# Improving Visibility and Control at the Site Level for Vaccine Trials

## How WCG Site Augmentation Supports Research Sites for Improved Enrollment, Retention, and Trial Management

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As more vaccine candidates enter clinical trials, sponsors are confronting a resource problem when selecting investigators and sites: That is, there doesn't seem to be enough of them to go around.

"There are dozens if not hundreds of global trials competing for the same airspace," said Patrick McNamara, Senior Director of Business Development at WCG ThreeWire. "Sponsors are vying for the same time, energy, and labor at trial sites to enroll their studies. With some vaccine trials requiring thousands of participants, the volume of work those programs demand has become a rate limiting factor."

The pandemic has further exacerbated those challenges: Sites that were financially constrained felt the impacts of COVID-19 more acutely as furloughs and elective procedure delays dwindled limited resources even further.

By now, many providers have little appetite for taking on new trials and the obligations that come with them.

In this new moment, people have more awareness than ever about what it means to contribute to clinical research for the greater good. They want to engage, but they don't know how. And sites, for their part, don't have the resources to help them.

Sponsors can navigate these challenges with site-level support services from WCG ThreeWire. With this white-glove service, sites receive the benefit of WCG's clinical research professionals, technology, and strategy allowing them to take on more trials and serve more people at no additional cost.

In turn, sponsors can fill enrollment goals faster, diversify participant representation, retain more people, and enter the data they need to bring more lifesaving therapies to market.



## A NEW MOMENT FOR RESEARCH AWARENESS

**The pandemic brought awareness of clinical trials into the public view like never before. How does this heightened attention impact sponsors and where does inclusion and diversity fit into the conversation? Find out in this white paper resource.**

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# The Growing Demand for Customized Site-Level Support

**The demand/capacity imbalance of clinical research dictates how trials are prioritized in this increasingly competitive site landscape. And at this rate, sites won't be able to sustainably support clinical research. After all, there are only so many hours in the day for site staff.**

Sites have long been a "grey" area where sponsors may feel like they have less control and insight: Sponsors draft protocols and organize study teams, but the only entity that can enroll participants are study sites.

This becomes even more evident for vaccine trials, which typically require the highest volume of participants: A site that would normally enroll one to two patients a week may have to increase to 5, 10, or 20 patients a week. As we saw with COVID-19 vaccine trials, the more participants, the more work required of sites. They're arranging transportation, screening patients, entering data, creating documents, doing regulatory filings, and much more.



### MEETING COVID-19 ENROLLMENT GOALS WITH SITE SUPPORT

**During a public health crisis, time is precious. When a top five pharma company needed support enrolling tens of thousands of patients for its vaccine trial, they turned to WCG ThreeWire to deliver comprehensive recruitment, enrollment, and retention support—without sacrificing data integrity. Through a multi-channel media campaign, study website, patient interaction center, and 225 clinical research coordinator placements, we supported the enrollment of more than 30,000 patients in just over three months.**

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> **There's a large amount of ongoing engagement, e-diary compliance, checkups, and appointment reminder calls with participants of a vaccine trial."**
>
> ***Patrick McNamara***
> *Senior Director of Business Development at WCG ThreeWire*

Those many demands limit the sites' capacity for patient flow and data management, which can negatively affect the trial experience and thus lead to attrition and noncompliance. Healthcare labor shortages and financial austerity add an even greater burden atop struggling hospitals and clinics. Sponsors are observing these challenges (which directly affect their trial outcomes) from the sidelines—with seemingly less control.

Many vendors offer a one-size-fits-all model for site support to address those challenges, but they're lacking. Generic staffing services overlook each site's individual needs, from geographic resource limitations to socioeconomic differences of patient populations. Now more than ever, sites need a tailored approach.

Sponsors have an opportunity to provide that customized help while gaining more visibility and control over trial execution, but there's a nuance: Sites want to be supported, not micromanaged. Sponsors must overcome the misconception that they're impeding on the site's budget or otherwise overreaching.

That starts with communication—and by creating a sustainable and trusted feedback loop between sponsors and sites.

# How WCG Site Augmentation Can Help

**WCG Site Augmentation helps sponsors accelerate clinical trial continuity by advancing their strategic site relationships. That support makes all the difference: With an ongoing feedback loop between sponsor and site, trials can pivot in real-time to keep research and timelines on track.**

We go beyond what a clinical trial staffing agency can provide. WCG Site Augmentation mitigates the modern-day challenges of sponsor/site relationships so that there is a high degree of visibility of the trial execution in real-time—and also a high degree of control around essential clinical trial activities such as enrollment, retention, data entry, and other critical study tasks.

With our model, sponsors connect to sites more efficiently for a greater sense of transparency and communication back and forth. Facilitating that relationship removes burdens from sites so that they have more time to focus on their patients and other priorities.

"Communication between sites and sponsors is critical to avoid some of the misconceptions you tend to find among prospective sites," said Jamie Harper, Director of Site Engagement and Relations at WCG ThreeWire. "We work to foster that communication by helping sites understand that the support we're providing is sponsor-funded and that it saves them time. With our support, sites can focus on the priorities that matter most to them: caring for patients."

Our unique approach accounts for site-specific needs with site-specific solutions. Here's a sampling of what we provide:

## DEDICATED PERSONNEL

WCG ThreeWire deploys onsite clinical research professionals (including study coordinators, clinical research coordinators, and clinical research nurses) across 40 countries. As temporary members of the study team during critical phases of ongoing trials, deployed personnel provide dedicated and exclusive support for their assigned protocols. And when work can be done from afar, we provide remote research support. This support is direly needed in trials with large enrollment goals that create volume related bottlenecks for sites.

## PARTICIPANT ENGAGEMENT

While WCG ThreeWire supports patient screening and identification through social media and advertising awareness, the primary focus is on participant engagement. We work directly with participants who are learning about the study for the first time, introducing them to the study site and providing a high-touch experience throughout their participation in the trial.

To start, every candidate coming from an external referral is contacted within 24 hours. Once enrolled, we conduct ongoing outreach to participants for appointment reminders, eCOA training, and more.

“We’re looking to support both the potential participants and the study sites throughout the clinical trial process, and support them from referral through enrollment,” McNamara said. “This patient-centric approach increases compliance and patient engagement, which is why we focus a lot more of our time and energy on contacting interested patients and bringing them into study sites.”

## RESOURCE SUPPORT

In addition to providing dedicated personnel and patient engagement, WCG Site Augmentation fulfills other activities based on site needs—from concierge and transportation support to data entry, regulatory filing, and more. We also develop and manage targeted educational content, such as waiting room videos and comprehensive study websites, so that participants stay informed throughout their experience.

## WHAT DO SITES THINK?

**Sites love working with us: After receiving support from WCG ThreeWire, 95 percent of sites ask to work with us again. Why? It's simple, McNamara says: "We go in as a collaborative partner to support them, not as a punitive or micromanaging measure."**

**Because of that collaborative and transparent approach, we're viewed as an extension of the study team—a qualified resource for not just the site study staff but also for the patients as a trusted point-of-contact.**

# The Future of Site Support for Vaccine Trials

> **We see no horizon in which the number of clinical trials is not increasing. Clinical trial volume and complexity will increase beyond the rate that sites can feasibly support that volume of participants and work. This underscores the importance of improving site support."**

***Patrick McNamara***
*Senior Director of Business Development at WCG ThreeWire*

As long as there are clinical trials, sites will stay in demand. And at least for the foreseeable future, the momentum of clinical research will only accelerate. Of course, trials aren't just growing in number; they're also growing in scale and complexity. That requires more time, energy, and resources from study sites while those sites continue to face their own economic and labor pressures.

Meanwhile, research participants are more interested in clinical trials than ever. The COVID-19 pandemic has highlighted the lifesaving value of volunteering in a vaccine study—and people worldwide genuinely want to learn more about what it means to be a study participant.


"In this current moment, people have a greater understanding not only that clinical trials exist, but that they can quickly lead to therapies and medicines for the greater good," McNamara said. "The opportunity now is to capitalize on that awareness by educating and engaging potential participants in a patient-centric way so that they can feel more informed and empowered in their choice to participate."

This convergence of trends highlights the ongoing need for sponsors to pivot their strategy and better support sites to serve more people. In so doing, sponsors can also gain more visibility and control over the "grey" areas of site-based trial activities.

WCG Site Augmentation can help with a comprehensive white-glove approach, giving sponsors resource flexibility, competitive strength, more trial coverage, and ultimately, strategic site relationships.

**Learn more at www.wcgclinical.com/siteaugmentation**

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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.

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