

Molly Hair Director, Clinical Research Solutions and New Product Development, WCG ThreeWire

As the clinical trial industry moves from crisis to recovery mode, everyone is grappling with uncertainty. Sites continue to be hampered by resource and bandwidth issues, and many still aren't fully staffed—with as many as 1.4 million healthcare workers facing lay-offs due to COVID-19.1

Now more than ever, sites are in need of extra resources. WCG's Site Augmentation Solution can provide it, empowering sites to help bring new therapies to market.

WCG Clinical Research Coordinators (CRCs) are a key part of these Site Augmentation services. These clinical teams by streamlining enrollment, enhancing patient retention, ensuring timely data entry and query resolution, and providing site administrative support every step of the way.

They make sure things get done. But to know what needs to get done, they must understand each site's needs.

#### **IDENTIFYING THE NEED**

No two sites will have identical needs. And even successful sites may need assistance. Take Site A, for instance.

Site A is meeting all its targets. Everything looks good, but their study coordinator is going on maternity leave in a couple of weeks. The site plans to reassign her duties to others. How will that affect the study? We can assess the situation and provide the right CRC to mitigate any negative impact.

Site B may be on target for recruitment and enrollment, but it's struggling with a backlog of regulatory work. WCG CRCs can step in, enter the data, and eliminate the backlog.

Site C may have guaranteed 10 patients, but a chart review finds only six who qualify. How do they get from 6 to 10 on a deadline? What's the right solution? We come up with a plan and then provide the staffing to execute it.

Let's stick with Site C for a moment.

# RECRUITMENT ACCELERATION AND ENROLLMENT

Working on-site or remotely, WCG CRCs help sites meet recruitment and enrollment goals. How they accomplish that depends on the site. Some may need help pre-screening patient charts and flagging weekly appointments.



Others may need someone to schedule appointments, make reminder calls and provide education. And some may need help with patient identification, including reaching out to the community, processing media referrals, and networking with referring physicians. By identifying the site's resource gaps and deploying WCG CRCs to fill them, we allow sites to meet their targets.

In addition, when WCG CRCs take on tasks associated with enrollment and traditional recruitment, the study team has more time to spend with patients.

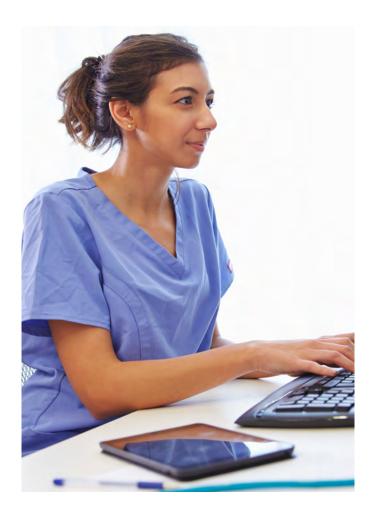
CRCs can also help with patient engagement.

#### PATIENT RETENTION AND ENGAGEMENT

Superior recruitment and enrollment strategies matter little without patient retention and engagement.

It's tricky, though: There's no template, no single solution for patient retention. What we do know is this: Patients must have the right information. They need resources and support. They need to feel valued and appreciated.

Sometimes, WCG CRCs help sites show appreciation through phone calls, thank you notes, study-branded materials, etc. But that's just a small part of it. What truly matters is making the connection.



Clinical research is deeply personal. It can mean finding a therapy that will transform the quality and/or length of a person's life. So, of course, study participants are anxious—an anxiety compounded by the uncertainty COVID-19 created.

As medically trained professionals who understand both the study protocol and patient unease, WCG CRCs can talk with patients, answer questions, and provide them with information about the study.

WCG CRCs make personal connections with patients, often going beyond what the protocol requires. They can be that friendly voice for

someone who needs a little handholding. They are a trusted professional who can talk with a patient on the patient's schedule, even outside a site's normal business hours. We know this goes a long way to relieve patient anxiety.

They become the patient's liaison to the study team, ensuring they receive all the study updates, including timeline changes and protocol amendments. WCG CRCs often handle scheduling and following up for labs, imaging, and regular site visits. They can also provide practical assistance, such as connecting patients with transportation services or teaching them to use ePRO.

All this makes patients feel valued and lessens the patient burden, improving retention.

## DATA ENTRY AND QUERY RESOLUTION

Depending on what the site needs, WCG CRCs may have minimal patient contact. Many focus on data entry.

They can manage real-time data entry, and they can resolve backlogs. WCG can assess how far behind sites are and scale the service so the backlog is cleared on schedule.

We've found that some think this aspect can be handled by a temporary general staffing. After all, it's just logging data into a portal, right? Wrong. In fact, it's much more. Whoever is entering the data needs a medical background. They need to understand clinical trials. They need context.



The same applies to query resolution. WCG CRCs can resolve queries, whether it's as simple as walking down the hall to talk to a PI or getting to the bottom of a serious dosing issue. They know how to read a source document and navigate the processes and workflows in place to get an answer.

### MEETING THE SITE WHERE IT IS

Each site is unique. WCG has provided thousands of CRCs at sites across the globe as part of our end-to-end patient recruitment solution.

Each site will have a different set of enrollment challenges, as well as all those other issues involved with getting a trial off the ground and keeping it running smoothly. That's why WCG trains and deploys CRCs based on each site's unique needs.

WCG CRCs can provide an array of services to sponsors, CROs, and sites, including:

- · Prescreening patient charts
- · Prescreening and flagging weekly appointments
- Scheduling appointments
- Placing reminder calls
- Media referral processing
- Study education
- · Physician referral networking
- Community outreach
- Document creation and completion
- Ongoing document management
- Monitoring prep visits
- General supplementary study coordinator support

### AGILE, NIMBLE AND RESPONSIVE

WCG CRCs don't merely perform tasks: They solve problems and adapt as the situation changes. That agility is essential in this time of continuous uncertainty and change. Sites can't anticipate every challenge, but they need to pivot quickly when a new one arises. WCG CRCs have the skills and tools to help them do this.

Throughout the COVID-19 pandemic, we've been working with sponsors, CROs, and sites and to keep trials going through our on-site and remote support.

We were recently brought on to a global Crohn's disease study to help overburdened study teams increase enrollment, and keep patients retained while awaiting pending flare. Through the on-site and remote support of our CRCs, WCG-supported sites increased enrollment by an average of 31% compared to sites that we did not support.

These are extraordinary times. But even in ordinary times, sites face a constellation of challenges. As a key part of our Site Augmentation Solution, WCG CRCs can help meet those challenges.

Our team is ready to discuss the bandwidth issues at your site. If you would like to see how our support can work for you, please email us at info@wcgclinical.com.

want to HELP YOUR SITES MEET THEIR FULL POTENTIAL?

Speak to an expert

Our Site Augmentation services are customized. But for us, customization is a process. Our iterative process and structure give us the agility and flexibility to meet your ever-changing needs.



- 1 **Evaluate** sites' study goals and existing resources to meet those goals
- Develop a plan based on individual site needs
- 3 Deploy a customized support strategy to ensure proper resourcing at each site
- 4 Assess performance through the evaluation of study metrics
- 5 Adjust support strategy to address shifting study and site needs

  Repeat

## **REFERENCES**

<sup>1</sup> Newsweek (2020). "Nurses and health care workers experience record job losses amid pandemic, despite new unemployment figure propping to 13.3 percent."

# ABOUT THE AUTHOR



# Molly Hair, Director, Clinical Strategic Solutions and New Product Development, WCG ThreeWire

Molly is currently the Director of Clinical Strategic Solutions and New Product Development at WCG ThreeWire. With more than 14 years of experience in clinical trial patient recruitment, Molly works with clinical research sites to develop and deploy unique support strategies based on their individual needs. Prior to her time at WCG ThreeWire, Molly worked as a lead recruitment coordinator at an independent research unit, where she led recruitment efforts on more than 150 clinical trials in a wide range of therapeutic areas.



We are the worlds leading provider of solutions that measurably improve the quality and efficiency of clinical research.

Comprised of two segments, the industry's first central IRB – WCG IRB – and first clinical services organization, 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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