site burden over the last decade

70% increase in procedures required in Phase 3 trials [2]

86% increase in endpoints in Phase 3 trials [2]

300% increase in data collection in Phase 3 trials [2]

contract negotiations today include time and technology for remote monitoring, and the most attractive sponsors will cover those costs. For the long term, discussions around monitoring will require site, sponsor and EHR team involvement.

RECRUITMENT

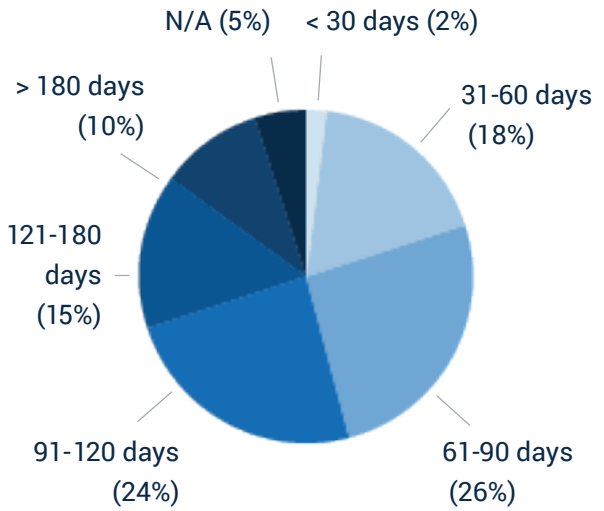
Third-party vendors can supply needed horsepower to facilitate recruitment – a major obstacle to study start (see adjacent graphic). However, third parties face institutional barriers due to health system structures, concerns about medical record access and the lack of standard contract language.

Naturally, there are issues regarding security, with today's data hacking and breaches, concerns around flash drives and cyberattacks on health organizations. But how do we find potential subjects without diving into EHRs? The industry continues to seek solutions.

An added challenge is diversifying the trial enrollment process, which requires a research staff that looks like the people we want to attract. Moving forward, diversity and inclusiveness will be a distinguishing characteristic for sponsors – not just enrolling subjects in the desired enrollment window competitively, but enrolling the very subjects that sponsors are seeking. These efforts will yield the most meaningful real-world outcomes from clinical trials. Solutions start with getting providers who have roots in the communities involved in these discussions, as

TRIAL ACTIVATION - TIME MATTERS

What's your study startup timeline?



trust and transparency are core issues. Taking care to the communities, instead of having the communities come to inconvenient locations, may offer advantages as we work to identify the needs of diverse populations.

STANDARDIZATION

At the height of the pandemic, study enrollment was frozen for many studies except cancer trials, and standard processes shifted because of staffing, access and budgetary issues. From a clinician standpoint, we want to save patients' lives, but our normal, pre-pandemic standards and processes have been disrupted.

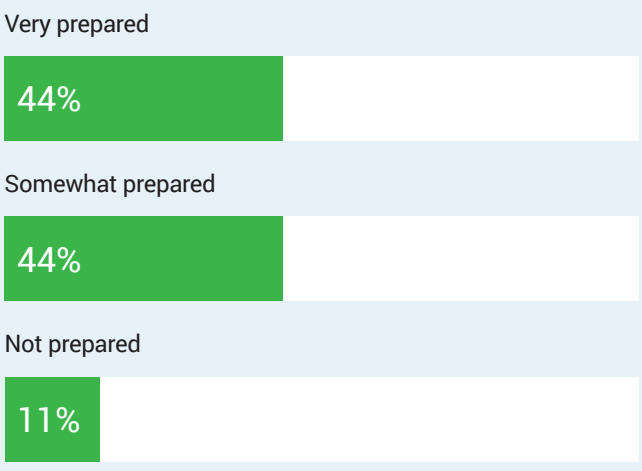
Fortunately, sites continued to have internal training seminars, providing an internal clinical-trial-coordinator network to address standardization. Moving forward will require attention to organization-wide consistency for new policies, processes, enhancements and course corrections – especially for those managing multiple sites.

Some sites are reporting an uptick in FDA audits, and so readiness is critical (see graphic). Larger organizations may have internal audit capabilities and departments, but smaller organizations may benefit from an outside provider that stages mock audits and assesses preparedness. A "stress test" can reveal how robust systems are and how prepared teams are for audits.

SITE INSPECTION READINESS - IS YOUR SITE PREPARED?

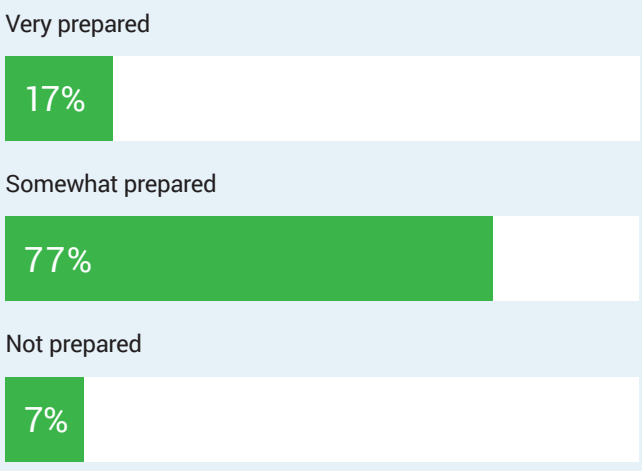
If you are with a SITE organization, how prepared are you for a site inspection?

POLL RESULTS (single answer required):



If you are with a SPONSOR or CRO, how prepared are your SITES for an inspection?

POLL RESULTS (single answer required):



THE "NEW NORMAL"

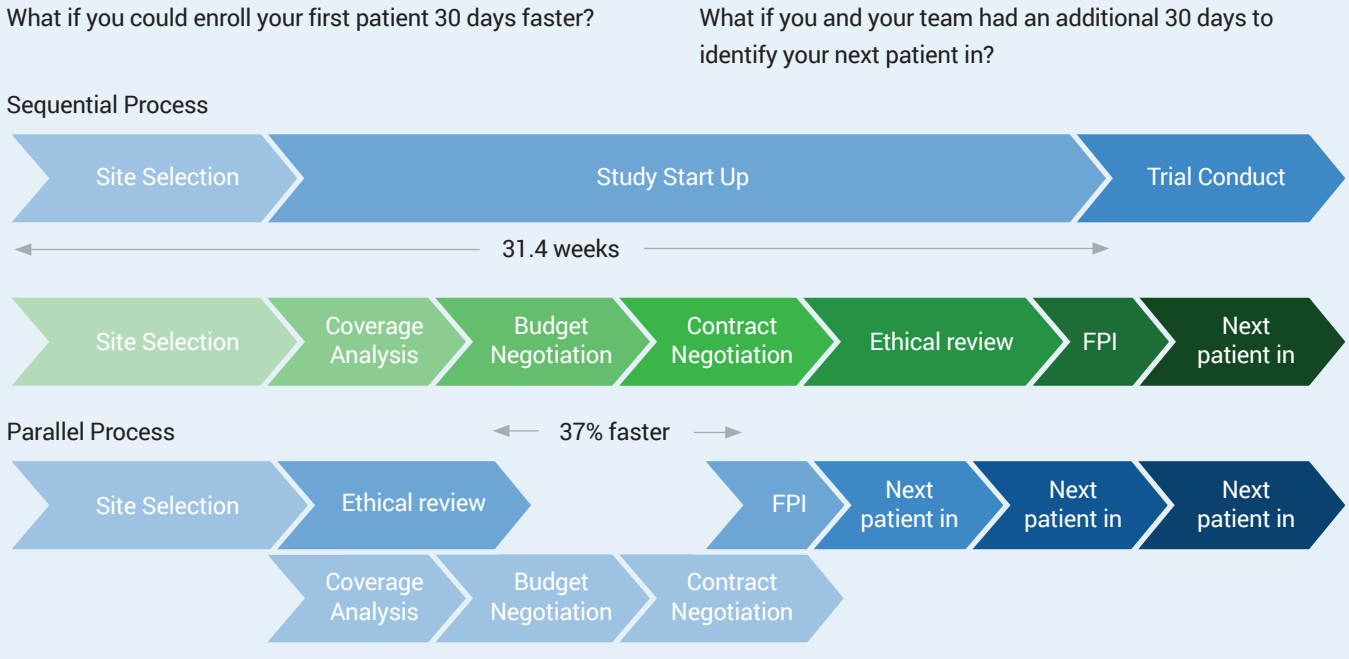
Any silver lining to the COVID experience will be "lessons learned" and new solutions. Everyone is overworked and overwhelmed, but we will reorganize so that everyone can work at the top of their license – from PIs to CRAs to clinical trial directors.

Next, we must bring teams together to communicate and work in parallel, not serial or siloed fashions (see graphic). We will use our "lessons learned" to move forward more effectively and efficiently.

Sites are pivoting from COVID studies back to those begun a year (or more) earlier. The key is not to lose momentum and not to revert to old inefficiencies. Electronic records, extreme focus on patient visits, converting staff workspaces into landing spaces and increasing patient rooms to take on a larger volume of studies are all on the radar screen. Sites are working to adjust and keep up with trends to facilitate the needs of coordinators.

The "new normal" will likely include immunizations studies, COVID therapies plus the mainstay studies. Approaches that allow teams to spend less time on administrative tasks and more time on patient care will keep sites focused on producing quality studies that lead to groundbreaking healthcare advances.

OPTIMIZING STUDY START UP THROUGH PARALLEL PROCESSING



As the world's leading provider of Managed Research Solutions that measurably improve the quality and efficacy of clinical research, WCG is helping organizations re-imagine the research business model.

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